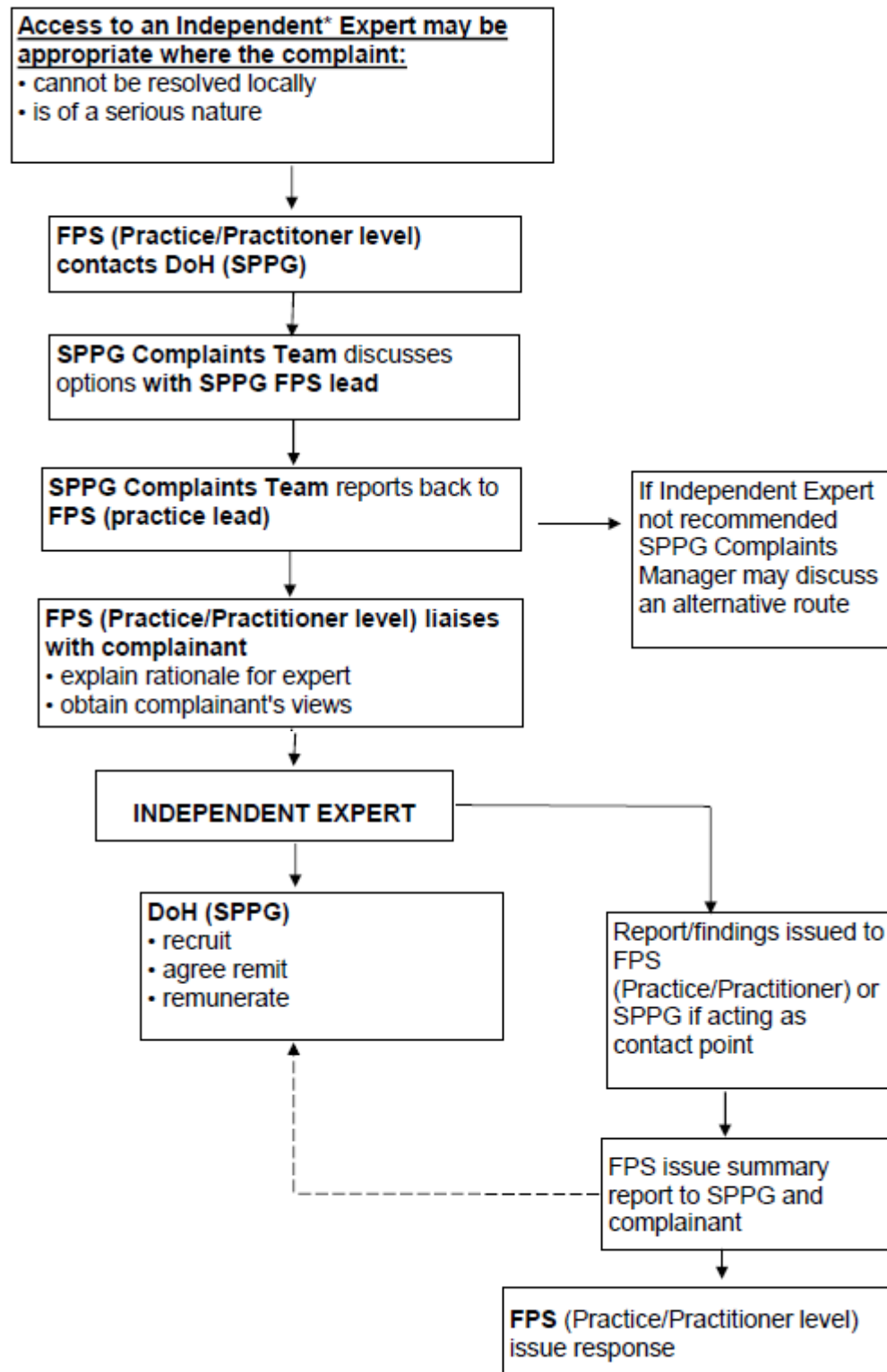


Independent Experts – FPS Access



*Definition of "Independent" = an Independent Expert must be recruited from another LCG area (and in certain circumstances outside Northern Ireland) and must have no connection with any of the parties to the complaint to avoid calling into question their objectivity and independence.

ANNEX 10: LAY PERSONS

1. Lay persons may be beneficial in providing an independent perspective of non-clinical/ technical issues within the local resolution process. Lay persons are NOT intended to act as advocates, conciliators or investigators. Neither do they act on behalf of the provider or the complainant. The lay persons involvement is to help bring about a resolution to the complaint and to provide assurances that the action taken was reasonable and proportionate to the issues raised. For example, the lay person could accompany the investigator during the investigation process where the complainant is considered unreasonable ([Annex 13 refers](#)).

2. Input from a lay person may be valuable to test key issues that are part of the complaint, such as:

- communication issues;
- quality of written documents;
- attitudes and relationships; and
- access arrangements (appointment systems).

3. It is essential that both the provider and the complainant have agreed to the involvement of a lay person.

4. Lay persons should have appropriate training in relation to the HSC complaints procedure and have the necessary independence and communication skills.

FPS arrangements

5. The Practice/Practitioner should approach the SPPG Complaints Team for advice.

6. Where a request for a lay person is received the SPPG Complaints Team **may** liaise with the relevant FPS lead to consider the best way forward. Where it is considered that a lay person's involvement would aid resolution then the SPPG Complaints Team will advise the FPS practice. In some cases the SPPG Complaints Team **may** consider an alternative to a lay person.

Agreement and consent

7. The FPS Practice/ Practitioner/ HSC Organisation/SPPG Complaints Team must contact the complainant and discuss the rationale for involving a lay person and provide an opportunity to allow the complainant to agree to such an approach and consent to share information. Once received, the HSC organisation/SPPG Complaints Team (on behalf of FPS) will make the necessary arrangements.

8. Where it has been agreed that a lay person will be involved the Practice/Practitioner/HSC Organisation/SPPG Complaints Team should clearly define the remit of the appointment for the purposes of:

- explaining the issue(s) to be resolved;
- ensuring all parties understand the focus of the issue(s);
- ensuring all parties understand what lay person involvement means;
- agreeing the timescales;
- agreeing to the provision of a final report, and
- explaining what happens when this process is complete.

9. The layperson's findings/report will be forwarded to the Practice/Practitioner/HSC Organisation/SPPG Complaints Team. The full report will be made available by the Practice/ Practitioner/HSC Organisation/SPPG Complaints Team (for FPS only) and to the complainant.

10. The letter of response to the complainant is the responsibility of the Practice/Practitioner/HSC Organisation/SPPG Complaints Team.

Appointment of lay persons

11. The HSC organisation or SPPG Complaints Team (on behalf of FPS) is responsible for communicating with, ascertaining the availability of and formally appointing an appropriate lay person. In addition it is responsible for all other arrangements, including training, performance management and remuneration.

Monitoring

12. The SPPG Complaints Team will monitor the effectiveness and usage of lay person arrangements within HSC Trusts and FPS.

ANNEX 11: HONEST BROKER ROLE

1. “Honest broker” is the term used to describe the role of the SPPG Complaints Team in supporting and advising FPS on the handling of complaints. The complainant or the Practice/Practitioner can ask the SPPG Complaints Team to act in this role at any point in the complaints process. It is expected that the SPPG Complaints Team will not carry out the investigation but it is also expected that it will add value to the process by providing support and advice to FPS.

2. It is not an alternative to local resolution. Neither is it an opportunity for the SPPG Complaints Team to take over an investigation. Rather it is about facilitating communications and building relationships between the Practice/Practitioner and the complainant or reaching positions of understanding. The honest broker will act as an intermediary and is available to both, the complainant or Practice/Practitioner staff throughout the complaints process. For example, the honest broker may:

- provide advice to both the complainant and the Practice/Practitioner;
- act as a link between both parties and/ or negotiate with them; and
- facilitate and attend meetings between/with both parties together or separately.

3. Paragraphs 2.16 to 2.21 outline the options available to complainants when pursuing FPS complaints. This includes an option to lodge their complaint directly with the SPPG Complaints Team. Where the complainant contacts the SPPG Complaints Team the options available to resolve the complaint will be explained:

- that the complaint can be copied to the relevant practice/pharmacy for investigation, resolution and response; or
- that the SPPG Complaints Team can act as honest broker between the complainant and the Practice/Practitioner.

4. FPS co-operation in complaints of this type is essential for the role of honest broker to effectively assist in the successful local resolution of complaints. FPS will be asked for their agreement should the complainant prefer the SPPG Complaints Team's involvement.

5. Where the SPPG Complaints Team has been asked to act as honest broker they will:

- act as intermediary between the complainant and the practice/ pharmacy;
- make arrangements for independent expert advice, conciliation, lay person assistance, where appropriate;
- provide advice to the complainant and the Practice/Practitioner on target timescales²⁴; and
- where there is a delay, ensure the complainant is advised as set out in paragraph 3.39.

6. Whichever process is used it is important to note that the Practice/Practitioner are responsible for the investigation and the response. The SPPG Complaints Team, however, must ensure that:

- a written response is provided by the Practice/Practitioner to the complainant and any other person subject to the complaint (whether this is direct from the Practice/Practitioner or from the SPPG Complaints Team after receiving a report from the Practice/Practitioner;
- the response is of sufficient quality and addresses the complainant's concerns;
- the written response is provided within target timescales and where this is not possible that the complainant is informed; and
- the response notifies the complainant of their right to refer their complaint to the Ombudsman should they remain dissatisfied with the outcome of the complaints procedure.

7. The complainant may contact the SPPG Complaints Team for further advice and support.

²⁴ For 'honest broker' this is 20 working days from receipt of the complaint: for FPS, this is 10 working days from receipt of the complaint.

ANNEX 12: ADULT SAFEGUARDING

Definition of vulnerable adult

1. The regional policy 'Adult Safeguarding – Prevention and Protection in Partnership' defines the terms 'adult at risk of harm' and 'adult in need of protection'²⁵.

2. The definition of an 'adult at risk of harm' takes account of a complex range of interconnected personal characteristics and/or life circumstances, which may increase exposure to harm either because a person may be unable to protect him/herself or their situation may provide opportunities for others to neglect, exploit or abuse them. It is not possible to definitively state when an adult is at risk of harm, as this will vary on a case by case basis. The following definition is intended to provide guidance as to when an adult may be at risk of harm, in order that further professional assessment can be sought.

3. An 'adult at risk of harm' is a person aged 18 or over, whose exposure to harm through abuse, exploitation or neglect may be increased by their:

a) **personal characteristics**

AND/OR

b) **life circumstances**

Personal characteristics may include, but are not limited to, age, disability, special educational needs, illness, mental or physical frailty or impairment of, or disturbance in, the functioning of the mind or brain.

Life circumstances may include, but are not limited to, isolation, socio-economic factors and environmental living conditions.

²⁵ 'Adult Safeguarding – Prevention and Protection in Partnership' (July 2015) (<https://www.health-ni.gov.uk/publications/adult-safeguarding-prevention-and-protection-partnership-key-documents>), p10

4. An **'adult in need of protection'** is a person aged 18 or over, whose exposure to harm through abuse, exploitation or neglect may be increased by their:

a) **personal characteristics**

AND/OR

b) **life circumstances**

AND

c) who is **unable to protect** their own well-being, property, assets, rights or other interests;

AND

d) where the action or inaction of another person or persons is causing, or is likely to cause, him/her to be harmed.

5. In order to meet the definition of an 'adult in need of protection' either (a) or (b) must be present, in addition to both elements (c), and (d).

6. The decision as to whether the definition of an 'adult in need of protection' is met will demand the careful exercise of professional judgement applied on a case by case basis. This will take into account all the available evidence, concerns, the impact of harm, degree of risk and other matters relating to the individual and his or her circumstances. The seriousness and the degree of risk of harm are key to determining the most appropriate response and establishing whether the threshold for protective intervention has been met.

Reportable offences and allegations of abuse

7. Very careful consideration must be given to complaints alleging offences that could be reportable to the police, and there should be explicit policies about the arrangements for such reporting. Where it is apparent that a complaint relates to abuse, exploitation or neglect of an adult at risk then the regional *'Adult Safeguarding Operational Procedures'* (September 2016) and the associated *'Protocol for Joint Investigation of Adult Safeguarding Cases'* (August 2016) should be activated (see paragraph 1.26).

ANNEX 13: UNREASONABLE OR ABUSIVE COMPLAINANTS

1. HSC staff must be trained to respond with patience and empathy to the needs of people who make a complaint, but there will be times when there is nothing further that can reasonably be done to assist them. Where this is the case and further communications would place inappropriate demands on HSC staff and resources, consideration may need to be given to classifying the person making a complaint as an unreasonable, demanding or persistent complainant.

2. In determining arrangements for handling such complainants, staff need to:

- ensure that the complaints procedure has been correctly implemented as far as possible and that no material element of a complaint is overlooked or inadequately addressed;
- appreciate that even habitual complainants may have grievances which contain some substance;
- ensure a fair approach; and
- be able to identify the stage at which a complainant has become habitual.

3. The following *Unacceptable Actions Policy*²⁶ should only be used as a last resort after all reasonable measures have been taken to resolve the complaint.

Unacceptable Actions Policy

4. People may act out of character in times of trouble or distress. There may have been upsetting or distressing circumstances leading up to a complaint. HSC organisations do not view behaviour as unacceptable just because a complainant is forceful or determined. In fact, it is accepted that being persistent can be a positive advantage when pursuing a complaint. However, we do consider actions that result in unreasonable demands on the HSC organisation or unreasonable behaviour towards HSC staff to be unacceptable. It is these actions that HSC organisations aim to manage under this policy.

²⁶ Unacceptable Actions Policy based on best practice guidelines issued by the [Scottish Public Services Ombudsman](#)-Updated 18 January 2017

Aggressive or abusive behaviour

5. HSC organisations understand that many complainants are angry about the issues they have raised in their complaint. If that anger escalates into aggression towards HSC staff, it will consider that unacceptable. Any violence or abuse towards staff will not be accepted.

6. Violence is not restricted to acts of aggression that may result in physical harm. It also includes behaviour or language (whether verbal or written) that may cause staff to feel afraid, threatened or abused. Examples of behaviours grouped under this heading include threats, physical violence, personal verbal abuse, derogatory remarks and rudeness. HSC organisations will judge each situation individually and appreciate individuals who come may be upset. Language which is designed to insult or degrade, is racist, sexist or homophobic or which makes serious allegations that individuals have committed criminal, corrupt or perverse conduct without any evidence is unacceptable. HSC organisations may decide that comments aimed at third parties are unacceptable because of the effect that listening or reading them may have on staff. HSC organisations also consider that inflammatory statements and unsubstantiated allegations can be abusive behaviour.

7. HSC organisations expect its staff to be treated courteously and with respect. Violence or abuse towards staff is unacceptable and staff should refer to the Zero Tolerance campaign launched in 2007 to clarify the HSC position in relation to attacks on the workforce. HSC staff understand the difference between aggression and anger. The anger felt by many complainants involves the subject matter of their complaint. However, it is not acceptable when anger escalates into aggression directed towards HSC staff.

Unreasonable demands

8. HSC organisations consider these demands become unacceptable when they start to (or when complying with the demand would) impact substantially on the work of the organisation.

9. Examples of actions grouped under this heading include:

- repeatedly demanding responses within an unreasonable timescale;
- insisting on seeing or speaking to a particular member of staff when that is not possible; and
- repeatedly changing the substance of a complaint or raising unrelated concerns.

10. An example of such impact would be that the demand takes up an excessive amount of staff time and in so doing disadvantages other complainants.

Unreasonable levels of contact

11. Sometimes the volume and duration of contact made to the HSC organisation by an individual causes problems. This can occur over a short period, for example a number of calls in one day or one hour. It may occur over the life-span of the complaint when a complainant repeatedly makes long telephone calls to the organisation or inundates the organisation with copies of information that has been sent already or that is irrelevant to the complaint.

12. The HSC organisation considers that the level of contact has become unacceptable when the amount of time spent talking to a complainant on the telephone, or dealing with emails or written correspondence impacts on its ability to deal with that complaint, or with other people's complaints.

Unreasonable use of the complaints process

13. Individuals with complaints have the right to pursue their concerns through a range of means. They also have a right to complain more than once about an organisation with which they have a continuing relationship, if subsequent incidents occur.

14. However, this contact becomes unreasonable when the effect of the repeated complaints is to harass, or to prevent the organisation from pursuing a legitimate aim or implementing a legitimate decision. The HSC organisation considers access to a complaints system to be important and it will only be in exceptional circumstances that

it would consider such repeated use is unacceptable, however it reserves the right to do so in those exceptional circumstances.

Unreasonable refusal to co-operate

15. When the HSC organisation is looking at a complaint, it will need to ask the individual who has complained to work with them. This can include agreeing with the HSC organisation the complaint it will look at; providing it with further information, evidence or comments on request; or the individual summarising the concerns or completing a form for the HSC organisation.

16. Sometimes, an individual repeatedly refuses to cooperate and this makes it difficult for the HSC organisation to proceed. The HSC organisation will always seek to assist someone if they have a specific, genuine difficulty complying with a request. However, the HSC organisation consider it is unreasonable to bring a complaint to it and then not respond to reasonable requests.

Examples of how the HSC manage aggressive or abusive behaviour

17. The threat or use of physical violence, verbal abuse or harassment towards HSC staff is likely to result in a termination of all direct contact with the complainant. All incidents of verbal and physical abuse will be reported to the police.

18. HSC organisations will not accept any correspondence (letter, fax or electronic) that is abusive to staff or contains allegations that lack substantive evidence. The HSC organisation will tell the complainant that it considers their language offensive, unnecessary and unhelpful and ask them to stop using such language. It will state that it will not respond to their correspondence if the action or behaviour continues.

19. HSC staff will end telephone calls if they consider the caller aggressive, abusive or offensive. The staff member taking the call has the right to make this decision, tell the caller that their behaviour is unacceptable and end the call if the behaviour persists. In extreme situations, the HSC organisation will tell the complainant in writing that their name is on a “no personal contact” list. This means that it will limit contact with them to either written communication or through a third party.

Examples of how the HSC deal with other categories of unreasonable behaviour

20. The HSC organisation has to take action when unreasonable behaviour impairs the functioning of its office. It aims to do this in a way that allows a complainant to progress through its process. It will try to ensure that any action it takes is the minimum required to solve the problem, taking into account relevant personal circumstances including the seriousness of the complaint and the needs of the individual.

21. Where a complainant repeatedly phones, visits the organisation, raises issues repeatedly, or sends large numbers of documents where their relevance is not clear, the HSC organisation may decide to:

- limit contact to telephone calls from the complainant at set times on set days;
- restrict contact to a nominated member of staff who will deal with the future calls or correspondence from the complainant;
- see the complainant by appointment only;
- restrict contact from the complainant to writing only;
- return any documents to the complainant or, in extreme cases, advise the complainant that further irrelevant documents will be destroyed; and
- take any other action that the HSC organisation considers appropriate.

22. Where the HSC organisation considers correspondence on a wide range of issues to be excessive, it may tell the complainant that only a certain number of issues will be considered in a given period and ask them to limit or focus their requests accordingly.

23. In exceptional cases, the HSC organisation will reserve the right to refuse to consider a complaint or future complaints from an individual. It will take into account the impact on the individual and also whether there would be a broader public interest in considering the complaint further.

24. The HSC organisation will always tell the complainant what action it is taking and why.

The process the HSC follows to make decisions about unreasonable behaviour

25. HSC staff who directly experience aggressive or abusive behaviour from a complainant have the authority to deal immediately with that behaviour in a manner they consider appropriate to the situation in line with this policy. With the exception of such immediate decisions taken at the time of an incident, decisions to restrict contact with the organisation are only taken after careful consideration of the situation by a more senior member of staff. Wherever possible, the HSC organisation will give the complainant the opportunity to change their behaviour or action before a decision is taken.

How the HSC lets people know it has made this decision

26. When a HSC member of staff makes an immediate decision in response to aggressive or abusive behaviour, the complainant is advised at the time of the incident. When a decision has been made by senior management, a complainant will always be told in writing²⁸ why a decision has been made to restrict future contact, the restricted contact arrangements and, if relevant, the length of time that these restrictions will be in place. This ensures that the complainant has a record of the decision.

The process for appealing a decision to restrict contact

27. It is important that a decision can be reconsidered. A complainant can appeal a decision to restrict contact. If they do this, the HSC organisation will only consider arguments that relate to the restriction and not to either the complaint made to the organisation or its decision to close a complaint. An appeal could include, for example, a complainant saying that: their actions were wrongly identified as unacceptable, the restrictions were disproportionate; or that they will adversely impact on the individual because of personal circumstances.

28. A senior member of staff who was not involved in the original decision will consider the appeal. They have discretion to quash or vary the restriction as they think best. They will make their decision based on the evidence available to them. They

must advise the complainant in writing²⁷ that either the restricted contact arrangements still apply or a different course of action has been agreed.

How the HSC record and review a decision to restrict contact

29. The HSC organisation records all incidents of unacceptable actions by complainants. Where it is decided to restrict complainant contact, an entry noting this is made in the relevant file and on appropriate computer records. A decision to restrict complainant contact as described above, may be reconsidered if the complainant demonstrates a more acceptable approach. A member of the Senior Management Team reviews the status of all complainants with restricted contact arrangements on a regular basis.

²⁷ Unacceptable Actions Policy based on best practice guidelines issued by the [Scottish Public Services Ombudsman](#)-Updated 18 January 2017

ANNEX 14: CHILDREN ORDER REPRESENTATIONS AND COMPLAINTS PROCEDURE

1. Under the Children (NI) Order 1995²⁸ (the Order) HSC Trusts are statutorily required to establish a procedure for considering:
 - any representations (including any complaint) made to it about the discharge of its functions under Part IV of, and paragraph 4 of Schedule 5 to, the Order, and
 - matters in relation to children accommodated by voluntary organisations and privately run children's homes, and
 - those personal social services to children provided under the Adoption Order (NI) 1987²⁹.
2. HSC Trusts functions are outlined in Article 45 of, and paragraph 6 of Schedule 5 to, the Order and in the Representations Procedure (Children) Regulations (NI) 1996³⁰.
3. Departmental guidance on the establishment and implementation of such a procedure is included at Chapter 12 of the Children Order Guidance and Regulations, Volume 4 (a flowchart to aid decision making is attached).
4. The HSC Trusts should familiarise themselves with these requirements.

²⁸ Children (NI) Order 1995: <http://www.legislation.gov.uk/nisi/1995/755/contents>

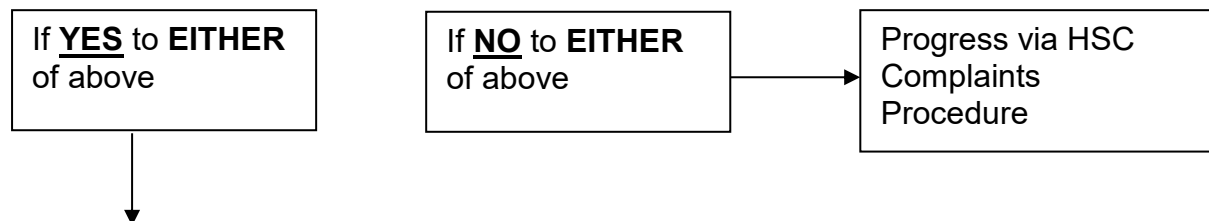
²⁹ Adoption Order (NI) 1987: <http://www.legislation.gov.uk/nisi/1987/2203/contents>

³⁰ Representations Procedure (Children) Regulations (NI) 1996: <http://www.legislation.gov.uk/nisr/1996/451/contents/made>

CHILDREN ORDER REPRESENTATIONS AND COMPLAINTS PROCEDURE**1. Complaint: Does it fit the definition of a Children Order complaint as below?**

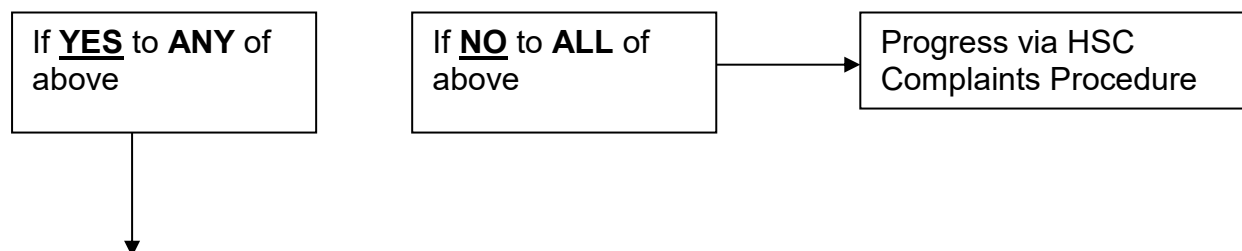
“...Any representation (including any complaint) made to the Trust ... about the discharge of any of its functions under Part IV of the Order in relation to the child.”
(Children (NI) Order 1995, Article 45(3))

“A written or oral expression of dissatisfaction or disquiet in relation to an individual child about the Trust’s exercise of its functions under Part IV of, and para 6 of Schedule 5 to, the Children Order.”
(Guidance & Regulations – Vol. 4, Para 12.5 – DHSS)

**2. Does it meet the criteria of what may be complained about under Children Order?**

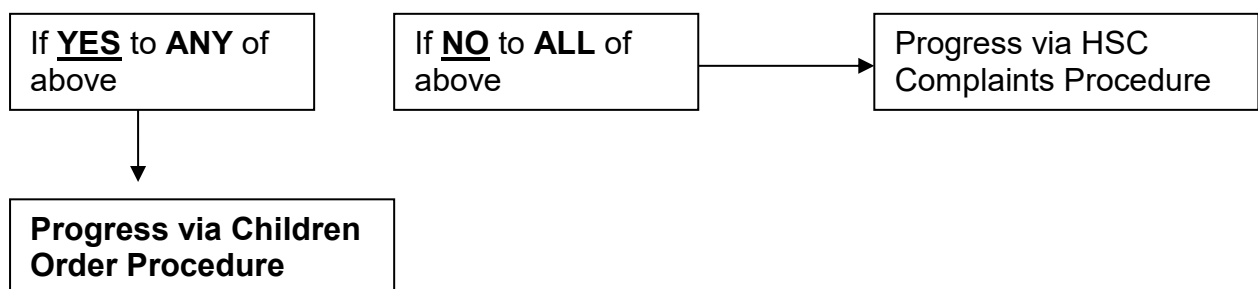
“... about Trust support for families and their children under Part IV of the Order.”
(Vol. 4, Para 12.8)

- a. Day care;
- b. Services to support children within family home;
- c. Accommodation of a child;
- d. After care;
- e. Decisions relating to the placement of a child;
- f. The management or handling of a child’s case (in respect of Part IV services);
- g. Process involved in decision making (in respect of Part IV services);
- h. Denial of a (Part IV) service;
- i. Exemptions to usual fostering limit;
- j. Matters affecting a group of children (receiving a Part IV service);
- k. Issues concerning a child subject to Adoption Services.



3. **Complainant:** Does he/she fit the definition of a Children Order complainant?

- a. **Any child** who is being looked after by the Trust;
- b. **Any child** who is not being looked after by the Trust, but is in need;
- c. A parent **of his**;
- d. Any person who is not a parent of his but who has **parental responsibility for him**;
- e. Any Trust foster parent;
- f. Such other person as the Trust considers has a sufficient interest in **the child's welfare** to warrant his representations being considered by the Trust, i.e.
 - the person who had the day to day care of the child within the past two years;
 - the child's Guardian ad Litem;
 - the person is a relative of the child (as defined by Children Order, Article 2(2));
 - The person is a significant adult in the child's life, and where possible, this is confirmed by the child;
 - a friend;
 - a teacher;
 - a general practitioner.
 (Children (NI) Order 1995 Article 45(3))



NB: In order for a complaint to be eligible to be considered under the Children Order Procedure, the answer to 1 and 2 and 3 **MUST** all be **YES**.

Consent: The (Trust) should always check with the child (subject to his understanding) that a complaint submitted reflects his views and that he wishes the person submitting the complaint to act on his behalf. (Where it is decided that the person submitting the complaint is not acting on the child's behalf, that person may still be eligible to have the complaint considered).

Definitions of Key Terms

Throughout the standards and guidelines the following terms have the meanings set out below:

Complaint	“an expression of dissatisfaction that requires a response”
Complainant	an existing or former patient, client, resident, family, representative or carer (or whoever has raised the complaint)
Chief Executive	the Chief Executive of the HSC organisation
Complaints Manager	the person nominated by an HSC organisation to handle complaints
DoH ³¹	Department of Health in Northern Ireland
Family Practitioner Service (FPS)	family doctors, dentists, pharmacists and opticians
Honest Broker	this is the term used to describe the role of the SPPG on behalf of DoH in FPS complaints
HSC Organisation	an organisation which commissions or provides health and social care services and for the purpose of this guidance includes HSC Trusts, the Northern Ireland Ambulance Service (NIAS), the Business Services Organisation (BSO), the Public Health Agency (PHA), Family Practitioner Services (FPS), Out-of-Hours Services, and pilot scheme providers
Local Resolution	the resolution of a complaint by the organisation, working closely with the service user

³¹ Formally the Department for Health, Social Services and Public Safety (DHSSPS)

NIBTS	Northern Ireland Blood Transfusion Service
NIPSO	Northern Ireland Public Services Ombudsman (NIPSO, known as ‘the Ombudsman’)
Out of-Hours services	refers to immediate necessary treatment provided by FPS 6.00 pm to 8.00 am Monday – Friday, weekends and local holidays
PCC	Patient and Client Council
Pilot Scheme	a small-scale experiment or set of observations undertaken to decide how and whether to launch a full-scale project (refers to personal dental services provided by an HSC Trust in this case)
Pilot Scheme Complaints Procedure	is a complaints procedure established by the pilot scheme
Practice based complaints procedure	is an FPS complaints procedure established within the terms of the relevant regulations
Registered Provider	person carrying on or managing the establishment or agency
RQIA	Regulation, Quality and Improvement Authority which is the organisation responsible for regulating, inspecting and monitoring the standard and quality of health and social care services provision by independent and statutory bodies in Northern Ireland
Registered Establishments and Agencies	for example, residential care homes, nursing homes, children’s homes, nursing agencies, independent clinics/hospitals, etc. registered with
Regulated Sector	and regulated by the RQIA

Senior Person	refers to registered establishments and agencies
Service User	means the person designated to take responsibility for delivering the organisation's complaints process e.g. a Director in the HSC Trust means a patient, client, resident, carer, visitor or any other person accessing HSC services
Special Agency	For example the NI Blood Transfusion Service (NIBTS)
SPPG	Strategic Planning and Performance Group, DoH (formerly HSC Board)



Principles of Good Administration



Principles of Good Administration

Good administration by public bodies means:

- 1 Getting it right
- 2 Being customer focused
- 3 Being open and accountable
- 4 Acting fairly and proportionately
- 5 Putting things right
- 6 Seeking continuous improvement

Introduction

This document gives our views on the *Principles of Good Administration*. It should be read in conjunction with our *Principles of Good Complaint Handling* and *Principles for Remedy*.

These Principles draw on over 40 years' experience of investigating and reporting on complaints to propose a clear framework within which public bodies should seek to work. At the same time, the *Principles of Good Administration* helps clarify the expectations against which the Parliamentary and Health Service Ombudsman will judge performance.

The Principles set out here are intended to promote a shared understanding of what is meant by good administration and to help public bodies in the Ombudsman's jurisdiction provide a first-class public service to their customers.



Principles of Good Administration

Good administration by public bodies means:

1 Getting it right

- Acting in accordance with the law and with regard for the rights of those concerned.
- Acting in accordance with the public body's policy and guidance (published or internal).
- Taking proper account of established good practice.
- Providing effective services, using appropriately trained and competent staff.
- Taking reasonable decisions, based on all relevant considerations.

2 Being customer focused

- Ensuring people can access services easily.
- Informing customers what they can expect and what the public body expects of them.
- Keeping to its commitments, including any published service standards.
- Dealing with people helpfully, promptly and sensitively, bearing in mind their individual circumstances.
- Responding to customers' needs flexibly, including, where appropriate, co-ordinating a response with other service providers.

3 Being open and accountable

- Being open and clear about policies and procedures and ensuring that information, and any advice provided, is clear, accurate and complete.
- Stating its criteria for decision making and giving reasons for decisions.
- Handling information properly and appropriately.
- Keeping proper and appropriate records.
- Taking responsibility for its actions.

4 Acting fairly and proportionately

- Treating people impartially, with respect and courtesy.
- Treating people without unlawful discrimination or prejudice, and ensuring no conflict of interests.
- Dealing with people and issues objectively and consistently.
- Ensuring that decisions and actions are proportionate, appropriate and fair.

5 Putting things right

- Acknowledging mistakes and apologising where appropriate.
- Putting mistakes right quickly and effectively.
- Providing clear and timely information on how and when to appeal or complain.
- Operating an effective complaints procedure, which includes offering a fair and appropriate remedy when a complaint is upheld.

6 Seeking continuous improvement

- Reviewing policies and procedures regularly to ensure they are effective.
- Asking for feedback and using it to improve services and performance.
- Ensuring that the public body learns lessons from complaints and uses these to improve services and performance.

These Principles are not a checklist to be applied mechanically. Public bodies should use their judgment in applying the Principles to produce reasonable, fair and proportionate results in the circumstances. The Ombudsman will adopt a similar approach in deciding whether maladministration or service failure has occurred.

The supporting text for each Principle follows.

1 Getting it right

- All public bodies must comply with the law and have regard for the rights of those concerned. They should act according to their statutory powers and duties and any other rules governing the service they provide. They should follow their own policy and procedural guidance, whether published or internal.
- Public bodies must act in accordance with recognised quality standards, established good practice or both, for example about clinical care.
- In some cases a novel approach will bring a better result or service, and public bodies should be alert to this possibility. When they decide to depart from their own guidance, recognised quality standards or established good practice, they should record why.
- Public bodies should provide effective services with appropriately trained and competent staff. They should plan carefully when introducing new policies and procedures. Where public bodies are subject to statutory duties, published service standards or both, they should plan and prioritise their resources to meet them.
- In their decision making, public bodies should have regard to the relevant legislation. Decision making should take account of all relevant considerations, ignore irrelevant ones and balance the evidence appropriately.
- Public bodies necessarily assess risks as part of taking decisions. They should, of course, spend public money with care and propriety. At the same time, when assessing risk, public bodies should ensure that they operate fairly and reasonably.

2 Being customer focused

- Public bodies should provide services that are easily accessible to their customers. Policies and procedures should be clear and there must be accurate, complete and understandable information about the service.
- Public bodies should aim to ensure that customers are clear about their entitlements; about what they can and cannot expect from the public body; and about their own responsibilities.
- Public bodies should do what they say they are going to do. If they make a commitment to do something, they should keep to it, or explain why they cannot. They should meet their published service standards, or let customers know if they cannot.
- Public bodies should behave helpfully, dealing with people promptly, within reasonable timescales and within any published time limits. They should tell people if things take longer than the public body has stated, or than people can reasonably expect them to take.
- Public bodies should communicate effectively, using clear language that people can understand and that is appropriate to them and their circumstances.
- Public bodies should treat people with sensitivity, bearing in mind their individual needs, and respond flexibly to the circumstances of the case. Where appropriate, they should deal with customers in a co-ordinated way with other providers to ensure their needs are met; and, if they are unable to help, refer them to any other sources of help.

3 Being open and accountable

- Public administration should be transparent and information should be handled as openly as the law allows. Public bodies should give people information and, if appropriate, advice that is clear, accurate, complete, relevant and timely.
- Public bodies should be open and truthful when accounting for their decisions and actions. They should state their criteria for decision making and give reasons for their decisions.
- Public bodies should handle and process information properly and appropriately in line with the law. So while their policies and procedures should be transparent, public bodies should, as the law requires, also respect the privacy of personal and confidential information.
- Public bodies should create and maintain reliable and usable records as evidence of their activities. They should manage records in line with recognised standards to ensure that they can be retrieved and that they are kept for as long as there is a statutory duty or business need.
- Public bodies should take responsibility for the actions of their staff.

4 Acting fairly and proportionately

- Public bodies should always deal with people fairly and with respect. They should be prepared to listen to their customers and avoid being defensive when things go wrong.
- Public bodies should treat people equally and impartially. They should understand and respect the diversity of their customers and ensure equal access to services and treatment regardless of background or circumstance.
- The actions and decisions of a public body should be free from any personal bias or interests that could prejudice those actions and decisions, and any conflict of interests should be declared. Public bodies should not act in a way that unlawfully discriminates against or unjustifiably favours particular individuals or interests.
- People should be treated fairly and consistently, so that those in similar circumstances are dealt with in a similar way. Any difference in treatment should be justified by the individual circumstances of the case.
- When taking decisions, and particularly when imposing penalties, public bodies should behave reasonably and ensure that the measures taken are proportionate to the objectives pursued, appropriate in the circumstances and fair to the individuals concerned.
- If applying the law, regulations or procedures strictly would lead to an unfair result for an individual, the public body should seek to address the unfairness. In doing so public bodies must, of course, bear in mind the proper protection of public funds and ensure they do not exceed their legal powers.

5 Putting things right

- When mistakes happen, public bodies should acknowledge them, apologise, explain what went wrong and put things right quickly and effectively.
- Putting things right may include reviewing any decisions found to be incorrect; and reviewing and amending any policies and procedures found to be ineffective, unworkable or unfair, giving appropriate notice before changing the rules.
- The actions of a well-run public body can sometimes bear more heavily on an individual because of their particular circumstances, even though statutory duties, service standards or both have been met. Public bodies should be alert to this and respond flexibly to avoid or, where appropriate, put right any such undue effect.
- Public bodies should provide clear and timely information about methods by which people can appeal or complain. They should provide information about appropriate organisational or independent ways of resolving complaints. They should also consider providing information about possible sources of help for the customer, particularly for people who may find the complaints process daunting.
- Public bodies should operate effective complaints procedures which investigate complaints thoroughly, quickly and impartially; and which can provide an appropriate range of remedies to the complainant and any others similarly affected when a complaint is upheld. As a minimum, an appropriate range of remedies should include an explanation and apology from the public body to the complainant, remedial action by the public body, financial compensation for the complainant or a combination of these. The remedy offered should seek to put the complainant back in the position they would have been in if nothing had gone wrong. Where this is not possible - as will often be the case - the remedy offered should fairly reflect the harm the complainant has suffered.

6 Seeking continuous improvement

- Public bodies should review their policies and procedures regularly to ensure they are effective; actively seek and welcome all feedback, both compliments and complaints; use feedback to improve their public service delivery and performance; and capture and review lessons learned from complaints so that they contribute to developing services.



Principles of Good Complaint Handling



Principles of Good Complaint Handling

Good complaint handling means:

- 1 Getting it right
- 2 Being customer focused
- 3 Being open and accountable
- 4 Acting fairly and proportionately
- 5 Putting things right
- 6 Seeking continuous improvement



Introduction

This document gives our views on the *Principles of Good Complaint Handling*. We want public bodies and complainants to understand what we mean by good complaint handling and to be clear about what we expect from public bodies when dealing with complaints. We will also apply the Principles to any complaints made to us about our own service.

These *Principles of Good Complaint Handling* should be read in conjunction with our *Principles of Good Administration* and *Principles for Remedy*. Everyone has the right to expect a good service from public bodies and to have things put right if they go wrong. When things do go wrong, public bodies should manage complaints properly so customers' concerns are dealt with appropriately. Good complaint handling matters because it is an important way of ensuring customers receive the service they are entitled to expect. Complaints are a valuable source of feedback for the public body; they provide an audit trail and can be an early warning of failures in service delivery. When handled well, complaints provide an opportunity for public bodies to improve their service and reputation.

We understand there is often a balance between responding appropriately to complaints and acting proportionately within available resources. However, prompt and efficient complaint handling can save the public body time and money by preventing a complaint from escalating unnecessarily. Learning from complaints can reduce the number of complaints in the future.

The public bodies within our jurisdiction are many and varied, and sometimes complainants will be individuals and sometimes organisations. Accordingly, the systems that public bodies have in place for handling complaints will depend on their own circumstances. However, certain Principles should be common to all. Good complaint handling should be led from the top, focused on outcomes, fair and proportionate, and sensitive to complainants' needs. The process should be clear and straightforward, and readily accessible to customers. It should be well managed throughout so that decisions are taken quickly, things put right where necessary and lessons learnt for service improvement. In many of the complaints investigated by the Ombudsman we have found that poor complaint handling itself constituted maladministration or service failure leading to an injustice or hardship for the complainant. This was so even in cases in which we did not uphold the original complaint.

The Principles set out here are intended to promote a shared understanding of what is meant by good complaint handling and to help public bodies in the Parliamentary and Health Service Ombudsman's jurisdiction deliver first-class complaint handling to all their customers.

Principles of Good Complaint Handling

Good complaint handling by public bodies means:

1 Getting it right

- Acting in accordance with the law and relevant guidance, and with regard for the rights of those concerned.
- Ensuring that those at the top of the public body provide leadership to support good complaint management and develop an organisational culture that values complaints.
- Having clear governance arrangements, which set out roles and responsibilities, and ensure lessons are learnt from complaints.
- Including complaint management as an integral part of service design.
- Ensuring that staff are equipped and empowered to act decisively to resolve complaints.
- Focusing on the outcomes for the complainant and the public body.
- Signposting to the next stage of the complaints procedure, in the right way and at the right time.

2 Being customer focused

- Having clear and simple procedures.
- Ensuring that complainants can easily access the service dealing with complaints, and informing them about advice and advocacy services where appropriate.
- Dealing with complainants promptly and sensitively, bearing in mind their individual circumstances.
- Listening to complainants to understand the complaint and the outcome they are seeking.
- Responding flexibly, including co-ordinating responses with any other bodies involved in the same complaint, where appropriate.

3 Being open and accountable

- Publishing clear, accurate and complete information about how to complain, and how and when to take complaints further.
- Publishing service standards for handling complaints.
- Providing honest, evidence-based explanations and giving reasons for decisions.
- Keeping full and accurate records.

4 Acting fairly and proportionately

- Treating the complainant impartially, and without unlawful discrimination or prejudice.
- Ensuring that complaints are investigated thoroughly and fairly to establish the facts of the case.
- Ensuring that decisions are proportionate, appropriate and fair.
- Ensuring that complaints are reviewed by someone not involved in the events leading to the complaint.
- Acting fairly towards staff complained about as well as towards complainants.

5 Putting things right

- Acknowledging mistakes and apologising where appropriate.
- Providing prompt, appropriate and proportionate remedies.
- Considering all the relevant factors of the case when offering remedies.
- Taking account of any injustice or hardship that results from pursuing the complaint as well as from the original dispute.

6 Seeking continuous improvement

- Using all feedback and the lessons learnt from complaints to improve service design and delivery.
- Having systems in place to record, analyse and report on the learning from complaints.
- Regularly reviewing the lessons to be learnt from complaints.
- Where appropriate, telling the complainant about the lessons learnt and changes made to services, guidance or policy.

These Principles are not a checklist to be applied mechanically. Public bodies should use their judgment in applying the Principles to produce reasonable, fair and proportionate results in all the circumstances of the case. The Ombudsman will adopt a similar approach when considering the standard of complaint handling by public bodies in her jurisdiction.

The supporting text for each Principle follows.

1 Getting it right

All public bodies must comply with the law and have regard for the rights of those concerned. They should act according to their statutory powers and duties, and any other rules governing the service they provide. They should follow their own policy and procedural guidance on complaint handling, whether published or internal.

Good complaint handling requires strong and effective leadership. Those at the top of the public body should take the lead in ensuring good complaint handling, with regard to both the practice and the culture. Senior managers should:

- set the complaint handling policy, and own both the policy and the process
- give priority and importance to good complaint handling, to set the tone and act as an example for all staff
- develop a culture that values and welcomes complaints as a way of putting things right and improving service
- be responsible and accountable for complaint handling
- ensure that effective governance arrangements underpin and support good complaint handling
- ensure the policy is delivered through a clear and accountable complaint handling process
- ensure learning from complaints is used to improve service.

Public bodies should consider the policy and practice of complaint handling as an integral part of the service they provide to customers.

Staff should be properly equipped and empowered to put things right promptly where something has gone wrong. They should be supported by clear lines of authority and decision making that are flexible enough to respond to complaints effectively and authoritatively.

Complaint handling should focus on the outcomes for the complainant and, where appropriate, others affected. Public bodies should put in place policies and procedures to ensure complainants are treated fairly, to aid decision making and to ensure fair outcomes. Those policies and procedures should allow staff the flexibility to resolve complaints promptly and in the most appropriate way while still learning from complaints.

Public bodies should make it clear to complainants when they have provided their final response to a complaint. At that stage, public bodies should provide clear and accurate information about the next stage of the complaint process so the complainant is clear about what to do next if they remain dissatisfied. If the complaints procedure is not the most appropriate way for a customer to take forward their concern, public bodies should also clearly direct them to the most appropriate way, for example through alternative appeals mechanisms.

2 Being customer focused

Public bodies should do the following:

- Ensure their complaints procedure is simple and clear, involving as few steps as possible. Having too many complaint handling stages may unnecessarily complicate the process and deter complainants from pursuing their concerns.
- Ensure that their complaint handling arrangements are easily accessible to their customers.
- Let their customers know about any help or advice that may be available to them if they are considering making a complaint. For example, Community Legal Advice offers wide-ranging legal advice and the Independent Complaints Advocacy Service (ICAS) provides advocacy for NHS complainants.
- Deal with complaints promptly, avoiding unnecessary delay, and in line with published service standards where appropriate. Resolving problems and complaints as soon as possible is best for both complainants and public bodies.
- Acknowledge the complaint and tell the complainant how long they can expect to wait to receive a reply. Public bodies should keep the complainant regularly informed about progress and the reasons for any delays, and provide a point of contact throughout the course of the complaint.
- Treat complainants sensitively and in a way that takes account of their needs.
- Use language that is easy to understand, and communicate with the complainant in a way that is appropriate to them and their circumstances. For example, public bodies should make arrangements for complainants with special needs or those whose first language is not English.
- Listen to and consider the complainant's views, asking them to clarify where necessary, to make sure the public body understands clearly what the complaint is about and the outcome the complainant wants.
- Respond flexibly to the circumstances of the case. This means considering how the public body may need to adjust its normal approach to handling a complaint in the particular circumstances.
- Ensure, where complaints raise issues about services provided by more than one public body, that the complaint is dealt with in a co-ordinated way with other providers. If a public body cannot respond, it should refer the complainant quickly to other sources of help.

3 Being open and accountable

Public bodies should do the following:

- Ensure that information about how to complain is easily available. They should provide clear, accurate and complete information to their customers about the scope of complaints the organisation can consider; what customers can and cannot expect from the complaint handling arrangements, including timescales and likely remedies; and how, when and where to take things further.
- Be open and honest when accounting for their decisions and actions. They should give clear, evidence-based explanations, and reasons for their decisions. When things have gone wrong, public bodies should explain fully and say what they will do to put matters right as quickly as possible.
- Create and maintain reliable and usable records as evidence of their activities. These records should include the evidence considered and the reasons for decisions. Public bodies should manage complaint records in line with recognised standards to ensure they are kept and can be retrieved for as long as there is a statutory duty or business need. This can include the need to respond to complaints or to provide relevant information to the Ombudsman.
- Handle and process information properly and appropriately, in line with the law and relevant guidance. So while their policies and procedures should be transparent, public bodies should also respect the privacy of personal and confidential information, as the law requires.
- Take responsibility for the actions of their staff and those acting on behalf of the public body.

4 Acting fairly and proportionately

Public bodies should do the following:

- Understand and respect the diversity of their customers and ensure fair access to services regardless of background or circumstances.
- Investigate complaints thoroughly and fairly, basing their decisions on the available facts and evidence, and avoiding undue delay. Public bodies should deal with complaints objectively, fairly and consistently, so that similar circumstances are handled similarly. Any different decisions about two similar complaints should be justified by the circumstances of the complaint or complainant.
- Seek to ensure, where a complaint relates to an ongoing relationship between the public body and complainant, that staff do not treat the complainant any differently during or after the complaint.
- Avoid taking a rigid, process-driven, 'one-size-fits-all' approach to complaint handling, and ensure the response to an individual complaint is proportionate to the circumstances. This means taking into account the seriousness of the issues raised, the effect on the complainant, and whether any others may have suffered injustice or hardship as a result of the same problem.
- Ask a member of staff who was not involved in the events leading to the complaint to review the case. The public body can still put things right quickly for the complainant where appropriate.
- Act fairly towards staff as well as customers. This means ensuring members of staff know they have been complained about and, where appropriate, have an opportunity to respond.

A minority of complainants can be unreasonably persistent or behave unacceptably in pursuing their complaints. Public bodies should have arrangements for managing unacceptable behaviour.

5 Putting things right

Providing fair and proportionate remedies is an integral part of good complaint handling. Where a public body has failed to get it right and this has led to injustice or hardship, it should take steps to put things right. That means, if possible, returning complainants and, where appropriate, others who have suffered the same injustice or hardship as a result of the same maladministration or poor service, to the position they were in before this took place. If that is not possible, it means compensating complainants and such others appropriately.

In many cases, a prompt explanation and an apology will be a sufficient and appropriate response and will prevent the complaint escalating. Apologising is not an invitation to litigate or a sign of organisational weakness¹.

There is a wide range of appropriate responses to a complaint that has been upheld. These include:

- an apology, explanation and acknowledgement of responsibility
- remedial action, which may include reviewing or changing a decision on the service given to an individual complainant; revising published material; revising procedures, policies or guidance to prevent the same thing happening again; training or supervising staff; or any combination of these
- financial compensation for direct or indirect financial loss, loss of opportunity, inconvenience, distress, or any combination of these.

When deciding the level of financial compensation, public bodies should consider:

- the nature of the complaint
- the impact on the complainant
- how long it took to resolve the complaint
- the trouble the complainant was put to in pursuing it.

Remedies may also need to take account of any injustice or hardship that has resulted from pursuing the complaint as well as from the original dispute.

Further information about the Ombudsman's views on how public bodies should provide remedies is set out in the Ombudsman's *Principles for Remedy* available on our website at: www.ombudsman.org.uk.

¹ Section 2 of the *Compensation Act 2006* states: 'An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty'. This section of the Act applies to England and Wales only.

6 Seeking continuous improvement

Good complaint handling is not limited to providing an individual remedy to the complainant: public bodies should ensure that all feedback and lessons learnt from complaints contribute to service improvement.

Learning from complaints is a powerful way of helping to improve public service, enhancing the reputation of a public body and increasing trust among the people who use its service. Public bodies should have systems to record, analyse and report on the learning from complaints. Public bodies should feed that learning back into the system to improve their performance.

It is good practice for public bodies to report publicly on their complaint handling performance. This should include reporting on the number of complaints received and the outcome of those complaints. Where complaints have led to a change in services, policies or procedures, public bodies could report those changes. Reporting on complaint handling performance can help to:

- motivate staff
- promote achievement
- drive improvement in service delivery
- boost public confidence in the complaint process
- encourage potential complainants to access the scheme properly
- enable public bodies to identify patterns in complaints.

Public bodies should ensure they:

- tell the complainant when lessons have been learnt as a result of their complaint
- state any changes they have made to prevent the problem recurring.



Principles for Remedy



Principles for Remedy

Good practice with regard to remedies means:

- 1 Getting it right
- 2 Being customer focused
- 3 Being open and accountable
- 4 Acting fairly and proportionately
- 5 Putting things right
- 6 Seeking continuous improvement



Introduction

This document gives our views on the Principles that should guide how public bodies provide remedies for injustice or hardship resulting from their maladministration or poor service. It sets out for complainants and bodies within the Parliamentary and Health Service Ombudsman's jurisdiction how we think public bodies should put things right when they have gone wrong and our approach to recommending remedies.

These *Principles for Remedy* should be read in conjunction with our *Principles of Good Administration* and *Principles of Good Complaint Handling*.

Remedying injustice and hardship is a key aspect of the Ombudsman's work. Not all maladministration or poor service results in injustice or hardship, but where it does, our underlying principle is to ensure that the public body restores the complainant to the position they would have been in if the maladministration or poor service had not occurred. If that is not possible, the public body should compensate them appropriately.

We aim to secure suitable and proportionate remedies for complainants whose complaints are upheld and, where appropriate, for others who have suffered injustice or hardship as a result of the same maladministration or poor service. We want public bodies to be fair and to take responsibility, to acknowledge failures and apologise for them, to make amends, and to use the opportunity to improve their services.

There is a range of appropriate responses to a complaint that has been upheld. These will include both financial and non-financial remedies. Financial compensation will not be appropriate in every case, but public bodies should not rule it out as a form of remedy for justified complaints. We understand that, for public bodies, there is often a balance between responding appropriately to people's complaints and acting proportionately within available resources. However, finite resources should not be used as an excuse for failing to provide a fair remedy.

The Ombudsman's *Principles for Remedy* accords with HM Treasury's guidelines on remedy as set out in *Managing Public Money*¹ and is cited as best practice in the NHS *Finance Manual*².

The Principles set out here are intended to promote a shared understanding of how to put things right when they have gone wrong and to help public bodies in the Ombudsman's jurisdiction provide fair remedies.

¹ www.hm-treasury.gov.uk/psr_mpm_index.htm

² www.info.doh.gov.uk/doh/finman.nsf

Principles for Remedy

Good practice with regard to remedies means:

1 Getting it right

- Quickly acknowledging and putting right cases of maladministration or poor service that have led to injustice or hardship.
- Considering all relevant factors when deciding the appropriate remedy, ensuring fairness for the complainant and, where appropriate, for others who have suffered injustice or hardship as a result of the same maladministration or poor service.

2 Being customer focused

- Apologising for and explaining the maladministration or poor service.
- Understanding and managing people's expectations and needs.
- Dealing with people professionally and sensitively.
- Providing remedies that take account of people's individual circumstances.

3 Being open and accountable

- Being open and clear about how public bodies decide remedies.
- Operating a proper system of accountability and delegation in providing remedies.
- Keeping a clear record of what public bodies have decided on remedies and why.

4 Acting fairly and proportionately

- Offering remedies that are fair and proportionate to the complainant's injustice or hardship.
- Providing remedies to others who have suffered injustice or hardship as a result of the same maladministration or poor service, where appropriate.
- Treating people without bias, unlawful discrimination or prejudice.

5 Putting things right

- If possible, returning the complainant and, where appropriate, others who have suffered similar injustice or hardship, to the position they would have been in if the maladministration or poor service had not occurred.
- If that is not possible, compensating the complainant and such others appropriately.
- Considering fully and seriously all forms of remedy (such as an apology, an explanation, remedial action, or financial compensation).
- Providing the appropriate remedy in each case.

6 Seeking continuous improvement

- Using the lessons learned from complaints to ensure that maladministration or poor service is not repeated.
- Recording and using information on the outcome of complaints to improve services.

These Principles are not a checklist to be applied mechanically. Public bodies should use their judgment in applying the Principles to produce reasonable, fair and proportionate remedies in the circumstances. The Ombudsman will adopt a similar approach in recommending remedies.

The supporting text for each Principle follows.

1 Getting it right

Where maladministration or poor service has led to injustice or hardship, the public body responsible should take steps to provide an appropriate and proportionate remedy.

The public body should:

- ideally, return complainants and, where appropriate, others who have suffered injustice or hardship as a result of the same maladministration or poor service, to the position they were in before the maladministration or poor service took place
- if that is not possible, compensate them appropriately.

The public body should also ensure they keep any commitments to provide remedies, including ensuring they do not repeat any failures.

In many cases, an apology and explanation may be a sufficient and appropriate response. Public bodies should not underestimate the value of this approach. A prompt acknowledgement and apology, where appropriate, will often prevent the complaint escalating. Apologising is not an invitation to litigate or a sign of organisational weakness³.

It can benefit the public body as well as the complainant, by showing its willingness to:

- acknowledge when things have gone wrong
- accept responsibility
- learn from its maladministration or poor service
- put things right.

In putting right any injustice or hardship suffered as a result of maladministration or poor service, the public body should assess all the relevant circumstances in a balanced way. This means taking into account both objective evidence and more subjective views of the impact of the injustice or hardship. In some cases, the remedy will be easy to work out; in others, it will be more difficult because of the number of factors to take into account.

Offering remedies should not necessarily be limited to formal complaints. A timely response may ensure that the person decides not to make a formal complaint.

³ Section 2 of the *Compensation Act 2006* states: 'An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty'. This section of the Act applies to England and Wales only.

2 Being customer focused

Public bodies should promptly identify and acknowledge maladministration and poor service, and apologise for them.

An apology means:

- acknowledging the failure
- accepting responsibility for it
- explaining clearly why the failure happened
- expressing sincere regret for any resulting injustice or hardship.

In some cases, it may also be appropriate to express sympathy. Public bodies should consider:

- which organisational level the apology should come from
- who should apologise
- the most appropriate form of apology, for example in person, by telephone or in writing.

It is important to manage expectations from the start, and to explain clearly to the complainant what is and is not possible, so they understand what may be achieved for them. It is possible that the complainant may:

- expect too much
- not fully understand their rights and responsibilities
- have contributed to or prolonged the injustice or hardship.

Public bodies should make clear to complainants that remedies aim to:

- return them to the position they would have been in if the maladministration or poor service had not happened, if possible
- compensate them appropriately, if that is not possible.

Public bodies should do the following:

- consider the wishes and needs of the complainant in deciding an appropriate remedy, but remedies should not lead to a complainant making a profit or gaining an advantage
- behave professionally and with regard to individual circumstances
- aim to remedy injustice or hardship in a timely way. If the complaint is about a very complex or sensitive issue, or involves more than one service provider, the complainant should be given a single point of contact
- consider all the circumstances of the case and try, wherever possible, to offer a remedy that is calculated fairly and impartially but is still appropriate.

3 Being open and accountable

Public bodies should provide clear guidance about the criteria they use for deciding remedies. Staff should know the circumstances in which they may offer remedies, and what they may and may not offer.

Criteria for deciding remedies should be clear. But they should not be applied rigidly or mechanically in a way that prevents staff and their managers considering the fairest and most appropriate remedy in all the circumstances.

Public bodies should be open and clear with complainants about what remedies may be available to them, and in what circumstances. If the internal governance of a public body means that some kinds of remedy are available only through a formal complaints procedure, it should be open and clear about that fact.

When offering a remedy, public bodies should explain to the complainant how they reached their decision. They should also keep a clear record of the decision and the reasons for it.

4 Acting fairly and proportionately

Remedies should be fair, reasonable and proportionate to the injustice or hardship suffered.

The public body should consider how the circumstances of the case have affected the complainant in all ways. Even if an offer of remedy is not legally required, the public body should consider whether it has acted fairly and how its decisions have affected:

- the complainant
- where appropriate, others who have suffered injustice or hardship as a result of the same maladministration or poor service.

When considering a remedy, it is reasonable for a public body to take into account any way in which the complainant has contributed to, or prolonged, the injustice or hardship.

Each case must be considered on its own merits. Any guidance or procedure that public bodies use to decide remedies should be flexible enough to enable the public body to consider fully:

- the individual circumstances
- the need to provide an appropriate remedy for the injustice or hardship sustained.

At the same time, people should be treated consistently. Decisions on remedies should take proper account of previous decisions made on similar facts. Any difference in remedies between similar cases should be justified by the objective features or the individual circumstances of the case.

If applying the law, regulations or procedures strictly would lead to an unfair remedy for an individual, the public body should seek to address the unfairness. In doing so, public bodies must, of course, bear in mind the proper protection of public funds and ensure they do not exceed their legal powers.

5 Putting things right

Where maladministration or poor service has led to injustice or hardship, public bodies should try to offer a remedy that returns the complainant to the position they would have been in otherwise. If that is not possible, the remedy should compensate them appropriately. Remedies should also be offered, where appropriate, to others who have suffered injustice or hardship as a result of the same maladministration or poor service.

There are no automatic or routine remedies for injustice or hardship resulting from maladministration or poor service. Remedies may be financial or non-financial.

An appropriate range of remedies will include:

- an apology, explanation, and acknowledgement of responsibility
- remedial action, which may include reviewing or changing a decision on the service given to an individual complainant; revising published material; revising procedures to prevent the same thing happening again; training or supervising staff; or any combination of these
- financial compensation for direct or indirect financial loss, loss of opportunity, inconvenience, distress, or any combination of these.

Public bodies should:

- calculate payments for financial loss by looking at how much the complainant has demonstrably lost or what extra costs they have incurred
- apply an appropriate interest rate to payments for financial loss, aimed at restoring complainants to the position they would have been in if the maladministration or poor service had not occurred
- consider what interest rate to pay and explain the reasons for the chosen rate.

Factors to consider when deciding the level of financial compensation for inconvenience or distress should include:

- the impact on the individual – for example whether the events contributed to ill health, or led to prolonged or aggravated injustice or hardship
- the length of time taken to resolve a dispute or complaint
- the trouble the individual was put to in pursuing the dispute or complaint.

Remedies may need to take account of injustice or hardship that results from pursuing the complaint as well the original dispute. Financial compensation may be appropriate for:

- costs that the complainant incurred in pursuing the complaint
- any inconvenience, distress or both that resulted from poor complaint handling by the public body.

Remedial action may include improvements to the public body's complaints policy or procedures.

6 Seeking continuous improvement

Part of a remedy may be to ensure that changes are made to policies, procedures, systems, staff training or all of these, to ensure that the maladministration or poor service is not repeated. It is important to ensure that lessons learnt are put into practice.

It is a false economy and poor administrative practice to deal with complaints only as they arise and to fail to correct the cause of the problem. Learning from complaints, and offering timely and effective remedies, gives the best outcome in terms of cost effectiveness and customer service – benefiting the service provider, the complainant and the taxpayer.

The public body should ensure that the complainant receives:

- an assurance that lessons have been learnt
- an explanation of changes made to prevent maladministration or poor service being repeated.

Quality of service is an important measure of the effectiveness of public bodies. Learning from complaints is a powerful way of helping to develop the public body and increasing trust among the people who use its services. So systems should exist to:

- record, analyse and report on the outcomes of complaints and remedies
- apply the information to improving customer service.

Guidance on issuing an apology

When we investigate a complaint and find maladministration, we may recommend that the public service provider offers an apology. In these circumstances the complainant may have been waiting a considerable period of time for the organisation to provide a full explanation as to what went wrong and to acknowledge any failings.

What is an apology?

An apology can be defined as a 'regretful acknowledgement of an offence or failure'. Mistakes can be made by one member of staff, a whole team or there may be systemic failures within an organisation. When things do go wrong, most people who have had a bad experience may simply seek an acknowledgement and, if appropriate, to be given an explanation and an apology.

Why apologise?

In many cases an apology and explanation may be a sufficient and appropriate response to a complaint. The value of this approach should not be underestimated. A prompt acknowledgement and apology, where appropriate, can often prevent the complaint escalating. It can help restore dignity and trust in the public service provider and can be the first step in putting things right.

What are the implications of an apology?

Although there is no legislation in this area of law which applies specifically to Northern Ireland, the Compensation Act 2006 governing England and Wales states that 'an apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or statutory duty.' The timely provision of a full apology may in fact reduce the chances of litigation.

What is a meaningful apology?

Each complaint is unique so your apology will need to be based on the individual circumstances. It is important when you are making an apology, you understand how and why the person making the complaint believes they were failed and what they want in order to put things right. Failing to acknowledge the complainant's whole experience is only a partial apology and therefore less effective.

To make an apology meaningful you should:

- Accept you have done wrong. You should include identifying the failure along with a description of the relevant action or omission to which the apology applies. This should include any failings that the Ombudsman identified in the investigation that warrant an apology. Your description must be specific to show that you understand the effect your act or omission has had on the complainant. It must also acknowledge if appropriate, that the affected person has suffered disappointment, hurt, anxiety, upset or loss.
- Clearly explain why the failure happened and include that the failure was not intentional or personal. If there is no explanation, however, one should not be offered. Care should be taken to provide full explanations rather than excuses.
- Demonstrate that you are sincerely sorry. An apology should be an expression of sorrow or at the very least an expression of regret. The nature of the harm done will determine whether the expression of regret should be made in person as well as being reinforced in writing; or simply in writing.
- Reassure the complainant that you will not repeat the failure. This may include a statement of the steps that have been taken, or will be taken, to address the failure, and, if possible, to prevent a reoccurrence.
- Provide the complainant with a statement of specific steps proposed to address the grievance or problem, by mitigating the harm or offering a remedy.

How should I make an apology?

There is no 'one size fits all' apology but the following points reflect some general good practice:

1. The timing of an apology is very important. Once you establish that you have done wrong, apologise. If you delay, you may lose your opportunity to apologise.
2. The language you use should be clear, plain and direct.
3. Your apology should not be conditional by qualifying the apology by saying for example: 'I apologise if you feel that the service provided to you was not acceptable' or 'if mistakes have been made, I apologise'.
4. To make an apology meaningful, do not distance yourself from the apology. Generalised apologies such as 'I am sorry for what occurred' or 'mistakes were made' do not sound natural or sincere. It is much better to accept responsibility by stating 'It was my fault'.

5. Avoid enforced apologies such as 'I have received the Investigation report from the Ombudsman and am therefore carrying out the recommendations by apologising to you for the shortcomings identified in it.'
6. It is also very important to apologise to the right person or the right people.

Who should apologise?

If, in the Investigation report, the Ombudsman has made a recommendation that an apology should be provided to the complainant, then we would expect to see the Chief Executive, Director or Head of Department of the public service provider involved making the apology.

Who should receive the apology?

The apology should be sent directly to the complainant who is named in the Investigation report. We will not, as a matter of course, review apologies prior to them being issued. However, in order to monitor compliance with the Ombudsman's recommendations, we would expect to receive a copy of the apology letter within the time requested.

The benefits to organisations of apologising

It is important to remember that an apology is not a sign of weakness or an encouragement to take legal action. An apology can be a sign of confidence and competence and demonstrates a willingness to learn from mistakes and a commitment to put things right. To apologise in a fulsome and timely manner is good administrative practice and is an important part of effectively managing complaints.

Contact Details

You can contact us in the following ways:

Freepost: Freepost NIPSO

or
The Northern Ireland Public Services Ombudsman
Progressive House
33 Wellington Place
BELFAST
BT1 6HN

Telephone: 028 9023 3821 **or Freephone:** 0800 34 34 24

Text Phone: 028 9089 7789

Email: nipso@nipso.org.uk

or
By calling, 9.00am & 5.00pm, Monday to Friday,
at the above address.

Records Matter

A view from regulation and oversight bodies
on the importance of good record keeping



Good record keeping is the responsibility of every public servant, including those at a senior level who are responsible for fostering a good records keeping culture in their organisations and making sure that decisions are recorded properly.





Paul McFadden
Deputy Ombudsman
Northern Ireland
Public Services Ombudsman



Kieran Donnelly CB
Comptroller and Auditor General
Northern Ireland Audit Office



Ken Macdonald
Head of ICO Regions
Information Commissioner's Office

Foreword

We are pleased to issue this joint foreword to the important and topical issue of good record keeping.

We know that the job of delivering services to members of the public is a busy and challenging one. However we are aware that for many organisations the practice of good record keeping is not given the priority it deserves. The importance of good record keeping cannot be overstated. This is because records provide evidence of activity. They can help to tell us why a decision was made, who made it and when. They are necessary to create confidence in any decision making process, to promote accountability and transparency, and to enable others to verify what has been done. Good record keeping is also vital for corporate memory.

This publication does not give detailed guidance on how to create records - this should be contained within the policies and procedures of organisations. The aim of this guide is to demonstrate the importance of keeping good quality records. It aims to show why a culture of good record keeping is vital for a responsive public sector. Its content is formed from our collective experience of complaint handling, investigations, audits and inspections carried out over many years.

Good record keeping means:

- complying with legal, regulatory, business, and accountability requirements;
- creating a written record of decisions and key matters discussed in meetings, conversations, emails, etc;
- documenting the reasons for decisions;
- saving records in a structured or managed way so they can be easily retrieved; and,
- following any relevant policies and procedures

We often come across some excellent examples of good record keeping during our work. Unfortunately we also see the consequences of poor record keeping practices. For example, the evidence sessions of the Renewable Heat Incentive Inquiry highlighted significant issues with the quality of record keeping, including a lack of records on who took key decisions, how these decisions were made, and what was actually agreed.

In our view there is a need for more compliance work to ensure proper record keeping is observed as we move forward. One important caveat is that holding excessive documentation can be just as bad as keeping inadequate records. Common sense must be exercised to ensure that sensible, accurate, open and proportionate records are maintained.

This publication looks at our findings and recommendations in a number of cases. It is split into two main sections – **‘Creating Records’** and **‘Managing Records’**.

As regulation and oversight bodies, our various powers enable us to:

- release a report, highlighting where problems have occurred;
- recommend changes to existing practices; or,
- impose fines

Our reports can lead to criticism of public bodies, potentially leading to reputational damage. However, at the heart of our work is the aim of improving public services in Northern Ireland. We believe that by highlighting these cases, organisations will be able to see that often only a small amount of attention to the discipline of good record keeping is needed to prevent similar mistakes being made in the future.

We hope you find the publication useful.



Section One - Creating Records

In a work context, information is constantly being created. When someone sends an email, drafts a brief, writes a report, adds data to a spread sheet, or makes notes of a meeting, information is created for a specific business purpose.

It is not necessary to save every single piece of information as a business record. However, the cases highlighted here help to demonstrate how important it is for public bodies to make formal records of their actions, and in particular in relation to their decision-making.

At its most basic, the simple act of recording what has been decided, and why, could save a considerable amount of time and effort in the future. For example, it is not unusual for people to leave a meeting with different interpretations of what was discussed. An agreed record helps everyone have a common understanding of what has been decided, as well as remind people of who is responsible for undertaking an action or task.

Recording decisions can also help a public body defend its actions when challenged. For example, it will be able to show how its decisions were reached and that it has properly thought through the consequences of its actions.

A lack of proper records also makes it more difficult to convince others that a body has behaved properly. In an audit, investigation, or in the event of legal challenge, it may be difficult to prove that due process was followed if a body is unable to provide the relevant documents.

Finally, given the need for public services to be citizen-focused, it is important to acknowledge that poor record keeping can have a devastating effect on service users, particularly within areas such as health or social care. If something has gone wrong, accurate information is crucial to an understanding of what happened and why.

From a regulation and oversight perspective, if there is good record keeping it is possible to get the full story from the documentary record without the need for supplementary questioning of the people that have been involved.

However, it is important to note that this does not mean excessive documentation - it means maintaining sensible, necessary, accurate, open and proportionate records.



Case Study 1

In an audit of a Departmental Funding Scheme, the Northern Ireland Audit Office (NIAO) found that, in some instances there was a lack of detail around how funding allocations and prioritisations were agreed.

It discovered that one project, which was initially ranked as the 27th highest scoring project, subsequently moved up to seventh. This enabled it to receive £870,000 in funding.

In its report, the NIAO said that these types of decisions should be clearly documented, as a clear audit trail can justify why decisions were made and demonstrate that assessment processes have been applied fairly, consistently and transparently.

Key message

Every day, people in the public sector make decisions about how to spend public money. Good record keeping can help to show that the money has been spent wisely.



Case Study 2

A man complained that a government agency did not look properly at the impact of four planning applications near his house. An Ombudsman investigation found that the agency did not make proper records of its decision-making in the case. It did not record the reasons why it chose not to do a detailed Transport Assessment of the applications. It also failed to record the reasons why it thought the accident history in the area was not relevant.

Although there was no evidence to show that the agency had made the wrong decision, the Ombudsman found there had been maladministration because of the agency's failure to record its decision-making.

Key message

Giving reasons for decisions is a key tenet of good administration and is essential for fairness and transparency. Records can act as a 'shield' for a public body to defend its actions when challenged.

Case Study 3

When a member of the public said that he had waited too long for a Housing Association to repair his home, the Ombudsman asked it for all documents about the case. The investigation found that the Maintenance Officer who visited the house did not make a note of what condition it was in, nor what repairs were needed.

There was also no record of whether or not the man, who was registered disabled, needed the help of an Occupational Therapist. Important internal discussions about the case, and conversations between staff from the Housing Association and the tenant had not been documented on file.

The report into the complaint was critical of the record keeping at numerous points in this case. As a result of these and other failures the Ombudsman recommended that the body should apologise to the complainant and remind its staff about the importance of good record keeping.

Key message

Accountability of public sector bodies is crucial. Bodies must take a comprehensive view of how they are documenting information. They need to recognise that information has a value, particularly personal data and that not demonstrating due care and attention can lead to risks to individual's rights and freedoms as well as repercussions, such as reputational damage.

Section Two - Managing Records

Managing records in the public sector should be viewed as a core corporate function, as well as a statutory obligation. The most senior official within a public body has overall responsibility for its records management compliance. Therefore it is important that they engrain a culture of accountability within their organisation. It also means ensuring staff are properly trained and resourced to carry out these vital functions.

Describing information and records accurately allows users to understand what they are, where they came from, what has happened to them and the relationships they have with other information assets.

Making information easy to find and use also has a significant impact on the efficiency of an organisation. It is vital to ensure information is discoverable, accessible and usable. This is important for business reasons but also to comply with the Freedom of Information Act 2000, the Environmental Information Regulations 2004, the General Data Protection Regulations (GDPR) and the Data Protection Act 2018.

Developments in technology have resulted in a change in how decisions are made and recorded, leading to a blurring of the lines between personal and business communications. This presents challenges in documenting decisions, alongside complications for the retention and accessibility of records. However, it is worth noting here that changes in technology do not change the statutory information rights obligations of public authorities. If a phone call, messaging app, email or social media exchange relates to a key business discussion or decision, the information needs to be captured and managed appropriately. This applies to personal as well as business accounts.

Information security is also an important issue for the public sector. Organisations need to ensure that the information and records they create are secured so they cannot be:

- tampered with or inappropriately altered;
- inappropriately deleted or misplaced; or
- accessed by unauthorised personnel.



Case Study 1

A police officer who added new information to the Police National Computer (PNC) mistakenly added it to the record of another individual with a similar name and the same date of birth. The information related to allegations that the man presented a risk to others.

As a result the innocent individual was reported to social services and he was prevented from looking after his son and grandson. After intervention from the Information Commissioner's Office (ICO), the force involved admitted there had been human error. It corrected the mistake, apologised to the man and reminded its staff about the importance of accuracy during data input.

Key message

Policies and procedures for effective record keeping are essential but only when they are supported by regular training and guidance for staff. All staff handling records should be provided with mandatory training on commencement of employment regardless of their grade or role and refresher training should be provided at regular intervals.

Case Study 2

The NIAO reported on the events that led to the collapse of an arm's length body and highlighted completely inadequate record keeping as a key factor. One of the most worrying issues was around the documentation supporting the appointment of a Chief Executive. The early stages of the appointment process was contracted out to a private HR firm which did not keep detailed records. The Chief Executive appointed did not have the qualifications set out in the job specification and did not meet the essential criteria, yet still passed the four stages of the recruitment process.

As part of the appointment process was contracted out, the parent department did not seem to be aware that the individual did not meet the essential criteria for the post.

Key message

Where third parties, are involved in public administration, it is essential that the public body retains the control over the documentation. Public bodies should ensure that records are kept and managed in a way that safeguards the integrity of staff and maximises public confidence in the organisation's ability to deliver public services properly. Documentary evidence is needed to provide assurance that things have been done properly.



Case Study 3

A member of the public complained to the Ombudsman about the care and treatment her husband received in hospital before his death. Part of her complaint was that four pages of notes which contained information about her husband's final days were missing from his medical file.

The Trust was unable to explain to the family why the four pages were missing. This, and the considerable delay in providing the family with the file, led to them believing that his medical record had been tampered with.

Because it could not provide robust evidence to back up its findings, the Ombudsman was unable to accept the Trust's conclusions that the missing pages did not contain records relevant to the patient's care.

The Trust agreed to apologise to the man's family and to provide a financial award to acknowledge the distress its actions had caused.

Key message

Incomplete records can lead to suspicions of wrongdoing or a sense that the body has something to hide.

Case Study 4

A box containing personal information for 25 candidates who attended an assessment centre was lost by a third-party provider. The documentation included copies of passports, qualification certificates and background security clearance documents.

The ICO discovered that there was no audit trail for the handling and storage of the records. Even though the box was delivered to and signed for by the third-party provider, it still could not be found. The ICO also said that checks of the building to try and locate the information were not properly carried out.

Following the incident, the data controller reviewed the security of its processes. It awarded the contract to a new supplier and refined the transportation process to include pre and post-assessment checks to safeguard delivery. It also developed a data protection checklist to be applied following completion of all assessments, and introduced an electronic process to avoid the need for hard copies to be sent to a third-party supplier via courier.

Key message

Information security is essential to good record keeping. Maintaining the confidentiality, availability and integrity of information is vital to ensuring that the citizen can be confident that public bodies are looking after their data.

The essentials of good record keeping

Good record keeping practice in organisations is dependent on individual members of staff knowing when to create and save records. However, staff making these judgments need to be supported by appropriate policies and procedures.

In preparing their guidance to staff, all bodies should have reference to the General Data Protection Regulations and the Data Protection Act 2018. These make it a statutory requirement for organisations to properly record their processing of personal information and the decisions lying behind that processing.

Bodies should also consider their wider records management responsibilities in line with the Section 46 Code of Practice of the Freedom of Information Act 2000. These include having in place arrangements that support records management, having efficient and effective storage systems for records, and knowing what records they hold and where they are.

As general good practice, all bodies should always strive to keep accurate official records and handle all information as openly and transparently as possible. They should also consider, as a matter of good practice, adopting a duty to document. This would assist public authorities in complying fully with their obligations under information rights legislation.

Good record keeping can be achieved by following a number of key principles.

These include:

Capturing all key decisions and actions, as well as the rationale behind them

This can often be with just a short file note, but should be done throughout the decision-making process, and as close as possible to when key decisions are made.

Managing records and information effectively and appropriately

Bodies should identify what should be kept and follow structured retention systems which allow them to show that any records destroyed were done so as part of normal business practice.

Obtaining buy-in from all staff, especially senior management

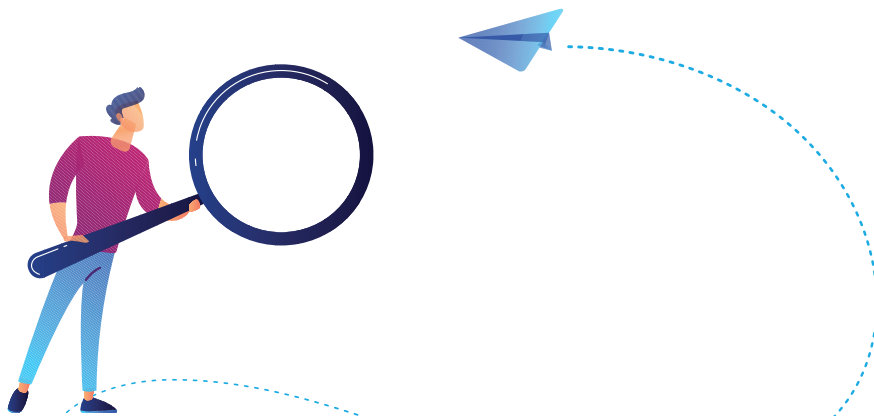
Leadership from the top helps to create a culture of good record keeping in organisations, leading to greater business efficiency, reduced risk and improved corporate knowledge.

Appropriate training

All staff should understand their record keeping responsibilities and be aware of all relevant policies and practices within their organisation.

Using information and communication technologies with integrity

This means ensuring that all communications undertaken in the course of business, using all methods or technologies, are sympathetically integrated into the work of public bodies and a proper record of discussions and decision making is preserved.



Conclusion

Our investigations, audits and inspections help us shine a light on the issue of record keeping in public bodies. The case studies chosen for this publication demonstrate the impact of poor practice in this area, and show how vital it is to embed good quality record keeping throughout organisations.

Put simply, the examples from this publication and our wider experience from the field of regulation and oversight demonstrate the fact that for all organisations and citizens, **records matter**.



About us

The Northern Ireland Public Services Ombudsman (NIPSO)

The Ombudsman looks at complaints made about health and social care services, government departments and agencies, social housing providers, local government and education.

The Ombudsman receives over 2,000 enquiries and complaints each year.

www.nipso.org.uk

The Northern Ireland Audit Office (NIAO)

The Comptroller and Auditor General is Head of the NIAO. He and the NIAO are totally independent of Government. He certifies the accounts of Government Departments and a range of other public sector bodies. He has statutory authority to report to the Assembly on the economy, efficiency and effectiveness with which Departments and public bodies use their resources. The NIAO's work covers 108 public organisations which spend over £25.7 billion of public money annually.

www.niauditoffice.gov.uk

The Information Commissioner's Office (ICO)

The Information Commissioner's Office is the UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals.

Each year, the ICO addresses tens of thousands of enquiries, written concerns and complaints about information rights issues.

www.ico.org.uk

Northern Ireland Public Services Ombudsman
33 Wellington Place
Belfast
BT1 6HN

Northern Ireland Audit Office
106 University Street
Belfast
BT7 1EU

The Information Commissioner's Office – Northern Ireland
3rd Floor
14 Cromac Place
Belfast
BT7 2JB

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Signposting to the Ombudsman – a guide for public authorities

All listed authorities within the Ombudsman's jurisdiction have a statutory obligation to signpost complainants to the Ombudsman's office where the listed authority's complaints handling procedure is exhausted.

Section 25 of the Public Services Ombudsman Act (Northern Ireland) 2016 states:

- 25.—**(1) This section applies where a listed authority's complaints handling procedure is exhausted.
- (2) The authority **must**, within 2 weeks of the day on which the complaint handling procedure is exhausted give the person aggrieved a written notice stating –
- (a) that the complaints handling procedure is exhausted, and
 - (b) that the person aggrieved may, if dissatisfied, refer the complaint to the Ombudsman.
- (3) A notice under subsection (2) **must** –
- (a) inform the person aggrieved of the time limit for referring the complaint to the Ombudsman; and
 - (b) provide details of how to contact the Ombudsman.

Below is an example of how this statement can be worded:

You have now completed our internal complaints procedure and this is our final response. If you remain dissatisfied you may refer your complaint to the Northern Ireland Public Services Ombudsman (NIPSO). The Ombudsman can investigate complaints about public service providers in Northern Ireland.

NIPSO's contact details are:

Progressive House, 33 Wellington Place, Belfast, BT1 6HN or Freepost NIPSO. The Freephone number is 0800 342424 or you can email to nipso@nipso.org.uk.

Please note you must normally make your complaint to the Ombudsman within 6 months of the date of this letter.



Quality Care - for you, with you

Southern Health and Social Care Trust

Incident Management Procedure

October 2014

Procedure Checklist

Name of Procedure:	Incident Management Procedure
Purpose of Procedure:	To describe the Trusts systems and processes in relation to Incident Management
Directorate responsible for Procedure:	Corporate Governance, Office of the Chief Executive
Name & Title of Author:	Mrs Margaret Marshall, Interim Asst Director CSCG
Does this meet criteria of a Procedure?	Yes
Trade Union consultation?	No
Equality Screened by:	
Date Procedure submitted to Policy Scrutiny Committee:	
Members of Policy Scrutiny Committee in Attendance:	
Policy Approved/Rejected/Amended	
Policy Implementation Plan included?	
Any other comments:	
Date presented to SMT	
Director Responsible:	Chief Executive
SMT Approved/Rejected/Amended	
SMT Comments	
Date received by Employee Engagement & Relations for database/Intranet/Internet:	
Date for further review	

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1.0 Introduction:

The consistent identification, monitoring and review of incidents is central to the Trust's strategic and operational processes to ensure it can achieve its vision for safe and effective care. As recommended in the document „Safety First: a Framework for Sustainable Improvement in the HPSS“ (HPSS 2006) the Trust recognises that incident reporting is a fundamental element of its Risk Management Strategy.

1.1 Purpose:

The purpose of this procedure is to guide all employees of the Trust in the following:

- Identification, reporting, review, monitoring and learning from all incidents which have resulted in or had the potential to result in injury or harm to a person or damage to property or the environment, or a breach of security, confidentiality, policy or procedure.
- Analyse incident trends, root causes, associated costs and to develop appropriate action plans to eliminate or minimise exposure to associated risks.
- Enable staff to participate in, and effect change by ensuring that mechanisms are in place to learn from incidents which occur and that resulting changes in care, policy or procedures are embedded in local practice.
- Notification and recording of incidents from third party organisations from which the Trust commissions services.
- Notification of incidents where appropriate to other relevant agencies, for example the Regional Health and Social Services Board (RHSCB), Regulation Quality and Improvement Authority (RQIA), Department of Health, Social Services and Public Safety (DHSSPS) via appropriate Early Alerts, HM Coroner, Northern Ireland Adverse Incident Centre (NIAIC), Health & Safety Executive Northern Ireland (NIHSE), Police Service of Northern Ireland (PSNI), etc. Please see **Appendix 2**.

1.2 Scope of the Procedure:

The following procedure applies to all employees of the SHSCT. Some aspects, including reporting a serious adverse incident, also applies to independent providers / contractors commissioned or engaged by the Trust. It addresses the Trust's governance responsibilities in relation to incidents and is one element of the Trust's Risk Management Strategy.

2.0 The Roles and Responsibilities:

2.1 Chief Executive:

The Chief Executive is the responsible Officer for the Trust's statutory duty of quality and is required to drive the delivery of the Trust's corporate priorities, particularly the priority to provide safe, high quality care. Through the overview of this Trust Policy and Procedure, the Chief Executive will seek to embed the Trust's corporate values throughout the organisation, to promote the Trust's values of all staff being open and honest and acting with integrity, to listen and learn and to embrace change for the better.

The Assistant Director for Clinical and Social Care Governance (AD CSCG) reports directly to the Chief Executive and will provide the Chief Executive, Trust Board, Senior Management Team (SMT) and Governance Committee with an on-going overview of this Policy and Procedure through the continuous corporate review and monitoring of Incidents and Serious Adverse Incidents (SAIs).

2.2 Assistant Director of Clinical and Social Care Governance (AD CSCG):

The AD CSCG will provide leadership to ensure a systematic and organisation-wide approach to the reporting of clinical and social care incidents and near misses and will work with SMT to embed a culture of appropriate and timely reporting, analysis and learning across the organisation.

The Assistant Director will participate in monthly meetings with the Clinical and Social Care Governance Coordinators in order that there is a corporate oversight in relation to incidents, risks, trends and learning within the organisation.

It is the responsibility of the AD CSCG to present a trend analysis report quarterly of all incidents reported in the Trust to:

- Senior Management Team (SMT)
- the Governance Committee
- CSCG Working Body

This report will be used by the SMT to inform organisational risk management and governance priorities and will escalate concerns in relation to trends and /or learning.

On behalf of the Chief Executive and SMT, the AD CSCG will provide assurance reports to Governance Committee in relation to the adoption and implementation of procedures relating to incident reporting, monitoring and learning. This includes evidence of cross organisational learning through appropriate forums including the Trust Governance Working Body.

The AD CSCG will act as a conjugate between the Directorates and the Chief Executive, appraising the latter of all major and catastrophic incidents, internal reviews and Serious Adverse Incidents. They will also liaise on behalf of the Trust with the Department, the Public Health Agency (PHA) and the HSCB to ensure the Trust contributes to and is involved in any Regional opportunities for learning.

2.3 Directors:

- Directors are responsible for leading a culture of openness, transparency and learning within their area of responsibility and for ensuring that the actions from any learning are appropriate and the most effective way to minimise risk and provide good care services
- Directors shall ensure that processes are in place to effectively identify, report, review, monitor and learn from all incidents within their Directorate and that the processes are as laid out within this procedure
- They shall ensure that the reviewing, learning from and monitoring of incidents is included on the agenda of all directorate, divisional and team governance meetings
- They shall ensure that action plans and learning to be implemented from incidents are an effective response with an appropriate timescale, prioritised and are reviewed on an on-going basis at directorate governance meetings
- Directors shall consider learning from moderate, major and catastrophic incidents and any trends identified from insignificant / minor incidents to inform directorate governance priorities, education, training and directorate and organisational learning. The latter should be identified through the Directorate Governance forum and be escalated to the AD CSCG for dissemination via the Trust Governance Working Body
- They shall ensure that all current risks recognised from this governance of incidents are considered for the Directorate / Corporate Risk Register
- Training – liaise with the appropriate Executive Directors with responsibility for professional and organisational training

2.4 Assistant Directors & Associate Medical Directors (AMD's for clinical incidents):

All incidents recorded on Datix Web must be reviewed by an **Incident Review Team** on a **weekly** basis. It is the responsibility of all Assistant Directors / Associate Medical Directors (AMDs) to put in place **Incident Review Teams** within their divisions/teams. The membership of an Incident Review Team should include a Head of Service / Senior Manager and an identified Clinician where **clinical incidents** are under review.

The Assistant Director / AMDs must also:

- Lead a culture of openness, transparency and learning within their area of responsibility and ensure that the actions from any learning are appropriate and the most effective way to minimise risk and provide high quality care and services

- Include the management, review, monitoring and learning from incidents on the agenda of divisional, service and team governance meetings
- Ensure that action plans and learning to be implemented from incidents are an effective response, appropriately time bound, prioritised and are reviewed on an on-going basis at divisional meetings
- Consider learning from moderate, major and catastrophic incidents and any trends highlighted from insignificant / minor incidents when identifying directorate and divisional governance priorities, education, training and organisational learning in a timely way
- Organisational learning should be identified through to the Directorate Governance forum and be escalated to the AD CSCG for dissemination via the Trust Governance Working Body
- Identify training needs to the appropriate Heads within the Trust
- Ensure through their Heads of Service that any barriers to implementing the learning from moderate, major or catastrophic incidents is risk assessed using the SHSCT risk assessment matrix, highlighted at Directorate Governance Fora and placed on the appropriate risk register if not immediately actioned

2.5 Head of Service/ Team Manager:

It is the Head of Service/Team Manager's responsibility to:

- Lead a culture of openness, transparency and learning within their area of responsibility and ensure that the actions from any learning are appropriate and the most effective way to minimise risk and provide high quality care and services
- Include the management, review, monitoring and learning from incidents on the agenda of service and team governance meetings
- Ensure that action plans and learning to be implemented from incidents are an effective response, appropriately time bound, prioritised and are reviewed on an on-going basis at team meetings
- Consider learning from moderate, major and catastrophic incidents and any trends highlighted from insignificant / minor incidents when identifying service and team governance priorities, education, training and organisational learning in a timely way
- Escalate any barriers to implementation of action plans relating to incidents to the appropriate Assistant Director and consider if they need to be placed on the appropriate Risk Register
- Ensure through the function of the **Incident Review Team** that feedback is provided to the incident reporter on the outcome of incident investigations for all moderate, major and catastrophic incidents

2.6 Incident Review Team:

- The purpose of the **Incident Review Team** is to review all incidents, determine any learning from them, make recommendations as to what would constitute an effective response which will minimise risk and communicate this within their teams (and to Heads of Service / Team Manager if they are not part of the Incident Review Team). Learning / effective response to any risks highlighted should then be communicated to the appropriate Head of Service / Team Manager for action within the operational teams. Any barriers to implementation of action plans relating to incidents should be escalated by the appropriate Head of Service to the Assistant Director.

The Review Teams should also consider and review the following:

- The information submitted by the reporter including the incident grade
- Consider the need for additional internal and/or external reporting e.g. Health and Safety, RIDDOR, NIAIC, HSCB, RQIA, Adult Safeguarding (PVA). See **Appendix 2**
- Develop time bound and prioritised action plans as appropriate. All **moderate, major** and **catastrophic** incidents reported will require an action plan which **must** include relevant learning points
- Feedback the outcome of the review of **moderate, major and catastrophic** incidents to the incident reporter
- Inform Assistant Director of any immediate learning which could minimise the risk of further reoccurrence of incident
- Close all incidents following completion of the review process

All Incident Review Teams should adhere to the Datix Web User Guide for Managers/Reviewers which can be accessed from the Trust intranet site. See Hyperlink:

http://vsrintranet.southerntrust.local/SHSCT/documents/DatixWeb_InvestigatorsFinalApproversguidance2012.pdf

2.7 The Directorate CSCG Coordinator:

The CSCG Coordinator will ensure that processes are in place for the recording, reviewing, monitoring and learning from incidents and will provide timely and appropriate information on incidents to the Directorate. Reports will be tailored for Directors, Assistant Directors, Heads of Service and Team Managers.

The CSCG Coordinator will also be responsible for interpreting and analysing incident information to identify risks and/or trends. They will feedback this information to the Directorate through the Directorate Governance structures.

The CSCG Coordinator will provide regular and timely information to the Directorate on the action plans and learning arising from incidents and SAI"s and the progression of these action plans.

On behalf of the Director, the CSCG Coordinator is responsible for monitoring that within each service team, incident information is being acted on appropriately in order to mitigate risk, improve quality of care and patient and client safety and facilitate teams to make any links required from issues identified in incident management to appropriate Risk Registers. They will also ensure that a process is in place to escalate any concerns relating to incidents to the appropriate Director, and that there are appropriate processes in place to identify SAIs in line with the Health & Social Care Board (HSCB) process.

The CSCG Coordinator will participate in monthly meetings with the Assistant Director of Clinical and Social Care Governance in order that there is a corporate oversight in relation to incidents, risks, trends and learning within the organisation.

2.8 All SHSCT Staff:

All SHSCT staff are required to provide safe, high quality care and this includes the reporting of incidents for organisational learning and good risk management as defined below and further in **Appendix 1**, in accordance with this procedure and participate in any subsequent review if required.

3.0 Procedure for the Identifying and Reporting of Incidents – ALL STAFF

3.1 Incident Identification:

A useful definition of an incident is:

“Any event or circumstance that could have or did lead to harm, loss or damage to people, property, environment or reputation.”

The incident may arise during the course of the business of the Trust or any of its commissioned / contracted services.

However this is not an exhaustive definition and using the incident reporting system specifically for clinical outcomes which are unexpected and / or unexplained, but are not believed to be associated with an adverse incident, is also encouraged by the Trust as a means of triggering a thorough review of such cases. These reviews are a beneficial mechanism of providing assurance to staff, patients, clients, carers and relatives that any learning related to any aspect of the case is sought and acted upon.

3.1.1 Other Systems for Reporting:

An incident can sometimes also be reported through other systems such as Adult Safeguarding, Case Management Review, Mortality and Morbidity meetings, etc.

The Trust mechanism for recording all incidents is **Datix Web** and the electronic incident form (IR1) should be completed as soon as possible after the incident occurs or is discovered to have occurred. Staff should then think through what other reporting systems, such as notifying their Line Manager, may need to be considered.

3.1.2 Incidents Occurring Within Services Contracted or Commissioned by the Trust:

Incidents occurring in contracted / commissioned services which are not observed / witnessed by Trust staff and / or not reported to Trust staff are dealt with under the regional contractual arrangement with independent providers. This states that all incidents occurring within the regulated sector which are notifiable to RQIA will also be notified to the appropriate Trust via a central email. From here they will be distributed to the appropriate Directorate for review as per section 4 of this procedure.

If a member of Trust staff observes or witnesses an incident occurring within a service contracted or commissioned by the Trust or has an incident reported to them by a Trust client and / or their family / carers which relates to care provided by a contracted or commissioned service i.e. domiciliary care services, private nursing home, etc. then the member of staff has a duty to report the incident using the Trust Datix web system. The staff member will also instruct the contracted service to report the incident via their reporting mechanisms (which include notifying RQIA and Trust of significant incidents) and this instruction should be documented by Trust staff. If reported to the Trust by the contracted service the Datix incident reports should be merged by the appropriate governance team. **The original incident should be reviewed as per section 4 of this procedure.**

3.1.3 Immediate Action Checklist Following Identification of an Incident:

When an incident is identified and before it is reported please complete the following **immediate action checklist**:

- The extent of injuries/damages to person(s) or property should be ascertained and a determination made regarding the need for emergency or urgent treatment / action. For patient / client care related incidents, contact the relevant medical team to assess where required. The situation must be made safe
- Appropriate obvious treatment / actions should be taken to minimise the likelihood of the incident recurring
- Any equipment involved in the incident should be removed from use and clearly labeled, "Do not use", until appropriate checks can be carried out. Do not dispose of equipment involved in an incident
- **The patient/client and/or their relatives / carers** should be informed, as soon as possible of the incident and of any treatment that may be necessary taking into consideration any consent issues and referring to the Trust's "Being Open" guidance in **Appendix 4**

- Any incident involving a patient or client, and the action taken, should be recorded in their healthcare record
- If the incident is major or catastrophic and requires an immediate action plan to prevent further harm the line manager (if out of hours, the Senior Out of Hours Manager) should be informed
- For incidents requiring further in-depth investigation e.g. SAls/Internal Root Cause Analysis (RCA"s) / Reviews, patient/client records should be returned as soon as is practical to the Directorate Governance Coordinator to ensure all recorded information is available for review. Retrospective notes are permitted as long as these are clearly marked as being made in retrospect
- Where appropriate and where it would be beneficial to assist in the investigation of the incident, photographs should be taken and retained as evidence – this is particularly useful in Health and Safety type incidents or where damage had occurred to property
- CCTV footage should be sourced and a copy made for all cases which would be subject to PSNI investigation.
- Security staff and/or the PSNI should be informed where appropriate
- Consideration should also be given to the need to activate site based emergency / contingency plans if necessary (in line with current emergency procedures)

3.2 Reporting an Incident:

Where: All incidents must be recorded electronically via the Datix Web based form (IR1 form) which can be accessed as follows from the Trust intranet site. **(Trust intranet/ useful links/ other useful links and scroll down to click on „Datix Web“)**

By Whom: This form must be completed by either the member of staff involved in or who has witnessed the incident, or by the person the incident has been reported to.

When: All incidents should be reported via the electronic reporting form (IR1 form), no later than the end of the working shift or day during which it occurred **or** its occurrence became known.

How: Information concerning the incident must be accurate, complete and factual. The description of the incident should not contain opinions, conclusions, subjective or speculative statements. The following instructions should be followed when filling in the electronic incident form. *See Hyperlink below:*

http://vsrintranet/SHSCT/documents/DatixWebIR1FormUserGuidance_000.pdf

Incidents given an initial severity rating of major or catastrophic (as a minimum) will automatically be triggered to the appropriate Head of Service/Team Manager, relevant Assistant Director and the Assistant Director of Governance in an email via Datix Web.

In circumstances where the incident is considered as a potential **Serious Adverse Incident (SAI)**, (see **Appendix 1** for the definition of an SAI) immediate telephone contact should be

made to the relevant Head of Service/ Line Manager or Out of Hours Manager if appropriate. They will notify the appropriate Director, Assistant Director/Associate Medical Director and Clinical and Social Care Governance Coordinator at the earliest opportunity. The incident will then be reviewed by the latter group against the HSCB SAI criteria and the DHSSPS Early Alert criteria. This group must complete a major/catastrophic incident checklist for all incidents screened as possible SAs. This checklist, regardless of the outcome of the screening process, will be held by the Directorate CSCG Coordinator and copied to the Assistant Director of Governance via the Corporate Governance Office. (See **Appendix 6**) In the event of the incident meeting the Serious Adverse Incident criteria; **section 5.0** of this procedure should be followed and where appropriate, the Director should brief the Chief Executive on SAs as soon as possible.

4.0 Procedure for Reviewing, Monitoring and Learning from Incidents:

All incidents are to be reviewed on a weekly basis by the service area's Incident Review Team. As indicated earlier the purpose of the Incident Review Team is to undertake a local assessment / review of the incident in a timely manner. This review should include:

- Quality assure the information submitted via the Datix system and the initial severity rating given to the incident. Where the review team believes the severity rating should be changed – the incident reporter should be contacted and this should be discussed and agreed
- Calculate the actual and potential risk rating for the incident using the Risk Grading Matrix and impact Table – this is explained on the Datix screen and also in **Appendix 3**
- Consider the need for additional internal and /or external reporting e.g. RIDDOR, NIAIC, HSCB, RQIA, Vulnerable Adults (PVA), Fire (**See Appendix 2 for guidance on advisory contacts re: these additional reporting routes**)
- If the incident is also an adult safeguarding review (this will be recorded on Datix) then the Incident Review team should link with the adult safeguarding Designated Officer (DO) for that incident. If the incident is proceeding to a safeguarding investigation the Incident Review Team should participate in that or at a minimum, review the learning from that investigation and implement as appropriate
- Develop and agree learning and action plans as appropriate. All **moderate, major** and **catastrophic** incidents reported will require a time bound action plan which **must** include relevant learning points. This learning should be communicated and actioned within teams
- Feedback the outcome of the review of **moderate, major and catastrophic** incidents to the incident reporter
- Inform the Assistant Director of any immediate learning which could minimise the risk of further reoccurrence of the incident
- Any barriers to implementation of action plans relating to incidents should be escalated to the appropriate Head of Service and the Assistant Director

- Close all incidents following completion of the review process

4.1 Incident Review:

The following risk assessment process should be applied to all incidents at the time of occurrence in order to decide what level of investigation is required and at what level within the Trust the investigation should be conducted.

Step One – What was the impact of the incident at the time of the incident? (Actual Harm)

- 4.1.1 The person reporting the incident should undertake this stage of the assessment, entering it on the IR1 form (DIF1). Based on the actual impact of the incident at the time of occurrence (taking into account psychological as well as physical harm) a judgment is made as to the incident's severity in the range Insignificant to Catastrophic.
- 4.1.2 Incidents assessed as causing actual **major** or **catastrophic** harm at the time of the incident must be given immediate consideration for further in depth analysis.
- 4.1.3 For incidents causing lesser levels of actual harm further questions need to be asked to decide on the level of investigation required.

Step Two – What might the impact be if the incident happens again? (Potential harm)

4.1.4 Where the potential harm of the incident is being considered, staff must ask the following in the context of "if no further action was taken".

- Was the harm caused by a chance happening?
- Could the actual harm caused realistically have been a lot worse?
- How many people might be hurt if it happened again?
- How seriously might someone be hurt if it happened again?
- What are the control measures already in place, today?

4.1.5 It is important that grading on actual harm and potential harm are completed as separate exercises. This will ensure that the most severe incidents where the level of actual harm is higher are dealt with as a priority. All incidents with a lower level of actual harm but with a potential for a higher level of harm must be managed appropriately.

Step one	Deciding what was the impact / harm of the incident today (actual)
Step two	Where there is insignificant to moderate actual impact/harm, deciding what might the realistic impact/harm be if the incident were to happen again under similar circumstances. (potential impact)
Step three	Decide what are the chances of the incident happening again under similar circumstances. At this stage consideration should also be given

- to reviewing similar incidents that have happened in the past.
(Likelihood)
Step four Decide what the overall risk grading for the event is by plotting:
Impact multiplied by likelihood = risk grading

The level of review applied to an incident is determined by the actual severity (impact) of the incident and/or the potential impact and is as follows:

INSIGNIFICANT AND MINOR – These incidents will usually not require detailed review, however the following questions should be asked to establish any learning:

- What happened?
- Did what happened vary from what should have or was expected to happen?
- If so, why?
- What is the learning from this incident?

However, these incidents could be subject to detailed review if similar incidents are found to occur frequently i.e. where there is a trend. It is the review team's responsibility to identify such trends and advise the appropriate Head of Service/Team Manager or Assistant Director regarding improvements or action plans required if a trend is identified. Heads of Service and Assistant Directors should also be identifying and analysing trends through their Team / Service / Divisional Governance meetings. Action plans and lessons learnt from this trend analysis should be discussed and actions recorded in the notes of team, service and divisional governance meetings.

MODERATE – These incidents **must** be reviewed as part of the incident review process on a weekly basis. The review team must ensure that an investigation is completed within four weeks and that there is a documented action plan and learning points recorded on Datix Web. These actions and the learning should then be reviewed by the team, division and directorate with respect to progress of implementation.

In undertaking a Moderate Incident review the following questions should be answered **as a minimum**:

- What happened?
- Did what happened vary from what should have or was expected to happen?
- If so, why?
- What is the learning from this incident?

Further guidance on incident review is available in **Appendix 7**.

The Heads of Service and Assistant Directors are responsible for reviewing implementation of any actions and learning following an investigation. Action plans and implementation of learning should also be reviewed at the Directorate Governance forum by the Director.

MAJOR AND CATASTROPHIC - This level of incident will, as previously described, have been automatically notified by the Datix system to the Head of Service, relevant Assistant Director and the Assistant Director of Governance at the time of reporting. It is the responsibility of the relevant Assistant Director to inform the Director and Associate Medical Director (AMD) (in the case of clinical incidents) and the appropriate CSCG Coordinator for that area of the incident.

The incident must be considered against the HSCB (October 2013) criteria for a Serious Adverse Incident (SAI) by the relevant Director, Assistant Director, AMD and CSCG Coordinator. This review of the incident should be documented by the CSCG Coordinator on the major / catastrophic incident checklist which must be completed by the group. Regardless of the outcome of the screening, the completed checklist should be shared with the Assistant Director of Governance via the Corporate Governance Office. In the event of the incident meeting the SAI criteria, **section 5.0** of this procedure should be followed.

If the incident does not meet the SAI criteria the relevant Director may either appoint an independent internal team to review the incident using a Root Cause Analysis methodology (the method used to review an SAI -see section 5) or the incident may be reviewed by the service Incident Review Team. (See **Appendix 7**)

Whatever the method of reviewing the incident – either as an SAI, an internal review by an independent team within the Trust or by the clinical review team within the division itself, the service team involved in the incident **must** be informed of the decision regarding how the incident is to be reviewed at the earliest opportunity, by the Assistant Director / Associate Medical Director, and **before** the review commences.

Where an incident is to be reviewed internally by an independent team or if it is the subject of an SAI, the patient /client and/or family/carer must be informed of this review at the earliest opportunity (as per the HSCB SAI guidance April 2014) as should the coroner where the case has previously been referred to them. This action forms part of the major / catastrophic incident checklist and should be documented. In exceptional cases where it is not appropriate to share this decision with the patient /client and/or family/carer, the reasons for this decision **must** be documented on the checklist and on the SAI notification form.

The findings and recommendations of the review - irrespective of how it is carried out, will be discussed and documented at relevant team, service, division, Morbidity and Mortality meetings and directorate governance meetings.

The Heads of Service and Assistant Directors are responsible for reviewing implementation of any actions and learning following an investigation.

Action plans and implementation of learning will also be reviewed at the Directorate Governance forum by the Director.

Cross Directorate learning points should be escalated to the Assistant Director of Governance by the CSCG Coordinators when they meet monthly.

The findings and recommendations of an internal review of an incident or an SAI should be shared with the patient / client and/or family / carer, RQIA and the coroner (if previously referred) at the earliest opportunity.

5.0 Procedure for Reporting and Completing a Review of a Serious Adverse Incident (SAI):

Following the review meeting of the relevant Director, Assistant Director, AMD and CSCG Coordinator where it is agreed to report an incident as a SAI, the SAI notification should be electronically reported to the HSCB, via the Corporate Governance Office, as per the HSCB Procedure for the Reporting of SAIs (HSCB October 2013)

See Hyperlink:

[http://www.hscboard.hscni.net/publications/Policies/102%20Procedure for the reporting a nd followup of Serious Adverse Incidents-Oct2013.pdf](http://www.hscboard.hscni.net/publications/Policies/102%20Procedure%20for%20the%20reporting%20and%20followup%20of%20Serious%20Adverse%20Incidents-Oct2013.pdf)

The Directorate CSCG Coordinator will populate the HSCB SAI notification form on behalf of the appropriate Director and forward to the Corporate Governance Office for the attention of the Assistant Director of Governance. All SAI notification forms **must** be fully completed and accurate with an appropriate Datix ID number when submitted to the Corporate Governance Office and should be done so **within 72 hours** of the incident occurring. The Director / their designate should also report the SAI to the Chief Executive.

If the SAI concerns the death of a patient and the death has been reported to the Coroner by the appropriate medical professional this will have been recorded on the major/catastrophic review checklist and the SAI Notification. In this case the Corporate Governance Office will automatically inform Litigation (litigation generic email account) of the SAI review and this will on completion be submitted to the Coroner.

Where the SAI notification form indicates that the RQIA should be informed the Corporate Governance Office will automatically share the notification and report (when finalised) with the RQIA.

If the SAI requires an Adult Safeguarding Investigation, the Adult Safeguarding Investigation will inform the SAI process. The PVA Designated Officer will liaise with the appropriate Governance Coordinator, relevant HoS, and a representative from the Adult Safeguarding Team to compose the Adult Safeguarding Investigation review team membership. That review team must be approved by the Director, Assistant Director, and where appropriate AMD. The PVA Investigation Officer will produce an Adult Safeguarding Investigation report which will be submitted to HSCB/RQIA and to the Coroner if appropriate etc as the SAI report.

5.1 Procedure for Conducting a SAI Review (This procedure should also be applied when conducting an Independent Internal Review):

Timescale	Action	Lead
0-72hrs	Discuss with Director, Assistant Director, AMD and CSCG Coordinator. Consider the incident against HSCB (Oct 2013) definition of a SAI and using the Major/Catastrophic incident checklist.	Director / CSCG Coordinator
0-72hrs	If above group decides the incident is an SAI they will inform the service team involved in the incident of their decision and the patient/client and/or their relatives. This group should identify nominations for the SAI review team including a Chair. (Advice for Chairpersons - see Appendix 8) Those nominated should have had no involvement in the incident for review, should be from another site / team and should be available to participate during the subsequent 12 weeks. There is the option to nominate external independent persons from other organisations onto the review team – this is done via the Director and Chief executive. This option may be useful when there is a need to engage the appropriate expertise, the incident is particularly distressing for staff involved or is particularly sensitive, where carers and relatives have expressed significant dissatisfaction with a service team or the organisation at an early stage, where a service team is small and based on one site only, where the case may be subject to external or legal scrutiny at a later stage or at any other time where it may be deemed to offer a benefit.	Director / AD/AMD/CSCG Coordinator
0-72hrs	Following confirmation of their involvement all review group nominees will receive an email with the following information: • Notification of their nomination and who nominated them. • Membership and Chair of the group • A brief description of the incident • Timescale for completion of the report • Guide to RCA methodology. The relevant A/D will check and ensure the case note /records have been forwarded to the CSCG Coordinator.	CSCG Coordinator
Week 1	CSCG Coordinator and Chair of review group will agree draft terms of reference for the review. Draft terms of reference and a copy of the case note / records will be circulated with potential dates for meeting 1 of the review. All relevant information will be distributed to the group for consideration prior to meeting 1 of the group.	Chair/CSCG Coordinator
Week 2-3	Meeting 1 will take place. This meeting will normally agree a terms of reference – including the scope of the review. The timeline of events will be discussed - and all relevant points for further analysis identified together with any points needing further clarity from the professional team involved in the incident. It is often useful and appropriate to meet with some / all of the staff involved in the incident so they can give their account to the review team in person, indicate their thought processes at the time and clarify any	Review Team

	outstanding issues. The appropriate members of the review can meet those of similar profession from the team involved in the incident.	
Week 3-6	Actions from meeting 1 will be completed, including follow up meetings with staff involved in the incident and all information can be forwarded to CSCG Coordinator.	Review team
Week 6	Meeting 2 can take place. It may be appropriate in less complex cases to have Draft 1 of the report tabled at this meeting for further discussion. However this meeting is more likely to pull together all information received and to analyse the incident and make conclusions, recommendations and propose an action plan.	Review team / CSCG Coordinator
Week 7-9	A complete draft of the report will be prepared by members of the review team and circulated to all for comment.	Review team /CSCG Coordinator
Week 9-10	Comments from the review team will be reviewed by the Chair and CSCG Coordinator / review facilitator and a final draft agreed and then circulated to the review team.	Chair/ CSCG Coordinator
Week 10-12	The final draft will be circulated / shared with all members of the service team involved in the incident for factual accuracy checking and information. The Final Draft will then be forwarded to the appropriate Director, Associate Medical Director and Assistant Director for quality assurance prior to presentation at Directorate governance meetings.	Chair/CSCG Coordinator
Week 12	Following approval by AD CSCG the report will be submitted to HSCB/ RQIA via the Corporate Governance Office. The report may also be submitted to SMT for information sharing / discussion and if a case involves a death being reviewed by the Coroner it will be shared with their office also.	CSCG Coordinator / Corporate Governance

5.2 Points of Best Practice When Undertaking a SAI Review (Applicable when undertaking an Internal Review of an Incident also):

- The service team involved in the incident are provided with support and assistance following the incident and during and after the review. See **Appendix 5**
- The patient / client and/ or relatives are informed of the review taking place, **BEFORE** it commences, to provide assurance to them that any learning related to the incident is identified and acted upon. See **Appendix 4**
- The service team involved in the incident are informed as soon as possible and **BEFORE** it commences how the incident will be reviewed. They are kept informed with respect to review progress and they can interface with the review team to provide additional information and or clarity when required. The draft review report should be shared with the service team involved in the incident for factual accuracy and information
- The review must be chaired by someone with relevant professional experience and expertise from another geographical area of the Trust who has had no involvement in the case or direct line management responsibility for any of the team involved in the incident

- The review team should be multidisciplinary and have the appropriate expertise to review the incident appropriately. They must be independent from being involved in the care and treatment provided to the patient / client
- There is the option of seeking external independent review team members and this should be considered at the outset by the Director, Assistant Director, and Associate Medical Director and CSCG Coordinator. This option can be used at any time throughout the review
- The facts, findings and recommendations from the review will be shared with the patient /client and /or family / carers. See **Appendix 4**
- Where the case has previously been referred to the Coroner, their office will receive a copy of the review report
- Learning and action plans from SAI"s will be managed in the same way as that from other incidents – **see section 4**

(subject to service users consent)

APPENDIX 1:**KEY DEFINITIONS**

Definitions: The following terms describe events, which are defined as incidents and will be recorded and reported within the scope of this procedure and through Datix Web.

Terminology	Definitions
Incident/ Near Miss	Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation arising during the course of the business of an HSC organisation / Special Agency or commissioned service (including a breach of security or confidentiality). However this is not an exhaustive definition and using the incident reporting system specifically for clinical outcomes which are unexpected and / or unexplained, but are not believed to be associated with an adverse incident, is also encouraged by the Trust as a means of triggering a thorough review of such cases. These reviews are a beneficial mechanism of providing assurance to staff, patients, clients, carers and relatives that any learning related to any aspect of the case is sought and acted upon.
Near Miss	Incidents that do not lead to harm but could have, are referred to as near misses.
Serious Adverse Incident (SAI)	The following criteria will determine whether or not an adverse incident constitutes a Serious Adverse Incident (SAI) Serious Adverse Incident Criteria:- serious injury to, or the unexpected/unexplained death (<i>including suspected suicides and serious self-harm</i>) of : a service user a service user known to Mental Health services (including Child and Adolescent Mental Health Services (CAMHS) or Learning Disability (LD) within the last two years) a staff member in the course of their work a member of the public whilst visiting an HSC facility. unexpected serious risk to a service user and/or staff member and/or member of the public unexpected or significant threat to provide service and/or maintain business continuity serious assault (<i>including homicide and sexual assaults</i>) by a service – on other service users, – on staff or – on members of the public occurring within a healthcare facility or in the community (where the service user is known to mental health services including CAMHS or LD within the last two years). - serious incidents of public interest or concern involving theft, fraud, information breaches or data losses.
Harm	Injury (physical or physiological), disease, suffering, disability or death. In most instance harm can be considered to be unexpected if it is not related to the natural cause of the service user's illness or underlying harm („Doing Less Harm, National Patient Safety Agency)
Concern	A worry or “gut feeling” about something that could lead to an incident. To highlight a situation which could lead to a full blown incident or suboptimal standards of equipment, practice or performance.

APPENDIX 2:***When and How an Incident Should Also Be Reported To Other Sources***

All adverse incidents should initially be reported using the Datix Web incident management system. However some incidents should also be reported to other sources either internally within the Trust and / or externally to other agencies. The following table provides a list of types of incident and where they should be reported to following being recorded as an incident. There is also a list of useful contacts and Web links for additional advice and help.

TYPE OF INCIDENT	WHERE ELSE IT SHOULD BE REPORTED TO	USEFUL CONTACTS AND LINKS ON HOW TO REPORT IT
Potential Adult Safeguarding Incident	Definition available on the link opposite	Info available from Trust Intranet: http://vsrintranet.southerntrust.local/SHSCT/HTML/PandP/documents/SAFEGUARDINGVULNERABLEADULTSPROCEDUREGUIDANCEVERSION4.pdf Report form available on: http://vsrintranet/SHSCT/HTML/PandP/documents/PVA1BLANK.pdf
Health and Safety Incident	Via the Datix Web form Incidents should be automatically reviewed by Health and Safety	Contact: (Internal) Health & Safety Dept Number: [redacted] Email: http://vsrintranet.southerntrust.local/SHSCT/HTML/HR/documents/ReportableDiseases.pdf
MHRA	Should be notified (although voluntary) when an Adverse Drug Reaction occurs (ADR)	A paper form can be found in the back of every BNF or alternatively can be completed online at www.mhra.gov.uk/yellowcard
RIDDOR	An Incident is RIDDOR reportable if: 1) The injury sustained is major, 2) If a member of the public on Trust premises is killed or taken to hospital 3) If the injury is sustained is an „Over 3 day injury“ 4) If there has been a Dangerous occurrence	Appropriate information should be completed on the Datix Web IR1 form which alerts the Trust's Internal Health and Safety Dept. The above department is also contactable on [redacted]

	5) If a notification of a reportable work-related disease has been received Further guidance available on Trust Intranet	
SABRE SHOT	For adverse blood reactions and events the MHRA (above) has a web based system for reporting known as SABRE - *Serious Adverse Blood Reactions and Events* The hospital blood bank should be informed who will inform a member of the Trust Transfusion Team and the Haemovigilance practitioner will complete online reporting to SABRE. There is an option in the SABRE reporting system also to report to the Serious Hazards of Transfusions (SHOT) enquiry. All SABRE incidents are discussed at the Hospital Transfusion Committee meetings.	For further information on both SABRE and SHOT please visit www.mhra.gov.uk
CMR	Case Management Review	<i>New processes have been put in place under Safeguarding Board NI.</i>
Fire	Relates to all fire Incidents:	An FPN 11 Form should be completed within 24 hours of the Fire Incident. FPN 11 form is available on the Intranet at: http://vsrintranet.southerntrust.local/SHSCT/HTML/PandP/PandP.html and should be sent to: Fire Safety Department, Meadowview, Daisy Hill Hospital, when completed.
RQIA	RQIA are notified about Incidents such as -serious injury to, or the unexpected/unexplained death -unexpected serious risk to service user and / or staff member and / or member of the public -unexpected or significant threat to provide service and / or maintain business continuity.	Corporate Governance Office to notify RQIA on receipt of appropriate SAI Notification form.

	-serious assault (<i>including homicide and sexual assaults</i>) by a service user -serious incidents of public interest or concern involving theft, fraud, information breaches and data losses	
HM Coroner	There is a general requirement under section 7 of the Coroners Act (Northern Ireland) 1959 that any death must be reported to the coroner if it resulted, directly or indirectly, from any cause other than natural illness or disease for which the deceased had been seen and treated within 28 days of death.	Guidance on reporting a death to the coroner available at: http://www.courtsni.gov.uk/en-GB/Publications/UsefulInformationLeaflets/Documents/Working%20with%20the%20Coroners%20Service%20for%20Northern%20Ireland/Working%20with%20the%20Coroners%20Service%20for%20Northern%20Ireland%20(PDF).pdf and on the Trust Intranet at: http://vsrintranet.southerntrust.local/SHSCT/HTML/clinical_guidelines.html Corporate Governance Office to also notify Coroner on receipt of SAI Notification form
NIAIC	An incident is NIAIC reportable if it relates to a <u>Medical Device</u>	Contact: Specialist Estates Services Dept (internal) Medical Devices Liaison Officer Email: Nigel [Personal information redacted by the USI]
DHSSPS Early Alert	Guidance available on Early Alerts at: http://vsrintranet.southerntrust.local/SHSCT/HTML/PandP/PandP.html	Notification sent by Corporate Governance Office
HSCB Early Alert	As above -	Notification sent by Corporate Governance Office

Appendix 3

DOMAIN	IMPACT (CONSEQUENCE) LEVELS [can be used for both actual and potential]				
	INSIGNIFICANT (1)	MINOR (2)	MODERATE (3)	MAJOR (4)	CATASTROPHIC (5)
PEOPLE (Impact on the Health/Safety/Welfare of any person affected: e.g. Patient/Service User, Staff, Visitor, Contractor)	Near miss, no injury or harm.	- Short-term injury/minor harm requiring first aid/medical treatment. - Minimal injury requiring no/ minimal intervention. - Non-permanent harm lasting less than one month (1-4 day extended stay). - Emotional distress (recovery expected within days or weeks). - Increased patient monitoring	- Semi-permanent harm/disability (physical/emotional injuries/trauma) (Recovery expected within one year). - Increase in length of hospital stay/care provision by 5-14 days.	- Long-term permanent harm/disability (physical/emotional injuries/trauma). - Increase in length of hospital stay/care provision by >14 days.	- Permanent harm/disability (physical/emotional trauma) to more than one person. - Incident leading to death.
QUALITY & PROFESSIONAL STANDARDS/ GUIDELINES (Meeting quality/ professional standards/ statutory functions/ responsibilities and Audit Inspections)	- Minor non-compliance with internal standards, professional standards, policy or protocol. - Audit / Inspection – small number of recommendations which focus on minor quality improvements issues.	- Single failure to meet internal professional standard or follow protocol. - Audit/Inspection – recommendations can be addressed by low level management action.	- Repeated failure to meet internal professional standards or follow protocols. - Audit / Inspection – challenging recommendations that can be addressed by action plan.	- Repeated failure to meet regional/ national standards. - Repeated failure to meet professional standards or failure to meet statutory functions/ responsibilities. - Audit / Inspection – Critical Report.	- Gross failure to meet external/national standards. - Gross failure to meet professional standards or statutory functions/ responsibilities. - Audit / Inspection – Severely Critical Report.
REPUTATION (Adverse publicity, enquiries from public representatives/media Legal/Statutory Requirements)	- Local public/political concern. - Local press < 1day coverage. - Informal contact / Potential intervention by Enforcing Authority (e.g. HSENI/NIFRS).	- Local public/political concern. - Extended local press < 7 day coverage with minor effect on public confidence. - Advisory letter from enforcing authority/increased inspection by regulatory authority.	- Regional public/political concern. - Regional/National press < 3 days coverage. Significant effect on public confidence. - Improvement notice/failure to comply notice.	- MLA concern (Questions in Assembly). - Regional / National Media interest >3 days < 7days. Public confidence in the organisation undermined. - Criminal Prosecution. - Prohibition Notice. - Executive Officer dismissed. - External Investigation or Independent Review (eg, Ombudsman). - Major Public Enquiry.	- Full Public Enquiry/Critical PAC Hearing. - Regional and National adverse media publicity > 7 days. - Criminal prosecution – Corporate Manslaughter Act. - Executive Officer fined or imprisoned. - Judicial Review/Public Enquiry.
FINANCE, INFORMATION & ASSETS (Protect assets of the organisation and avoid loss)	- Commissioning costs (£) <1m. - Loss of assets due to damage to premises/property. - Loss – £1K to £10K. - Minor loss of non-personal information.	- Commissioning costs (£) 1m – 2m. - Loss of assets due to minor damage to premises/ property. - Loss – £10K to £100K. - Loss of information. - Impact to service immediately containable, medium financial loss	- Commissioning costs (£) 2m – 5m. - Loss of assets due to moderate damage to premises/ property. - Loss – £100K to £250K. - Loss of or unauthorised access to sensitive / business critical information - Impact on service contained with assistance, high financial loss	- Commissioning costs (£) 5m – 10m. - Loss of assets due to major damage to premises/property. - Loss – £250K to £2m. - Loss of or corruption of sensitive / business critical information. - Loss of ability to provide services, major financial loss	- Commissioning costs (£) > 10m. - Loss of assets due to severe organisation wide damage to property/premises. - Loss – > £2m. - Permanent loss of or corruption of sensitive/business critical information. - Collapse of service, huge financial loss
RESOURCES (Service and Business interruption, problems with service provision, including staffing (number and competence), premises and equipment)	- Loss/ interruption < 8 hour resulting in insignificant damage or loss/impact on service. - No impact on public health social care. - Insignificant unmet need.	- Loss/interruption or access to systems denied 8 – 24 hours resulting in minor damage or loss/ impact on service. - Short term impact on public health social care. - Minor unmet need. - Minor impact on staff, service delivery	- Loss/ interruption 1-7 days resulting in moderate damage or loss/impact on service. - Moderate impact on public health and social care. - Moderate unmet need. - Moderate impact on staff, service	- Loss/ interruption 8-31 days resulting in major damage or loss/impact on service. - Major impact on public health and social care. - Major unmet need. - Major impact on staff, service delivery	- Loss/ interruption >31 days resulting in catastrophic damage or loss/impact on service. - Catastrophic impact on public health and social care. - Catastrophic unmet need. - Catastrophic impact on staff, service

DOMAIN	IMPACT (CONSEQUENCE) LEVELS [can be used for both actual and potential]				
	INSIGNIFICANT (1)	MINOR (2)	MODERATE (3)	MAJOR (4)	CATASTROPHIC (5)
	Minimal disruption to routine activities of staff and organisation.	and organisation, rapidly absorbed.	delivery and organisation absorbed with significant level of intervention. Access to systems denied and incident expected to last more than 1 day.	and organisation - absorbed with some formal intervention with other organisations.	delivery and organisation - absorbed with significant formal intervention with other organisations.
ENVIRONMENTAL (Air, Land, Water, Waste management)	Nuisance release.	On site release contained by organisation.	- Moderate on site release contained by organisation. - Moderate off site release contained by organisation.	Major release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc).	Toxic release affecting off-site with detrimental effect requiring outside assistance.

Risk Likelihood Scoring Table

Likelihood Scoring Descriptors	Score	Frequency (How often might it/does it happen?)	Time framed Descriptions of Frequency
Almost certain	5	Will undoubtedly happen/recur on a frequent basis	Expected to occur at least daily
Likely	4	Will probably happen/recur, but it is not a persisting issue/circumstances	Expected to occur at least weekly
Possible	3	Might happen or recur occasionally	Expected to occur at least monthly
Unlikely	2	Do not expect it to happen/recur but it may do so	Expected to occur at least annually
Rare	1	This will probably never happen/recur	Not expected to occur for years

Likelihood Scoring Descriptors	Impact (Consequence) Levels				
	Insignificant(1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Almost Certain (5)	Medium	Medium	High	Extreme	Extreme
Likely (4)	Low	Medium	Medium	High	Extreme
Possible (3)	Low	Low	Medium	High	Extreme
Unlikely (2)	Low	Low	Medium	High	High
Rare (1)	Low	Low	Medium	High	High

APPENDIX 4:***Guidelines on being open with patients, service users, families and carers when things go wrong or outcomes are unexpected and /or unexplained***

- Any incident involving a service user should be discussed with this individual as soon as is appropriate by a senior member of the service team and preferably the lead professional. If the service user is a child or is unable to give consent due to their physical condition or mental capacity the incident should be discussed with their named next of kin contact. If the service user is able to provide consent and wishes the incident to be discussed with another carer or relative, the service team should facilitate this request.
- Specifically those incidents graded moderate, major and catastrophic should be discussed immediately with the service user and/or their relatives / carers, with consent. Those incidents of an insignificant and minor nature which occur out of hours can be discussed with those required at the most appropriate time within the next 24 hours.
- When discussing an incident with a service user and / or designated relatives / carers, the lead professional should outline the facts of the incident as known, the actual and potential consequences for the service user and how the team will review the incident for future learning. If the service user and/or designated carers / relatives wish to have the outcome of the incident review fed back to them the service team should consider this as good practice and should be conducted with consent of the service user if applicable. These interactions should be documented and attached to the incident report on Datix.
- If an incident meets the criteria for notification as an SAI or internal RCA, (**refer to Section 5**) the service user and / or designated relatives / carers must be informed of this decision before the SAI / RCA review begins. Where possible this should be undertaken by the Lead professional involved in the service user's care. Where this is not possible due to relations being strained or it is judged to be inappropriate the Chair of the SAI /RCA review group supported by the Directorate CSCG Coordinator will undertake this role. This

individual will continue as the point of contact for the service user and / or designated relatives / carers throughout the period of the review and until the findings have been fed back.

- When an SAI / RCA review is completed and has been approved by the Directorate the point of contact for the service user and / or designated relatives / carers should offer to feed back the factual findings and recommendations of the review. This can include a meeting between parties and / or giving the review document to the service user and / or designated relatives / carers. How this process of review feedback is managed should be guided as far as possible by the wishes of the service user and / or designated relatives / carers.

APPENDIX 5:***Guidance on Support for Staff following an Incident***

The Trust promotes an open, honest and participatory culture in which adverse incidents can be reported, discussed and reviewed to enable lessons to be identified, active learning to take place and the necessary changes made to improve our services and practices. A key part of that culture involves the need to support staff when an adverse incident occurs and during its review.

Depending upon the nature and circumstances of an adverse incident the levels of support required by staff will vary. Such support can be provided by line managers in a number of ways, for example:

- Providing immediate assistance/aid if required.
- Contacting the relevant staff member(s) as soon as possible following the incident to discuss.
- Facilitating an immediate informal and/or formal debrief of the staff / team involved in the incident. This should include providing staff with the opportunity to discuss their involvement and/or the circumstances leading up to the incident and how they feel about it. It is usually best to do this in a team setting with all those involved in the incident present.
- Informing staff of the Directorate's processes in relation to incident review; keeping staff informed of likely next steps in that process and informing staff of who they can contact for advice including the Directorate Governance Office who coordinate all serious adverse incident reviews.
- At any time staff can seek advice from outside their team, for example from Directorate and Corporate Governance Offices, the Trust Litigation Department, Trust Legal Advisors or via the appropriate professional bodies.
- Line managers should be visible to all staff members. Physical presence by line managers post-incidents helps decrease anxiety related to an review and provides an accessible resource for clarification of any issues staff may have.
- Providing information on the Trust and external support systems currently available for staff who may be distressed by incidents. This includes counselling services offered by professional bodies; stress management courses; Occupational Health Services, Carecall or Hospital Chaplains.

APPENDIX 6:**Major / Catastrophic Incident Checklist**

Directorate:	
Reporting Division:	
Date of Incident:	
Incident (IR1) ID:	
Grade of Incident:	
If Incident involved the death of a service user, was the coroner informed:	
Names / Designations of those considering Incident: <i>(Should include Director, Assistant Director, AMD & CSCG Coordinator)</i>	
Brief Summary of Incident:	
Summary of discussions re SAI / RCA/ Major / Catastrophic incident review:	
Decision on Level Review Type AND rationale for this:	
Nominated Review Team: <i>(Consider need / benefit of independent external expertise)</i>	

Is it appropriate to inform the Medical Executive/Executive Directorate of Nursing?	☐ YES ☐ NO
Contact for service user and / or designated relatives / carers: <i>(Either Lead Professional or Chair of Review)</i>	
Date and by whom service user and / or designated relatives / carers informed of review taking place: <i>(If there is an exceptional case where this is inappropriate rationale must be documented):</i>	
If case referred to the Coroner - Date and by whom coroner informed of SAI / Internal Review :	
<i>(Corporate Governance Office / Litigation to complete)</i> Date and by whom Trust Litigation Dept informed:	
Does this incident meet the DHSSPS Early Alert Criteria including rationale:	
POST REVIEW COMPLETION: Date and by whom and how Review is shared with the service user and / or designated relatives / carers: <i>(In exceptional cases where this is inappropriate rationale should be documented)</i>	
Date and by whom and how Review is shared with the Coroner:	

This form once completed, regardless of Outcome, should be shared with the AD of Governance via Corporate Governance Office

APPENDIX 7:***Incident Review Guidance***

A key principle of the CSC governance framework is that incidents are reviewed and analysed to find out what can be done to prevent their recurrence. Therefore, a key principle of the incident review is that when an incident occurs the important issue is not „who is to blame for the incident?“ but „how and why did it occur?

Although there will be some incidents which require review using methodologies as contained within e.g. individual agency reviews, adult safeguarding reviews, health and safety reviews, the majority of incidents can be reviewed using the National Patient Safety Agency (NPSA) Root Cause Analysis Tools. Nonetheless all incident reviews will ask the core questions of:

- What actually happened? (*The facts*)
- How did what happened vary from what should have or was expected to happen?
- Why did it happen in that way? (*The causes*)
- Is there any learning to share with the team or wider Trust services to minimise the likelihood of recurrence?

The above can be expanded to include where appropriate:

- Was there anything about the task/procedure involved?
- Was there anything about the way that the team works together or perceives each other's roles?
- Was there anything about the equipment involved?
- Was there anything related to the working environment or conditions of work?
- Was there anything about the training and education of the staff in relation to their competence to:-
(a) provide the care/service required, and

(b) manage the incident when it occurred?

- Was there anything relating to communication systems between individual members of the team, departments, or electronic communications, for example, test results via computer?
- Was there anything about the availability, or quality of any guidance notes, policies or procedures?
- Was there anything about the Trust's strategy, its strategic objectives and priorities?

Further detailed advice in relation to incident review techniques including Root Cause Analysis (RCA) Methodologies can be sought from the Directorate Governance Coordinators or visiting the NPSA RCA toolkit resource [here](#).

APPENDIX 8***Brief Guidance on the Role and Responsibilities of an SAI Review Chairperson***

The Chairperson leads an SAI Review Team. The Chairperson's main aim is to ensure that the SAI Review Team explores in an open, fair and critical manner the circumstances surrounding the incident, and establishes what, if any, lessons arising need to be incorporated into practice in order to prevent or minimise the likelihood of reoccurrence of the incident. The review should identify not only areas for improvement but also areas of good practice. The Chairperson will be assisted by the relevant Governance Coordinator or their nominated review facilitator.

The main responsibilities of the review Chairperson are:

1.0 Prior to the Review

- 1.1 Reviewing all relevant case notes, statements, synopsis of care reports and relevant sections of policies and procedures related to the incident to enable them to lead the initial meeting of the Review Team.
- 1.2 In conjunction with the Governance Coordinator, prepare a draft Terms of Reference for consideration by the Review Team at the initial meeting.

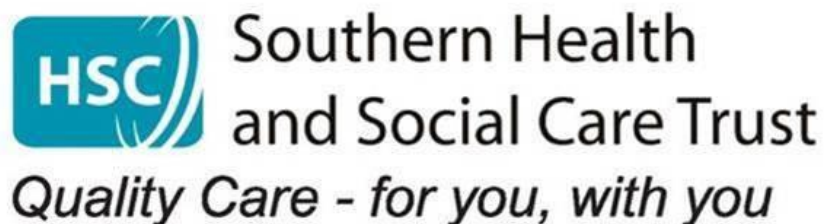
2.0 During the Review

- 2.1 Ensuring that all attendees at the review are introduced to each other and are aware of their role.
- 2.2 Facilitating a process that is conducive to learning and analysis without interference from personal disagreements, criticisms, perceptions or dissatisfaction.
- 2.3 Ensuring that the review is open, fair and participative. That if required appropriate members of the Review Team are delegated to meet members of the service team involved in the incident to obtain clarity on events.

- 2.4 Chairing the Review in a manner which ensures that: all salient facts, a clear chronology of events and interventions, areas of strength/weakness of policy or practice are identified and clear action plans are formulated and agreed.
- 2.5 Ensuring that Review Team members, service teams and patients / clients and /or relatives and carers are kept informed with respect to the review and its progress as required. See **Appendix 4** and **section 5**.

3.0 Following the Review

- 3.1 Liaising with the Governance Coordinator to ensure that a comprehensive report with recommendations / action points and timescales (where relevant) is produced and agreed ensuring that the service team involved in the incident are given an opportunity to check the information they have contributed to the report for factual accuracy. The Chairperson should sign off/approve the report prior to it being sent to the AMD /Assistant Director / Director.
- 3.2 If there are queries / comments raised by the AMD / Assistant Director/ Director following their review of the draft report, the Chair should consider these and reconvene the Review Team if necessary to address same.
- 3.3 Report practices, systems or other issues which the Review Team feel require immediate attention to the relevant Assistant Director, Head of Service and AMD, where appropriate.
- 3.4 If the Chairperson is the nominated contact with the patient/client and or family/ carers, they will be responsible for sharing the facts/ recommendations and action plan with them as outlined in **Appendix 4**.



Southern Health & Social Care Trust
Adult Safeguarding Policy, Prevention and Protection in Partnership
version 3.0

Lead Policy Author & Job Title:	Deborah Hanlon, Head of Service Adult Safeguarding
Directorate responsible for document:	Mental Health & Disability Services
Issue Date:	01 September 2021
Review Date:	01 September 2023



Policy Checklist

Policy name:	Southern Health & Social Care Trust Adult Safeguarding Policy, Prevention and Protection in Partnership version 3.0
Lead Policy Author & Job Title:	Deborah Hanlon, Head of Service Adult Safeguarding
Director responsible for Policy:	Exec Director for Social Work has lead responsibility for adult safeguarding but all Directorates have responsibility for implementing the policy.
Directorate responsible for Policy:	Mental Health & Disability Services
Equality Screened by:	Patricia Trainor
Trade Union consultation?	Yes ☒ No ☐
Policy Implementation Plan included?	Yes ☒ No ☐
Date approved by Policy Scrutiny Committee:	01 September 2021
Date approved by SMT:	N/A
Policy circulated to:	Eg Directors, Assistant Directors, Heads of Service for onward distribution to line managers, Global email, Staff Newsletter
Policy uploaded to:	Sharepoint – adult safeguarding tile

Version Control

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Supersedes:	Southern Health & Social Care Trust Adult Safeguarding Policy, Prevention and Protection in Partnership version 3.0		
Version History			
Version	Notes on revisions/modifications and who document was circulated or presented to	Date	Lead Policy Author
Version 2.0	Updated to reflect new Regional Policy and Procedures 2016/17	01/04/2017	Deborah Hanlon
Version 3.0	Updated to include new legal references. To be reviewed in line with regional developments from Interim Adult Protection Board NI	01/09/2021	Deborah Hanlon

Contents

[illegible]

1.0 Introduction

1.1 The Southern Health and Social Care Trust Adult Safeguarding Policy, “Prevention and Protections in Partnership” is intended to provide staff with guidance and support in responding appropriately to incidents of alleged, suspected or confirmed harm of adults at risk and adults in need of protection. The Trust policy reflects the Regional Adult Safeguarding: Prevention and Protection in Partnership Policy” (DHSS&PS 2015)

2.0 Purpose and Aims

2.1 This policy aims to ensure that all Trust staff, including students, volunteers working on Trust premises and services commissioned by the Trust involved in the care of adults at risk who are subject to alleged harm or serious harm, respond in a co-ordinated and consistent way to support and protect such adults.

2.2 This policy is designed to provide a clear, comprehensive and consistent approach to the management of concerns of alleged harm or serious harm of adults at risk within the Southern Health and Social Care Trust. The Southern Health & Social Care Trust is fully committed to delivering on the regional policy and supporting regional procedures. “Adult safeguarding Operational Procedures. Adults at risk of harm and adults in need of protection.” 2016 (Appendix 1). The regional procedures set out the Trust’s expectations regarding recognising alleged harm to an adult at risk and providing an appropriate alternative response. The regional procedures also set out at the Trust’s expectations for recognising, reporting and responding to concerns of alleged serious harm to an adult in need of protection. This includes responsibilities and requirements for investigation and providing protective in preventions.

3.0 Definitions

3.1 The Trust has adopted the definitions of an adult at risk and an adult in need of protection, from the DHSS&PS regional policy. The policy

defines “an adult at risk of harm” as

“a person aged 18 or over, whose exposure to harm through abuse, exploitation or neglect may be increased by their (A) personal characteristics and/or (B) life circumstances.”

Furthermore, the policy defines “an adult in need of protection” as

“A person aged 18 or over whose exposure to harm through abuse, exploitation or neglect may be increased by their (A) personal characteristics and/or (B) life circumstances

AND

(C) who is unable to protect their own well-being, property, assets, rights or other interests

AND

(D) where the action or inaction of another person or persons is causing, or is likely to cause, him/her to be harmed.”

In order to meet the definition of an ‘adult in need of protection’ either (A) or (B) must be present, in addition to both elements (C), and (D).
(DHSS&PS 2015)

3.2 The definition of “harm” contained within the regional policy is

“Harm is the impact on the victim of abuse, exploitation or neglect. It is the result of any action whether by commission or omission, deliberate, or as the result of a lack of knowledge or awareness which may result in the impairment of physical, intellectual, emotional, or mental health or well-being. The full impact of harm is not always clear from the outset, or even at the time it is first reported. Consideration must be given not only to the immediate impact of harm and risk to the victim, but also the potential longer term impact and the risk of future harm.

Harmful conduct may constitute a criminal offence or professional misconduct. A number of factors will influence the determination of the seriousness of harm. A single traumatic incident may cause harm or a number of 'small' incidents may accumulate into 'serious harm' against one individual, or reveal persistent or recurring harm perpetrated against many individuals." (DHSS&PS 2015)

3.3 The definition of "serious harm" contained within the regional policy is

"The judgement of what constitutes 'serious harm' is a complex one and demands careful application of professional judgement against a number of criteria. Assessments conducted by or on behalf of statutory HSC professionals should include consideration of the following:

- a) The impact on the adult at risk;*
- b) The reactions, perceptions, wishes and feelings of the adult at risk;*
- c) The frailty or vulnerability of the adult at risk;*
- d) The ability of the adult at risk to consent and participate in the decision making process;*
- e) The illegality of the act(s);*
- f) The nature, degree and extent of harm;*
- g) The pattern of the harm-causing behaviour;*
- h) Previous incidents, including any previous HSC Trust involvement*
- i) The level of threat to the adult at risk's right to independence;*
- j) The apparent intent of the alleged perpetrator and extent of premeditation;*
- k) The relationship between the alleged perpetrator and the adult at risk;*
- l) The context in which the alleged harm takes place;*
- m) the risk of repetition or escalation of harm involving increasingly serious acts relating to this individual or other adults at risk; and*

n) The factors which mitigate the risk through service provision or wider arrangements.

There are no absolute criteria for judging when harm has become ‘serious harm’; however this decision should include consideration of the degree, severity, duration and frequency of harm. The seriousness of harm depends on the impact experienced by the individual. Particularly careful consideration must be given to cases where the adult is unable to understand the impact harm is having on them. This will demand the application of professional judgement to consider all of the available evidence, the concerns and the wishes of the individual and to determine the seriousness of harm and the most appropriate intervention.” (DHSS&PS 2015)

3.4 The definition of “abuse” contained within the regional policy is

“Abuse is ‘a single or repeated act, or lack of appropriate action, occurring within any relationship where there is an expectation of trust, which causes harm or distress to another individual or violates their human or civil rights’⁵. Abuse is the misuse of power and control that one person has over another. Abuse may be perpetrated by a wide range of people, including those who are usually physically and/or emotionally close to the individual and on whom the individual may depend and trust. This may include, but is not limited to, a partner, relative or other family member, a person entrusted to act on behalf of the adult in some aspect of their affairs, a service or care provider, a neighbour, a health or social care worker or professional, an employer, a volunteer or another service user. It may also be perpetrated by those who have no previous connection to the victim”. (DHSS&PS 2015)

4.0 Policy Statement

4.1 The Southern Health & Social Care Trust recognises that abuse is a violation of an individual's human and civil rights. The Trust has zero tolerance in relation to all forms of abuse and exploitation. The Trust is fully committed to ensuring that adults who are subject to alleged harm, serious harm or abuse are supported and protected.

4.2 The Southern Health & Social Care Trust is fully committed to delivering on "Adult Safeguarding: Prevention and Protection in Partnership" (DHSS&PS 2015) and has developed a Corporate Adult Safeguarding Blueprint for 2017 -2022 to oversee the implementation of the new Regional Policy and Procedures.

4.3 It is the policy of the Trust that all commissioned services are expected to recognise, respond and report concerns regarding adults at risk of harm to the relevant service group within the Trust. All commissioned services are expected to have in place an Adult Safeguarding Champion and where appropriate appointed persons, to deliver on the adult safeguarding responsibilities as outlined in the regional policy and procedures. Commissioned services are also expected to recognise, respond and report concerns regarding adults in need of protection to the Trust Adult Protection Gateway Team. Services commissioned by the Trust are also required to comply with legislative requirements and regional policies, procedures and protocols. Furthermore, commissioned services must have in place Adult Safeguarding and Protection arrangements that are compatible with the Southern Trust's Adult Safeguarding and Protection arrangements. These requirements are delivered through Service Level Agreements.

5.0 Scope of Policy

5.1 This policy is relevant to all staff, students and volunteers working within the Trust who, either directly or indirectly come into contact with adults at risk who may be subject to alleged, harm serious harm or abuse. This policy is a of particular relevance to staff working within Older People and Primary Care, Learning Disability Services, Mental Health Services, Physical Health & Disability Services including Sensory impaired and Acute Services. The policy recognises that harm and abuse of adults at risk can happen anywhere including community, hospital, residential care facilities and day care. It is therefore applicable in all setting and covers all types of harm and abuse including neglect and recognises that adults who are at risk cannot always protect themselves from harm.

5.2 The policy also applies to services commissioned by the Trust.

6.0 Responsibilities

6.1 Responsibility of the Chief Executive

As Accountable Officer, the Trust's Chief Executive has overall responsibility for ensuring that arrangements are in place to enable all staff to comply with this Policy.

6.2 Responsibility of Executive Director of Social Work

Policies and Procedures are in place in relation to Adult Safeguarding and to ensure the commitment of appropriate resources so that staff are adequately trained and for providing assurances to SMT on compliance with the policy and procedures.

6.3 Responsibility of the Adult Safeguarding Champion(ASC)

The ASC within the Southern Trust is the Assistant Director responsible for Adult Safeguarding. The ASC provides strategic and operational leadership and oversight in relation to adult safeguarding and is responsible for implementing its adult safeguarding policy. The ASC will ensure that, at a minimum, the Southern Trust safeguards adults at risk by:

- Recognising that adult harm is wrong and should not be tolerated
- Being aware of the signs of harm from abuse, exploitation and neglect
- Reducing opportunities for harm, abuse, exploitation and neglect to occur
- Knowing how and when to report adult safeguarding concerns to HSC Trusts and / or the PSNI

The ASC will delegate operational day to day responsibility for safeguarding to appointed persons within the Southern Trust. Appointed persons will report directly through existing management structures on safeguarding matters.

The ASC will compile and analyse corporate adult safeguarding information which will be reported in the annual Southern Trust Position Report for the Local Adult Safeguarding Partnership and Delegated Statutory Function Report.

6.4 Responsibility of Senior Management

All Trust Directors, Assistant Directors, Service Heads and Senior Managers have responsibility for the effective implementation of this policy and the associated procedures. They will ensure that the required action is implemented and monitored and that information required to evidence compliance is provided. They will also ensure that a requirement to comply with this policy is included in all Service Level Agreements.

6.5 Responsibility of Line Managers

All managers have responsibility for the application of this policy. They should ensure staff are aware of and abide by the requirements of the policy and attend appropriate training.

All line managers should ensure they undertake training provided for managers responding to adult at risk of harm concerns. Line managers should be familiar with the regional adult safeguarding policy and procedures and deliver appropriate alternative safeguarding responses. They should also ensure adequate numbers of staff are trained as Designated Adult Protection

Officers, Investigating Officers and Specialist Interviewers (ABE), sufficient to meet the needs of the service.

6.6 Responsibility of all Staff Working in the Trust

All those working in the Trust have a responsibility to adhere to the principles and aims of this policy and the associated procedures and guidance. They must attend appropriate training and have a clear understanding of their role and responsibility.

7.0 Legislative Compliance, Relevant Policies, Procedures and Guidance

7.1 It is recommended that staff working in the field of Adult Safeguarding and Protection read this document in conjunction with:

- The Public Interest Disclosure (NI) Order 1998
- Adult Safeguarding: Prevention and Protection in Partnership Regional Policy (DHSS&PS Sept 2015)
- Protocol for Joint Investigation of Adult Safeguarding Cases. (HSCB, PSNI, RQIA 2016.)
- Achieving Best Evidence – a practitioner’s guide.
- The Family Homes and Domestic Violence (NI) Order 1998
- Domestic Abuse and Civil Proceedings Act (NI)2021
- Stopping Domestic and sexual violence and abuse in Northern Ireland: 2021-2022
- The Safeguarding Vulnerable Groups Order (N.I.) 2007 Guidance on Consent & capacity DHSPPS
- Adult Safeguarding in Northern Ireland Regional and Local Partnership Arrangements March 2010.
- DHSS&PS Guidance in Safeguarding of Service User’s Finances with residential and Nursing Homes (Feb 2015)
- Mental Capacity Act (NI) 2016
- General Data Protection Regulation and the Data Protection Act 2018

7.2 This Policy does not operate independently of other Southern Trust policies & procedures. Policies and procedures such as complaints whistle blowing and disciplinary procedures should be implemented concurrently in order to ensure the protection of adults at risk of harm.

8.0 Equality and Human Rights Considerations

8.1 This policy has been screened for equality implications as required by Section 75 and schedule 9 of the Northern Ireland Act 1998. Equality commission guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity so that greatest resources can be devoted to these.

Using the Equality Commission's screening criteria; no significant equality implications have been identified. The policy will therefore not be subject to an equality impact assessment.

Similarly, this policy has been considered under the terms of the Human Rights Act 1998, and was deemed compatible with the European Convention Rights contained in the Act.

9.0 Alternative formats

9.1 This document can be made available on request in alternative formats, e.g. plain English, Braille, disc, audiocassette and in other languages to meet the needs of those who are not fluent in English.

10.0 Records Management

10.1 The supply of information under the Freedom of Information does not give the recipient or organisation that receives it the automatic right to re-use it in any way that would infringe copyright. This includes, for example, making multiple copies, publishing and issuing copies to the public. Permission to re-use the information must be obtained in advance from the Trust.

11.0 Sources of Advice and Further Information

11.1 Line Managers should be contacted in the first instance, in relation to any specific queries on policy content. Line Managers should then escalate queries which they are unable to address, to the Policy Author.

12.0 References

“Adult Safeguarding: Prevention and Protection in Partnership” Regional Policy (DHSS&PS 2015)

Protocol for Joint Investigation of Adult Safeguarding Cases (Sept 2016)

Achieving Best Evidence – a practitioners guide (Jan 2012)

Mental Capacity Act (NI) 2016

Adult Safeguarding Northern Ireland – Regional and Local Partnership Arrangements, DHSSPS March 2010

Appendix 1

<http://vsrintranet.southerntrust.local/SHSCT/HTML/PandP/documents/adult-safeguarding-operational-procedures.pdf>

Appendix 2**POLICY IMPLEMENTATION PLAN**

POLICY TITLE:	"Southern health & Social Care Trust Adult Safeguarding Prevention and Protection in Partnership Policy" Aug 2017
ACCOUNTABLE DIRECTOR:	Paul Morgan
POLICY AUTHOR:	Deborah Hanlon; Head of Service Adult Safeguarding
CO-ORDINATOR FOR IMPLEMENTATION PLAN:	Helen McCormick; Trust Adult Safeguarding Specialist Manager
DATE APPROVED BY POLICY SCRUTINY COMMITTEE:	15/3/18
DATE APPROVED BY SMT:	

KEY TASKS	ACTION TAKEN/PLANNED	LEAD	TIMESCALE
Communicating and Engaging staff	1. Circulate the policy, and procedures to all staff via Directorates	D. Hanlon	Immediately following approval by SMT
	2. Information on the policy to be included in the staff E-brief	D. Hanlon	Immediately following approval by SMT
	3. Copy of the policy and procedures to be uplifted onto the Trust Intranet	D. Hanlon	Immediately following approval by SMT
	4. Copy of the policy and procedures to be tabled at the different professional governance meetings for discussion.	D. Hanlon	Immediately following approval by SMT
	5. Circulate the policy and procedures to all Voluntary sector, statutory and independent sector partners for their information	D. Hanlon via contracts dept., PHWB team and the LASP	Immediately following approval by SMT
Involving service users and carers	The Local Adult Safeguarding Partnership (LASP) and SHSCT Corporate Blueprint "Prevention and empowerment workstream" will be consulted on the best way of informing service users and carers about the Trust policy and how it can be assessed.	H. McCormick	Immediately following approval by SMT

KEY TASKS	ACTION TAKEN/PLANNED	LEAD	TIMESCALE
Training	1. Awareness raising sessions to be held for Senior Managers to familiarise them with their role and responsibilities. This will include the new role of the Trust Adult Safeguarding Champion and the delegated responsibilities to line managers through the existing reporting structures. 2. Managers training scheduled in year and are delivered by SSTDT. This will include the delegated responsibilities for appointed persons managing adult at risk of harm cases through alternative safeguarding responses. 3. All previously trained Designated Officers have received updated training to include new responsibilities as Designated Adult Protection Officers.	SSTDT	Ongoing annual Training available Completed and ongoing Completed
Evaluation	1. The Trust participated in the Regional 10,000 Voices Adult Safeguarding Service User Experience Survey. The adult protection Gateway team supported staff engagement with project. Further Ongoing work is being undertaken to ensure continuation of learning from user experience in adult protection cases	H. McCormick and E. Colton	By 31/03/18

Adult Safeguarding

Prevention and Protection in Partnership

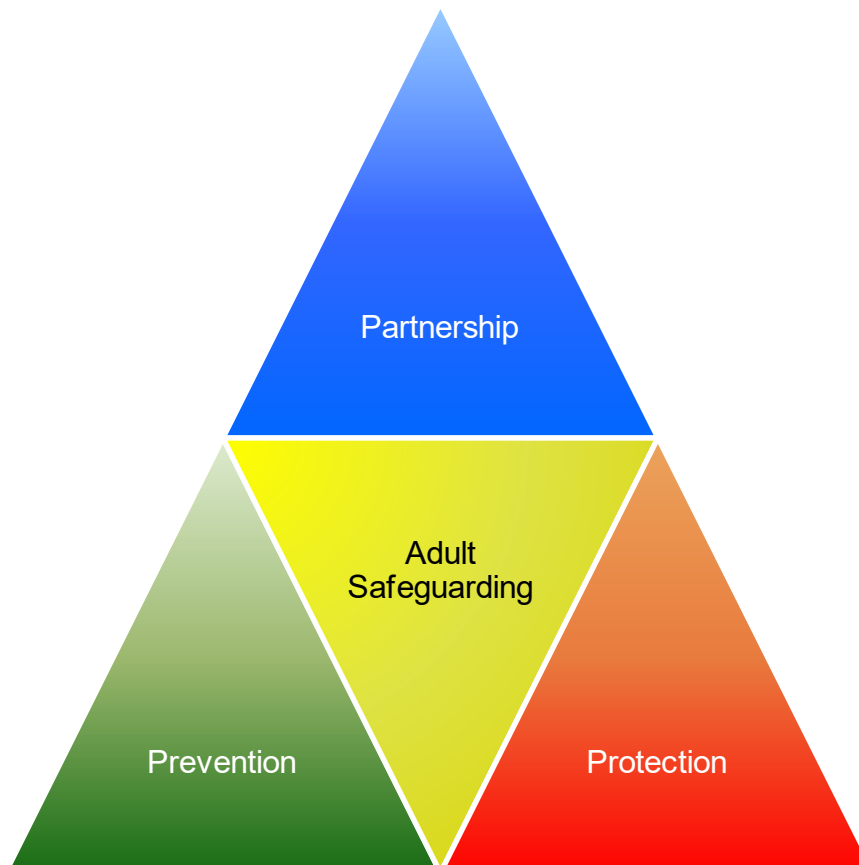


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This policy document replaces Part 1 of 'Safeguarding Vulnerable Adults: Regional Adult Protection Policy & Procedural Guidance' September 2006.

Foreword by the Minister for Health, Social Services and Public Safety

As each of us goes through life we encounter many challenges. For the most part we are able to overcome them, equipped with our experiences, knowledge and with support from friends or family.

The challenges of dealing with abuse, exploitation or neglect should never arise, but they can and they do. The harm caused can have a devastating and long-lasting impact on victims, their families and carers.

Unfortunately, some adults are more at risk of harm than others. Safeguarding adults at risk is a priority for the Northern Ireland Executive and a Programme for Government commitment.

As far as possible, the aim of the policy is to prevent harm from occurring in the first place, to offer effective protection to those who are harmed and to provide them access to justice.

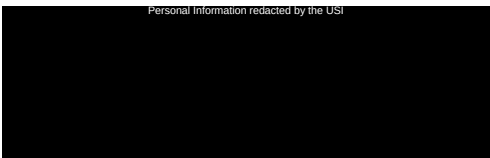
This policy makes it clear that we must not tolerate harm to adults caused by abuse, exploitation or neglect. It promotes partnership working for the purpose of safeguarding and seeks to keep adults safe wherever they live and whenever they access services.

It is acknowledged that safeguarding adults is complex and challenging and requires the careful exercise of professional judgement.

I want to acknowledge the very positive contribution to safeguarding delivered by a wide range of organisations across the statutory, voluntary, community, independent and faith sectors. I believe this adult safeguarding policy sets the way forward for all of us to work together to improve adult safeguarding practice.

I am confident that the implementation of this policy will prevent and reduce the risk of harm and improve safeguarding outcomes and I commend it to you.

Personal Information redacted by the USI



Simon Hamilton MLA
Minister for Health, Social Services and Public Safety

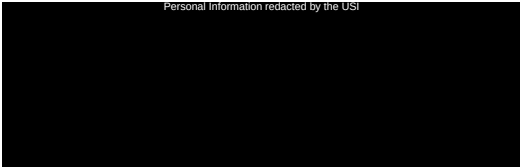
Foreword by the Minister of Justice

As Ministers we are committed to ensuring that steps are taken to identify those who may be at risk of harm and, working together with others, improve the safeguards that are in place to protect them. Along with other institutions and bodies, we can provide increased protections and ensure that where a crime has been committed support services and access to justice are available. There are many areas in which adult safeguarding issues are of interest to the criminal justice sector, including a range of crime types such as domestic and sexual violence, hate crime and human trafficking among others. The publication of this adult safeguarding policy improves the safeguards that are in place and, in conjunction with a range of changes to the criminal justice system in recent years, means that more support is available for those who are unfortunate enough to become a victim of crime.

Recent improvements to the criminal justice system mean that those that are at risk of harm and the victim of crime are provided with additional support and entitlements. A victim and witness care unit has been established, providing victims of crime with a single point of contact for as much of the criminal justice system as possible. Registered intermediaries schemes are enabling those with significant communication difficulties to give evidence to the police and at court. In addition, a range of special measures continue to be available to enable vulnerable and intimidated victims and witnesses give their best evidence to both the police and at court. A Victim Charter has also been published, setting out the services to be provided to, and entitlements of, victims of crime as they move through the criminal justice process. This will be placed on a statutory footing later this year.

While it will never be possible to remove the potential for harm to occur, what we can do is ensure that there is effective support and protection for those individuals who have been subject to harm as they move through the criminal justice process. We can also provide increased access to justice for victims and their families when harm does occur and a crime has been committed. We want to place a greater focus on early intervention, protection and enabling those who suffer harm to have a greater voice within the justice process. The publication of the new adult safeguarding policy is a key development in this area.

Personal Information redacted by the USI



David Ford MLA
Minister of Justice

1. INTRODUCTION

Everyone has a fundamental right to be safe. Whatever the cause, and wherever it occurs, harm caused to adults by abuse, exploitation or neglect is not acceptable. This policy emphasises that safeguarding is everyone's business and that as good citizens we should all strive to prevent harm to adults from abuse, exploitation or neglect.

The aim of this policy is to improve safeguarding arrangements for adults who are at risk of harm from abuse, exploitation or neglect. It has been jointly developed and published by the Department of Health, Social Services and Public Safety (DHSSPS) and the Department of Justice (DOJ) on behalf of the Northern Ireland Executive. It sets out how the Northern Ireland Executive intends adult safeguarding to be taken forward across all Government Departments, their agencies and in partnership with voluntary, community, independent and faith organisations. A key objective is to reduce the incidence of harm from abuse, exploitation or neglect of adults who are at risk in Northern Ireland; to provide them with effective support and, where necessary, protective responses and access to justice for victims and their families. The policy contributes to fulfilment of a Northern Ireland Executive Programme for Government commitment to deliver a package of measures to safeguard children and adults who may be at risk of harm and to promote a culture where safeguarding is everyone's business.

The policy requires a cross-departmental approach within government because the delivery of improved safeguarding outcomes is the business of us all, as individuals, as members of communities, as providers of services, and as Government Departments responsible for the delivery of strategies and policies which directly or indirectly impact on the lives of all adults including those at risk. The policy requires us to put all individuals who may be at risk at the centre, to listen to and respect their views, and to work in partnership with them and on an inter-agency basis to create a society which has a zero-tolerance of harm to the most vulnerable adults living in Northern Ireland.

Within this policy the term 'safeguarding' is used in its widest sense, that is, to encompass both activity which **prevents** harm from occurring in the first place and activity which **protects** adults at risk where harm has occurred or is likely to occur without intervention.

By introducing this policy we aim to raise awareness of harm to adults at risk, define what harm is, how it manifests itself and importantly how we respond to it. The act of protecting against harm is principally the responsibility of Health and Social Care Trusts (HSC Trusts), and the Police Service of Northern Ireland (PSNI) where a crime is alleged or suspected. However the responsibility of preventing harm is shared more widely. It extends beyond statutory providers of services to the voluntary and community sector, financial institutions, the legal profession, faith-based organisations, independent health and social care providers, carers and all citizens.

2. WHAT DO WE MEAN BY SAFEGUARDING

The majority of adults live full, independent lives free from harm caused by abuse, exploitation or neglect. However, there is a growing recognition that some adults, for a wide variety of reasons, may have been harmed or may be at risk of harm. The full extent of the incidents of harm caused to adults in Northern Ireland is not known but it is suspected to be significantly under-reported.

The language of adult safeguarding previously focused on protection and used the term 'vulnerable adult.' This was widely misinterpreted, often used out of context and, for some, the term implied weakness on the part of the adult, which many found unacceptable. This policy moves away from the concept of 'vulnerability' and towards establishing the concept of 'risk of harm' in adulthood. It places the responsibility for harm caused with those who perpetrate it. Harm resulting from abuse, exploitation or neglect violates the basic human rights of a person to be treated with respect and dignity, to have control over their life and property, and to live a life free from fear. Harm can have a devastating and long lasting impact on victims, their families and carers. It is the impact of an act, or omission of actions, on the individual that determines whether harm has occurred. Any action which causes harm may constitute a criminal offence and/or professional misconduct on the part of an employee.

Adult safeguarding is based on fundamental human rights and on respecting the rights of adults as individuals, treating all adults with dignity and respecting their right to choose. It involves empowering and enabling all adults, including those at risk of harm, to manage their own health and well-being and to keep themselves safe. It extends to intervening to protect where harm has occurred or is likely to occur and promoting access to justice. All adults at risk should be central to any actions and decisions affecting their lives.

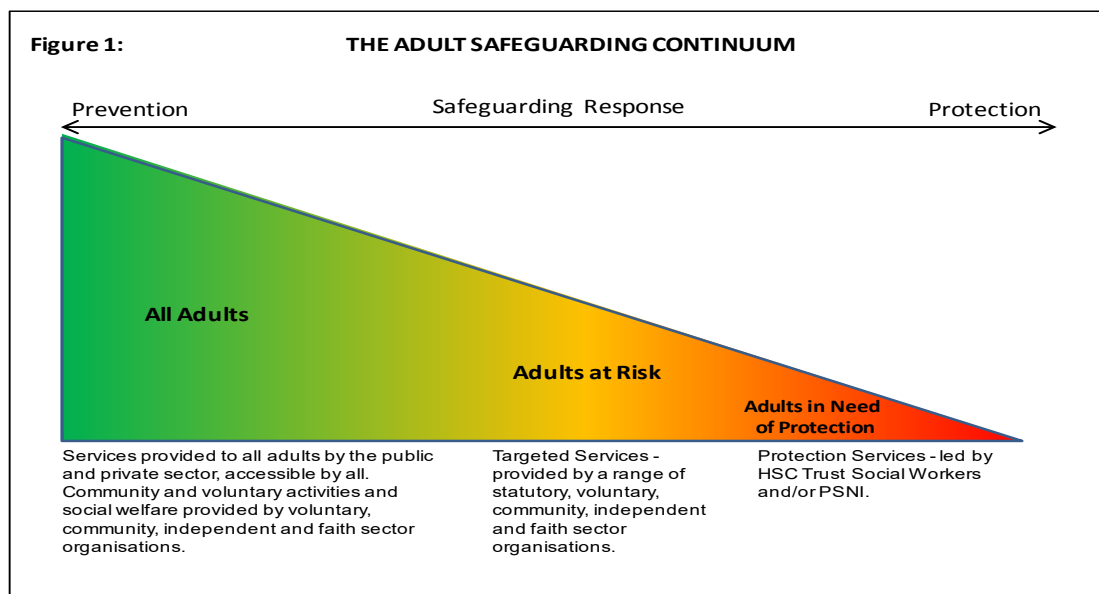
Safeguarding adults is complex and challenging. The focus of any intervention must be on promoting a proportionate, measured approach to balancing the risk of harm with respecting the adult's choices and preferred outcome for their own life circumstances. The right of a person with capacity to make decisions and remain in control of their life must be respected. Consideration of 'capacity' and 'consent' are central to adult safeguarding, for example, in determining the ability of an adult to make lifestyle choices, such as choosing to remain in a situation where they risk being harmed or where they choose to take risks. There should always be a presumption of capacity to make decisions unless there is evidence to suggest otherwise and current guidance for professionals in respect of determining capacity should be followed (see section 12). However there are also some circumstances when it may be necessary to consider the protection and rights of others, and overriding the withholding of consent may be necessary to ensure the protection of others.

Preventative Safeguarding includes a range of actions and measures such as practical help, care, support and interventions designed to promote the safety, well-being and rights of adults which reduce the likelihood of, or opportunities for, harm to occur. Effective preventative safeguarding requires partnership working, that is, individuals, professionals and agencies working together to recognise the potential for, and to prevent, harm. Prevention is therefore the responsibility of a wide range of

agencies, organisations and groups; indeed it is the responsibility and concern of us all as good citizens and neighbours. All professionals and service providers across the public, private, statutory, voluntary, community, independent, and faith sectors that come into contact with adults, including those who may be at risk of harm, must be alert to the individual's needs and any risks of harm to which they may be exposed. Prevention will strive towards early intervention to provide additional supports at all levels for adults whose personal characteristics or life circumstances may increase their exposure to harm.

Protective Safeguarding will be targeted at adults who are in need of protection, that is, when harm from abuse, exploitation or neglect is suspected, has occurred, or is likely to occur. The protection service is led by HSC Trusts and the PSNI. The input of other individuals, disciplines or agencies may be required, either in the course of an investigation of an allegation of harm or in the formulation and delivery of a care and protection plan.

Figure 1 shows the continuum of adult safeguarding activity from prevention to protection.



3. THE AIMS OF THIS POLICY

This policy aims to:

- promote zero-tolerance of harm to all adults from abuse, exploitation or neglect;
- influence the way society thinks about harm to adults resulting from abuse, exploitation or neglect by embedding a culture which recognises every adult's right to respect and dignity, honesty, humanity and compassion in every aspect of their life;
- prevent and reduce the risk of harm to adults, while supporting people's right to maintain control over their lives and make informed choices free from coercion;
- encourage organisations to work collaboratively across sectors and on an inter-agency and multi-disciplinary basis, to introduce a range of preventative measures to promote an individual's capacity to keep themselves safe and to prevent harm occurring;
- establish clear guidance for **reporting** concerns that an adult is, or may be, at risk of being harmed or in need of protection and how these will be **responded** to;
- promote access to justice for adults at risk who have been harmed as a result of abuse, exploitation or neglect;
- promote a continuous learning approach to adult safeguarding.

3.1. WHO IS THIS POLICY FOR?

The policy is intended to assist organisations, their staff and volunteers who are in contact with or providing services to adults across the statutory, voluntary, community, independent and faith sectors. While it is intended to be applied by managers, employees and volunteers in the course of the delivery of services and organisational activity, it can also be applied by individuals acting as responsible citizens at home and in local communities.

There is an expectation that all organisations and their staff will work in partnership as they apply this policy to their work with adults who may be at risk of harm or in need of protection. Appendix 1 lists some examples of organisations for whom this policy may have specific relevance, however this is not intended to be an exhaustive list.

4. UNDERPINNING PRINCIPLES

All Adult Safeguarding activity must be guided by five underpinning principles:

A Rights-Based Approach: To promote and respect an adult's right to be safe and secure; to freedom from harm and coercion; to equality of treatment; to the protection of the law; to privacy; to confidentiality; and freedom from discrimination.

Agencies and professionals who intervene in the lives of adults at risk should be guided by current best practice, the law and respect for rights set out in the European Convention on Human Rights¹ and enshrined in domestic law by the Human Rights Act 1998², acting in accordance with relevant UN and EU Conventions³ on the Rights of Persons with Disabilities and the UN Principles for Older Person's 1991⁴. Any intervention to safeguard an adult at risk should be human rights compliant. It should be reasonable, justified, proportionate to the perceived level of risk and perceived impact of harm, carried out appropriately, and be the least restrictive of the individual's rights and freedoms. It cannot be arbitrary or unfair, and all adults should be offered the same services on an equal basis.

An Empowering Approach: To empower adults to make informed choices about their lives, to maximise their opportunities to participate in wider society, to keep

For adults at risk of harm, empowerment is a process through which individuals are: enabled to recognise, avoid and stop harm; facilitated to make decisions based on informed choices including provision of support for those who lack capacity to make decisions; assisted to balance taking risks with quality of life decisions; supported and enabled to seek redress; and for adults who have been harmed, a process whereby they are enabled to recover their self-confidence and self-determination and make informed choices about how they wish to live their lives.

A Person-Centred Approach: To promote and facilitate full participation of adults in all decisions affecting their lives taking full account of their views, wishes and feelings and, where appropriate, the views of others who have an interest in his or her safety and well-being.

A person-centred approach is a way of working with an individual to identify how he or she wishes to live their life and what support they require. A person-centred approach to adult safeguarding demonstrates respect for the rights of the individual

¹ The *European Convention on Human Rights* can be accessed at: http://www.echr.coe.int/Documents/Convention_ENG.pdf

² The *Human Rights Act 1998* can be accessed at: <http://www.legislation.gov.uk/ukpga/1998/42/contents>

³ Relevant Conventions include The *UN Convention on the Rights of Persons with Disabilities*, the *UN Convention on the Elimination of Discrimination Against Women* (CEDAW), and the *EU Istanbul Convention* on domestic and sexual violence against women

⁴ The *UN Principles for Older Person's (1991)* can be accessed at: <http://www.un.org/documents/ga/res/46/a46r091.htm>

at its core, in particular, respect for the right of the individual to make their own informed choices and decisions. A person-centred approach should result in the individual making informed choices about how he or she wants to live and about what services and supports will best assist them, with cognitive and communication support being provided where necessary. Where the person lacks capacity to make a decision, best interest decisions should be made by professionals which take all available information into account, including information about previously expressed preferences or choices made by the person being safeguarded.

A Consent-Driven Approach: To make a presumption that the adult has the ability to give or withhold consent; to make informed choices; to help inform choice through the provision of information, and the identification of options and alternatives; to have particular regard to the needs of individuals who require support with communication, advocacy or who lack the capacity to consent; and intervening in the life of an adult against his or her wishes only in particular circumstances, for very specific purposes and always in accordance with the law.

Consideration of consent is central to adult safeguarding in determining the ability of an adult at risk to make lifestyle choices, including choosing to remain in a situation where they risk being harmed; determining whether a particular act or transaction is harmful or consensual; and determining to what extent the adult can and should be asked to take decisions about how best to deal with a given safeguarding situation. For consent to be valid, the decision needs to be informed, made by an individual with capacity to make decisions and made free from coercion, constraint or undue influence. Each decision must be considered on its own merits as an adult may possess capacity to make some decisions but not others and/or the adult's lack of capacity to make decisions may be temporary rather than permanent. A consent-driven approach to adult safeguarding will always involve making a presumption that the adult at the centre of a safeguarding decision or action has the capacity to give or withhold consent unless it is established otherwise (see section 12).

A Collaborative Approach: To acknowledge that adult safeguarding will be most effective when it has the full support of the wider public and of safeguarding partners across the statutory, voluntary, community, independent and faith sectors working accountability are clearly defined and understood. Working in partnership and a person-centred approach will work hand-in-hand.

Harm resulting from abuse, exploitation or neglect can be experienced by adults in a range of circumstances, regardless of gender, age, class or ethnicity. Adults who are at risk, suitably supported, must be central to the partnership, either as participants in preventative activities or protection intervention, or as contributors to decision-making in connection with the development of safeguarding policy, strategy and procedures. Where it is not possible for the adult at risk to contribute directly as participants or contributors, consideration must be given as to how they can be suitably supported to ensure that they are involved at an appropriate level. Successful adult safeguarding requires effective arrangements for all involved to work together. The strength of a collaborative approach will depend on the commitment and support from the highest level to safeguarding adults at the highest level.

5. KEY DEFINITIONS

The risk of harm occurs in all socio-economic, racial and ethnic groups, regardless of gender, age or sexual orientation. All adults at risk should be supported and empowered to minimise their own exposure to risk and to find their own balance between taking risks and making the most of the strengths in their own life circumstances.

The definition of an 'adult at risk of harm' takes account of a complex range of interconnected personal characteristics and/or life circumstances, which may increase exposure to harm either because a person may be unable to protect him/herself or their situation may provide opportunities for others to neglect, exploit or abuse them. It is not possible to definitively state when an adult is at risk of harm, as this will vary on a case by case basis. The following definition is intended to provide guidance as to when an adult may be at risk of harm, in order that further professional assessment can be sought.

An '**Adult at risk of harm**' is a person aged 18 or over, whose exposure to harm through abuse, exploitation or neglect may be increased by their:

- a) **personal characteristics**

AND/OR

- b) **life circumstances**

Personal characteristics may include, but are not limited to, age, disability, special educational needs, illness, mental or physical frailty or impairment of, or disturbance in, the functioning of the mind or brain. **Life circumstances** may include, but are not limited to, isolation, socio-economic factors and environmental living conditions.

An '**Adult in need of protection**' is a person aged 18 or over, whose exposure to harm through abuse, exploitation or neglect may be increased by their:

- a) **personal characteristics**

AND/OR

- b) **life circumstances**

AND

- c) who is **unable to protect** their own well-being, property, assets, rights or other interests;

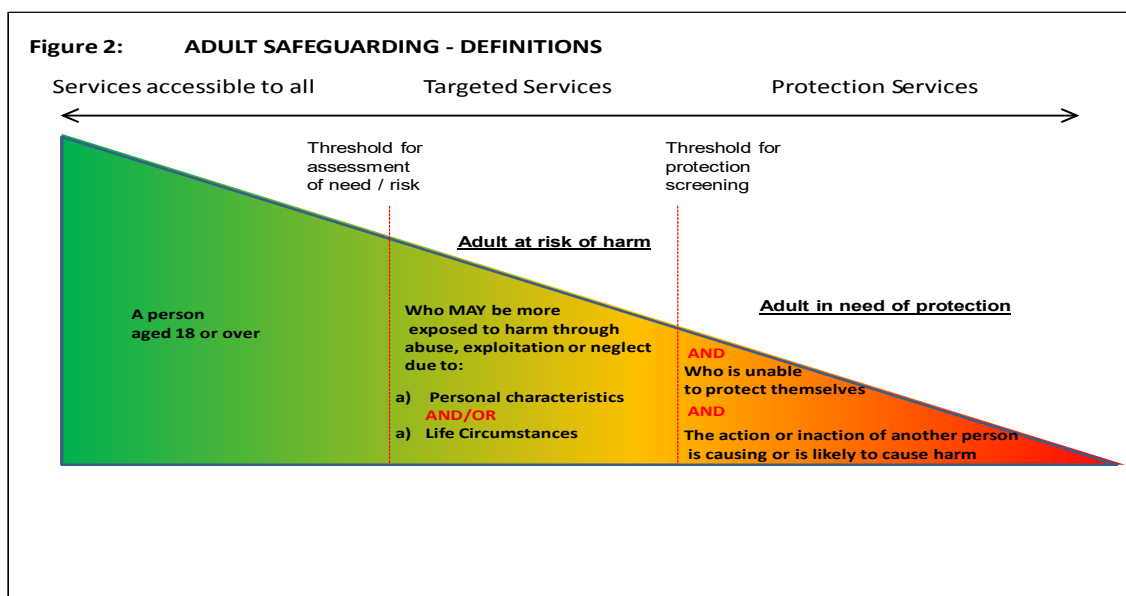
AND

- d) where the **action or inaction of another person or persons** is causing, or is likely to cause, him/her to be harmed.

In order to meet the definition of an 'adult in need of protection' either (a) or (b) must be present, in addition to both elements (c), and (d).

The decision as to whether the definition of an 'adult in need of protection' is met will demand the careful exercise of professional judgement applied on a case by case basis. This will take into account all the available evidence, concerns, the impact of harm, degree of risk and other matters relating to the individual and his or her circumstances. The seriousness and the degree of risk of harm are key to determining the most appropriate response and establishing whether the threshold for protective intervention has been met.

Figure 2 below shows where the definitions sit on the continuum of adult safeguarding activity.



Harm is the impact on the victim of abuse, exploitation or neglect. It is the result of any action whether by commission or omission, deliberate, or as the result of a lack of knowledge or awareness which may result in the impairment of physical, intellectual, emotional, or mental health or well-being.

The full impact of harm is not always clear from the outset, or even at the time it is first reported. Consideration must be given not only to the immediate impact of harm and risk to the victim, but also the potential longer term impact and the risk of future harm.

Harmful conduct may constitute a criminal offence or professional misconduct.

A number of factors will influence the determination of the seriousness of harm. A single traumatic incident may cause harm or a number of 'small' incidents may accumulate into 'serious harm' against one individual, or reveal persistent or recurring harm perpetrated against many individuals.

The judgement of what constitutes '**serious harm**' is a complex one and demands careful application of professional judgement against a number of criteria.

Assessments conducted by or on behalf of statutory HSC professionals (see section 10) should include consideration of the following:

- a) the impact on the adult at risk;
- b) the reactions, perceptions, wishes and feelings of the adult at risk;
- c) the frailty or vulnerability of the adult at risk;
- d) the ability of the adult at risk to consent and participate in the decision making process;
- e) the illegality of the act(s);
- f) the nature, degree and extent of harm;
- g) the pattern of the harm-causing behaviour;
- h) previous incidents, including any previous HSC Trust involvement
- i) the level of threat to the adult at risk's right to independence;
- j) the apparent intent of the alleged perpetrator and extent of premeditation;
- k) the relationship between the alleged perpetrator and the adult at risk;
- l) the context in which the alleged harm takes place;
- m) the risk of repetition or escalation of harm involving increasingly serious acts relating to this individual or other adults at risk; and
- n) the factors which mitigate the risk through service provision or wider arrangements.

There are no absolute criteria for judging when harm has become 'serious harm'; however this decision should include consideration of the degree, severity, duration and frequency of harm. The seriousness of harm depends on the impact experienced by the individual. Particularly careful consideration must be given to cases where the adult is unable to understand the impact harm is having on them. This will demand the application of professional judgement to consider all of the available evidence, the concerns and the wishes of the individual and to determine the seriousness of harm and the most appropriate intervention.

Abuse is 'a single or repeated act, or lack of appropriate action, occurring within any relationship where there is an expectation of trust, which causes harm or distress to another individual or violates their human or civil rights'⁵.

Abuse is the misuse of power and control that one person has over another. Abuse may be perpetrated by a wide range of people, including those who are usually physically and/or emotionally close to the individual and on whom the individual may depend and trust. This may include, but is not limited to, a partner, relative or other family member, a person entrusted to act on behalf of the adult in some aspect of their affairs, a service or care provider, a neighbour, a health or social care worker or professional, an employer, a volunteer or another service user. It may also be perpetrated by those who have no previous connection to the victim.

⁵ Action on Elder Abuse: definition of abuse 1993 which can be accessed at: <http://www.elderabuse.org.uk/Mainpages/Abuse/abuse.html>. This was later adopted by the World Health Organisation - http://www.who.int/ageing/projects/elder_abuse/en/

The main forms of abuse are:

Physical abuse

Physical abuse is the use of physical force or mistreatment of one person by another which may or may not result in actual physical injury. This may include hitting, pushing, rough handling, exposure to heat or cold, force feeding, improper administration of medication, denial of treatment, misuse or illegal use of restraint and deprivation of liberty.

Sexual violence and abuse

Sexual abuse is any behaviour perceived to be of a sexual nature which is unwanted or takes place without consent or understanding⁶. Sexual violence and abuse can take many forms and may include non-contact sexual activities, such as indecent exposure, stalking, grooming, being made to look at or be involved in the production of sexually abusive material, or being made to watch sexual activities. It may involve physical contact, including but not limited to non-consensual penetrative sexual activities or non-penetrative sexual activities, such as intentional touching (known as groping). Sexual violence can be found across all sections of society, irrelevant of gender, age, ability, religion, race, ethnicity, personal circumstances, financial background or sexual orientation.

Psychological / emotional abuse

Psychological / emotional abuse is behaviour that is psychologically harmful or inflicts mental distress by threat, humiliation or other verbal/non-verbal conduct. This may include threats, humiliation or ridicule, provoking fear of violence, shouting, yelling and swearing, blaming, controlling, intimidation and coercion.

Financial abuse

Financial abuse is actual or attempted theft, fraud or burglary. It is the misappropriation or misuse of money, property, benefits, material goods or other asset transactions which the person did not or could not consent to, or which were invalidated by intimidation, coercion or deception. This may include exploitation, embezzlement, withholding pension or benefits or pressure exerted around wills, property or inheritance.

Institutional abuse

Institutional abuse is the mistreatment or neglect of an adult by a regime or individuals in settings which adults who may be at risk reside in or use. This can occur in any organisation, within and outside the HSC sector. Institutional abuse may occur when the routines, systems and regimes result in poor standards of care, poor practice and behaviours, inflexible regimes and rigid routines which violate the dignity and human rights of the adults and place them at risk of harm. Institutional abuse may occur within a culture that denies, restricts or curtails privacy, dignity, choice and independence. It involves the collective failure of a service provider or an organisation to provide safe and appropriate services, and includes a failure to ensure that the necessary preventative and/or protective measures are in place.

⁶ The definitions of 'sexual violence and abuse' and 'domestic violence and abuse' will be amended to reflect those included within their revised strategies once published.

Neglect occurs when a person deliberately withholds, or fails to provide, appropriate and adequate care and support which is required by another adult. It may be through a lack of knowledge or awareness, or through a failure to take reasonable action given the information and facts available to them at the time. It may include physical neglect to the extent that health or well-being is impaired, administering too much or too little medication, failure to provide access to appropriate health or social care, withholding the necessities of life, such as adequate nutrition, heating or clothing, or failure to intervene in situations that are dangerous to the person concerned or to others particularly when the person lacks the capacity to assess risk.

This policy does not include self harm or self neglect within the definition of an 'adult in need of protection'. Each case will require a professional Health and Social Care (HSC) assessment to determine the appropriate response and consider if any underlying factors require a protection response. For example self harm may be the manifestation of harm which has been perpetrated by a third party and which the adult feels unable to disclose.

Exploitation is the deliberate maltreatment, manipulation or abuse of power and control over another person; to take advantage of another person or situation usually, but not always, for personal gain from using them as a commodity. It may manifest itself in many forms including slavery, servitude, forced or compulsory labour, domestic violence and abuse, sexual violence and abuse, or human trafficking.

This list of types of harmful conduct is not exhaustive, nor listed here in any order of priority. There are other indicators which should not be ignored. It is also possible that if a person is being harmed in one way, he/ she may very well be experiencing harm in other ways.

5.1. Related Definitions

There are related definitions which interface with Adult Safeguarding, each of which have their own associated adult protection processes in place.

Domestic violence and abuse

Domestic violence and abuse is threatening behaviour, violence or abuse (psychological, physical, verbal, sexual, financial or emotional) inflicted on one person by another where they are or have been intimate partners or family members, irrespective of gender or sexual orientation. Domestic violence and abuse is essentially a pattern of behaviour which is characterised by the exercise of control and the misuse of power by one person over another. It is usually frequent and persistent. It can include violence by a son, daughter, mother, father, husband, wife, life partner or any other person who has a close relationship with the victim. It occurs right across society, regardless of age, gender, race, ethnic or religious group, sexual orientation, wealth, disability or geography.

Human trafficking

Human trafficking involves the acquisition and movement of people by improper means, such as force, threat or deception, for the purposes of exploiting them. It can take many forms, such as domestic servitude, forced criminality, forced labour, sexual exploitation and organ harvesting. Victims of human trafficking can come from all walks of life; they can be male or female, children or adults, and they may come

from migrant or indigenous communities.

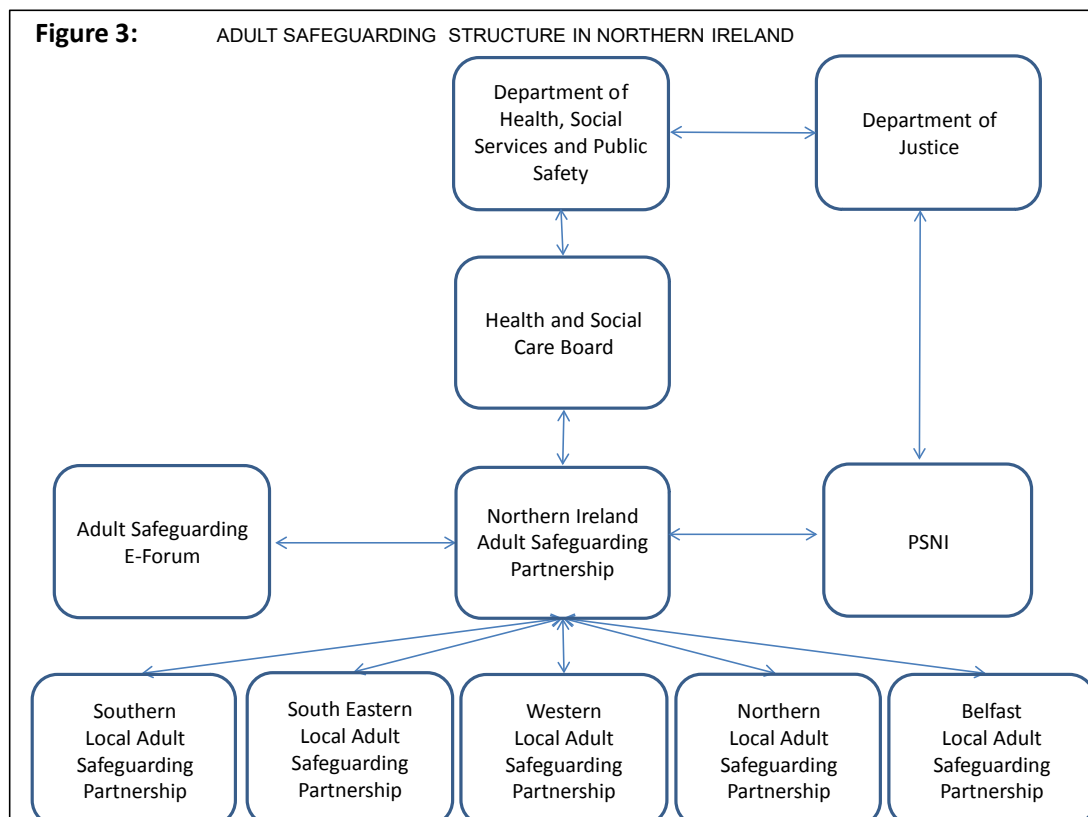
Hate crime

Hate crime is any incident which constitutes a criminal offence perceived by the victim or any other person as being motivated by prejudice, discrimination or hate towards a person's actual or perceived race, religious belief, sexual orientation, disability, political opinion or gender identity.

Victims of domestic violence and abuse, sexual violence and abuse, human trafficking and hate crime are regarded as adults in need of protection. There are specific strategies and mechanisms in place designed to meet the particular care and protection needs of these adults and to promote access to justice through the criminal justice system. It is essential that there is an interface between these existing justice led mechanisms and the HSC Trust adult protection arrangements described in this policy.

6. THE ADULT SAFEGUARDING INFRASTRUCTURE

The **Northern Ireland Adult Safeguarding Partnership (NIASP)** and five **Local Adult Safeguarding Partnerships (LASPs)** were established under the Adult Safeguarding in Northern Ireland, Regional and Local Partnership Arrangements (2010)⁷. They are collaborative partnerships with a responsibility for adult safeguarding in Northern Ireland. The partnerships are tasked by DHSSPS, with the support of the DOJ, with the delivery of improved adult safeguarding outcomes by way of a strategic plan⁸, operational policies and procedures and effective practice, which will be developed and implemented in accordance with this policy. An outline of the structure is provided in Figure 3 below.



6.1. The Northern Ireland Adult Safeguarding Partnership (NIASP)

The NIASP is a regional collaborative body led by the Health and Social Care Board (HSCB). It is supported in its work by all its constituent members, who have made a commitment to adult safeguarding. The membership is drawn from the main statutory, voluntary, community, independent and faith organisations involved in adult safeguarding across the region and includes representation from service providers and users. The NIASP is responsible for promoting and supporting a co-ordinated

⁷ *Adult Safeguarding in Northern Ireland – New Regional and Local Partnership Arrangements – March 2010* can be accessed at: http://www.dhsspsni.gov.uk/asva-_march_2010.pdf

⁸ The *NIASP Strategic Plan* can be accessed at: <http://www.hscboard.hscni.net/NIASP/Publications/NIASP%20-%20Strategic%20Plan%202013-2018.pdf>

and multi-agency approach and for creating a culture of continuous improvement in adult safeguarding practice and service responses. The NIASP strategy promotes ownership of adult safeguarding issues within all partner organisations and across all professional groups and service areas.

The HSCB has lead responsibility for the effective working of the NIASP, which is chaired by the Director of Social Care and Children's Services, or a nominated deputy. The Chair ensures that safeguarding matters are brought to the attention of the appropriate Directors in the HSCB and the Public Health Agency (PHA). The Chair is accountable to the HSCB and is responsible for ensuring that there are robust governance arrangements in place and compliance with the HSCB's responsibility for Delegated Statutory Functions.

Each member representative is accountable to their employing organisation and should be of sufficient seniority to bring adult safeguarding issues to the attention of NIASP and to make decisions on behalf of their organisation. Each representative should ensure that any actions and decisions taken by the NIASP are shared and implemented as appropriate within their organisation.

6.2. Local Adult Safeguarding Partnerships (LASPs)

The five LASPs are located within, and accountable to, their respective HSC Trusts. Their role is to implement the NIASP Strategic Plan, policy and operational procedures locally. Each LASP has responsibility to promote all aspects of safeguarding activity in its area and to promote multi-disciplinary, multi-agency and interagency cooperation, including the sharing of learning and best practice. They will be visible within, and engage locally with, communities to raise the profile of adult safeguarding.

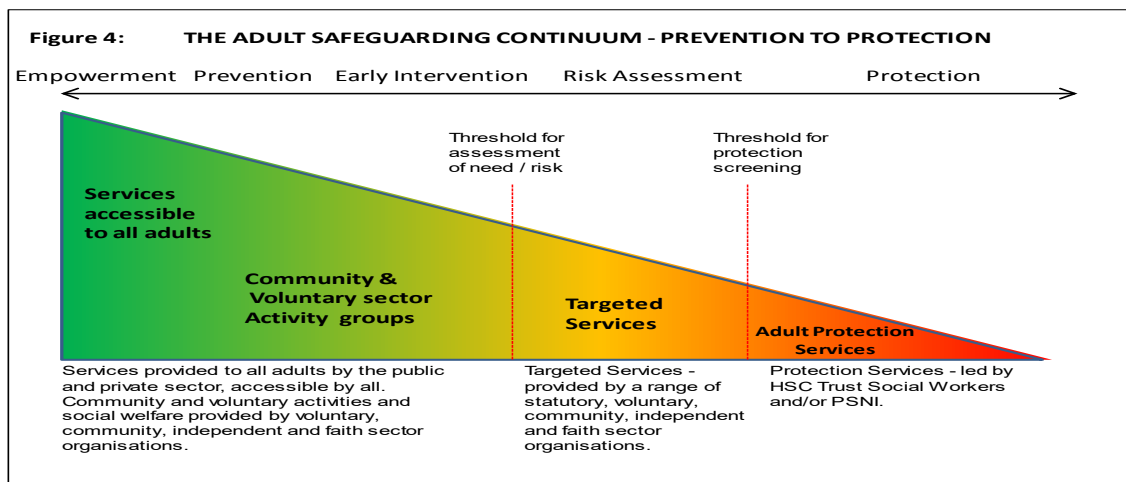
The LASP is chaired by the HSC Trust's Executive Director of Social Work or a senior designated nominee. It is responsible for ensuring that there are robust governance arrangements in place and ensuring compliance with the agreed statutory functions delegated by the HSCB.

Each partner organisation should be represented at a sufficiently senior level so that the LASP is effective in the implementation of guidance, policy and procedures at a local level, including engagement with service users, families, carers and the wider public. Each representative should be sufficiently senior to represent his/her organisation's views, to make decisions on its behalf and to ensure that safeguarding issues are dealt with in line with the organisation's established governance arrangements. Each representative should ensure that any actions and decisions taken by the LASP are shared and implemented as appropriate within their organisation.

7. THE CONTINUUM OF SAFEGUARDING – PREVENTION TO PROTECTION

Safeguarding is a broad continuum of activity. It ranges from the empowerment and strengthening of communities, through prevention and early intervention, to risk assessment and management, including investigation and protective intervention. At all stages along this continuum, safeguarding interventions will aim to provide appropriate information, supportive responses and services which become increasingly more targeted and specialist as the risk of harm increases. Presenting safeguarding activity in this way is intended to reflect the importance of prevention and early intervention, both as a means of improving the safety and quality of life and outcomes for all adults and reducing the risks of incidents of harm and need for more intrusive protection interventions. This is not intended to suggest that any stage or intervention along the continuum is mutually exclusive of the others. Throughout the continuum it is essential to recognise the importance of promoting empowerment and self-determination and the rights of all adults to make informed lifestyle choices.

Figure 4 below shows adult safeguarding interventions as a continuum of activity.



Local communities and services provided to the adult population are the starting point of the adult safeguarding continuum. Individuals will in the first instance be supported by their families and friends and by local community involvement and support. Using community development approaches, and working in partnership with local communities and organisations, we must build stronger, self-reliant communities and effective working relationships that promote people's rights, challenge inequalities and improve local support. Building safer communities involves helping adults to minimise their own exposure to the risk of harm from abuse, exploitation or neglect by empowering, equipping and enabling them to keep themselves safe, while at the same time enabling them to live their lives and pursue their interests to the fullest extent possible. Within communities there are a range of public and private services which will be available to and accessed by all adults.

This policy advocates that where there are potential interfaces with adults who may be at risk of harm, the organisations delivering such services should consider how adult safeguarding may be relevant to them and the actions they can take to prevent harm arising from abuse, exploitation or neglect to those using their services.

Within communities there are **recreational social, sporting or educational activities** available to all adults provided by a range of organisations across the statutory, voluntary, community, independent and faith sectors. Organisations providing these activities contribute to safeguarding adults by ensuring that these activities are delivered in a way which keeps adults safe. These organisations will need to assure themselves and everyone who comes in contact with them, that the organisation is committed to best safeguarding practice and to uphold the rights of all adults to live a life free from harm from abuse, exploitation and neglect. These organisations should have in place a culture of zero-tolerance of harm to adults which necessitates: the recognition of adults who may be at risk and the circumstances which may increase risk; knowing how adult abuse, exploitation or neglect manifests itself; and being willing to report safeguarding concerns. This extends to recognising and reporting harm experienced anywhere, including in the person's own home, in any care setting, in the community, and within organised community or voluntary activities (see section 8).

Voluntary, community, faith and independent service and/or activity providers are at the forefront of **preventative** safeguarding responses within the community. To be effective, preventative safeguarding requires everyone in society to work as partners, that is, individuals, families, carers, professionals and agencies working together to keep individuals safe and to prevent harm from abuse, exploitation or neglect.

One of the key ways of preventing escalation of the risk of harm is to intervene early. **Early intervention** is part of the safeguarding continuum and provides help and support to prevent problems reaching a point where a protection response becomes necessary.

In circumstances where community based activities can no longer meet the needs of an adult, or where there are emerging safeguarding concerns, contact should be made with the local HSC Trust for a professional **assessment of needs and/or risks**. All actions or interventions must be person centred and put the adult in need or at risk of harm at the centre of decision making.

If the concern relates to serious harm a referral may be made directly to the Adult Protection Gateway Service.

Very often it is the General Medical Practitioner (GP) who will be the first point of contact for adults and their families where an individual's needs are changing and they require further support. GPs and other allied health professionals, such as opticians, pharmacists, dentists or therapists, have a key role in the identification of risks of harm and ensuring appropriate referral to the HSC Trust for a further assessment of needs and/or risks.

Targeted services are services delivered specifically to 'adults who may be at risk' in order to meet assessed needs and/or address risks. The scale and intensity of service provision and intervention is likely to increase in proportion to the level of assessed need or risk. As the level of need or risk increases HSC Trusts may need to take action to prevent or manage any identified need or risk of harm, through provision of a service such as domiciliary based care, supported living, residential or nursing care. Targeted services will normally be delivered by, commissioned or contracted by, HSC Trusts. However voluntary, community, independent and faith

sector organisations may provide services targeted specifically at groups of adults at risk for recreational, social, sporting or educational purposes.

Targeted services include all services which fall under the definition of Regulated Activity contained within Schedule 2 of the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007⁹. This includes all health and social care services, whether delivered by statutory or independent providers, such as hospitals and GPs.

Many adults at risk will spend most of their time where they live, particularly those adults with restricted mobility and/or limited capacity to make decisions. These people may be more heavily dependent upon targeted services and the support of others, and their level of risk may increase as they spend much of their time in their home, often alone, or with the same people surrounding them, and with greater dependency on individuals or carers.

All targeted service providers, must be zero-tolerant of harm. There is an expectation that providers of targeted services will have robust governance and safeguarding procedures in place within their organisations to ensure that care is delivered in a way which instils confidence amongst those who use the service, staff, management, regulators and the public.

There is an expectation that commissioners of services will require, by way of service level agreements or contracts, the providers of targeted services to have robust governance and safeguarding regimes in place. There is an expectation that as employers, both service providers and commissioners must also ensure their organisations promote zero-tolerance of harm to adults within the workplace.

As the risk of harm increases, the safeguarding response required to mitigate it also increases. At the higher end of the safeguarding continuum is the **Adult Protection Gateway Service**. This service is provided for 'adults in need of protection', that is, those adults for who harm from abuse, exploitation or neglect, is a reality either because it has already occurred or, without intervention, is at serious risk of occurring. Protection interventions are led by social workers within the HSC Trusts and/or PSNI officers; the latter primarily where a crime or criminal act is alleged or suspected. These lead agencies will engage with the adult in need of protection in the first instance. They will also require information, action and support from other disciplines, agencies and organisations to assist with an adult protection or criminal investigation, or to contribute to the development and delivery of a care and protection plan for an adult in need of protection.

⁹ The SVG Order can be accessed at: <http://www.legislation.gov.uk/nisi/2007/1351/contents>

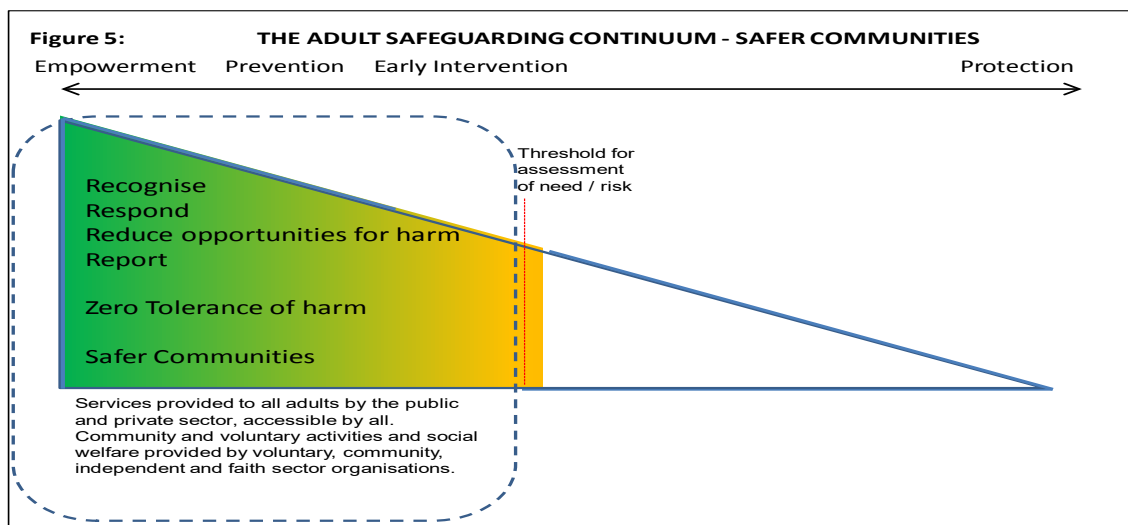
8. PREVENTION – PROMOTING SAFER COMMUNITIES AND SAFER ORGANISATIONS

The prevention of harm requires the promotion and creation of:

- **safer communities**, that is, safe places for all adults to live in, including those who may be at risk; and
- **safer organisations**, that is, safe places where all adults, including those who may be at risk, access and receive services or participate in organised activities.

Whether living in communities or working or volunteering in organisations, each of us needs to be zero-tolerant of potentially harmful behaviours against others, and when we suspect something is wrong, to report it (see section 10).

Figure 5 shows where safer communities sit on the Adult Safeguarding continuum.



8.1. Safer Communities

A key objective of this policy is to promote safer communities for adults to live in and safer organisations for them to be actively part of. The more socially isolated people are the greater the risk of harm arising from abuse, exploitation or neglect. The creation of safer communities for all adults is the responsibility of central and local government; of statutory sector service providers; and of voluntary, community, independent and faith sector providers. Local communities, neighbours and citizens also have a key role to play.

Empowerment is key to the promotion of safer communities and the prevention of harm. We should seek to connect people with the resources, activities and services that promote involvement and minimise opportunities for people to cause harm to others. Communities should aim to create opportunities to encourage and empower people to participate as fully as possible in their communities and broader society. Safer communities can play a vital signposting role in connecting people with local resources and supports that enable them to resolve their own problems and challenges.

There are a number of strands to the creation of safer communities that will greatly contribute to the prevention of harm.

Effective Health and Social Care Policies and Strategies

Being fit and well means people are better placed to ensure their personal safety.

Initiatives which:

- aim to prevent slips, trips and falls;
- promote healthy eating, exercise and the sensible use of alcohol;
- ensure good dental and eye care;
- promote personal resilience, self awareness and independence;
- encourage and assist people where necessary to feel safe in their own home

all contribute to assisting people to be better able to address their personal well-being and safety. This requires effective health and social care planning and implementation, robust public health strategies and responses, and commissioning and delivery underpinned by standards frameworks¹⁰ which set out the care that patients, clients, their carers and wider family can expect to receive.

Effective Community Safety Policies and Strategies

People who feel safe in their homes and community are more likely to feel in control of their lives and to take positive steps to ensure their personal safety. A number of types of crime – such as doorstep crime; distraction burglaries; bogus callers; rogue traders; cold callers and cyber crime are of particular concern with regard to adults at risk in our communities. The work of voluntary and community groups is critical to help adults who may be at risk to live safer lives and minimise their exposure to risk of harm through the promotion of local initiatives to provide information and support.

The ‘Building Safer, Shared and Confident Communities – A Community Safety Strategy for Northern Ireland 2012-2017’¹¹ contains commitments to reduce fear of crime and help people to feel safer through regional and local programmes to increase trust and confidence. Through engagement with the voluntary and community sector, the strategy aims to:

- improve understanding of fear of crime and deliver tailored projects to reduce fear;
- promote intergenerational projects to bring old and young together to increase confidence;
- promote positive perceptions of young people; and
- engage with the media on reporting of crime and anti-social behaviour and its impact on fear and confidence.

The Policing and Community Safety Partnerships (PCSPs)¹² which operate in each council area are central to the delivery of safer communities. Each PCSP works with its local community to identify and address issues of concern in the local area and

¹⁰ Frameworks for Mental Health and Wellbeing, Learning Disability and Older People's Health and Wellbeing can be accessed at: http://www.dhsspsni.gov.uk/mhsf_final_pdf.pdf

http://www.dhsspsni.gov.uk/learning_disability_service_framework_june_2013.pdf

http://www.dhsspsni.gov.uk/service_framework_for_older_people-2.pdf

¹¹ <http://www.dojni.gov.uk/community-safety-strategy-2012-2017.htm>

¹² Further information on PCSPs can be obtained from www.pcsp.org

PCSP Policing Committees work with local PSNI to develop local policing plans and monitor their performance in enhancing community safety in their area. They also work to secure the co-operation of the public to prevent crime and enhance community safety.

Effective Awareness of Adult Harm and Abuse and Responsibility to Report

Adult abuse is underreported. People may not report their concerns for a number of reasons, including not recognising it for what it is or fear of 'getting it wrong'. It is a reality that the adult who is at risk is often dependent on the person whose behaviour is, either intentionally or unintentionally, causing the harm.

Public awareness campaigns and education programmes can help the public to recognise that adult harm and abuse is unacceptable in a civilised society and encourages the reporting of concerns to the HSC Trust and the Adult Protection Gateway Service. Education programmes in schools and colleges encompassing 'good citizenship' principles and social responsibilities can help begin the shift towards a society which is zero-tolerant of adult harm.

Many public and private service providers within the community are well placed to identify early indications that an adult may be at risk, for example banks or legal services such as solicitors. Providers of services who are in a position of trust, in particular GPs and providers of primary care services, will have access to information regarding adults which may suggest they are at risk of harm. Service providers should be aware of the signs of harm to adults within their respective sectors, and should ensure organisational procedures are in place to guide staff when concerns are identified. All those working to provide services to the community generally have a responsibility to refer concerns to their local HSC Trust, and to cooperate and share information where necessary with any adult safeguarding investigations.

8.2. Safer Organisations

The continuum of adult safeguarding outlines the wide range of organisations involved in people's lives, from the small community activity groups through to larger organisations and statutory services. All organisations should ensure that any service they deliver is underpinned by the principles of respect and treating others with dignity (see section 4). This is the first and crucial step to ensuring that services are high quality, that the focus is on the individual receiving the service which may help to provide support and that harm is prevented. Increasing levels of need and risk are likely to lead to greater targeting of service provision, which, in turn, requires a heightened awareness of risk of harm and more robust measures will be required to prevent harm.

Robust governance arrangements are key to an organisation's ability to keep adults safe from harm. A range of governance arrangements exist, which should not and cannot operate in isolation. No single governance measure will ensure the safety of adults at risk. Both internal governance and external measures are vital to ensure that safeguarding concerns are identified early and escalated to enable appropriate action to be taken. Governance arrangements must be brought together to provide a level of assurance to managers and leaders that the organisation is doing all it can to keep adults in receipt of its services safe from harm.

Each organisation will have its own internal governance arrangements depending on the size of the organisation and the nature of its activities. The governance arrangements should be proportionately robust to enable managers at all levels, including the Chief Executive and Board members where applicable, to assure themselves that the organisation is delivering a safe, high quality service to all, and that it is effectively adhering to the adult safeguarding expectations appropriate to the organisation.

Senior managers should create a culture where staff and volunteers feel that their role and contribution is valued and that they are empowered, and supported in decision making by line managers. Senior management must ensure good governance is cascaded throughout the organisation. Line managers should ensure decisions taken by their staff which relate to adult safeguarding are consistent with organisational safeguarding policies.

Where an organisation permits, by way of contracts or otherwise, the use of its facilities or services by third parties to provide services or activities to adults, assurances should be sought from the third party that it is adhering to the appropriate level of governance as described below.

8.3. Minimum Safeguarding Expectations

At a minimum, any public service, voluntary, community, independent or faith organisation providing recreational social, sporting or educational activities or services will be expected to safeguard adults who may be at risk by:

- **recognising** that adult harm is wrong and that it should not be tolerated;
- **being aware** of the signs of harm from abuse, exploitation and neglect;
- **reducing opportunities for harm** from abuse, exploitation and neglect to occur; and
- **knowing how and when to report** safeguarding concerns to HSC Trusts or the PSNI.

8.4. Internal Governance – Policy and Procedures

The following policies and procedures are the building blocks of good governance that contribute to safe high quality care and they should be robustly implemented by any organisation.

These are essential for any organisation delivering, commissioned or contracted to deliver targeted services.

- Robust selection and recruitment procedures;
- Effective management, support, supervision and training of staff;
- Procedures for responding to, recording and reporting safeguarding concerns in a timely manner to the HSC Trusts;
- Procedures for cooperating within the organisation and with others as required to address safeguarding concerns;
- Procedures for assessing and managing risks;
- Management of reporting and escalating untoward/adverse incidents;

- Procedures for managing comments, complaints and suggestions;
- Procedures on the management of records, confidentiality, and the sharing of information, (see section 14);
- A written code of behaviour/conduct;
- A disciplinary policy, including referral to regulatory bodies where relevant; and
- A whistle-blowing policy.

Care and Service Standards

All providers of targeted services are required to have in place the above governance arrangements and, depending on the nature and level of the service delivered, providers may also be required to ensure compliance with care and/or service standards and regulations against which they will be inspected or audited. Where there are breaches in compliance with standards or regulations and the quality of care or the safety of service users is compromised, the role of inspection and that of the relevant regulator is critical in addressing the safeguarding concern and the prevention of harm.

All organisations providing targeted services to adults who may be at risk must have the above governance arrangements in place, supported by the implementation of an adult safeguarding policy.

Adult Safeguarding Policy

The **Adult Safeguarding Policy** will clearly demonstrate the organisation's commitment to a zero tolerance of adult harm. The policy must be owned and supported by senior management and be accessible to all within the organisation.

A key element of the adult safeguarding policy will be the nomination of **Adult Safeguarding Champions (ASC)**¹³. An ASC must be accessible to all service areas in the organisation as a source of advice and guidance. The nominated ASCs should be senior people within the organisation, suitably trained, experienced and skilled to carry out the role (see section 15).

The role of the **Adult Safeguarding Champion** is:

- to provide information and support for staff on adult safeguarding within the organisation;
- to ensure that the organisation's adult safeguarding policy is disseminated and support implementation throughout the organisation;
- to advise within the organisation regarding adult safeguarding training needs;
- to provide advice to staff or volunteers who have concerns about the signs of harm, and ensure reporting to HSC Trusts where there is a safeguarding concern (see section 10);
- to support staff to ensure that any actions take account of what the adult wishes to achieve – this should not prevent information about any risk of

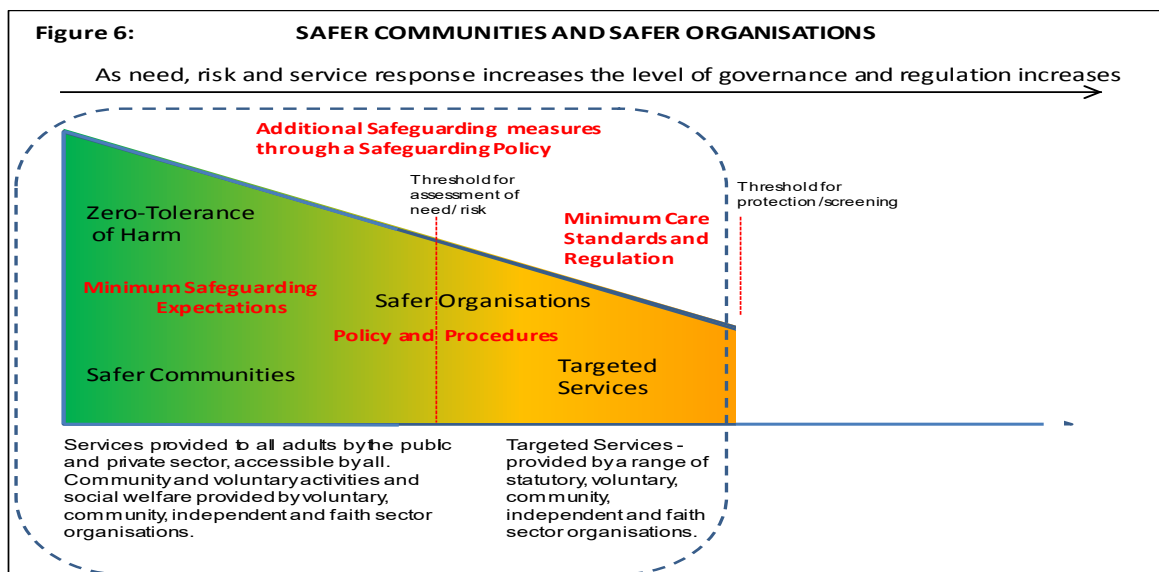
¹³ The term Adult Safeguarding Champion is intended to encompass the roles of the 'Nominated Manager' referred to in the Volunteer Now Standards and Guidance document 'Safeguarding Vulnerable Adults – a Shared Responsibility' and the role of the 'Alerting Manager' in the NIASP Adult Safeguarding Strategic Plan 2013-2018.

serious harm being passed to the relevant HSC Trust Adult Protection Gateway Service for assessment and decision-making;

- to establish contact with the HSC Trust Designated Adult Protection Officer (DAPO) (see section 11), PSNI and other agencies as appropriate;
- to ensure accurate and up to date records are maintained detailing all decisions made, the reasons for those decisions and any actions taken;
- to compile and analyse records of reported concerns to determine whether a number of low-level concerns are accumulating to become significant; and make records available for inspection.

Where the ASC is not immediately available, this should not prevent action being taken or a referral being made to the HSC Trust in respect of any safeguarding concern.

Figure 6 below shows the relationship between safer communities, safer organisations and the increasing governance arrangements.



As the level of need or risk and service intervention increases, more robust governance measures and requirements will apply.

9. EXTERNAL GOVERNANCE

9.1. Commissioning/ Subcontracting Arrangements

Services for adults at risk may be commissioned or sub-contracted by a range of organisations across the statutory, voluntary, community, independent or faith sectors. This may include, for example, commissioning by the NIHE, local councils, PSNI and other justice organisations, or the HSC sector. Any organisation which commissions or sub-contracts provision of a service for adults at risk to another third party organisation retains responsibility and accountability for the quality of the provision of that service.

The HSCB, HSC Trusts and the PHA may commission or purchase health and social care services from third party providers, whether from the voluntary, community, independent or faith sectors. This will include GP and other primary or health care services, such as private hospitals, nursing or residential care, supported housing, day care or domiciliary care services.

It is critical that all commissioning or subcontracting organisations ensure that it is a condition of all contracts or service level agreements with service providers that there are robust governance arrangements in place within those provider organisations to ensure that adults at risk are safe from harm and receive a high quality service.

HSC Trusts must provide advice and guidance to adults who may be at risk who are commissioning their own care, for example those in receipt of direct payments or self directed support, outlining what they should expect from their service provider in terms of governance arrangements and good safeguarding practice.

Those who have a role in the management and monitoring of **contracts** have a responsibility:

- to specify and issue contracts for the purchase of services commissioned to address identified needs;
- to acquire and maintain a sufficient level of knowledge about adult safeguarding relevant to their role;
- to require that all services meet their safeguarding requirements described in this policy and other standards of quality set by the DHSSPS;
- to work closely with service providers to assist them to address ongoing concerns that may relate to contractual/service level agreement requirements;
- to monitor the quality of the performance of service providers and identify any deterioration in standards of care and risks this may present;
- to regularly audit the third party service provider to ensure the service is being delivered in accordance with the contract and this policy;
- to escalate any concerns about the provision of care to the care manager / key worker or senior management; and
- where requirements are not being met, to use appropriate reporting mechanisms to ensure adults at risk are kept safe, and where necessary impose appropriate sanctions.

All professionals with responsibility for carrying out the **care management** process and function must:

- ensure that needs and risks to the adult at risk are identified and assessed, taking account of their views and preferences;
- ensure that there is a personalised care plan detailing the needs of the adult and specifying how the service provided will safely meet the needs and mitigate any risks identified;
- ensure the care plan is being implemented as agreed by the service provider;
- ensure that the care plan is reviewed regularly, as specified in the Care Management Guidance, or more frequently as required in order to respond to changing needs and/or risks;
- ensure a safe and high quality service is provided, noting any patterns emerging which suggest that there may be a cause for concern and acting upon any such concerns;
- ensure that they are informed of any incidents, accidents or “near misses” in respect of the individuals for whom they have commissioned care;
- ensure that they are informed of any changes in financial circumstances that come to the attention of the HSC Trust;
- ensure that they are informed of any complaints made and action taken to address them;
- analyse trends to identify patterns which may indicate low-level concerns or poor quality care issues which may accumulate to indicate that there is a risk of harm; and
- escalate concerns which may indicate serious harm or risk of serious harm to an adult at risk (see section 10).

9.2. Professional Regulation

Regulatory bodies are responsible for establishing and operating statutory schemes of regulation underpinned by professional standards and Codes of Conduct relating to the conduct and practice of their respective professions. They maintain registers of workers who meet those standards and this information is publicly available. Within the health and social care sector for example, doctors, nurses, social workers and allied health professionals must register with their respective regulatory body before being able to practice. Where risks of harm to a service user are identified, all professionals must act in accordance with any professional Code of Conduct agreed with their regulatory body.

A person who is the subject of an investigation by their regulatory body may also be under investigation in respect of an adult protection investigation. Where both investigations run in parallel, the adult protection investigation must take precedence to ensure that the rights and safeguarding needs of adults at risk are being protected and the integrity of any criminal investigation is maintained.

9.3. Legal Requirements

Where there are statutory requirements linked to safeguarding or quality of service provision, all organisations will need to be assured that they are fully compliant with the requirements of the law.

Of particular relevance to adult safeguarding is the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007, which seeks to protect children and vulnerable adults from harm caused by those who work closely with them. Schedule 2 of this Order contains a definition of Regulated Activity, and anyone engaging in Regulated Activity should have their suitability checked through AccessNI prior to employment.

The **Disclosure and Barring Service**¹⁴ (DBS) is responsible for maintaining the list of individuals barred from engaging in Regulated Activity with children and vulnerable adults across England, Wales and Northern Ireland. A regulated activity provider must refer anyone to the DBS who has harmed or poses a risk of harm to a child or a 'vulnerable adult' and who has been removed from working (paid or unpaid) in regulated activity, or would have been removed had they not left. The DBS will decide whether the person should be barred from working in regulated activity with children, or adults, or both.

It is an offence to knowingly engage a barred person in regulated activity and it is an offence to engage or offer to engage in regulated activity if you are barred.

Within the health and social care sector, HSC Trusts, voluntary, community, independent and faith sector providers must be assured that they are fully compliant with the duty of quality imposed on them by the Health and Personal Social Services (Quality, Improvement and Regulation) (NI) Order 2003¹⁵ and the Regulations made under that Order.

9.4. Regulation

There is a broad range of regulators, auditors and inspectorates which are relevant to adult safeguarding. Each has a specific role in measuring and ensuring that organisations comply with their own particular service or quality standards and the regulatory framework within which they operate.

Regulation, inspection and audit should make clear the expectation that service providers must meet the relevant quality standards, detect failings in provision of care or services early, and take appropriate action when sub-standard care is found.

Regulation needs to be responsive and proportionate, with the aim of ensuring public confidence in the services provided. This can only be achieved by a highly coordinated, integrated and expert regulatory system employing intelligent and thoughtful inspection. It will require the ability to apply both qualitative and quantitative judgement and to take effective enforcement action when necessary.

¹⁴ Information on the Disclosure and Barring Service can be accessed at:

<http://www.nidirect.gov.uk/disclosure-and-barring-protecting-children-and-vulnerable-adults>

¹⁵ The 2003 Order can be accessed at: <http://www.legislation.gov.uk/nisi/2003/431/contents>

The Role of Regulation and Quality Improvement Authority (RQIA)

The RQIA is the independent regulator of the health and social care sector and has an important role in promoting continuous improvement in the quality and safety of care delivered across the range of health and personal social services. RQIA registers and inspects a range of services described in the Health and Personal Social Services (Quality, Improvement and Regulation) Order (Northern Ireland) 2003. These services are subject to regulation and are provided by both the statutory and independent sectors. RQIA's regulatory function operates within a framework of regulations and standards produced by DHSSPS.

RQIA inspections and reviews are conducted across a range of HSC settings in the statutory, independent and voluntary sectors. RQIA has a specific role in inspecting mental health and learning disability hospital wards. RQIA, through its inspections and reviews, makes an independent assessment of the safety, quality and availability of health and social care services. Within the regulated care sector, inspections may be announced or unannounced, and examine compliance with regulations and minimum standards in the areas of care, medicines management, estates and finance. Other inspections or reviews can be commissioned and conducted across a range of health and personal social services. Where the service inspected is not meeting the required quality standards, or where compliance issues or concerns are identified, there are a range of robust sanctions and powers available to RQIA.

The RQIA has a key preventative role in adult safeguarding practice. As the independent regulator, RQIA has both a responsibility and the authority to ensure that safety and quality of care concerns which put service users at risk are addressed in the services which they inspect. The RQIA also has a key role in service improvement with the aim of encouraging improvement in the quality of the services they inspect and securing public confidence in the provision of those services by keeping the Department of Health, Social Services and Public Safety informed of their availability and their quality.

Governance information is essential to RQIA in the conduct of its inspections and reviews. It assists with the assessment of the service with specific regard to safeguarding performance. There are core governance elements which should be included in all inspections conducted within regulated services. These are the number, nature and outcome of:

- complaints made;
- safeguarding concerns raised with the Adult Safeguarding Champions;
- notifiable incidents or accidents which occurred as appropriate to that service setting; and
- any disciplinary procedures conducted.

Information collected during inspections and other information which may come to the attention of the RQIA, from a range of sources, including statutory notifications, must be collated and analysed to ensure trends are identified. In particular, information on complaints, notifiable incidents and accidents should be triangulated as these are key indicators of risk to service users. Inspectors should be aware that a number of low-level concerns could suggest patterns or trends which accumulate to a risk of serious harm to one or more adults.

Enforcement action is an essential element of the responsibilities of RQIA. There is a range of enforcement options which RQIA can use to ensure compliance with regulations and minimum standards, to effect improvements and to afford protection to service users. In most circumstances, and where appropriate, RQIA will make recommendations and requirements for quality improvement through regulation and inspection activity. Where a service is identified as being at risk of failing to meet minimum standards and/or comply with regulations, RQIA will consider the various options to enable the registered establishment or agency to make the necessary improvements. RQIA will normally adopt a stepped approach to enforcement. However, this would not rule out the option of moving directly to legal action, including prosecution, if the circumstances require. RQIA may increase inspection activity to monitor compliance and ensure that the necessary improvements are being made. RQIA may escalate enforcement actions at any time, proportionately and in relation to the level of risk to service users and the seriousness of any breach of regulation. RQIA will follow up enforcement action to ensure that quality improvements are achieved. In certain circumstances, where there is deemed to be a risk of serious harm to service users, RQIA may take urgent action. Such circumstances include, but are not exclusive to, those falling under the Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults (2009). This may involve, where necessary, using its powers to cancel registration and/or to seek the urgent closure of a registered service. RQIA publishes its enforcement policy and procedures online, along with copies of its inspection reports¹⁶.

The RQIA will notify any serious concerns in relation to the quality of service provision or risk of harm to an individual/s to the relevant HSC Trust or the PSNI, and will be a key partner contributing to investigations with the other agencies to protect adults at risk who are in receipt of a regulated service.

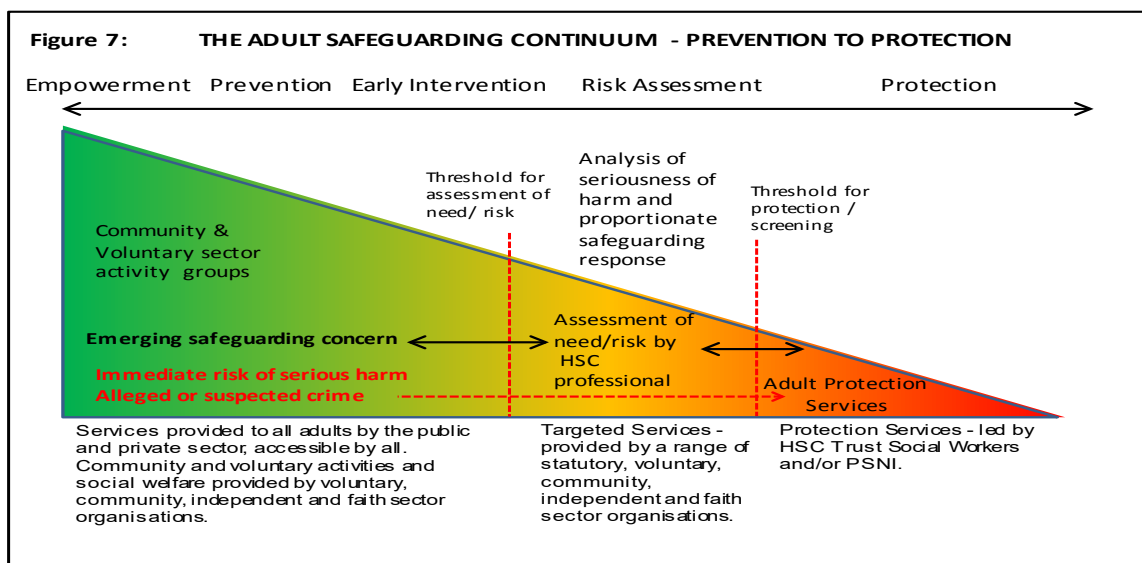
¹⁶ RQIA publications are available on www.rqia.org.uk

10. REFERRAL PATHWAY FOR SAFEGUARDING CONCERNS

If there is a clear and immediate risk of harm or a crime is alleged or suspected, the matter should be referred directly to the PSNI or HSC Trust Adult Protection Gateway Service.

However in most circumstances there will be an emerging safeguarding concern which should normally be referred to the HSC Trust, for a professional assessment. It will be a matter for HSC professionals to judge whether the threshold for an adult protection intervention has been met, or whether alternative responses are more appropriate. Referrals can be made from any source.

Figure 7 shows the pathway for reporting emerging safeguarding concerns through targeted HSC services and if necessary to the HSC Trust adult protection service.



All HSC Trusts must have a single point of access for receipt of referrals regarding concerns about adults who may be at risk, and will promote and publicise contact arrangements within its area. HSC Trust arrangements must accommodate referrals which do not obviously fit existing Programme of Care structures, ensuring there are no safeguarding gaps.

10.1. Risk Assessment

When any risk of harm is identified, a risk assessment must be undertaken to establish the degree of risk of harm to that individual and to others. It is the responsibility of suitably qualified statutory HSC professionals to undertake such risk assessments once a concern has been raised. In certain circumstances HSC Trusts may ask another organisation to conduct risk assessments on its behalf.

HSC professionals are required to put the individual's needs and wishes at the heart of the risk assessment process, and to use their expert skills and professional judgement so that the most appropriate and preferred course of action or outcome is found for each individual.

Assessment is a process which focuses on the individual and their circumstances at the time, recognising that needs and risks can change over time. Assessment will analyse and be sensitive to the changing levels of need and risk faced by an individual. It may require specialist assessments or expert opinion to inform the evidence gathering. All information should be analysed to determine the nature and level of risk. The assessment will inform a proportionate response based on the views and wishes and the preferred outcomes of the individual.

In gathering information to inform the assessment, professionals should be aware that this may also be required as part of a criminal investigation. Therefore it is critical to ensure that any potential evidence that may be later required by the PSNI is not compromised.

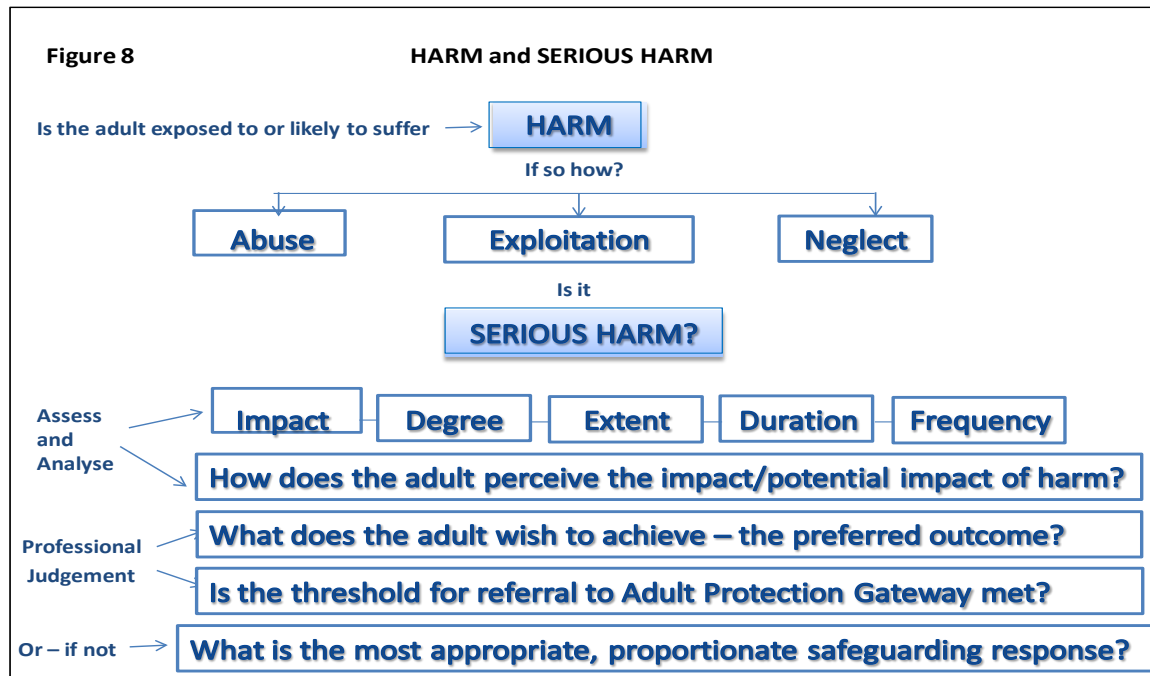
In making professional judgements, due regard should be given to the capacity of the adult to make informed choices, free from duress, pressure or undue influence and their capacity to make decisions to protect themselves from harm. All adults, including those at risk will always be assumed to have capacity to make decisions unless it has been determined otherwise (see section 12) and, ideally, a referral to the HSC Trust should be made with the adult's agreement and full participation. However, there may be circumstances in which the person concerned about an adult at risk may not be best placed to seek their consent to a referral being made, or the adult at risk is clearly stating that they do not want a referral to be made. Whilst the wishes of the adult should always be the paramount consideration, it is important to remember that there will be circumstances when other factors may be overriding, for example, where undue influence or coercion is suspected to have influenced the adult's decision or other people may be at risk. The inability to obtain an adult's consent in these circumstances should not prevent or delay concerns about that adult being reported to adult protection services. A balance must also be struck between an individual's human rights and the need to intervene to protect them from harming themselves or others.

Consideration should be given to the vulnerability of the alleged perpetrator. It is possible that a risk assessment may also be required for the perpetrator.

The analysis of risk will be central to decisions about future intervention. Any safeguarding intervention is not about being risk averse, nor simply about eliminating risk; adult safeguarding is about empowering and supporting people to make decisions that balance acceptable levels of risk in their lives. This may mean that individuals choose to live with risks or to take risks. The exercise of professional judgement in determining the level of risk of harm and whether a referral for an adult protection intervention is required is critical.

Where professionals have contact with an adult at risk they may have opportunities to identify risk of harm. Within the HSC sector this may be for example a GP, District Nurse, Social Worker or another Allied Health Professional, or may be within acute or hospital settings. Professionals must be alert to signs of harm and escalate their concerns to the Adult Protection Gateway Service with the local HSC Trust (see section 11).

Figure 8 illustrates the factors for consideration in determining whether harm has become 'serious harm'.



Where a risk assessment concludes that the adult is at risk of serious harm, or has experienced serious harm (see section 5), then consideration must be given to whether the threshold for referral to Adult Protection Gateway Service has been met.

10.2. Determining Whether the Thresholds for Referral to Adult Protection Gateway Service Are Met

In the majority of cases where serious harm has been identified, the thresholds for Adult Protection Gateway Service will be met. However it must be remembered that in some circumstances referral into the Adult Protection Gateway Service may not be the most appropriate response. This may include, for example, a peer on peer incident where capacity is an issue and alternative responses are more appropriate (see below). At all times the least intrusive and most effective response should guide the intervention. The following thresholds are intended as a guide.

Thresholds are not intended to be used as exclusion criteria, but should be used positively to assist professional judgements about making referrals into the HSC Trust Adult Protection Gateway Service, and, critically, to enable informed decisions in respect of the most appropriate or proportionate safeguarding response.

The threshold for referral to the HSC Trust Adult Protection Gateway Service is likely to be met if one or a number of the following characteristics are met:

- the perceptions of the adult(s) concerned and whether they perceive the impact of harm as serious;
- it has a clear and significant impact on the physical, sexual, psychological and/or financial health and well-being of the person affected;
- it has a clear and significant impact, or potential impact, on the health and

- well-being of others;
- it involves serious or repeated acts of omission or neglect that compromise an adult's safety or well-being;
- it constitutes a potential criminal offence against the adult at risk;
- the action appears to have been committed with the deliberate and harmful intent of the perpetrator(s);
- it involves an abuse of trust by individuals in a position of power or authority; and
- it has previously been referred to a regulated service provider for action, and has not been sufficiently addressed.

If there is doubt about whether the threshold for Adult Protection has been reached, the concern should be discussed with the HSC Trust Adult Protection Gateway Service and a DAPO will advise whether the matter meets the threshold for referral into the Adult Protection Gateway Service.

Where a criminal act is either alleged or suspected, a report must be made to the PSNI.

10.3. A Determination that the Threshold for Referral to Adult Protection Gateway Service is Not Met – Alternative Safeguarding Responses

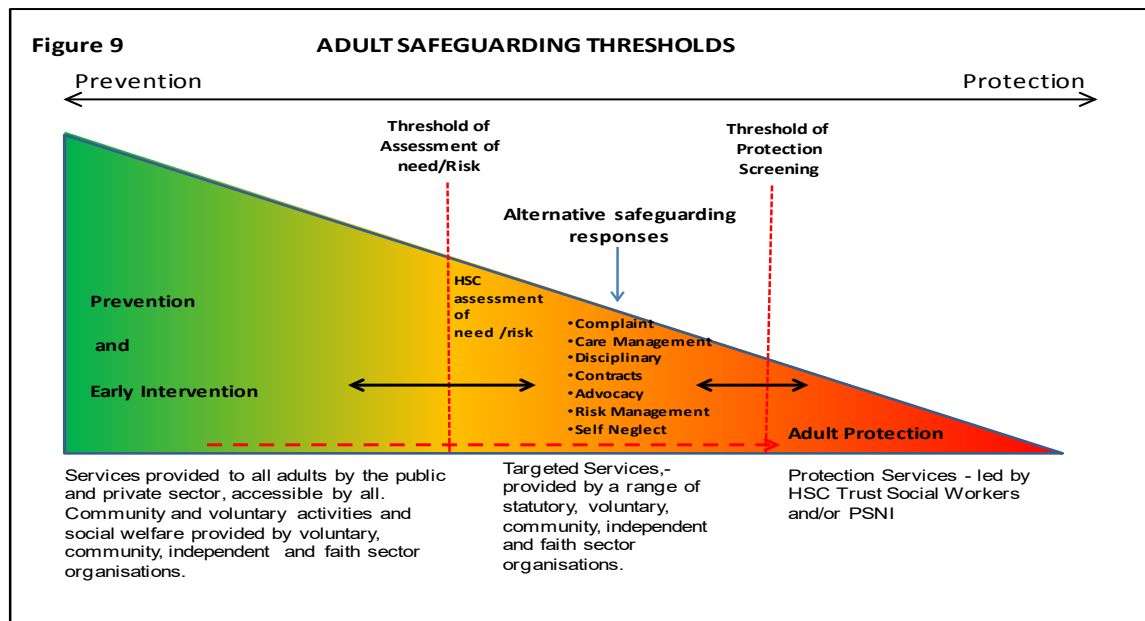
Where it is determined that the threshold for Adult Protection has not been met, other alternative courses of action should be explored with the adult. At all times the least intrusive and most effective response should be made. This is a matter for professional judgement, taking account of the individual circumstances and the wishes and views of the adult and may include:

- a) escalation to the service manager to address any issues about the quality of service provision;
- b) referral to the RQIA for action as the regulator in respect of quality of care concerns or where concerns have been raised and there has been a lack of action by the service provider;
- c) referral to a care manager/key worker for re-assessment and review of service user/carer's needs, views and care plan, or where appropriate a mental capacity assessment;
- d) action taken under complaints procedures;
- e) action taken under human resources/disciplinary procedures and referral to professional bodies, statutory regulatory bodies and/or the Disclosure and Barring Service where appropriate;
- f) referral to an advocacy service;
- g) referral to another service;
- h) a risk management intervention in relation to self neglect;
- i) a strategy to manage risks within a complex group living environment and the management of challenging behaviour;
- j) no further action required;

or a combination of two or more of the above.

Where an HSC Trust Adult Protection Gateway Service has agreed an alternative course of action, there must be mechanisms in place to ensure that those given lead responsibility to take certain actions report back to the DAPO on the outcome of the actions taken. All organisations involved in contributing to alternative courses of action will be expected to cooperate fully with HSC Trusts.

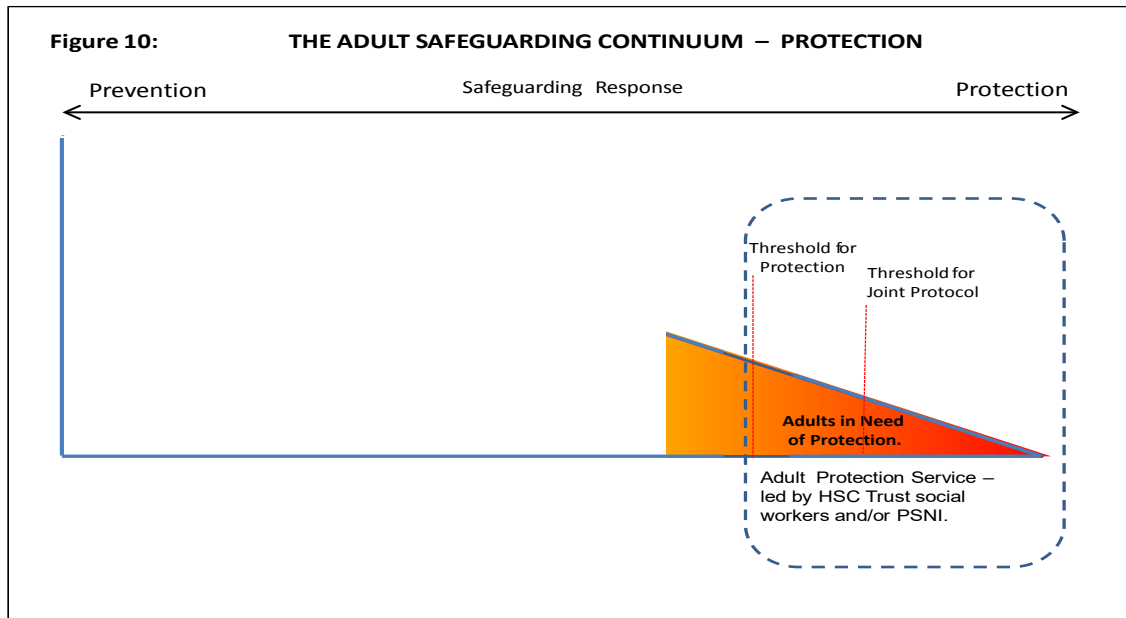
Figure 9 below shows where the thresholds sit in relation to the continuum of safeguarding activity.



Any safeguarding concerns relating to breaches of regulations or non-compliance with care or service standards are matters for the regulator, regardless of whether the threshold of serious harm has been reached. The HSC Trust should raise such concerns with the RQIA and will then co-ordinate an interagency response. The role of RQIA in inspection and regulation is outlined in section 9 and will be critical in the identification and prevention of safeguarding concerns or incidents in a proportionate manner to prevent unnecessary engagement of the Adult Protection Gateway Service.

11. ADULT PROTECTION SERVICES

Figure 10 shows the Adult Protection Service on the safeguarding continuum.



HSC Trusts and the PSNI are the lead agencies with responsibility for adult protection.

Each **HSC Trust** will have an Adult Protection Gateway Service which will receive adult protection referrals. Referrals outside normal working hours should be made to the Regional Emergency Social Work Service (RESWS). Referrals will be accepted from any source, irrespective of Programme of Care boundaries.

HSC Trusts will be the lead agency in terms of the co-ordination of joint Adult Protection responses. Within each HSC Trust, responsibility for the Adult Protection rests with the Executive Director of Social Work, and the lead profession within HSC Trusts is social work.

In circumstances where a crime is alleged or suspected, a referral to the **PSNI** should be made by telephoning 101, or in an emergency, 999. Both numbers are accessible on a 24 hour, 7 days per week basis. The PSNI will be the lead criminal investigative agency and will progress a criminal investigation where required.

The **PSNI** will be the lead criminal investigation agency and a report should be made to the PSNI where a crime is alleged or suspected. Within PSNI, responsibility for Adult Protection rests with the Chief Superintendent who has responsibility for the Public Protection Branch¹⁷.

A Joint Protocol will guide interagency referral, consultation and information exchange and working arrangements and will provide clarity in respect of the roles of

¹⁷ Responsibility for Adult Safeguarding within PSNI is subject to organisational change. Changes will be reflected within the policy once completed.

the PSNI and HSC Trusts in the delivery of the adult protection response. The Joint Protocol will outline when and how other agencies will be engaged for the purpose of an adult protection investigation and protection planning.

Regional adult protection procedures for HSC Trusts will be developed by the HSCB, endorsed by the NIASP and LASPs and implemented across the region to ensure that adult protection responses and practice are consistent across all HSC Trust areas. HSC Trusts will be responsible for implementing these procedures on behalf of the HSCB.

PSNI is guided by current the Association of Chief Police Officers (ACPO) guidance 'Safeguarding and Investigating the Abuse of Vulnerable Adults 2012' as well as established protocols such as Safeguarding Vulnerable Adults (Regional Adult Protection Policy and Procedural Guidance) 2006 and 'Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults' NIASP 2009. The Public Protection Branch (PPB) will be responsible for triaging reports under Joint Protocol arrangements. When a PPB passes the adult protection response to another branch of PSNI, the PPB will retain oversight and ensure ongoing engagement and communication with other partners under Joint Protocol.

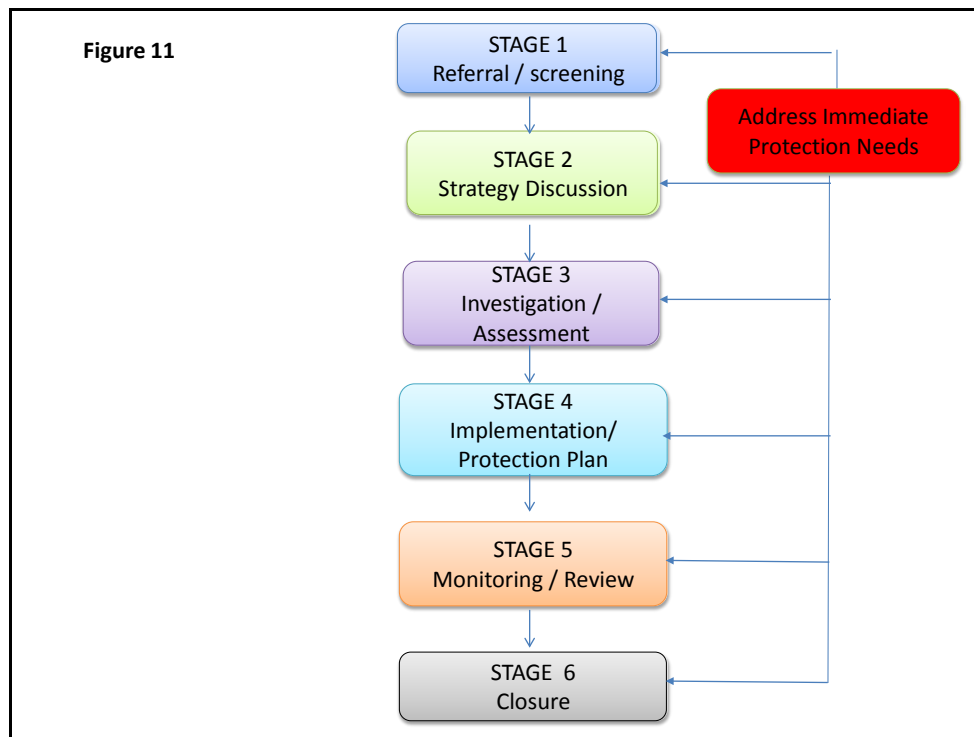
All operational adult safeguarding policies, procedures and protocols in support of this policy must be consistent with the underpinning principles contained in section 5 of this policy.

11.1. Adult Protection Process

Each adult protection intervention is likely to be unique and the response made must allow for flexibility and individualised decision-making. It is important that each adult protection intervention is conducted without undue delay, remains outcome focused, rather than process driven, and is subject to ongoing monitoring and review at an appropriately senior level. At all stages throughout the adult protection intervention, consideration should be given to whether the threshold for the Adult Protection Gateway Service continues to be met. Any action necessary to address immediate protection needs of the adult must be taken regardless of which stage of the process has been reached.

Each intervention will be made in accordance with an agreed process. A typical protection process is contained in figure 11 below encompassing 6 distinct stages. While presented in stages, the process is not intended to be linear in nature. It is possible that some stages will run in parallel and it may also require moving between stages in both directions. This policy does not advocate specific timescales for progressing through the stages of the protection process, because it is important that flexibility is maintained to allow for professional decision making. There can be complex issues to be managed such as fluctuating capacity to make decisions and complex investigations that may require interagency collaboration and consultation including cooperation with any PSNI investigations. Nonetheless, it is important that all adult protection interventions are progressed in a timely manner, and must not be allowed to drift unnecessarily.

Figure 11 shows the six stages of the Adult Protection Process.



At every stage the adult's human rights must be considered, and evidence of this recorded. The adult's rights, needs, views and wishes, should be central to the protection intervention to ensure that they receive the support needed to achieve an agreed outcome.

Processes and procedures in themselves will not protect, people and good practice will.

A **Designated Adult Protection Officer** (DAPO) will be responsible for the management of each referral received by a HSC Trust. DAPOs will be in place both within the Adult Protection Gateway Service, and within core services teams. Following initial screening by the Adult Protection Gateway Service, a DAPO in core services may be asked to manage the referral going forward.

Every DAPO must:

- be social work qualified;
- be working in a minimum of a band seven;
- have first line management responsibilities, or in a senior practitioner role;
- be suitably experienced; and
- have undertaken the necessary training (see section 15).

The role of the DAPO is to:

- make sure the needs, safety and wishes of the adult at risk are kept central to any actions and decisions taken;
- screen the referral;
- make contact with PSNI if a crime is alleged or suspected, or there is an

- immediate risk of harm to an adult at risk;
- make key decisions including whether the threshold for protection intervention has been met;
- manage and coordinate the adult protection intervention;
- ensure that any risks to the adult(s) and others potentially at risk are assessed and agreed actions taken;
- analyse needs and risk assessments to determine the most appropriate course of action;
- inform and involve other agencies as necessary, and work with them to plan and carry out actions taken;
- be responsible for coordinating the sharing of information between agencies;
- ensure the support needs of the adult at risk and others affected are considered throughout;
- ensure appropriate documentation and records are fully completed, including records of all decisions taken;
- make sure the adult at risk and the referrer are given regular feedback, insofar as this is possible;
- analyse the adult safeguarding data within their service area and contribute to the governance arrangements as appropriate; and
- ensure that the connections are made with related interagency mechanisms such as:
 - o Multi Agency Risk Assessment Conference (MARAC)
 - o Domestic and sexual violence services
 - o Public Protection Arrangements in Northern Ireland framework (PPANI)
 - o Human trafficking procedures
 - o Hate Crime Practical Action Scheme
 - o The Office of Care and Protection (or equivalent)
 - o Child Protection Gateway Service
 - o Business Services Organisation Counter-Fraud Unit.

The DAPO may decide to close the adult protection process at any stage if:

- it is agreed that further investigation, assessment or intervention is not required to protect the adult at risk;
- the DAPO decides that an alternative safeguarding response is more appropriate, proportionate and effective to address the concern identified;
- a Protection Plan has been agreed and is in place and is effectively addressing the needs of and the risks to the adult; or
- the adult chooses to withdraw from the protection process.

Where the safeguarding concern relates to the quality of care provided to an adult in receipt of a regulated HSC service, the DAPO will engage the RQIA to ascertain whether the provider is in breach of regulation or minimum standards. The RQIA will act on all safeguarding concerns where there are breaches of standards or regulation and, where necessary, use their powers of improvement or sanction to ensure that the provider addresses any breach of the minimum standards to the satisfaction of RQIA.

The PSNI will be the lead agency when a criminal investigation is required, and any other related investigations or assessments must be coordinated with the PSNI.

Responsibility for coordinating, and communicating the outcome of, the criminal investigation lies with the Detective Inspector PPB. A criminal investigation will take precedence over any other adult safeguarding process. For example, a disciplinary process should not commence until after the conclusion of an adult protection criminal investigation by the PSNI, or following approval by PSNI.

11.2. Large Scale and/or Complex Investigations

A large-scale adult protection investigation may be initiated when a number of adults at risk have allegedly been abused or patterns or trends are emerging which suggest serious concerns about the quality of care, which put the safety of service users at risk.

This could include any of the following:

- multiple concerns within one service provider;
- one person is suspected of causing harm to multiple adults and/or in a number of settings;
- a group of individuals are alleged to be causing harm to one or more adults;
- where care arrangements are complicated by cross-boundary considerations.

A large-scale adult protection investigation is likely to involve a range of organisations, and potentially a number of individual adult protection interventions.

Complex (i.e. organised or multiple) abuse is defined as abuse involving one or more abusers and a number of related or non-related adults at risk. The abuser concerned may be acting with others to abuse adults at risk, may be acting in isolation, or may be using an institutional framework or position of authority to access adults at risk for abuse.

Such abuse can occur both as part of a network of abuse across a family or community and within institutions such as residential or nursing homes, supported living facilities, day support settings and in other provisions such as voluntary groups. There may also be cases of adults at risk being abused through the use of the internet. Such abuse is profoundly traumatic for the adults at risk who are involved. The investigation of large scale and/or complex abuse requires specialist skills from PSNI and HSC Trust staff.

Every investigation will require careful and thorough planning, effective inter-agency working and attention to the needs of the adult(s) involved. Some investigations become extremely complex because of the number of people or places involved and the timescale over which the abuse is alleged to have occurred.

On receipt of information which may indicate organised or multiple abuses, the HSC Trust Designated Officer should immediately consider whether a report to the PSNI is appropriate, initiate a joint strategy meeting and, where necessary, establish a Strategy Management Group (SMG) to oversee the process of investigation. Core representatives of SMG are:

- PSNI;
- HSC Trust nominated DAPO;
- a senior manager from the relevant adult programme of care; and

- RQIA (where the allegation relates to a regulated service).

Appropriate legal advice will be necessary and should be sought through PSNI and HSC Trust legal advisers.

The SMG will:

- establish the principles and practice of the investigation, draw up an investigation plan and ensure regular review of progress against that plan;
- establish and manage an Investigative Team within their respective agencies;
- ensure co-ordination between the key agencies and Investigative Team
- address the issue of resourcing individual investigations;
- act in a consultative capacity to those professionals who are involved in the investigation;
- draw up a media strategy that will address who will take responsibility for responding to the media;
- agree communication strategy/liaison with victims/families and carers involved in the investigation;
- agree level of information sharing, where appropriate to do so, with the proprietor and the staff of the facility/service under investigation;
- at the conclusion of the investigation, discuss salient features of the investigation with a view to making recommendations for improvements either in policy or in practice.

11.3. Operational Protection Policies and Procedures

The HSCB's regional operational adult protection procedures will underpin this policy and provide guidance to support good practice and sound professional decision making. Procedures will be subject to regular review.

Operational policies and procedures should:

- a) clarify roles, responsibilities and expectations at all levels;
- b) outline the importance of, and interface with, the Joint Protocol;
- c) provide procedures for inter-agency working across the full range of organisations;
- d) provide a consistent framework to guide adult protection interventions;
- e) promote flexibility and a focus on outcome;
- f) describe how the threshold of serious harm is applied at each stage of the process to enable the most proportionate response to be identified;
- g) provide guidance on the management of adult protection referrals where more than one HSC Trust is involved;
- h) encourage reflective professional practice;
- i) support robust decision making;
- j) strengthen professional line management and governance arrangements;
- k) outline procedures for integration with the other investigations (see the role of the DAPO earlier in this section);
- l) define information exchange procedures;
- m) outline record keeping requirements; and
- n) describe how large scale and/or complex investigations should be conducted.

12. CONSENT AND CAPACITY

12.1. Consent

Consideration of consent is central to adult safeguarding. Consent is a clear indication of a willingness to participate in an activity or to accept a service, including a protection service. It may be signalled verbally, by gesture, by willing participation or in writing. No one can give, or withhold, consent on behalf of another adult unless special legal provision for particular purposes has been made for this.

For consent to be valid, it must be given voluntarily by an appropriately informed person who is able to consent to the intervention being proposed. In cases where the individual lacks capacity, decisions will usually be made on behalf of the individual in accordance with current legal provisions.

A consent-driven approach to adult safeguarding will always involve:

- a presumption that the adult at the centre of a safeguarding decision or action is able to give or withhold consent unless it is established otherwise;
- acknowledging that an adult who lacks capacity to make a decision cannot give consent but that he or she should still be involved in decision-making as far as possible and given appropriate support;
- acknowledging that everyone who has capacity to make a certain decision has the right to pursue a course of action that others may judge to be unwise, but that sometimes a balance must be struck between an individual's human rights and the need to intervene to protect others;
- providing support to an adult where they have withheld consent and this has been overridden;
- ensuring consent/non-consent is informed through the provision of full and accurate information, making sure that the information is conveyed in a way which the adult fully understands and taking all practicable steps to help the person make and communicate the decision; and
- understanding that the choices and decisions made by the individual at any one time are not seen as irrevocable or non-negotiable.

Where there is a concern that an adult may be at risk of, or experiencing, harm and there are concerns about coercion or undue influence, this should be referred to the HSC Trust in accordance with section 11.

12.2. Capacity

An adult will always be assumed to have capacity to make a decision unless it is suspected otherwise. Capacity can fluctuate, and is both issue and time specific, therefore should be kept under regular review in connection with any safeguarding intervention, in particular a protection intervention.

Where there is a reasonable doubt regarding the capacity of an adult to make a specific decision or series of decisions, a referral must be made to the HSC Trust. The organisation or individual making the referral may need to consider any reasonable and proportionate interim steps necessary to protect the adult pending

further enquiries by the HSC Trust. An HSC professional within the HSC Trust will conduct a capacity assessment in accordance with existing legislation and guidance.

Lack of capacity

Tensions between an adult's autonomy and the need to intervene to keep an adult safe makes deciding whether or not to intervene when an adult lacks capacity to make a decision particularly difficult, and one that must always requires professional judgement in respect of the individual circumstances of the adult.

Where an adult lacks capacity to make a certain decision, they should be supported so they can be involved to the fullest extent in the decision that affects their life. Any interventions and actions taken by the HSC Trust must be in the best interests of the person being safeguarded, and in accordance with existing legislation and policy. HSC Trusts should, where appropriate, consult relevant family members or carers when considering action to be taken regarding an adult who lacks capacity to make a decision.

12.3. Lack of Consent

In some circumstances it may be necessary for the withholding of consent to be overridden. Where consent to intervene is not provided by the adult at risk, action to progress a case may still be taken in circumstances where there is a strong overriding public interest, or where a crime is alleged or suspected. This may happen when:

- the person causing the harm is a member of staff, a volunteer or someone who only has contact with the adult at risk because they both use the service; or
- consent has been provided under undue influence, coercion or duress;
- other people are at risk from the person causing harm; or
- a crime is alleged or suspected.

In these circumstances, the adult should be informed of that decision, the reason for the decision, and reassured that as far as possible no actions will be taken which affect them personally without their involvement. Consideration should be given to any support the adult may need at this time, as they may be distressed by the prospect of their information being shared without their consent.

12.4. Advocacy

Advocacy involves enabling people to say what they want, to have their views heard, and empowering them to speak up for themselves. It informs the person about their options and helps them to take action when necessary to have their voice heard and secure their rights.

Whilst advocacy is a social work role, the use of independent advocacy services to support the adult at risk in making their choices may be appropriate, particularly for those who have difficulty being heard or expressing their views, or where there are conflicting interests. This is particularly the case where HSC staff, professionals or family are of the opinion that what the person wants is not in their best interests.

Advocacy can assist adults to be involved in, and influence, decisions taken about their care. It helps to ensure that the adult at risk remains central to the decision making process. Advocacy should not make decisions on behalf of the adult at risk, but always work in partnership with the adult they are supporting. People who are lack capacity to make a decision rely more heavily on others for many aspects of their care, treatment and support, and have the potential to benefit more from advocacy services to assist them exercise their rights.

13. ACCESS TO JUSTICE: SUPPORT FOR VICTIMS

Where a crime is alleged to have occurred there is a duty on PSNI to investigate. There are also a range of mechanisms in place to support a victim when giving a statement to the PSNI, evidence at court and in terms of emotional and practical support services more generally. The provision of these services requires effective cooperation across a range of organisations including the PSNI, HSC Trusts, the Public Prosecution Service and voluntary sector service and support providers.

Where a crime is reported to the PSNI a victim of crime information leaflet is available which provides contact details of general support services such as Victim Support NI and NSPCC Young Witness Service, as well as specialist support services, including for families bereaved through murder or manslaughter, victims of domestic and sexual violence, victims of trafficking and young victims of crime among others. The PSNI can refer victims of crime to Victim Support NI, where referral to specialist support services is also available dependent on the needs of the individual. Where an individual has concerns about their safety they should refer this to the police.

Victims of crime can have access to additional support to help them give evidence, as part of criminal proceedings where a person is under the age of 18, or where the quality of the evidence is likely to be affected because the person has mental health issues, learning or communication difficulties, a neurological disorder or a physical disability. Additional support is also available to those victims who are intimidated and the quality of whose evidence is likely to be affected because of fear or distress about testifying, for example, where the person is a victim of domestic violence, hate crime, trafficking, exploitation, bullying or abuse by professionals or carers or family members.

For these types of victims the PSNI will carry out interviews in accordance with 'Achieving Best Evidence in Criminal Proceedings' guidance. This sets out good practice in interviewing victims and witnesses and in preparing them to give their best possible evidence in court, so that they have an opportunity to access justice and provide their best evidence. Such interviews are normally video recorded.

Victims will have their needs assessed by the PSNI or Victim and Witness Care Unit (which provides a single point of contact from the point when the case file is transferred from the PSNI to the Public Prosecution Service).

Additional support at court, such as special measures¹⁸, may be applied for by the Public Prosecution Service, with final decisions taken by the judge on their availability. More than one special measure may be granted in a particular case, with this again a decision for the judge. The special measures, as set out below, include:

- screens/curtains in the courtroom so the victim does not have to see the defendant;

¹⁸ A leaflet on special measures is available at http://www.psnipolice.uk/special_measures_leaflet.pdf. The legislation governing special measures can be found at: <http://www.legislation.gov.uk/nisi/1999/2789/contents>

- a live video link allowing evidence to be given away from the courtroom, which also allows for a support to be present with the witness in the live link room;
- giving evidence in private, where the case involves a sexual offence, a slavery or human trafficking offence, or the person is deemed to be intimidated;
- video recorded statements – these allow the main evidence to be given using a pre-recorded video statement;
- using communication aids, such as alphabet boards (where the person's evidence is likely to be affected due to a learning or communication difficulty, mental health issue, physical disability etc.); and
- removal of wigs or gowns.

Another special measure is assistance from a communication specialist (a Registered Intermediary) when a person is telling the police what happened to them or is giving evidence in court. Registered Intermediaries are professionals with specialist skills in communication. The role of Registered Intermediaries is to facilitate the giving of evidence rather than provide a general support role. They assist a vulnerable person, who has a significant communication difficulty, during the criminal justice process if their communication difficulties would diminish the quality of their evidence. The Registered Intermediaries Schemes pilot is helping vulnerable people have access to justice where it may not have been possible before.

As well as help when giving evidence victims also have access to a range of general support services. Victim Support NI¹⁹ helps people who have been a victim of, or a witness to, a crime. They provide emotional support, information and practical help to victims, witnesses and others affected by crime through compensation, community and witness services. Victim Support NI can also refer victims to specialist support services, where appropriate and available.

A Victim Charter provides victims of crime with relevant information, sets out what their entitlements are and the standards of service that they can expect to receive as they move through the criminal justice process. It will also make clear to service providers exactly what their duties are in ensuring victims receive the right level of service. The Charter provides information on the support services that are available to victims of crime, including specialist services.

¹⁹ Further information on Victim Support NI can be found at: www.victimsupportni.co.uk/

14. INFORMATION MANAGEMENT AND INFORMATION SHARING

14.1. Information and Record Management

Information associated with adult safeguarding is likely to be of a personal and sensitive nature and its use is governed by the common law duty of confidentiality. At all times 'personal data' and 'sensitive personal data'²⁰ must be managed in accordance with the law, primarily the Data Protection Act 1998 (DPA) and the Human Rights Act 1998 which, among other things, gives individuals the right to respect for private and family life, home and correspondence.

The eight principles of the DPA state that personal data must be:

- processed fairly and lawfully and only for purposes compatible with the reason(s) for which the information was originally obtained;
- adequate, relevant and not excessive for the purposes for which it is processed;
- accurate and kept up to date;
- not kept for longer than is necessary;
- processed in line with the rights of the data subject;
- held securely; and
- not transferred to other countries outside the EEA without adequate protection.

All organisations providing targeted services to adults at risk must have an information management policy and associated governance arrangements in place which complies with the DPA and the Human Rights Act 1998. These policies must include the procedures to be followed by staff and volunteers in relation to:

- information management, including recording of information, its secure storage, and how this can be accessed and by whom;
- sharing information outside of the organisation for safeguarding purposes, and how requests for information will be considered and assessed (see Information Sharing for Safeguarding Purposes below);
- training to be provided to staff in relation to their duties under the DPA;
- subject access requests;
- complaints about information management; and
- identified breaches of data protection within the organisation.

Good records management standards and practices are required for the organisation to ensure confidentiality and that the security of service user information is respected. Many professionals are governed by a Code of Practice or Code of Conduct issued by the professional body with which they are registered, which will contain guidance on information management to support organisational policies. Guidance for voluntary, community, independent and faith sector organisations on the management of records, confidentiality and sharing of information is available in the Volunteer Now guidance document 'A Shared Responsibility'²¹. 'Good Management

²⁰ 'Sensitive Personal Data' is defined by Section 2 of the Data Protection Act 1998:
<http://www.legislation.gov.uk/ukpga/1998/29/section/2>

²¹ 'Safeguarding Vulnerable Adults: A Shared Responsibility' can be accessed at:
<http://www.volunteernow.co.uk/fs/doc/publications/vn-sva-web-full-colour.pdf>

Good Records'²² provides guidance for those who work within or under contract to Health and Social Care statutory organisations on the required standards of practice in the management of records.

14.2. Information Sharing for Safeguarding Purposes

In relation to adult safeguarding, the duty to share information about an individual can be as important as the duty to protect it. Effective safeguarding will depend on information being made available to those who need it at the right time. Proportionate information sharing may be required to prevent harm to the adult at risk or to others, and can facilitate preventative or early intervention approaches.

It is important that confidentiality is not confused with secrecy. Proportionality is the key in respect of the risks associated with deciding whether or not to share information.

Organisations and professionals should not give assurances of absolute confidentiality in adult safeguarding where there are concerns about risk of harm to one or more adults, nor should it be assumed that someone else will pass on information which may be critical to the prevention of harm to an adult.

Information sharing is one form of data processing, and as such is covered by principles and requirements of the DPA. The Information Commission's Office (ICO) has published a statutory Data Sharing Code of Practice²³ to assist organisations to comply with the DPA. The code is applicable to all organisations involved in sharing personal data, whether this is within different branches of the same organisation, or with a third party organisation. It contains guidance in factors to consider when deciding whether or not to share personal data, including checklists to assist organisations in their decision making.

Organisations that collect or hold personal data or sensitive personal data should explain in advance to the data subject how their information will be used, including under what circumstances the information might be shared. Guidance on how this can be undertaken is contained in the Privacy Notices Code of Practice²⁴ published by the ICO.

Targeted services providers must have procedures for staff and volunteers on how to share information in compliance with the DPA and the ICO Code of Practice. Decisions about what information should be shared and with whom should be taken on a case by case basis, and in accordance with organisational information management policies and the legal framework, and in line with this policy. The management interests of an organisation should not override the need to share information for safeguarding purposes.

²² 'Good Management Good Records' can be accessed at:
<http://www.dhsspsni.gov.uk/index/gmgr.htm>

²³ The Data Sharing Code of Practice can be accessed at:
https://ico.org.uk/media/for-organisations/documents/1068/data_sharing_code_of_practice.pdf

²⁴ The 'Privacy Notices Code of Practice' can be accessed at:
https://ico.org.uk/media/for-organisations/documents/1610/privacy_notices_cop.pdf

If anyone has concerns about risk of harm to an adult, they should seek advice from the relevant HSC Trust or the PSNI.

Personal data may be shared when:

- the adult has given his or her valid consent (which in the case of sensitive personal data must be explicit); or
- where information sharing is necessary for matters of life or death or for the prevention of serious harm to the individual; or
- where sharing is necessary for the purposes of the administration of justice;
- where sharing information is for public or statutory duties.

Where the decision is made to share information without consent, the organisation must ensure that the adult is clearly informed of what information will be shared, why it will be shared, and who it will be shared with, providing this does not increase the risk to the adult. Organisations should avoid asking for consent to share information when it is likely that a decision will be taken to share the information regardless of whether consent is given. Any sharing of information must meet conditions under Schedules 2 and 3 of the Data Protection Act.

If there is reason to believe that sharing information due to a statutory duty to disclose may increase the risk of harm, or where there is doubt about whether the organisation can or should share information, the organisation may wish to obtain legal advice.

Good record keeping of decision making is essential in cases where information sharing is being considered. Staff should maintain records of the information gathered which explains and justifies their decisions.

14.3. Sharing Information Between Agencies

Effective safeguarding cannot be achieved without organisations working collaboratively to ensure the safety of the adult at risk is prioritised. Working together is dependent on there being a clear framework for doing so, and adult safeguarding should be based on good communication across sector and agency boundaries.

The effective and timely sharing of information between organisations is essential to deliver high quality adult safeguarding services focused on the needs of the adult.

Agencies and organisations which are required to share information on a regular basis to safeguard adults at risk must have Information Sharing Agreements (ISAs) in place which identify key members of staff and contact points within the organisation through which information can be channelled, including out of normal working hours. The agreements should be agreed at Board/Director level and subject to regular review.

Member organisations of NIASP have all signed an information sharing agreement. This agreement will stipulate when information may be shared without the subject's consent.

An ISA should outline how organisations have agreed to share information and ensure compliance with legal requirements. The purpose of an ISA is:

- to facilitate the secure exchange of information in an appropriate format, where necessary, to ensure the health, well-being and safeguarding of adults at risk;
- to provide a framework for the secure and confidential sharing of personal data between the partner organisations;
- to promote consistency of information sharing across partner organisations; and
- to support professional decision making in individual cases.

When an HSC Trust has a contract or commissioning arrangement with a third party organisation, the contract or commissioning agreement must state how the third party organisation must handle any personal data obtained through provision of the service. This must include how the information will be securely stored, managed, disposed of, and where appropriate shared, in compliance with the DPA and the Human Rights Act 1998.

15. SAFEGUARDING TRAINING

Effective adult safeguarding requires a specific level of knowledge, expertise and skill and understanding. Adult safeguarding is complex and must be delivered by a confident, competent and trained workforce, which includes those working in a voluntary or unpaid capacity.

NIASP has a responsibility to develop an inter-agency and inter-disciplinary approach to adult safeguarding training and practice development. NIASP will develop and agree a Regional Adult Safeguarding Training Framework which will specify learning outcomes and core content to meet a range of identified training needs within partner organisations.

The framework will provide a number of levels of training which reflect the varying levels of expertise required and the differing needs of organisations across the safeguarding continuum. The appropriate level of training will be determined by the roles and responsibilities of the individual.

Service providers should use the NIASP framework to identify and set out training and development pathways for their staff and volunteers, to ensure they have the appropriate skills and knowledge to engage in preventative activity and respond to safeguarding concerns commensurate with their role. This may involve a combination of formal training events, and time for staff to reflect on their own practice and the practice of others. Records should be maintained of all training and development undertaken by staff and volunteers.

16. A CONTINUOUS LEARNING APPROACH

All practitioners, agencies and organisations involved in work with adults at risk must ensure that the highest possible standards of care, support and protection are provided and maintained at all times, and improvements identified and put in place on a continuous basis. The NIASP will foster a culture of collaborative learning and continuous practice and service improvement in connection with adult safeguarding. This will require knowledge and understanding of the 'system' at the front-line, the identification of and exploration of learning from cases with different outcomes for adults at risk of harm, or adults who have been harmed and the implementation of learning from both. The emphasis should be on learning for the purpose of positive proactive change and improvement. It will require the support of staff who will be responsible for the implementation of change.

The NIASP will promote a culture of continuous improvement and collaborative learning to improve outcomes for adults who may be at risk and their experience of the adult protection responses.

This does not mean that those responsible for harming an adult at risk by an act of commission or omission should not be held to account. A range of accountability mechanisms already exist, including disciplinary mechanisms. These should be used where it is appropriate to do so.

The ultimate aim is to establish a system which promotes continuous learning and improvement to:

- establish whether there are lessons to be learned about the way in which local professionals, agencies and organisations work together to safeguard adults at risk;
- identify clearly what those lessons are, how they will be acted upon, by whom and by when, and what is expected to change as a results;
- improve multi-disciplinary and interagency working, and promote better approaches to prevention, protection and support of adults at risk.

The NIASP will seek the full support, cooperation and participation of its member organisations to identify opportunities for learning and to bring these to the attention of the NIASP.

APPENDIX 1

This policy is of specific relevance to:

- all NI Government Departments, their agencies and arm's length bodies;
- local councils;
- the Health and Social Care Board and Health and Social Care Trusts;
- Business Services Organisation;
- The Northern Ireland Ambulance Service HSC Trust;
- The Public Health Agency;
- The Northern Ireland Adult Safeguarding Partnership and the five Local Adult Safeguarding Partnerships;
- The Police Service of Northern Ireland;
- The Public Prosecution Service;
- The Probation Board for Northern Ireland;
- Policing and Community Safety Partnerships;
- The Northern Ireland Prison Service;
- The Northern Ireland Housing Executive;
- The Social Security Agency;
- regulatory and Inspection bodies across all sectors, including: Criminal Justice Inspection Northern Ireland, the Regulation and Quality Improvement Authority, The Education and Training Inspectorate, the General Teaching Council for Northern Ireland, the Northern Ireland Social Care Council, the General Medical Council, the Nursing and Midwifery Council and the Charities Commission;
- schools;
- Domestic and Sexual Violence Partnerships;
- voluntary and community organisations who work with, provide services to, or engage in, activities with adults;
- voluntary and community organisation umbrella bodies;
- Faith organisations and communities;
- care staff agencies;
- organisations and individuals who provide personal care funded through direct payments or through an individual's own funds;
- carers;
- Carers NI and other advocacy groups representing carers;
- housing associations;
- supported housing providers, the Northern Ireland Federation of Housing Associations Private landlords;
- accommodation providers;
- financial institutions, including: banks, Post Offices and building societies;
- credit unions;
- professions, including solicitors and barristers;
- The Office of Care and Protection;
- Northern Ireland Courts and Tribunal Service;
- independent Providers of health and social care service, including: General Medical Practitioners, pharmacists, dentists, private hospitals, private sector providers of domiciliary care, residential and nursing care homes, independent counsellors and independent therapist services;
- Allied Health Professionals and their regulatory bodies;

- opticians;
- further and higher education institutions;
- advice groups and helplines; for example, disability groups such as Disability Action and Action for Hearing Loss;
- Self help, user and advocacy groups;
- leisure facilities; and
- members of the public.

APPENDIX 2

Glossary

Access NI	AccessNI is a criminal history disclosure service in Northern Ireland. By law some employers must check your criminal history before they recruit. When asked by these employers, AccessNI supplies criminal history information about job applicants, volunteers and employees.
Adult Protection Gateway Service	The Adult Protection Gateway Service is the central referral point within the HSC Trust for all concerns about an adult who is, or may be, at risk.
Care Plan	A care plan sets out the assessed care and support needs of an individual and how those needs will be met to best achieve the individual's desired outcome. The individual should be fully involved in the development of the care plan.
Care Management	Care Management embraces the key functions of: case finding; case screening; undertaking proportionate, person-centred assessment of individual's needs; determining eligibility for service(s); developing a care plan and implementing a care package; monitoring and reassessing need and adjusting the care package as required.
Child Protection Gateway Service	The Child Protection Gateway Service is the central referral point within the HSC Trust for all concerns regarding the safety and welfare of children.
CJINI	Criminal Justice Inspection Northern Ireland is the independent statutory inspectorate with responsibility for inspecting all aspects of the criminal justice system in Northern Ireland apart from the judiciary. It also inspects a number of other agencies and organisations that link into the criminal justice system. CJI is funded by the Department of Justice and the Chief Inspector reports to the Minister for Justice.
Delegated Statutory Functions	Delegated Statutory Functions refer to all requirements of legislation with which statutory HSC organisations must comply. In successive legislation, the Health and Social Care Board (HSCB) is designated as 'The Authority' that is required to fulfill all relevant statutes. The HSCB delegates this responsibility to HSC Trusts under legally binding schemes referred to as 'Schemes for the Delegation of Statutory Functions'.
Designated Adult Protection Officer	A social worker within the HSC Trust with responsibility for managing and co-ordinating the adult protection process. The DAPO must: • be social work qualified; • be working in a minimum of a band seven; • have first line management responsibilities, or in a senior practitioner role;

	• be suitably experienced; and • have undertaken the necessary training.
DHSSPS	The Department of Health, Social Services and Public Safety.
DOJ	The Department of Justice.
Direct Payments	Direct payments are paid by an HSC Trust to people who have been assessed by an HSC Trust to meet the eligibility criteria for assistance from social services. A payment is made in lieu of the service so that the person can arrange and pay for their own care and support services instead of receiving them directly from the HSC Trust.
ETI	The Education and Training Inspectorate. The organisation which provides inspection services and information about the quality of education being offered including that within schools, further education and work-based learning, where adults at risk may be enrolled.
HSCB	The Health and Social Care Board. This is the body responsible for arranging or 'commissioning' a comprehensive range of modern, effective and safe health and social services for the people of Northern Ireland.
HSC Trust	Health and Social Care Trust. There are five Health and Social Care Trusts in Northern Ireland, providing local and regional health and social care services to the Northern Ireland public. The use of "HSC Trust" in the Policy document refers to the following five HSC Trusts: • The Belfast Trust • The South Eastern Trust • The Southern Trust • The Northern Trust • The Western Trust.
Joint Protocol	The Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults 2009. The Protocol sets out a framework for joint working in a complex area of practice and emphasises the need to involve all other relevant agencies in information sharing, early assessment and the planning process. The overall aim of the Protocol is to prevent abuse by promoting a multi-agency approach to the protection of vulnerable adults, and to ensure that they receive equitable access to justice in a way that promotes their rights and well-being.
LASP	Local Adult Safeguarding Partnerships. The five local multi-agency, multi-disciplinary partnerships located within their respective HSC Trusts.
MARAC	A MARAC is a Multi-Agency Risk Assessment Conference. It is a forum for local agencies to meet with the aim of sharing information about the highest risk

	cases of domestic violence and abuse and to agree a safety plan around victims.
National Referral Mechanism	A framework which exists to assist in the formal identification of victims of human trafficking and help to coordinate support to potential victims to appropriate service. The Department of Justice (DOJ) funds organisations to provide this support to adult potential victims of human trafficking. The PSNI are the lead agency in managing this response. However, consideration should be given to use of the Joint Protocol arrangements.
NIASP	The Northern Ireland Adult Safeguarding Partnership. The regional multi-agency, multi-disciplinary partnership that brings together representatives from organisations and communities of interest who have a significant contribution to make to adult safeguarding.
Office of Care and Protection	Office of Care and Protection is the department of the Court with responsibility for the administrative work associated with Part VIII of the Mental Health Order. This includes matters relating to enduring or lasting powers of attorney, and court-appointed deputies.
PBNI	Probation Board for Northern Ireland. PBNI works alongside statutory and other partners to minimise the risk of harm posed by offenders. PBNI is a Non Departmental Public Body of the Department of Justice (DOJ).
PCSP	Police and Community Safety Partnerships. Local bodies made up of Councillors and independent people in each Council area. PCSPs work with their community to identify issues of concern in the local area and potential solutions, and prepare plans to address these concerns.
Personal data	Personal data means data which relate to a living individual who can be identified – (a) from those data, or (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual. It is important to note that, where the ability to identify an individual depends partly on the data held and partly on other information (not necessarily data), the data held will still be “personal data”. The definition also specifically includes opinions about the individual, or what is intended for them.
PPANI	Public Protection Arrangements Northern Ireland. The

	purpose of the PPANI framework is to reduce the risks posed by sexual and violent offenders when they are released into the community in order to protect the public, including previous victims, from serious harm.
PPT	Public Protection Team. These are located in police stations throughout Northern Ireland.
Programme of Care	The structure in HSC Trusts within which social care is commissioned and delivered in Northern Ireland.
Protection Plan	A plan agreed with the adult at risk (or the person representing them or their best interests) detailing the actions to be taken, with timescales and responsibilities, to support and protect the person from harm.
PSNI	The Police Service of Northern Ireland.
RQIA	The Regulatory and Quality Improvement Authority. Northern Ireland's independent health and social care regulator, responsible for monitoring and inspecting the availability and quality of health and social care services in Northern Ireland, and encouraging improvements in the quality of those services.
Sensitive Personal Data	Sensitive Personal Data means personal data consisting of information as to— (a) the racial or ethnic origin of the data subject, (b) his political opinions, (c) his religious beliefs or other beliefs of a similar nature, (d) whether he is a member of a trade union (within the meaning of the M1Trade Union and Labour Relations (Consolidation) Act 1992), (e) his physical or mental health or condition, (f) his sexual life, (g) the commission or alleged commission by him of any offence, or (h) any proceedings for a ny of fence c ommitted or alleged t o ha ve been c ommitted by hi m, the disposal of such proceedings or the sentence of any court in such proceedings. Sensitive P ersonal D ata has a hi gher t hreshold w hen considering whether or not it can be shared, and carries higher requirements for secure management.

APPENDIX 3

Bibliography

The list below contains a list of sources used during the development of this policy. There may have been other documents which were reviewed during the course of the policy development which have been omitted, and where these are identified these will be included in future updates of this document.

Document Title	Author
Adult Support and Protection: Ensuring Rights and Preventing Harm	Edinburgh, Lothian and Borders Executive Group
Evidence Review – Adult Safeguarding	Institute of Public Care
Haringey Safeguarding Adults Multi Agency Information Sharing Protocol	Haringey Council
Protecting adults at risk: London multi-agency policy and procedures to safeguard adults from abuse.	Social Care Institute for Excellence with the Pan London Adult Safeguarding Editorial Board
Protecting our Older People in Northern Ireland: A Call for Adult Safeguarding Legislation	Commissioner for Older People for Northern Ireland
Safeguarding Adults: a National Framework of Standards for good practice and outcomes in adults protection work	The Association of Directors of Social Services
Safeguarding Vulnerable Adults Regional Adult Protection Policy and Procedural Guidance	Health and Social Care Board
Safeguarding Vulnerable Adults A Shared Responsibility	Volunteer Now

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Southern Health
and Social Care Trust
Quality Care - for you, with you

Health & Safety at Work Policy

Lead Policy Author & Job Title:	Ray King, Head of Health & Safety Jennifer Taylor, Health & Safety Manager
Directorate responsible for document:	Finance, Procurement & Estates
Issue Date:	20 December 2018
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Policy Checklist

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Lead Policy Author & Job Title:	Ray King, Head of Health & Safety
Director responsible for Policy:	Helen O'Neill
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1.0 Introduction

This policy describes the Southern Health & Social Care Trust's (hereafter known as the Trust) approach to the management of health and safety. The principles of this policy apply to the holistic management of health and safety across the Trust.

2.0 Purpose and Aims

To provide a safe and healthy environment for its employees, service users, visitors, contractors and others who may be affected whilst at work, by the services it provides or whilst on its premises. A safe working environment can only be achieved and maintained with close co-operation and active participation from staff of all grades and disciplines.

To ensure the Trust complies with its statutory responsibilities under the Health & Safety at Work (NI) Order 1978 and other related legislation and to actively promote a positive health and safety culture.

To ensure that health and safety management in the Trust is based on a continuous improvement model and embraces the Trust risk management strategy and processes.

3.0 Policy Statement

The Trust has adopted this policy to:

- ensure compliance with statutory responsibilities under the Health & Safety at Work (NI) Order 1978 and other related legislation
- promote and develop a positive health and safety culture through consultation with internal and external stakeholders
- promote best practice in health and safety management
- confirm its commitment to ensuring, so far as is reasonably practicable:
 - ❖ a healthy and safe working environment,
 - ❖ adequate control of the health and safety risks arising from work activities,
 - ❖ consultation with employees on matters affecting their health and safety,
 - ❖ provision and maintenance of safe plant and equipment,
 - ❖ safe handling and use of substances,
 - ❖ provision of information, instruction, training and supervision for employees,
 - ❖ all employees are competent to do their tasks, and are given adequate training,
 - ❖ the prevention of accidents, incidents and cases of work related ill health.

Whilst the Trust promotes a positive approach to health and safety, failure to comply with this policy may invoke disciplinary procedures.

4.0 Scope of Policy

This policy applies to all employees and those undertaking work on behalf of the Trust (e.g. agency/bank/locum staff, volunteers, students on placement) and refers to all services and activities of the Trust.

5.0 Responsibilities

5.1 Trust Board

The overall responsibility for health and safety resides with **Trust Board**. The **Trust**

Board have a collective role in providing committed leadership and ensuring that adequate resources are allocated for the continuous improvement in health and safety performance.

5.2 Chief Executive

The Trust Board's responsibility for ensuring the implementation of this policy will be managed through the **Chief Executive** who, on behalf of the Trust Board will:

- Ensure an up to date statement of the Trust's policy for health and safety is prepared and brought to the attention of staff.
- Ensure resources are allocated to establish and maintain competent health and safety support and advice.
- Obtain commitment from senior management to the health and safety risk management process and encourage them to foster health and safety awareness.

5.3 Director of Finance, Procurement & Estates

The Chief Executive has appointed the **Director of Finance, Procurement & Estates** as Lead Director with responsibility for establishing and monitoring the implementation of the Health and Safety at Work Policy and the organisation and arrangements in regard to health and safety within the Trust.

5.4 Assistant Director of Estates/Head of Health & Safety

The **Assistant Director of Estates and the Head of Health and Safety** will support the Director of Finance, Procurement & Estates with the management and co-ordination of Trust wide initiatives in relation to health and safety and provide support to the Trust to enable it to meet and discharge its statutory and legal functions. Working closely with the relevant Directors and Senior Managers, both will take a lead role in developing systems and procedures for the effective promotion and maintenance of a positive health and safety culture within the Trust.

Physical areas within the Trust which do not fall within a particular Directorate (i.e. common areas/car parks, general entrances and thorough ways) will be the responsibility of the Assistant Director of Estates.

5.5 Directors

Directors are responsible for implementing the Trust Health and Safety at Work Policy within their directorates, operating a safety culture and maintaining strong communication of health and safety matters throughout their divisions. Each Director within the Trust is responsible for the health and safety within their Directorate and must address the Directorates specific health and safety concerns. In particular this will include:

- Ensuring that adequate resources, time and facilities are available to ensure achievement of health and safety objectives.
- Delegating appropriate staff specific duties relating to the implementation and monitoring of the health and safety at work policy.
- Ensuring that those staff with delegated safety responsibilities receives adequate support to discharge their duties.
- Ensuring health and safety management responsibilities are included in job descriptions, identified in individual performance reviews and that personal development plans that are prepared following appraisals which

will identify any specific areas of training and development required in relation to health and safety.

- Obtaining commitment from their managers to the health and safety risk management systems and encouraging them to foster health and safety awareness. Directors must ensure that detailed health and safety risks are assessed, and controlled within their area of responsibility. This includes the employment of safe working methods.
- Ensuring that divisional/directorate health and safety procedures are developed and maintained which reflects local risks and other issues.
- Prioritising identified unacceptable risks and detailing on the appropriate risk register.
- Ensuring that all incidents and near misses are reported and fully investigated and where necessary, appropriate remedial action and lessons learned and longer term objectives relating to health and safety are introduced.
- Ensuring annual audits are completed on the effectiveness of the health and safety management system within the directorate and that any shortcomings are identified and actioned

Directors may delegate these responsibilities to appropriate departmental heads but they remain accountable to the Chief Executive for health and safety matters overall within their directorate.

5.6 Assistant Directors

In support of the Director, the Assistant Director will be responsible for the implementation of the Health & Safety Policy within their area of responsibility. This includes:-

- Ensuring risk assessments are carried out and are kept up to date and under review.
- Ensuring any actions or recommendations arising from the risk assessment process are monitored and complete. Where health and safety risks have been placed on the directorate risk register they will be regularly reviewed.
- Ensuring staff within the division have received health and safety training commensurate to their work activities and level of exposure to risk
- Ensuring any lessons learnt from incidents, claims or complaints are embedded in the directorate.
- Lead and participate in the investigation of serious incidents and to liaise with the enforcement agency (HSCNI) when required.
- Ensuring Heads of Service and Line Managers have implemented local systems and procedures
- Oversee the annual health and safety audit exercise to enable continued improvements, and ensure all Heads of Service and Line Managers participate.
- Ensure any cause for concern in health and safety practice is escalated in a timely manner.
- Identification of appropriate resources.

5.7 Heads of Service

Heads of Service will be responsible for implementing this policy within their divisions, by operating a safety culture and:

- Ensuring the implementation of the Trust divisional/directorate health and safety policies & procedures.
- Ensuring health and safety management responsibilities are included in job descriptions, identified in individual performance reviews and that personal development plans that are prepared following appraisals will identify any specific areas of training and development required in relation to health and safety.
- Ensuring that managers implement the health and safety risk management process within their department and escalate inadequately controlled risk, using the Trust's risk management process.
- Delegating appropriate staff specific duties relating to the implementation and monitoring of the health and safety at work policy.
- Ensuring that those staff with delegated health and safety responsibilities receive adequate support and time to discharge their duties.
- In conjunction with the Health and Safety Department, and/or Education, Learning and Development, ensure appropriate health and safety training is identified and completed.
- Ensuring that arrangements are made for the induction of newly appointed and transferred staff so that they are made aware of the health and safety procedures in their specific area of work. Such induction training should take place at the earliest practicable time following appointment or transfer.
- Ensuring that any short-comings arising from the health and safety audit process are actioned.
- Completion of the annual health & safety audit and oversee any actions, improvements arising from it.

5.8 Managers/Supervisors/Team Leaders

Managers/Supervisors/Team Leaders are responsible for implementing this policy on a day by day basis by operating a safety culture and ensuring adequate communication, training and the assessment and monitoring of risks. In particular this will include:

- Assisting senior management in developing health and safety objectives and criteria to monitor performance, and advising them of all serious adverse incidents and unacceptable risks.
- Ensuring health and safety management responsibilities are included in job descriptions, identified in individual performance reviews and that personal development plans that are prepared following appraisals will identify any specific areas of training and development required in relation to health and safety.
- Developing, maintaining and reviewing departmental health & safety procedures which reflect local risks and other issues. This should detail the organisation and arrangements for identifying, assessment and preventing or controlling risks and the arrangements for the health and safety with the Trust training matrix ([click here for training matrix template](#))
- Undertaking health and safety risk assessments in accordance with the Trusts procedure and ensuring that risks that require to be escalated follow the Directorate procedures in line with the Trust Risk Management process.

- Consulting employees on the outcome of risk assessments or changes to working practices that may affect their health and safety, and ensuring that account is taken of their views.
- Ensuring that incidents are reported and investigated in accordance with Trust policy and that any action to prevent recurrence is implemented as soon as reasonably practicable.
- Ensuring that all machinery and equipment is maintained in a safe condition and take appropriate corrective action if a defect has been identified.
- Ensuring that staff induction and refresher training on health and safety issues is provided, covering policies/procedures, safe systems of work and safe operation of equipment and that staff training records are kept up to date.
- Ensuring that all staff are made aware of Trust and departmental health and safety policies/procedures, hazards and any other safety information which they require in order to perform their duties safely.
- Engagement and Undertaking of regular audits and to ensure that any shortcomings are actioned. Regular progress to be reported to the Head of Service.

5.9 Employees **Employees must:**

- Comply with this policy/related procedures and co-operate with supervisors and managers on all health and safety matters, this includes familiarising themselves with local procedures and practice especially when renewed or updated.
- take reasonable care of their own health and safety and that of others who may be affected by their acts or omissions at work,
- not interfere with or misuse anything provided to safeguard their health and safety,
- attend as required, health and safety training sessions which will be identified in accordance with the training matrix,
- report all health and safety concerns in a timely manner to their line manager,
- ensure that when driving on Trust business, using either a fleet vehicle, lease car or private vehicle (including motorcycles and bicycles) that they are aware of their responsibilities under the health and safety legislation, road traffic legislation and corporate manslaughter legislation. All staff should comply with the Highway code and ensure that all aspects of their work related driving duties are carried out to minimise risk.

This policy will be supported by a number of health and safety procedures/protocols.

6.0 HEALTH AND SAFETY ARRANGEMENTS

6.1 Committee and Group reporting structure. A Trust Health & Safety Committee has been established in accordance with the requirements laid down in Article 4(7) of the Health & Safety at Work (NI) Order 1978 and DHSSPSNI (2000) Circular HSS (Gen1) 4/2000, which facilitates consultation on all health and safety matters. The committee includes representation from recognised Trade unions and

professional bodies/ associations. Refer to Appendix 1 for the Terms of Reference of the Health & Safety Committee. The lead Director for Health and Safety will provide the Governance Committee and SMT with assurances on compliance against health & safety standards and recommendations for improving health and safety in the Trust.

6.2 Communication and consultation. The Trust is committed to open communication and consultation between staff at all levels and with trade union reps as an essential part of effective health and safety management. Consultation will be facilitated by means of the Trust Health and safety Committee, and via the Trade union engagement processes. The Trust will also use global email, Trust newsletters or other campaigns to provide organisational information to Directorates and Departments.

The Trust supports the appointment of health and safety representatives in accordance with the Safety Representative and Safety Committee Regulations. Details of all trade union health and safety representatives will be maintained by the Trade Union side office.

6.3 Training and Information. Training is an effective part of a health and safety management system. The Director of Finance, Procurement & Estates will ensure that general aspects of health and safety are incorporated in the Trust's mandatory training programme. Training statistics for the health and safety mandatory training will be collated by the Education, Learning and Development Department and will be reported via the Health and Safety Committee.

It will be the responsibility of all managers to identify the health and safety training needs of their staff as part of the personal development planning process taking into account the Trust's mandatory training programme. In particular, line managers must be able to demonstrate that they have provided key health and safety information to staff. Managers are responsible for identifying staff training needs and to allow staff to be released to attend health and safety training and updates appropriate to their role. As a minimum legal requirement, staff must be aware of the Trust's health and safety policy and associated documentation, the Trust's organisational arrangements for health and safety and common workplace hazards as well as the procedures to maintain a safe working environment for themselves and others.

The Trust supports paid time off, for trade union representatives, to undergo either TUC or union approved training in accordance with Safety representatives and safety committee Regulations and carry out their duties.

6.4 Incident Reporting. All incidents must be reported electronically via Datix in accordance with the Trust Incident Reporting Policy and Procedures ([click here for link to procedure](#)). All Incidents must be promptly investigated by managers to identify the cause and any remedial action required. The findings of the investigation must be recorded on Datix.

The Health and safety Department will undertake the reporting of incidents to the Health & Safety Executive, Northern Ireland (HSENI) which fall under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).

7.0 Specific Arrangements

7.1 First Aid at work. Any member of staff who works within an Acute or Sub- Acute site and has an accident at work which requires medical treatment should be referred to the nearest Emergency Department, Minor Injuries Unit or to Occupational Health Department, depending on the nature of their injury.

For other staff in Community facilities, Managers must maintain suitable numbers of trained First Aid personnel to deal with minor accidents and emergencies in the workplace. These personnel will have sufficient training in accordance with statutory requirements. Each Manager will also ensure that an appropriately stocked First Aid kit is available on the premises.

For further advice regarding First Aid, please refer to the Trusts First Aid Procedure ([click here for link to procedure](#)).

7.2 New or Expectant mothers. Employees are required to notify their manager once pregnancy is confirmed so that the manager can undertake a risk assessment in accordance with the Management of Health and Safety at Work Regulations (NI) 2000.

For further advice, please refer to the Trusts new and expectant mother procedure ([click here for link to procedure](#)).

7.3 Display Screen Equipment (DSE). Under the Health & Safety (Display Screen Equipment) Regulations 1992 all employers have a duty to ensure that a suitable and sufficient risk assessment has been carried out of employees' work stations including the software in use and the surrounding environment.

7.4 Hazardous Substances. All hazardous substances (including body fluids), that staff may come in contact with should be assessed under the requirements of the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003. Staff should refer to the Trusts COSHH Procedure ([click here for link to procedure](#)) for guidance on how to perform a risk assessment.

7.5 Driving at Work. Trust employees who use their vehicles for Trust Business, have a duty to ensure that their vehicles are roadworthy. Employees must hold a valid and appropriate driving licence, appropriate insurance cover (which covers them whilst on Trust Business), taxation and M.O.T.certificate.

7.6 Violence and Aggression to Staff. The Trust recognises that violence at work is a potential risk for a large number of staff within the service.

Local departmental health and safety arrangements must include details of risk assessment for the protection arrangements for staff, procedures for the recording of all incidents, the relevant training of staff etc. in order to minimise the risk to staff as far as reasonably practicable. Staff should refer to the Management of Violence and Aggression procedure and associated strategies ([click here for link to procedure](#)).

7.7 Stress at Work. While recognising that some work circumstances within Health and Social Care are unavoidably and inherently stressful, the Trust accepts responsibility to ensure that staff are, as far as is reasonably practicable, protected

from, and supported in dealing with stressful situations. Staff should refer to the Trust's Managing Stress in the Workplace Policy for further information ([click here for link to policy](#)).

7.8 Moving and Handling. The Trust wishes to reduce the risk of injury to staff undertaking **moving and handling** operations. All employees involved in manual/load handling activity must be conversant with The Trust's Manual Handling /LOLER Policy ([click here for link to policy](#)) and receive suitable training in accordance with the Policy. Moving and handling risk assessments are a legal requirement and should in place prior to any moving or handling activity taking place.

7.9 Water Quality. The Southern Health and Social Care Trust (Trust) accepts its responsibility under the Health and Safety at Work Order 1978 and the Control of Substances Hazardous to Health Regulations 2002 (as amended), to take all reasonable precautions to prevent or control the harmful effects of contaminated water (i.e. Legionellae, pseudomonas and other harmful water borne bacteria) to residents, patients, staff and other persons working at or using its premises.

The aim of this Policy is to maintain a structured management process for the management and control of its water systems including Legionella and Pseudomonas so as to ensure compliance with current guidelines (HTMs, HGNs and Model Engineering Specifications), legislation and Water Supply Regulations, as laid down in The Health and Safety Commission's Approved Code of Practice – L8 and the HTM 04-01 Addendum on *Pseudomonas*.

The Trust will undertake to:

- i. Identify and assess sources of risk;
- ii. Prepare a scheme for preventing, reducing or controlling the risk;
- iii. Implement and manage precautions;
- iv. Keep records of the precautions for each of the health care premises within the Trust's control.
- v. Appoint a Responsible and Deputy Responsible Persons.

7.10 Fire safety. The Trust recognises its responsibilities for the safety of patients, clients, staff, visitors and contractors in relation to fire safety. Staff should refer to the Trust Policy on Fire Safety and Arson Prevention Policy. Contractors are provided information through the 'Control of Contractors' document.

Governance arrangements under the Fire Safety and Arson Prevention Policy include a Fire Safety Committee which comprises of representatives from each Directorate as well as staff side representation.

7.11 Management of Asbestos. The Trust recognises its responsibilities for the safety of patients, clients, staff, visitors and contractors in relation to asbestos. Staff should refer to the Trust Policy on the Management of Asbestos. Contractors are provided information through the 'Control of Contractors' document.

The Trust has an electronic asbestos register which gives details of asbestos containing materials and access is provided to contractors and available to staff.

7.12 Management of Contractors. The Trust recognises its responsibilities for the safety of patients, clients, staff and visitors in relation to risks related to contractors. To ensure risks are minimised all contractors are issued with 'Control of Contractor' document which controls methods of working. The Trust operates a permit-to-work system for highest risks where works are risk assessed and control measures are implemented as necessary to minimise risks.

All contractors are also required to comply with the Construction (Design & Management) Regulations which require both the design and construction of works to be assessed with regard to minimising risks to health and safety.

7.13 Radiation Protection. The Trust recognises its responsibilities for the safety of patients, clients, staff and visitors in relation to radiation protection. Staff should refer to the Trust policy on the Safe use of Ionising & Non-ionising Electromagnetic Radiation.

7.14 Occupation of Premises with employees from other organisations. Where Trust employees share the workplace with employees of another organisation, the Trust must co-operate with the other employers to ensure compliance with health and safety legislation.

7.15 Inspection, audit and review. Formal safety auditing is an important part of any system of management control and will be undertaken on an annual basis to identify if the Trust is meeting its legal responsibilities and whether effective action is being taken to protect staff and service users.

The outcome of the annual health & safety audit will be presented to the Health & Safety committee. The Heads of Service are the nominated leads with the Director to oversee the audit and ensure that improvements and actions are complete. Other inspections may be carried out by external agencies such as the Health & Safety Executive for Northern Ireland, Local Authority Environmental Health Officers, Regulation & Quality Improvement Authority (RQIA).

The Trust is committed to ensuring that all policies are kept under review to ensure that they remain compliant with all relevant legislation and reflect organisational development.

8.0 Monitoring

Monitoring of this policy will be carried out by:

- The issue of an annual health and safety audit to Heads of Service.
- Production of an annual report to the Governance Committee.
- Investigating all RIDDOR incidents and instances of ill-health to prevent reoccurrence.
- Benchmarking with other Trusts on key incident areas such as sharps injuries, musculoskeletal injuries, violence and aggression.

9.0 Review of this Policy

This policy will be reviewed by the Director of Finance, Procurement and Estates within two years of earlier if required.

10.0 Sources of Advice & Further Information

Further advice and information regarding this policy document can be obtained from the Head of Health & Safety.

This policy should be read in conjunction with related policies and procedures

11.0 Equality & Human Rights Considerations

This policy has been screened for equality implications as required by Section 75 and Schedule 9 of the Northern Ireland Act 1998. Using the Equality Commissions screening criteria, no significant equality implications have been identified. The policy is therefore not subject to equality impact assessment.

This policy has been considered under the terms of the Human Rights Act 1998 and was deemed compatible with the European Convention Rights contained in the Act.

12.0 Legislative Compliance, Relevant Policies, Procedures and Guidance

This policy complies with:

- The Health & Safety at Work (NI) Order 1978
- The Management of Health and Safety at Work Regulations (NI) 2000
- Guidance on the Management of Risk Assessment

HEALTH & SAFETY COMMITTEE

TERMS OF REFERENCE

(Health and Safety at Work Policy (Ver. 05))

1. Constitution

A Health and Safety Committee is constituted and working according to the requirements laid down in HSS (Gen1) 4/2000 and Article 4(7) of the Health & Safety at Work (Northern Ireland) Order 1978, which facilitates consultation on all health and safety matters.

2. Membership

The Chair of the Health & Safety Committee is the Director of Finance, Procurement and Estates.

The membership will be made up of Directorate Representatives and Representatives from the Trade-Union / Professional Bodies within the Trust.

As required:

Representatives from other disciplines may be co-opted from time to time.

A quorum will be of 4 members.

Secretarial Support will be provided by the Health & Safety Department.

3. Frequency Of Meetings

Meetings will held every four months but at least twice per annum. Additional meetings may be arranged as and when required and will follow normal conditions i.e. record of minutes, quorum etc

4. Authority

The Health & Safety Committee is authorised by the Chief Executive to investigate any activity within its terms of reference.

5. Purpose

Promote co-operation between management and staff in instigating, developing and carrying out measures to ensure the health and safety at work of employees.

6. Responsibilities

The Health & Safety Committee has a responsibility to:

- 6.1 Monitor and study incident and notifiable disease statistics and trends including key performance indicators so that reports can be made to SMT via the Lead Director on any unsafe and unhealthy conditions and practices, together with recommendations for remedial action.
- 6.2 Ensure and oversee that all appropriate steps have been taken to minimise risk to the Trust and staff, through the promotion of pro-active risk assessments.
- 6.3 Examine safety inspection reports and forward plan an inspection programme on an annual basis.
- 6.4 Facilitate and support the key objectives of the controls assurance standard for Health and Safety.
- 6.5 Analyse information and reports provided by the enforcing authority inspectors e.g. HSENI and District Council inspectors. Consideration of reports from appointed safety representatives.
- 6.6 To give strategic direction and support for the development, introduction and monitoring of policies, procedures and safe systems of work.
- 6.7 To oversee and ensure the constant appraisal and effectiveness of all health and safety training and to escalate and report to the SMT as necessary.
- 6.8 Monitor the adequacy of safety and health communication and awareness in the workplace.
- 6.9 The provision of a link with the appropriate inspectors appointed by the enforcing authority.
- 6.10 To comment on relevant Trust Policies and Procedures.

7. Reporting

The minutes of the Health & Safety Committee shall be formally recorded and circulated to members and Directors for circulation to managers and staff. Minutes of the Health & Safety Committee will be made available to all staff via the Trust Intranet.

Reporting injuries, diseases and dangerous occurrences in health and social care

Guidance for employers

HSE information sheet

Health Services Information Sheet No 1 (Revision 3)

Introduction

This information sheet gives guidance on how the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) apply to the health and social care sector. It is aimed at employers and others in health and social care, who have a duty to report under RIDDOR.

RIDDOR requires employers and others to report deaths, certain types of injury, some occupational diseases and dangerous occurrences that **'arise out of or in connection with work'**. Generally, this covers incidents where the work activities, equipment or environment (including how work is carried out, organised or supervised) contributed in some way to the circumstances of the accident.

RIDDOR reports alert enforcing authorities to events and helps them to decide whether to investigate serious incidents. Reports enable HSE or local authorities (the 'enforcing authorities') to identify where and how health and safety risks arise, reveal trends and help target activities.

Some incidents are not reportable under RIDDOR. But this does not mean that the general provisions of the Health and Safety at Work etc Act 1974 ('the HSW Act') do not apply. Depending on the circumstances, the enforcing authority may decide it is appropriate to investigate such incidents. This is more likely to arise where serious management failures have contributed to, or had the potential to cause, death or serious injury.

What do you need to report?

The following are reportable, if they arise 'out of or in connection with work':

- the death of any person, whether or not they are at work (see 'Section 1');
- accidents which result in an employee or a self-employed person dying, suffering a specified injury, being absent from work or unable to do

their normal duties for more than seven days (see Section 2);

- accidents which result in a person not at work (eg a patient, service user, visitor) suffering an injury and being taken directly to a hospital for treatment, or if the accident happens at a hospital, if they suffer a specified injury (see Section 3);
- an employee or self-employed person has one of the specified occupational diseases or is exposed to carcinogens, mutagens and biological agents (see Section 2);
- specified dangerous occurrences, which may not result in a reportable injury, but have the potential to do significant harm (see Section 4).

Who should report?

The 'responsible person' has the duty to notify and report. This may be the employer of an injured person, a self-employed person or someone in control of premises where work is carried out. Who the responsible person is depends on the circumstances of the reportable incident (see Table 1).

The employment status of agency workers is not always clear to the agency, the worker, or to the business supplied with labour. In many cases, the employment agency is the legal employer, and is under the same legal obligations as any other employer to report accidents and ill health to their employees. In other cases, for instance where workers are self-employed, the duty is on the host business to report accidents, as the person in control of the premises where an accident occurs.

In practice, agencies should ensure that responsibility for reporting under RIDDOR is clearly assigned to the appropriate person based on the particular facts of the employment relationship. Agencies should ensure that reporting responsibilities are clearly understood by the host businesses and workers.

Where different organisations share responsibility for managing staff, the employer is responsible for ensuring adequate arrangements are in place for reporting incidents.

Table 1 The responsible person

Reportable incident	Injured person	Responsible person
Death, specified injury, over-seven-day injury or case of disease	An employee at work	That person's employer
Death, specified injury or over-seven-day injury	A self-employed person at work in premises under someone else's control	The person in control of the premises
Specified injury, over-seven-day injury or case of disease	A self-employed person at work in premises under their control	The self-employed person or someone acting on their behalf
Death or injury which means you have to be taken to hospital for treatment (or a specified injury occurring at a hospital)	A person not at work (but affected by the work of someone else), eg patient, volunteer or visitor	The person in control of the premises or, in domestic premises, the employer in control of the work activity
Dangerous occurrence		The person in control of the premises where (or in connection with the work at which) the dangerous occurrence happened

Failure to report a reportable injury, dangerous occurrence, or disease, in accordance with the requirements of RIDDOR, is a criminal offence, and may result in prosecution. Reporting an incident is **not** an admission of liability.

When to report

Although the Regulations specify varying timescales for reporting different types of incidents, it is advisable to report the incident as soon as possible.

In cases of a reportable death, specified injury, or dangerous occurrence, you must notify the enforcing authority without delay. You must report within 10 days of the incident.

Over-seven-day injuries must be reported within 15 days of the incident.

Diseases should be reported as soon as a registered medical practitioner (RMP) notifies you in writing that your employee suffers from a reportable work-related disease.

How to report

For general advice on how you should report, see the RIDDOR pages on HSE's website: www.hse.gov.uk/riddor.

All incidents can be reported online, however a telephone service remains for reporting **fatal and specified injuries only**.

Keeping records

You must keep a record of any reportable injury, disease or dangerous occurrence for three years. This must include:

- the date and method of reporting;
- the date, time and place of the event;
- personal details of those involved;
- the injury;
- a brief description of the nature of the event or disease.

You must still keep a record of all over-three-day injuries. If you are required to keep an accident book, under the Social Security (Claims and Payments) Regulations 1979, that record can be treated as a record for the purposes of RIDDOR.

Consultation

Under the Safety Representatives and Safety Committees Regulations 1977 and the Health and Safety (Consultation with Employees) Regulations 1996, employers must make relevant health and safety documents available to safety representatives.

This includes records kept under RIDDOR, except where they reveal someone's personal health information. For further information on consultation, see *Consulting employees on health and safety*.

Reporting requirements of other regulators

Other regulators in the health and social care sector administer a number of reporting requirements. These are separate to and distinct from the legal duty to report incidents under RIDDOR.

Sometimes regulators need to share information in accordance with their statutory responsibilities, especially where it may indicate a failure to follow legal responsibilities and put people at risk.

Section 1: Deaths in health and social care

You must report the death of any person, whether or not they are at work, if it is caused by an accident arising out of or in connection with work. However, under RIDDOR there is no requirement on anyone to report the death of:

- a self-employed person in premises where they are the owner or occupier; or
- an employee which occurs after one year from the date of the accident. If an employee dies after some delay as a result of an injury which is reportable, the employer must inform the enforcing authority about the death in writing, provided that it occurs within a year of the date of the incident. You must do this whether or not the original injury had been reported.

Deaths which are not reportable

- A patient or service user commits suicide. Suicides are not considered 'accidents' and are not RIDDOR reportable.
- A service user admitted to hospital for treatment contracts Legionnaires' disease and dies while in hospital. The death has to be caused by an accident to be reportable. Poor maintenance on a hot water system would not be considered an 'accident'.

Although RIDDOR does not apply in these instances, the general provisions of the HSW Act could still apply. The enforcing authority may, depending on the circumstances, decide it is appropriate to investigate such incidents. This is more likely to arise where serious management failures were a contributory factor.

Reporting Legionnaires' disease cases to other organisations

Public Health England (Formerly the Health Protection Agency)

In England and Wales RMPs have a duty to notify the proper officer of the relevant local authority of any suspected cases of Legionnaires' disease. The notification must be provided in writing within three days from the date of suspicion. There is more information on the Public Health England website at www.hpa.org.uk.

Health Protection Scotland (HPS)

In Scotland, the diagnostic laboratory has a duty to notify the local health board and Health Protection Scotland of any identified cases of Legionnaires' disease. This should be an urgent notification, ie within the same working day of identification, followed up in writing within ten days. You can find more information on the HPS website at www.hps.scot.nhs.uk.

Section 2: Injuries and ill health involving health and social care workers

This section covers accidents resulting in an employee or a self-employed person suffering a specified injury, or being absent from work or unable to do their normal duties for more than three days.

Specified injuries

The following are reportable specified injuries if they arise 'out of or in connection with work':

- fractures, other than to fingers, thumbs and toes;
- amputations;
- any injury likely to lead to permanent loss of sight or reduction in sight;
- any crush injury to the head or torso causing damage to the brain or internal organs;
- serious burns (including scalding) which:
 - cover more than 10% of the body; or
 - cause significant damage to the eyes, respiratory system or other vital organs;
- any scalping requiring hospital treatment;
- any loss of consciousness caused by a head injury or asphyxia;
- any other injury arising from working in an enclosed space which:
 - leads to hypothermia or heat-induced illness; or
 - requires resuscitation or admittance to hospital for more than 24 hours.

Lost-time accidents to employees

Over-seven-day injuries

Accidents must be reported where they result in an employee or self-employed person being away from work, or unable to perform their normal work duties, for more than seven consecutive days as the result of their injury. The seven-day period does not include the day of the accident, but does include weekends and rest days.

Over-three-day injuries

You must record accidents, but not report them where they result in a worker being incapacitated for more than three consecutive days. If you are an employer, who has to keep an accident book, the record you make in this will be enough.

Physical violence

A physical injury inflicted on one employee by another during a dispute about a personal matter, or an employee at work injured by a relative or friend who visits them at work about a domestic matter, is not reportable.

However, other acts of non-consensual violence to a person at work that result in death, a major injury or being incapacitated for over seven days are reportable and you must keep a record of over-three-day injuries.

Diseases, infections and ill health

You must report any instance where an RMP tells you in writing that one of your employees is suffering from a disease specified in RIDDOR, and the employee undertakes work linked with that condition.

Reportable diseases, infections and ill health include:

- carpal tunnel syndrome;
- severe cramp of the hand or forearm;
- occupational dermatitis;
- hand-arm vibration syndrome;
- occupational asthma;
- tendonitis or tenosynovitis of the hand or forearm;
- any occupational cancer;
- any disease attributed to an occupational exposure to a biological agent.

For the purposes of RIDDOR, an infection is the entry and multiplication of an infectious agent in the body, causing a damaging reaction to the tissue. The infection and damage caused may give clinical signs and symptoms of disease, or may be subclinical or 'asymptomatic'.

Colonisation (the presence and multiplication of infectious agents in or on the body, without a damaging reaction in the tissue) is not the same as infection and is not reportable as a disease.

Infections that could have been acquired as easily in the community as in work are not reportable, unless the infection was definitely acquired at work.

Self-employed people need to make their own arrangements to notify any reportable diseases and infections they suffer (for advice on how to report, see the RIDDOR pages on HSE's website at www.hse.gov.uk/riddor).

Reportable

- A nurse contracts active pulmonary TB after nursing a patient with the condition.
- A laboratory worker suffers from typhoid after working with specimens containing typhoid.

- A paramedic becomes hepatitis B positive after contamination with blood from an infected patient.
- A care assistant is splashed in the face with bodily fluids from a service user and becomes hepatitis B positive.
- A surgeon suffers dermatitis associated with wearing latex gloves during surgery.
- A maintenance worker contracts Legionnaires' disease after working on the hot water system.

In all of these cases it is clear that the disease is either attributable or contributed to by the work activity and an RMP has confirmed that this is the case.

Not reportable

- A nurse becomes colonised with MRSA and works with patients infected with MRSA.
- A cleaner catches chicken pox. Patients in areas where she has worked have chicken pox.
- A care home assistant is off work with influenza for two weeks, the influenza cannot be reliably attributed to their work activity, as it is common in the community.

In all of these cases, either infection has not occurred at work or the disease cannot be reliably attributed to the work activity, as it might easily have occurred at home or in the community.

Sharps injuries

A sharps injury is when a needle or other sharp instrument accidentally penetrates the skin. It is sometimes called a needlestick injury.

Sharps injuries must be reported:

- when an employee is injured by a sharp known to be contaminated with a blood-borne virus (BBV), eg hepatitis B or C or HIV. This is reportable as a dangerous occurrence;
- when the employee receives a sharps injury and a BBV acquired by this route sero-converts. This is reportable as a disease – see 'Diseases, infections and ill health';
- if the injury itself is so severe that it must be reported.

If the sharp is not contaminated with a BBV, or the source of the sharps injury cannot be traced, it is not reportable, unless the injury itself causes an over-seven-day injury. If the employee develops a disease attributable to the injury, then it **must** be reported.

Reportable

- A cleaner suffers a needlestick injury from a needle and syringe known to contain hepatitis B positive blood (reportable as a dangerous occurrence).

Not reportable

- A community nurse suffers a needlestick injury, does not sero-convert and the source of the sharp cannot be traced.
- A laboratory worker is injured by a blood specimen container. The patient is not known to have any infection.
- An employee is cut with a scalpel used on a patient not known to be contagious, but undergoing blood checks for hepatitis A.

Due to the sensitive nature of reporting diseases and infections caused by blood-borne viruses, the enforcing authority does not require you to name the injured person on the RIDDOR report. However, if the enforcing authority decides to investigate, you may be asked to provide this information. If it is a repeat incident to the same person, you need to inform the enforcing authority.

Stress

Stress is not reportable as an occupational injury, even when accompanied by a medical certificate stating it is work-related, because it does not result from a single definable accident.

Section 3: Injuries and ill health involving people not at work

This section covers accidents which result in a person not at work suffering an injury and being taken to a hospital, or if the accident happens at a hospital, suffering a specified injury which would have required hospital treatment.

Any injury to someone not at work must be reported if it results from an accident arising out of or in connection with work being undertaken by others and it:

- results in them being taken from the premises where the accident occurred directly to a hospital for treatment*, by whatever means (for example by taxi, private car or ambulance); or
- happens at a hospital and involves a specified injury.

In the past, there has been some misunderstanding as to the range of accidents that should be reported under RIDDOR when they involve members of the public who are patients, residents, service users or visitors. The following examples will help you decide about reportability.

*Examinations and diagnostic tests do not constitute 'treatment'.

Injuries to people not at work**Reportable**

- A patient is scalded by hot bath water and taken to hospital for treatment. The patient was vulnerable and adequate precautions were not taken.
- A service user receives a fractured arm when their arm becomes trapped in a bed rail.
- A visitor to the hospital is struck on the head by a car park barrier and receives a specified injury that requires hospital attention.
- A service user requires hospital treatment after sliding through a sling after being hoisted from a chair. The wrong-sized sling was used.

Not reportable

- A patient or visitor is injured by an act of physical violence from another patient.
- A patient receives a healthcare-associated infection while receiving treatment in hospital. Hospital associated infections acquired by patients are not reportable under RIDDOR.
- A patient admitted to hospital for treatment contracts Legionnaires' disease in hospital.

Patient/service user fall incidents

A fall is reportable under RIDDOR when it has **arisen out of or in connection with a work activity**. This includes where equipment or the work environment (including how or where work is carried out, organised or supervised) are involved.

Reportable

- A confused patient falls from a hospital window on an upper floor and is badly injured.
- A service user falls in the lounge area, there is previous history of fall incidents, but reasonably practicable measures to reduce the risks have not been put in place.
- A service user falls out of bed, is injured and taken to hospital. The assessment identified the need for bedrails but they, or other preventative measures, had not been provided.
- A service user trips over a loose or damaged carpet in the hallway.

Not reportable

- A service user falls and breaks a leg. They were identified as not requiring special supervision or falls prevention equipment. There are no slips or trips obstructions or defects in the premises or environment, nor any other contributory factors.
- A service user falls out of bed and is taken to hospital. There was a detailed assessment in the care plan identifying that fall protection was not required.
- A service user is found on the floor, no-one has seen it happen, and/or there are no obvious work-

related contributing factors. There was a detailed assessment in the care plan, which identified that fall protection was not required.

In some circumstances, it may not be clear whether the accident that caused the injury arose out of or was connected to the work activity.

Example 1

A service user (who is capable of understanding and following advice) falls off the toilet, having previously been advised not to get up, is injured and taken to hospital. They have been left alone for dignity reasons. Their care plan identified that the individual should have assistance or supervision.

Reportable

- The member of staff left the service user out of earshot and without a call bell they could use, or had not responded promptly when they did call, as adequate supervision had not been provided.

Not reportable

- The member of staff returned to help them as soon as they called to say they have finished. Or if the service user had got up without calling for help, it would not be reportable.

Example 2

An incontinent service user slips on their own urine when returning back from the toilet and receives a major injury.

Reportable if:

- the assessment had identified the resident needed help for toileting and it was not provided;
- the fall took place in an area of the home where it was foreseeable the resident may slip due to a spillage and the home had failed to assess risks from floor surfaces or act on their assessment.

Example 3

A patient falls from a stretcher while being manoeuvred into an ambulance and suffers a hip fracture.

Reportable if:

- the paramedics had chosen the wrong piece of equipment to move the patient, or had not received the appropriate training about safe use of the equipment, or were not following a safe system of work;
- the paramedics were aware the patient had a history of aggression and failed to take this into account when moving them. The patient

subsequently becomes aggressive and falls from the stretcher.

Not reportable if:

- the patient became unexpectedly aggressive, struggled and fell.

You may need to consult the patient's/service user's care plan to decide what care was assessed as being appropriate for them. If you still are unclear, ask for advice.

Self-harm

Acts of deliberate self-harm are not considered 'accidents' and are not RIDDOR reportable.

However, this does not mean that the general provisions of the HSW Act do not apply. The enforcing authority may, depending on the circumstances, decide that it is appropriate to investigate such incidents. This is more likely to arise where serious management failures were a contributory factor.

Clinical decisions

If a person is injured as a result of an accident arising directly from the conduct of any operation, any examination or other medical treatment being carried out by or under the supervision of an RMP or registered dentist, the injury is not reportable.

The supervision does not need to be direct for the exemption to apply – it is sufficient that the procedure being carried out was laid down by an RMP.

Reportable

- A patient suffering a serious injury as a result of a power failure during an operation (not caused by the conduct of the operation).

Not reportable

- During a surgical operation, a surgeon removes the wrong organ. The patient subsequently dies.
- A patient suffers a seizure following a medical procedure. The nursing assistant was following a procedure laid down by an RMP.
- A paramedic administers a drug to a patient who subsequently dies because of an allergic reaction. This would not be reportable, whether or not the correct procedure was being followed.
- A patient known to be allergic to penicillin is nevertheless given a penicillin-based drug under the supervision of an RMP and subsequently dies.

If there is a concern about the professional misconduct of an individual, you should ensure that the appropriate professional body is notified:

- General Medical Council for doctors;
- General Dental Council for dentists;
- Nursing and Midwifery Council for nurses;
- Health Professions Council for paramedics and allied health professionals.

For further advice you can also contact your local Public Advice and Liaison Service or the Independent Complaints Advisory Service.

Section 4: Dangerous occurrences in health and social care

Dangerous occurrences are certain specified near-miss events, which may not result in a reportable injury, but have the potential to do significant harm.

Reportable dangerous occurrences include the following:

- the collapse, overturning or failure of load-bearing parts of lifts and lifting equipment;
- the accidental release of a biological agent likely to cause severe human illness (a hazard group 3 or 4 pathogen);
- the accidental release or escape of any substance which may cause a major injury or damage to health;
- an electrical short circuit or overload causing fire or explosion;
- the explosion, collapse or bursting of any closed vessel or associated pipework forming a pressure system;
- an explosion or fire causing suspension of normal work for over 24 hours.

RIDDOR includes a full list of dangerous occurrences. For more information on the reportability of sharps injuries see Section 2.

Is the incident a reportable dangerous occurrence?

Reportable

- A patient hoist collapses or overturns.
- A laboratory worker spills a sufficient quantity of formaldehyde from a container to cause damage to the health of a worker or others present.
- A container of a TB culture is broken and releases its contents.
- A cleaner suffers a needlestick injury from a needle and syringe known to contain hepatitis B positive blood.

Not reportable

- An elderly woman with dementia wanders out of a care home into the car park/main road.

- There is a collision between two vehicles in a hospital car park and no-one is injured.
- A lifting sling fails during a lift. You don't need to report failures of lifting accessories.
- A community nurse suffers a needlestick injury, does not sero-convert and the source of the sharp cannot be traced.

Further reading

Consulting employees on health and safety: A brief guide to the law Leaflet INDG232(rev2) HSE Books 2013 www.hse.gov.uk/pubns/indg232.htm

Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit www.hse.gov.uk/. You can view HSE guidance online and order priced publications from the website. HSE priced publications are also available from bookshops.

This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

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Northern Ireland Adverse Incident Centre (NIAIC)

Reporting Adverse Incidents and disseminating Safety Information

Apr 2021

Version Control

This document is owned and controlled by the Head of Medical Device and Estates Safety Policy Branch

Version	Details	Date	Sign off
1.0	Issue date – previously known as DB2010(NI)-01	Oct 2017	
1.1	Revised to reflect changes required to meet requirements of Internal Audit recommendations	03/10/2018	DW
1.2	Revised as result of requirement to review and update document to remove reference to public reporting to NIAIC	10/3/2020	DW
1.3	Update to take into consideration current NIAIC and MHRA practices, including the withdrawal of MDA's and introduction of NatPSA's	Mar 2021	RS

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1. Introduction

1.1 The Northern Ireland Adverse Incident Centre

The Northern Ireland Adverse Incident Centre (NIAIC) operates as part of the Chief Medical Officers (CMO) Group within the Department of Health (DoH). The key aim of the NIAIC is to seek learning from investigations into reported adverse incidents involving medical devices, non-medical equipment, plant and buildings used within the healthcare environment across Northern Ireland and to issue safety information and guidance to help prevent recurrence.

The importance of open reporting of adverse incidents in the healthcare environment has been proven in many instances with additional learning and improvement being achieved. Therefore part of NIAIC's work is in encouraging a shift to a safety culture, where open reporting and balanced analysis are encouraged in principle and by example. This is in contrast to a blame culture, which encourages people to cover up errors for fear of retribution. Open reporting and a balanced analysis allows for focus on the true cause of the incident and any role of the underlying systems which enables improvements, if identified, to be made.

The introduction of effective clinical governance means that there is a shared goal between the individual and the organisation to minimise risk related to the use of medical devices, equipment and plant and thereby ensure that everyone who needs to use equipment can do so safely and effectively.

The NIAIC works closely with the Medicines and Healthcare products Regulatory Agency (MHRA) - the UK Competent Authority for Medical Devices, in relation to issues concerning medical device safety. The NIAIC also liaises closely with the NHS Improvement - England, Health Facilities Scotland and NHS Wales Shared Services Partnership - Facilities Services for safety issues concerning non-medical equipment, plant and building items.

Localised learning can be fed back to individuals and reporting organisations through investigation outcome closure letters. Wider generic learning is distributed to the healthcare environment through safety information released via the Northern Ireland Central Alerting Systems (NICAS). The NICAS is a web based application to notify users about new or updated safety information and can provide an assurance pathway to the DoH that the appropriate safety actions have been implemented by the HSC and other large acute service providers.

2. Reportable Events

2.1 What is an adverse incident?

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users including staff, patients or other persons.

For example:

- a patient, user, carer or professional is harmed while using a medical device;
- a patient, user, carer or professional is harmed, or has the potential to be harmed, due to insufficient information contained in the Instruction for Use (IfU) or decontamination guidance;
- a medical device failure causes a misdiagnosis or leads to inappropriate treatment;
- a patient's health deteriorates, treatment is interrupted or compromised due to medical device failure;
- a reduction in service due to an unexpected failure of a device or part of the estate.

The following are not considered as an adverse incident, although they can be reported for regional trending in order to understand ongoing issues:

- The incident occurred due lack of training, use off label or failure to adhere to the Instruction for Use (IfU), FSN's or Alert;
- The device or equipment was not maintained in accordance with the manufacturer's guidance;
- The failure occurred due to normal wear and tear, general maintenance issues or the device or equipment exceeds the manufacture's stated end of life; and
- Where the user or organisation has failed to implement adequate control measures to manage a known or accepted risk.

2.2 What is a medical device?

A medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,

- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

General workshop equipment such as power or machine tools, general purpose laboratory equipment or aids for daily living are not considered as medical devices. A list of examples of Medical Devices is provided in Appendix 1.

Note: An accessory is not considered to be a medical device. However, where an accessory is intended specifically by its manufacturer to be used together with the 'parent' medical device to enable the medical device to achieve its intended purpose, it should be considered as a medical device in its own right.

Note: Software and Applications (apps) on standalone computers and mobile devices are now classified as medical devices if the app is intended to

2.3 What are Estates equipment, plant and building items?

Estates equipment, plant and buildings are items directly managed and controlled by an Estates and Facilities Department. This does **not** include general IT systems, except where they are classified as a medical device (see above). Examples of non-medical equipment, plant and building items are provided in Appendix 2.

2.4 What should be reported to the NIAIC?

Any adverse incident (as defined in section 2.1) involving a medical device and estates, plant, equipment or buildings should be reported to the NIAIC. It is important to recognise that relatively minor incidents and near misses can have a greater significance if aggregated with other similar reports.

2.5 Why report?

The information from adverse incident reports can help identify safety issues with medical devices or equipment. It can prevent similar incidents happening again through analysis to provide new learning, which can then be disseminated, either locally or wider. It is important that users report all adverse issues with devices, although not all incidents reported will produce or require an outcome from the MHRA, NIAIC or the manufacturers, but will add to a body of evidence pertaining to the safety of the device. Lower level information may be recorded to assist in future investigation, general discussion or to establish if any trend in failures is developing or there is a need for additional action.

2.6 Who should report?

Any healthcare worker, in the public or private sector, may submit an adverse incident report directly to the NIAIC. Reporters from the Health and Social Care sector should copy their report to or submit it via their Medical Device Liaison Officers and follow the incident reporting procedures of their organisation.

Submitting a report of an adverse incident to the NIAIC does not negate the need for the user to take immediate action to protect safety or the need to report to other systems/ bodies including local incident registers, statutory bodies, etc. including the PSNI, Coroner, PHA or Health and Safety Executive (under RIDDOR).

Patients and members of the public are encouraged to report Medical Devices adverse incidents via the Yellow Card Reporting Scheme, operated by MHRA. Anonymised copies of these reports that originate from within Northern Ireland, will be provided to NIAIC for action if deemed necessary. Section 7.2 below provides information on the MHRA Yellow Card Scheme.

2.7 When should an incident report be made?

All incidents should be reported to the NIAIC as soon as possible. Serious cases should be reported by the fastest means possible. Initial incident reports should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information. Although further information may be requested or needed at a later date to assist the investigation. It is essential that the reporter provides an email address to initiate communications and enough information to identify the manufacturer and the model of the device/equipment in question

2.8 How do I report an incident?

Complete the appropriate NIAIC AI Form and return it via email or hard copy by post. AI Report forms may be downloaded/printed from the NIAIC pages of the DoH [website](#).

Postal Address: Northern Ireland Adverse Incident Centre
Medical Device and Estates Safety Policy Branch
Safety Strategy Unit, CMO Group
Department of Health
Room D1
Castle Buildings
Stormont Estate
Belfast, BT4 3SQ

Telephone: +44 (028) 90523868
Email: niaic@health-ni.gov.uk
Website: <https://www.health-ni.gov.uk/niaic>

2.9 What do I do with devices or equipment that has been involved in an adverse incident?

When a device has been involved or implicated in an adverse incident it is necessary to ensure that the device or equipment is clearly identified, its location is recorded and any history (event logs, settings, accessories, etc.) are maintained for investigation.

The following non exhaustive information is provided for guidance only:

- If the adverse incident is likely to be the subject of a legal enquiry or corporate investigation you should quarantine any devices associated with the incident, including all accessories. The quarantined equipment should not be released until you are provided with confirmation, from the investigating body that the devices are no longer required and may be released.
- If there is no likelihood of a legal enquiry or corporate investigation the device can be made available to the manufacturer or their service agent for analysis and repair. In doing so they should be advised that the device was implicated in a reportable adverse incident and they may be asked to provide a full report of their findings to the MHRA or the NIAIC.
- If the failure to return the device to operational use would affect service delivery and or the immediate safety of individuals, the device may be checked/repaired as quickly as possible, verified safe by a competent person and returned to service. All work carried out on the device including service records should be documented and maintained as continuity of evidence for future investigation.
- Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. The manufacturer/supplier should be contacted for advice prior to any further action being taken. The MHRA publication 'Managing Medical Devices' contains advice on decontaminating healthcare equipment. For additional information contact your local Infection Control Specialist, particularly if the item requires examination prior to any decontamination.

Important: If you are in any doubt about what to do with a device, contact your local medical device liaison officer or the NIAIC.

Do not send medical devices to the NIAIC unless specifically requested through the post

2.10 What does the NIAIC team do when it receives a report?

When an adverse incident report is received the details are recorded on the NIAIC Adverse Incident Register. The NIAIC team will assess the report to see if it meets the reporting criteria before undertaking any action. For medical device related incidents the MHRA will be notified and if necessary the details will be forwarded to the device manufacturer for inclusion on their post market surveillance register and

consideration for investigation or action. For estates reports the basic details maybe shared with other Devolved Administrations to assist with incident identification.

The NIAIC will monitor and review the manufacturer's response and any actions they propose to take. If it is felt necessary, the NIAIC may request additional information or highlight the issue to the MHRA or other Regulatory Bodies for consideration. If thought necessary, the NIAIC may visit site to gather further information to assist in the identification of new learning.

All reports are acknowledged and reporters advised of the nature and outcome of any investigation.

2.11 Reporting multiple occurrences of an incident

Although single reports have on occasion (by themselves) enabled the NIAIC, the MHRA or a manufacturer to bring about changes to the design or instructions for use of a device, multiple reports give increased leverage when assessing the need to initiate change. Hence we would recommend that you report each occurrence of an incident and do not assume that because a similar event was previously reported that there is no further need for additional reporting.

2.12 How long do reports remain open?

Incidents will remain open until the manufacturer completes their investigation or no further action is deemed necessary. On average, 70% of incidents are concluded within 10 weeks. Investigations maybe delayed by the lack of availability of the device or the need for a longer post market evaluation to gauge the scale of the problem.

For general enquiries about adverse incidents involving medical devices contact our Adverse Incident Centre: niaic@health-ni.gov.uk or 028 90523868.

2.13 Confidentiality, data protection and the provision of information to third parties

Unless notified to the contrary, the submission of a report to the NIAIC provides us with the authority to use the information provided as we consider appropriate in the interest of safeguarding public health. Please see the NIAIC Privacy Notice ([NIAIC Privacy Notice](#))

The NIAIC does not require patient names or other identifying information in order to carry its functions. Healthcare staff when reporting incidents should ensure that all patient details that may identify an individual are deleted or redacted from the report or any accompanying attachments.

The details that we do require are clearly detailed on the NIAIC Adverse Incident report forms. The reporter's full contact details (name, email address, post held etc.) are essential, as this allows the NIAIC or the manufacturer to contact the reporter to acknowledge receipt of the report, to request any further information or request the return of the device and provide the outcome of the investigation.

Technical and scientific information relevant to our investigations may be sought or shared with bodies such as the MHRA and/or the Department of Health as well as with the supplier or manufacturer.

3. Safety Information

3.1 NIAIC Safety Information

Safety information from the NIAIC will be distributed by the Northern Ireland Central Alerting System (NICAS), for information on this system see section 5.1.

3.2 National Medical Device Safety Information

The MHRA, as the UK Competent Authority for Medical Devices, is responsible for producing safety information in respect of medical devices. This information which will be distributed, in Northern Ireland, by the NIAIC if it is deemed appropriate.

Currently the MHRA issues three types of safety information.

3.2.1 National Patient Safety Alert – Medical Devices

The Medicines and Healthcare products Regulatory Agency (MHRA) is now an accredited issuer of National Patient Safety Alerts, a format devised by NHS England. National Patient Safety Alerts are alerts that require local executive management level action to reduce the risk of death or serious harm. These alerts follow the criteria and template agreed by the National Patient Safety Alerting Committee (NaPSAC) and are not be limited to medical device issues. Therefore, MHRA medical device alerts will be interleaved with other Patient Safety Alerts and the reference numbers for medical device alerts may not hold a consecutive reference number. The NIAIC will continue to require assurance on this type of alert via the NICAS.

3.2.2 Targeted Letters

Where a safety issue is limited to a number of known sites a Targeted Letter may be used to provide guidance on the action required. Depending on the severity of the issue they may require similar assurance to that of NatPSA's at executive level.

3.2.3 General Medical Device Safety Information

The MHRA will continue to provide a range of other medical device safety guidance under a number of different formats. These do not require local executive management assurance. Currently these take the form of; Medical Device Safety Bulletins and general safety information (found on their website), although the MHRA may introduce new categories to meet specific needs. The NIAIC will be releasing all these under the title Medical Device Safety Information (MDSI) until further advised.

3.2.4 Guidance Reports (formally Device Bulletins)

The MHRA continue to provide and update guidance reports (formally Device Bulletins).

Medical Device Alerts (MDAs) are no longer being generated and issued, although the Department and the NICAS websites will continue to display a list of those alerts that are still in force, with links to the original documents. If a MDA is not listed on these sites, it may have been either superseded or withdrawn.

3.3 Estates and Facilities Alerts (EFAs)

Estates and Facilities Alerts (EFAs) are produced nationally and distributed by the NIAIC to the Northern Ireland healthcare community. They contain safety information on estates issues to provide new learning or reinforce safety information.

EFAs were introduced at the start of 2010 as a national alerting system and are simultaneously published in England, Wales, Scotland and Northern Ireland. The alert in each of the Devolved Administrations will carry the same reference number.

EFAs replaced safety advice on estates, plant and buildings previously provided under the Medical Device/Equipment Alert (MDEAs) numbering system. The NIAIC website provides lists of all current EFA's. Please note that EFA's and MDEA's over 10 years old are not maintained by NIAIC, although may contain relevant information.

3.4 Northern Ireland Alerts (NIAs)

Northern Ireland Alerts (NIAs) are the NIAIC's means of communicating safety information for either medical devices or estate and facilities which is primarily focused on an issue applicable to Northern Ireland.

NIAs were introduced at the start of 2010, they are only published in Northern Ireland and are designed to give advice on local issues or advanced notification of safety problems still under national investigation i.e. they may be superseded by national advice at some point in the future.

4. Field Safety Corrective Actions and Field Safety Notices

4.1 What is a FSCA?

Under the terms of the Medical Devices Regulations, the manufacturer is responsible for the safe functionality of the devices they manufacture. If they find an issue related to the safe functionality or use of their device which could potentially cause serious harm or death they must report this to the MHRA (the UK Competent Authority for medical devices) along with an action plan on how they propose to managing the risk. The problem and their proposed action is detailed in a document called a Field Safety Corrective Action (FSCA). If this action plan requires the end user to take action on devices in their possession, the manufacturer will distribute a Field Safety Notice (FSN).

4.2 What is a FSN?

A Field Safety Notice (FSN) is a safety communication issued by a medical device manufacturer, or their representatives, to all of their known customers and users of the device. A FSN details; the immediate actions being taken by the manufacturer; what they proposes to do to reduce the risk of patient harm associated with the known issue; the action the user needs to take; the time scale for the action; and most importantly, a reply slip for the customer/user to acknowledge they have received the FSN.

4.3 What should an organisation do if it receives an FSN?

It is essential that organisations undertake the actions detailed in the FSN and reply to the manufacturer, acknowledging receipt and providing any information requested on the FSN. An organisation's reply to the manufacturer is the evidence that the manufacturer requires to provide assurance to the MHRA that the problem is being addressed in accordance with the FSCA. Without adequate assurance, from the manufacturer, that appropriate action has been taken on devices in service, the MHRA may take additional action where it is deemed necessary

In accordance with medical device alert (MDA-2014-037) organisations should ensure that they have systems and procedures in place for the appropriate collection and dissemination of FSNs. This information should then be distributed to all relevant personnel within their organisation and to ensure that the appropriate action has been taken. The above suggests that organisations should centrally record all FSNs sent to them and monitor the required action.

The MHRA currently place manufacturers' FSNs on its website for information only and do not distribute them, unless individual organisations sign up for the appropriate safety information on their website.

5. Northern Ireland Central Alerting System (NICAS)

5.1 The Northern Ireland Central Alerting System (NICAS)

The Northern Ireland Central Alerting System is a web based application utilised by the NIAIC for the issue of relevant safety information, including links to alerts applicable to the Northern Ireland healthcare environment. The application provides an assurance loop to the DoH from relevant HSC organisations. This requires those organisations to acknowledge they have received and taken the appropriate action.

The NICAS has four user access levels:

Actioner:	Actioners are generally persons working within HSC Organisations. The actioner is typically the MDLO or a person designated by the executive management team for medical devices, to carry out the assurance function on behalf of their organisation. This type of user receives an email to notify them that a new safety communication has been published on NICAS. This email also contains a copy of the published safety communication. Actioners will have a secure login, which provides full access to all the information on the NICAS website. They are required to acknowledge they have received the information and to provide assurance that the actions contained within the communication have been completed within their organisation. All users are responsible for ensuring that they keep their own contact details up to date.
Secure User:	This type of user receives an email to notify them that a new safety communication has been published on NICAS. This email also contains a copy of the published safety communication. The Secure user will have a secure login, which provides full access to all information on the NICAS website, however they cannot update assurance information for their organisation.
Registered User:	This type of user receives an email to notify them that a new safety communication has been published on NICAS. This email also contains a copy of the published safety communication. Registered users have web access to public facing information on the NICAS.
Public:	The public can viewed non secure information on the public facing web pages.

For general enquiries about NICAS contact our Adverse Incident Centre by email at niaic@health-ni.gov.uk or by telephone on 028 90523868.

6. Medical Device Liaison Officer (MDLO)

6.1 Role of medical device liaison officers (MDLOs) in HSC Trusts

The MDLO role is integral to improving medical device incident reporting and learning from incidents within HSC organisations. One of the MDLO's key roles is to promote the safe use of medical devices across their organisation, by encouragement and training in the reporting of adverse incidents, so that learning can be identified. As well as improving the quality of reporting, the MDLO will be the essential link between the identification and implementation of (local and national) medical device safety initiatives and investigating device related incidents in order to improve the safety of medical devices.

Roles and responsibilities should include:

- improve reporting of and learning from medical device incidents in the organisation;
- manage medical device incident reporting in the organisation; review all medical device incident reports to ensure data quality for local and national learning; where necessary investigate and get additional information from reporters;
- make sure that medical device incidents are sent to the NIAIC as soon as possible;
- receive and respond to requests for more information from the NIAIC about medical device incident reports;
- active membership of the regional Medical Devices Safety Network (NIAIC Webex);
- support the dissemination of medical devices and estates safety communications from the NIAIC throughout the organisation;
- provide assurance on behalf of their organisation into the NICAS that their organisation has acted on the published safety communications;
- act as an additional senior point of contact for manufacturers regarding Field Safety Notices and support the local action required by the organisation in relation to a Field Safety Notice
- maintain knowledge of issues arising regarding medical device safety – e.g. participate in national Medical Device Safety Officer Webex and chat forums.

7. Other reporting systems

7.1 Serious Adverse Incidents (SAIs) Reporting

Health and Social Care (HSC) Trusts, Family Practitioner Services (FPS) and Independent Service Providers (ISP) must report Serious Adverse Incidents (SAIs) arising during the course of business of an HSC organisation/Special Agency or commissioned service, to the Health and Social Care Board (HSCB) who are working in close partnership with the Public Health Agency (PHA) and the Regulation Quality Improvement Authority (RQIA) for the recording and follow up of SAIs.

All SAIs that involve Medical Devices, non-medical devices plant or building equipment **must also** be reported to the NIAIC utilising the NIAIC adverse incident form.

7.2 The MHRA Yellow Card Scheme

The Yellow Card Reporting Scheme is operated by the MHRA. The scheme enables safety reporting to be made for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, and all medical devices available on the UK market, however, in NI, medical device incidents should be reported to NIAIC in the first instance, who in turn mirror these to the MHRA.

During the period of the Covid epidemic the NIAIC supports the use of the MHRA's Yellow Card System to report failures or suspected side effects to medicines, vaccines or medical device and diagnostic adverse incidents used in coronavirus treatment. This system is open to either healthcare professionals or members of the public.

NB Within Northern Ireland any incident involving medical devices within the healthcare should be reported as per the guidance in this document. HSC Staff who report or are informed of any reporting via the Yellow Card scheme should ensure that their MDLO is notified and the NIAIC are copied in on the incident report.

7.3 SABRE & SHOT (reporting blood safety and quality incidents)

With the introduction of the Blood Safety and Quality Regulations 2005 No. 50 and The Blood Safety and Quality (Amendment) (No.2) Regulations 2005 No. 2898 (effective for the purposes of regulation on 8 November 2005), the MHRA became responsible for ensuring that blood products, blood establishments and blood banks are acceptably safe.

Incidents relating to blood safety and quality should not be sent to the NIAIC. Reports under these regulations are submitted to the MHRA using the dedicated online reporting system, **SABRE** (Serious Adverse Blood Reactions & Events). SABRE is accessible via the MHRA website (www.mhra.gov.uk). The system also prompts reporting to **SHOT** (Serious Hazards Of Transfusion <http://www.shotuk.org/>).

Enquiries concerning the reporting of blood safety incidents should be directed to:

MHRA

Email: sabre@mhra.gsi.gov.uk

Tel: 020 7084 3336

Fax: 020 7084 3109

SHOT

Email: shot@nhsbt.nhs.uk

Tel: 0161 423 4208

Fax: 0161 423 4395

7.4 RIDDOR

In addition to reporting medical device related incidents to the NIAIC, incidents involving an injury, occupational disease or dangerous occurrence, to an employee, whether involving medical devices or not, should also be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR (NI) 97) to the relevant enforcing authority for the premises at which the incident occurred. For healthcare premises, this will usually be the Health and Safety Executive Northern Ireland (HSENI). All notifications under RIDDOR should be sent to:

HSENI
83 Ladas Drive
Belfast
BT6 9FR

Tel: 028 9024 3249
Fax: 028 9054 6896
E-mail: mail@hseni.gov.uk
www.hseni.gov.uk

Online reporting and copies of report forms are available via their website.

8.0 Contacts

Enquiries concerning the content of this document should be addressed to: niaic@health-ni.gov.uk or by telephone on 028 90523868.

Annex 1

Examples of medical devices

Anaesthetic equipment
 Blood warming cabinets
 Catheters (e.g. urinary, cardiac)
 Chiropody equipment
 Dental equipment and materials
 Dressings
 Endoscopes
 Examination gloves
 Hospital beds
 Implants – powered (e.g. implantable defibrillators, pacemakers) and non-powered (e.g. heart valves, orthopaedic implants, bone cements)
 Incontinence products
 IV administration sets and pumps
 Ophthalmic equipment
 Patient monitoring equipment (e.g. cardiac monitors)
 Physiotherapy equipment
 Radiotherapy equipment (brachytherapy, external beam)
 Sphygmomanometers
 Surgical instruments and equipment
 Syringes and needles
 Thermometers
 Urine drainage systems
 Vaginal specula
 X-ray systems, ultrasound imagers and CT/MR scanners

For patient transportation or moving
 (but **not** including ambulance vehicles themselves):

Carry chairs
 Hoists and slings
 Slider boards and standing aids
 Stretchers and trolleys

For critical care:

Defibrillators
 Resuscitators
 Ventilators

For people with reduced mobility or physical impairment:

Communication aids
 Environmental controls
 Hearing aids
 Orthotics
 Prosthetic limbs

Pressure relief mattresses, cushions or pads
 Supportive seating
 Walking aids
 Wheelchairs (powered and non-powered)

For daily living:

Bathing and showering equipment
 Commodes
 Incontinence products
 Prescribable footwear
 Special chairs
 Urine drainage systems
It does not include devices or equipment with no medical function

In vitro diagnostic medical devices and their accessories:

Blood gas analysers
 Blood glucose meters
 Hepatitis and HIV test kits
 Pregnancy test kits
 Specimen collection tubes
 Urine test strips

Also included are:

Condoms
 Contact lenses and care products
 Intra-uterine devices (IUDs)

We are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices. For example:

Benchtop sterilizers
 Blood and tissue storage systems
 Disinfecting and sterilizing equipment
 Chemical and biological indicators used in sterilization processes

Annex 2

Examples of estates equipment and plant

Building, building components and lifts.

Demolitions and construction carried out under CDM regulations, including plant.

Engineering plant and services of all types (e.g boilers, generators, heating, ventilation, water, drainage, electrical installations) and any other fixed plant equipment, but not medical devices.

Fire protection installations and equipment.

Permanently installed sterilizers, bedpan washers and disposal units.

Equipment in laundries, catering departments, workshops and any other plant or equipment used for maintenance or cleaning.

Piped medical gas and vacuum systems, cryogenic liquid systems (CLS) including vacuum insulated evaporators (VIE's) and anaesthetic gas scavenging systems.

Fixed luminaries including examination lamps.

Lightning protection and electrostatic discharge systems.

Incinerators and other clinical waste treatment equipment.

Environmental aspects (buildings) and the Control of Substances Hazardous to Health (COSHH) Regulations.

Installation aspects of fume cupboards and microbiological safety cabinets, including ductwork and their interaction with ventilation systems.

Fixtures and fittings which have been installed to prevent patients self-harming.

Incorrect installation.

Policy Checklist

Name of Policy:	Management of Medical Devices and Equipment
Purpose of Policy:	This policy set out the systems and processes for managing medical devices and equipment, including; investigation, minimising risk and promoting continuous improvement. The systems and processes extend across the whole life cycle of any medical device / equipment item (i.e. from procurement to condemnation).
Directorate responsible for Policy	Acute Services
Name & Title of Author:	Nigel McClelland, EQMS Lead
Does this meet criteria of a Policy?	Yes
Trade Union consultation?	Not Applicable
Equality Screened by:	N/A
Date Policy submitted to Policy Scrutiny Committee:	12 December 2011 and 26 March 2012
Members of Policy Scrutiny Committee in Attendance: Vivienne Toal, Head of Employee Engagement & Relations (Chair), Anne Brennan, Senior Manager, Medical Directorate, Trevor Burns, Fire Safety Manager, (Specialist Estates), (for Danny McKeivitt), Anita Carroll, Assistant Director of Acute Services – Functional Support Services, Claire Graham, Head of Corporate Records (for Siobhan Hanna), Carmel Harney, Assistant Director of Allied Health Professionals, Governance & Workforce Planning, John Rafferty, Acting Head of Residential Care (for Brendan Whittle)	
Policy Approved/Rejected/Amended	Approved
Policy Implementation Plan included?	Yes
Any other comments:	None
Date presented to SMT	02 November 2011
Director Responsible	Mrs E. Gishkori, Acute Services
SMT Approved/Rejected/Amended	Approved
SMT Comments	Nil noted
Date received by Employee Engagement & Relations for database/Intranet/Internet	27 March 2012
Date for further review	January 2017

POLICY DOCUMENT – VERSION CONTROL SHEET	
Title	Management of Medical Devices and Equipment
Supersedes	Craigavon Area Hospital Group Trust Policy for the Management of Medical Devices and Equipment
Originator	Patient Safety & Quality Manager
Scrutiny Committee & SMT approval	Referred for approval by: Equipment Management Steering Group Date of Referral: Scrutiny Policy Committee Approval: SMT approval:
Circulation	Issue Date: Circulated By: Issued To: As per circulation List (details below)
Review	Review Date: 2 years from approval Responsibility of: EQMS Lead

Version Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Details of Significant Changes
01	Craigavon Area Hospital Group Trust Policy for the Management of Medical Devices and Equipment
02	SHSCT Policy for the Management of Medical Devices and Equipment Included arrangements for new Trust and structures
03	SHSCT Policy for the Management of Medical Devices and Equipment
04	Review of policy Includes references to ISO 9001:2008 Includes appropriate references to ISO 9001:2008, cls 5.3 Includes a reference for the definition of the term "Medical Device" Lists locations covered by ISO 9001:2008 Includes responsibilities: for Quality Manager (EQMS Lead) Internal Auditor Reformatting of the document to best follow Trust guidelines

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1. Introduction

- 1.1. This document sets out the Southern Health and Social Care Trust's (hereafter referred to as 'the Trust') policy for the management of medical devices and equipment.
- 1.2. The arrangements within this policy outline the requirements to enable the Trust to comply with its own internal standards, the requirements of Medicines and Healthcare products Regulatory Agency (MHRA) and health and safety statutes.
- 1.3. To assist the Trust in meeting the above requirements the Trust has adopted BS EN ISO 9001:2008 Quality Management Requirements as a management system. (Please note exclusions detailed below).
- 1.4. The Medical Devices and Equipment Quality Management System (EQMS) operated by the Trust adopt a systematic and whole life approach to the acquisition, deployment, maintenance (preventive maintenance and performance assurance), repair, training and disposal of medical devices and equipment.
- 1.5. This policy has been developed in accordance with the Trust's key principles for policy development.
- 1.6. This policy has been developed in consultation with internal stakeholders.

2. Definitions

2.1. Medical Device:

The term 'medical device' covers a broad range of products including those used every day in most health and social care settings and is defined as¹:

"Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease

¹ Directive 2007/47/EC

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.”

2.2. Equipment:

Products that are not medical devices but are used in Health and Social Care settings by clients or users (e.g. stair lifts, blood tissue storage systems, fluid warming cabinets and some disinfecting and sterilising equipment) are included under the term “Equipment” in this policy.

2.3. Quality Management System:

A collection of business processes focused on consistently meeting customer requirements, enhancing their satisfaction and including processes for continual improvement of the system. It is aligned with Trust’s purpose and strategic direction.

3. Purpose and Aims

3.1. The purpose and aims of this policy are to:

- Ensure that the Trust has in place suitable and robust arrangements to support the whole life approach to the management of medical devices and equipment within the Trust (i.e. identification of need, procurement, maintenance, repair, renewal/replacement, trial, storage and disposal).
- Support the development and maintenance of local medical device/equipment user training, (incorporating aspects of risk management and incident reporting)
- Support the development and management of appropriate processes to manage medical device and equipment related information.
- Inform relevant staff of their responsibilities with respect to medical devices and equipment management

4. Policy Statement

- 4.1. To maximise benefits and minimise risks to patients and staff the Trust has implemented a quality management system certified to ISO 9001:2008 for the management of medical devices and equipment.
- 4.2. Organisational arrangements and responsibilities are clearly defined and encompass all aspects of the life of equipment and the associated quality and operational procedures. This will include:
- Assessment of need,
 - Specification of equipment,
 - Identification of funding
 - Procurement
 - Acceptance
 - Training and competency
 - Commissioning
 - Life cycle management, (storage, use, decontamination, maintenance, end of life)
- 4.3. This policy provides a framework for continuous improvement of both the medical device and equipment management service and the quality management system, through the establishment and annual review of:
- quality objectives,
 - customer satisfaction
 - service and quality process performance
 - planned internal audits and
 - the identification and control of non-conformance.
- 4.4. This policy will be reviewed at least 3 yearly.
- 4.5. The Trust promotes a culture of openness, transparency and learning in relation to medical devices and equipment management.
- 4.6. The Trust will maximise benefits, and minimise risks to patients, clients and staff through the management system of equipment and medical devices.
- 4.7. This policy is supported by the Management of Medical Devices and Equipment Quality Manual.

- 4.8. All relevant personnel will be made aware of this policy and the need to adhere to the relevant procedures

5. Scope and Exclusions of the Policy

- 5.1. This policy applies to all medical devices and equipment that are either:

- Owned by the Trust or
- Loaned to community clients
- Other arrangements for example, on loan to the Trust by device manufacturers or other providers

- 5.2. The policy applies to:

- all Trust employees must adhere to this policy and associated procedures.
- the management of medical devices and equipment across the Trust regardless of which Directorate is charged with responsibility for the control and use of medical devices and equipment.
- patients and their carers must also adhere to the principles of care and maintenance of medical devices and/or equipment where medical devices and/or equipment is on loan to patients.

- 5.3. The scope of the ISO 9001:2008 quality management system applies to:

- Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ
- Lurgan Hospital, 100 Sloan Street, Lurgan, BT66 3NX
- Daisy Hill Hospital, 5 Hospital Rd, Newry BT35 8DR
- South Tyrone Hospital, Carland Rd, Dungannon BT71 4AU

- 5.4. Exclusions to the Quality Management System

Clause 7.3 Design and development

- This clause do not apply as no design and development activities are undertaken within the management of medical devices and equipment

6. Responsibilities

- 6.1. Responsibility of the Chief Executive

The Trust's Chief Executive, as "Accountable Officer" has:

- overall responsibility for ensuring the aims of this policy are met.
- delegated the day to day responsibility for establishing and monitoring the implementation of this policy to Directors.
- responsibility for ensuring periodic review of the Trust management of medical devices and equipment systems and associated processes.

6.2. Designated Executive Director

The Acute Services Director:

- is the designated Executive Director with lead responsibility for the management of medical devices and equipment. This responsibility includes the need to ensure that there are sufficient resources in place for the effective implementation of this policy across the organisation.
- is the Chairperson of the Trust Medical Devices Management and Equipment Steering Group.
- will report to the Chief Executive on matters relating to the management of medical devices.
- is responsible for ensuring the EQMS is appropriate to the delivery of safe and effective health and social care.

6.3. Responsibility of Senior Management

All Trust Directors, Assistant Directors, Associate Medical Directors, Heads of Service and Senior Managers

- have responsibility for the effective management of medical devices and equipment within the areas of their remit and control, and for ensuring that processes are fully implemented and monitored as part of the Trust's integrated governance requirements.
- must ensure that they have adequate arrangements in place to meet the responsibilities of the nominated Department Equipment Controllers in relation to equipment management.
- have responsibility to ensure that information required in relation to affecting this policy is provided in an accurate and timely manner.

6.4. Responsibility of Quality Manager (referred to within Acute Services as the Equipment Quality Management System Lead, EQMS Lead)

The EQMS Lead will:

- have a lead role in the management of the Quality Management System for medical devices / equipment
- is to ensure on-going management and improvement of the system against the ISO 9001:2008 QMS requirements
- where non-compliance / risk issues are identified these must be escalated to the Designated Executive Director for appropriate risk management
- publish an annual Internal Audit Schedule
- have knowledge, skill and experience of a quality management system(s) (e.g. ISO 9001, ISO 14001, etc)
- be an internal auditor
- be a senior manager within the organisation

6.5. Responsibility of the Ward / Department Manager

Each Department / Ward Manager:

- is responsible for ensuring that the necessary arrangements are in place to comply with the safe use of equipment and medical devices from assessment of need through use to disposal.
- is responsible for ensuring the maintenance of all records, which are required to meet the requirements of the ISO 9001:2008 QMS requirements
- nominate a suitable clinician(s) to be Department Equipment Controller(s)

6.6. Responsibility of the Department Equipment Controller

There will be a dedicated Department Equipment Controller appointed within each ward or department. Whilst the roles and responsibilities are outlined within the Operational Procedures the key responsibilities of the Department Equipment Controller include the following:

- ensure that there is an up to date Asset Register in place by liaising with the Estate Services, Electro-Biomedical Dept. and advising of any changes (additions; disposals / transfers);

- ensure that all records pertaining to medical devices / equipment are properly managed and maintained. This will include the need for all decontamination records / training records being kept up to date;
- be involved in the commissioning medical devices and equipment as appropriate;
- be involved in the acceptance process for newly purchased equipment and conduct initial inspection when equipment is delivered to department.
- ensure that arrangements are in place to ensure that equipment needing repair or maintenance is brought to the attention of the ward/department manager
- ensure that there are effective / traceable processes in place for any medical device / equipment that leaves the location where the equipment is based.
- participate in internal and external audits of the EQMS.

6.7. Responsibility of an Internal Auditor

There will be dedicated Internal Auditors appointed within divisions/departments. Whilst the roles and responsibilities are outlined within the Operational Procedures, the key competencies and responsibilities of the Internal Auditor include the following:

- undertake Trust internal auditor training
- be a senior clinician/manager
- undertake scheduled internal audits within designated clinical areas/departments, in conjunction with the nominated Equipment Controller
- feedback the outcome of the internal audit to the Ward Manager (if they are not the designated Equipment Controller) and the Equipment Controller. Copy the internal audit tool to the above staff and the Head of Service
- agree a time bound action plan with the Equipment Controller where any non-conformities are identified during the internal audit
- forward the internal audit tool to the Equipment Quality Management Lead for logging onto the information system
- reschedule and undertake internal audits within agreed timescales, where it has not been possible to complete these due to clinical pressures

- participate in the Trust's Internal Auditor Forum as required.

6.8. Responsibility of Equipment Management Steering Group

- See Quality Manual

6.9. Responsibility of Equipment Management Working Group

- See Quality Manual

6.10. Responsibility of Trust Staff

All Trust staff have a responsibility to adhere to the principles and aims of this policy and ensure that they operate in accordance with its supporting procedures. This includes the need for staff to ensure equipment is properly looked after and used in accordance with manufacturer's instructions.

7. Legislative Compliance, Relevant Policies, Procedures and Guidance

7.1. This policy shall be read in conjunction with the following Trust documents:

- Medical Devices and Equipment Management Quality Manual
- Health and Safety at Work Policy
- Provision and Use of Work Equipment Procedure

7.2. Statutes, guidance, circulars and other publications relevant to this policy are listed in the HPSS Controls Assurance Standard for Medical Devices and Equipment, and can be located at www.dhsspsni.gov.uk.

8. Equality and Human Rights Considerations

8.1. This policy has been screened for equality implications as required by Section 75 and Schedule 9 of the Northern Ireland Act 1998. Equality Commission guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity so that greatest resources can be devoted to these.

8.2. Using the Equality Commission's screening criteria, no significant equality implications have been identified. The policy will therefore not be subject to an equality impact assessment.

8.3. Similarly, this policy has been considered under the terms of the Human Rights Act 1998, and was deemed compatible with the European Convention Rights contained in the Act.

9. Alternative Formats

9.1. This document can be made available on request in alternative formats, e.g. plain English, Braille, disc, audiocassette and in other languages to meet the needs of those who are not fluent in English.

10. Copyright

10.1. The supply of information under the Freedom of Information does not give the recipient or organisation that receives it the automatic right to re-use it in any way that would infringe copyright. This includes, for example, making multiple copies, publishing and issuing copies to the public. Permission to re-use the information must be obtained in advance from the Trust.

11. Records Management

11.1. This document is published under the Trust's "Guidance on the Development and Implementation of a Trust Policy" policy and is managed within the Trust's "Management of Medical Devices and Equipment Quality Management System".

12. Sources of Advice and Further Information

12.1. Further advice and information regarding this document can be obtained from the EQMS Lead (Acute Services).



Southern Health
and Social Care Trust

Management of Equipment and Medical devices

Operational Procedures Manual

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Appendix A: DEFINITIONS AND TERMINOLOGY

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GLOSSARY OF TERMS

AIDS	ANTI IMMUNE DEFICIENCY SYNDROM
CCU	CORONARY CARE UNIT
CRC	CAPITAL RESOURCES COMMITTEE
EC	EUROPEAN COMMUNITY
FEA	FAIR EMPLOYMENT AGENCY
GATT	GENERAL AGREEMENT ON TARRIFFS AND TRADE
HPSS	HEALTH AND PERSONAL SOCIAL SERVICES
HWIP	Health and Wellbeing Investment Policy

ICU	INTENSIVE CARE UNIT
ISO	INTERNATIONAL STANDARDS ORGANISATION
IT	INFORMATION TECHNOLOGY
MHRA	MEDICAL AND HEALTH PRODUCTS REGULATORY AGENCY
NHS	NATIONAL HEALTH SERVICE
NIAIC	NORTHERN IRELAND ADVERSE INCIDENTS CENTRE
MEAG	MEDICAL EQUIPMENT ADVISORY GROUP
PC	PERSONAL COMPUTER
PEL	PROFESSIONAL ENGINEERS LETTER
PPQ	PRE PURCHASE QUESTIONNAIRE
QMS	QUALITY MANAGEMENT SYSTEM
RSS	REGIONAL SUPPLY SERVICE
SOP	STANDARD OPERATING PROCEDURES
TDP	Trust Delivery Plan
UK	UNITED KINGDOM
WIMS	WORKS INFORMATION AND MAINTENANCE SYSTEM

1.0 INTRODUCTION

The Trust has a responsibility to implement the recommendations detailed within "Medical Device and Equipment Management for Hospital and Community Based Organisations" DB9904 (NI) guidelines and all subsequent supplements on how such devices should be suitably deployed, monitored and controlled.

The Quality Management System (QMS), based on ISO9001:2008 for Quality Management Systems, which incorporates this document embodies the arrangements established by the Trust to meet its responsibilities and addresses the full life management of Equipment, Medical and Non Medical, from the justification of need and procurement, through in-service life and on to it's ultimate disposal. The system is fundamental to establishing and maintaining a culture of safe, efficient and high quality management of all Equipment.

This QMS will be applied to the management of all Equipment and devices used by the Trust within its own estate or in the community by patients/clients/staff and shall include equipment and devices owned, on loan, hired, rented or donated.

The QMS for the Management of Equipment and Medical Devices will help ensure that :-

- Organisational arrangements and responsibilities are clearly defined and understood and documentation is effectively managed
- Where a need for new or replacement equipment has been identified an appropriate assessment is carried out
- Full specifications are developed and agreed for all aspects of equipment with appropriate input from professional users, service providers and technical experts to ensure equipment is suitable and fit for purpose
- Adequate funding is secured from the most appropriate source
- Procurement is carried out in accordance with current regulations and best practice
- The acceptance procedure is fully applied before equipment is accepted into the Trust
- Training needs are correctly assessed and fully met for all equipment, which is new to a professional user. The competence of each professional user is assured before they are permitted to use that piece of equipment.
- For end users who are in receipt of community equipment or equipment on loan from the hospital environment the Trust must have adequate systems in place for the issuing use and receipt of equipment.

- The commissioning process is completed and signed off by the Trust before any equipment is made available for use
- The in-service life of all equipment is fully managed in accordance with Trust requirements. This includes: storage; decontamination; use; maintenance and repair/modifications
- Appropriate measures are in place to determine the end-of-life of equipment and manage its safe disposal in accordance with applicable legislation.
- Equipment suppliers will be subject to providing manufacturers instructions and appropriate training in respect of the equipment procured by the Trust. This will include the following :-
 - Training
 - User operation
 - Storage
 - Decontamination
 - Maintenance/repair/modifications
 - Disposal

The overall process is depicted in Process Map EMPM1.1.

2.0 DEFINITIONS

For the purposes of the QMS for the Management of Equipment and Medical Devices the following definitions are used (further definitions are contained in Appendix A):

2.1 Medical Device

Medical Device: The term 'medical device' covers a broad range of products including those used every day in most health and social care settings and is defined as:

Any device, instrument, apparatus, implement, material substance, or other article (used singly or in combination), together with any accessory thereto, which is intended by the manufacturer for:

diagnosis, prevention, monitoring, treatment of alleviation of human disease or injury;

investigation or modification of human anatomy or of human physiological process; which does not achieve it's principle intended action by pharmaceutical means, but which may be assisted in it's functioning by such means

From Medical Device and Equipment Management for Hospital and Community Based Organisations" DB9904 (NI) July 1999

A more extensive list of products which fall within the definition of medical device is provided on the Northern Ireland Adverse Incident Centre (NIAIC) website

2.1.1 Equipment

Products that are not medical devices but are used in Health and Social Care settings by clients or users (e.g. chair lifts, community aids and appliances, blood tissue storage systems, fluid warming cabinets and some disinfecting and sterilizing equipment). These products fall under the term “equipment” in this document.

A medical device is any instrument, apparatus appliance, material or health care product, excluding drugs, used for a patient/client or client for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease or injury or investigation, replacement or modification of the anatomy or of a physiological process or used in the vicinity of a patient/client.

2.1.2.1 End - Users

An End – User is an employee, carer, patient or client who uses a medical device or item of equipment in a healthcare facility or at home (e.g. wheelchair, chair lift etc.) There are two types of end user referred to in this guidance as follows;

2.1.2.2 Professional User

A professional user is the term used for staff employed by the Trust who use medical devices and equipment as part of their day to day role. Specific user requirements are needed to ensure staff are skilled in using such equipment

2.1.2.2.1 End user (public)

Adverse Incident: Adverse Incidents involving medical devices and equipment can produce, or have the potential to produce, unexpected or unwanted outcomes that affect the safety of patients, service users or other people e.g.

- A patient, client, user, carer or professional is injured as a result of a medical device or equipment failure or its misuse.
- A patient's or client's treatment is interrupted or compromised by a medical device or equipment failure
- Misdiagnosis due to medical device or equipment failure leads to inappropriate treatment

- A patient's or client's health deteriorates due to a medical device or equipment failure.

Carer: Throughout this standard Carers is used to mean informal carers (i.e. family members or friends who are unpaid) and paid care givers such as home helps, care assistants etc. who provide help and support.

Client: Someone who enters the community health or social care system and is provided with medical device(s) or equipment (e.g. bath hoists, walking aids, chair lifts etc.)

Clinical Supervisor: A clinically trained person responsible for the safe use of a medical device or equipment (e.g. ward manager)

Duty of Care: All employers are subject to legal and statutory requirements relating to 'the duty of care' that require employers to provide competent and safe staff employees, safe equipment and places of work, and a safe system of work.

Medical Device and Equipment Management Procedure: A document including policies and responsibilities for purchase, acceptance, issue/recall, decontamination, maintenance, repair, tracking, monitoring and replacement of medical devices and equipment, training and actions needed in case of breakdown or adverse event. The aim is to ensure that whenever a medical device or equipment is used, it should be:

- Suitable for its intended purpose – "buy it right";
- Properly understood by the professional and end-user – "use it right";
- Maintained in a safe and reliable condition – "keep it right".

Professional user and end-user knowledge and skills have major implications for safety. Instructions must be clear, concise and readily available. Training should be timely and effective, and include procedures for the routine maintenance of medical devices and equipment by Professional and end-users.

2.2 Risk Management

A key objective of the QMS is to minimise the risk both to the patient and the user of the equipment by identifying the hazards and eliminating the risks associated with the use of a specific piece of equipment. Where risks cannot be eliminated they must be reduced to an acceptable minimum and suitable control measures identified and implemented. These control measures will consist of a combination of engineering methods, safe systems of work, information, instructions and training.

Factors which often increase risk and contribute to adverse incidents involving equipment include:

- Inadequate training/knowledge in the use of equipment
- Lack of awareness of Safety Action Notices/Hazards
- Inferior quality, worn out or obsolete equipment
- Inadequate servicing/maintenance
- Use of inappropriate consumables for the equipment
- Inadequate documentation and records of previous failures

The Trust's Risk Management procedures require that :-

- Suitable and sufficient recorded risk assessments are carried out and adequate controls are put in place.
- All identified risks should be documented as part of a 'risk register' and systematically assessed and prioritised.
- Risk treatment plans should be developed and implemented (in order of priority and alongside other risk treatments which are necessary to deal with wider risks faced by the organisation, where appropriate) in order to minimise risk.
- Risks and the effectiveness of implemented risk treatments should be monitored and reviewed on a continuous basis.
- Risk Management/Governance committee(s), senior management and the Trust Board should be informed of any significant risks and associated risk treatment plans.
- All relevant staff, including those on fixed term contracts, bank and agency staff and other relevant stakeholders should receive information on systems in place to minimise equipment risks.
- Where appropriate, staff training should be undertaken.

Good records need to be maintained at all times.

2.3 Management Structure / Roles and Responsibilities

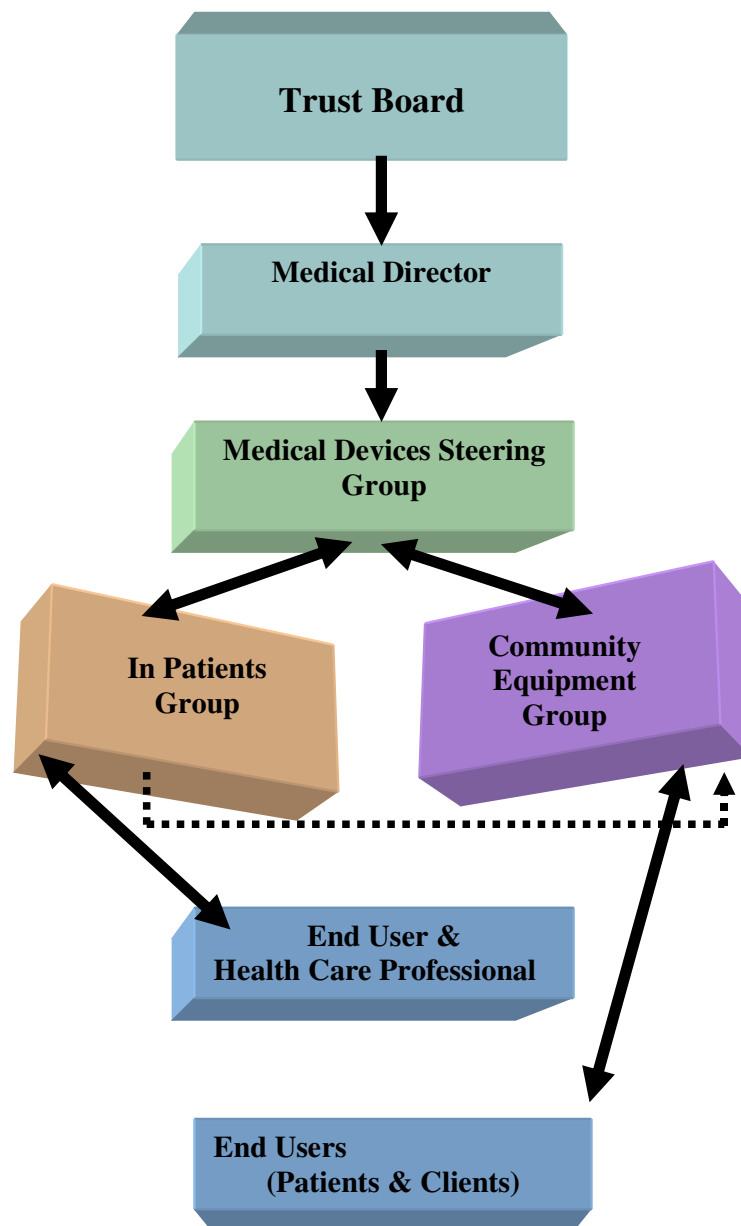
The Trust has a responsibility to ensure that an effective management structure exists for the Management of Equipment and Medical Devices.

The Senior Management Team oversees the risk management process and allocation of resources for the Trust. Part of their role is to:

- make informed decisions to support Trust-wide initiatives on medical devices and equipment;
- Ensure a training programme exists to meet the needs of specific staff and functions;
- To liaise with related groups and prioritise action against risk reporting on medical devices and equipment to the Trust Board
- Provide feedback to risk planning groups and staff on decisions taken or new development regarding medical devices and equipment

The roles and responsibilities of key personnel are recorded in the Trust Policy for the management of equipment and medical devices. Figure 1 illustrates the organisational arrangements and the roles of those elements critical to the management of Equipment.

Fig 1 Management Structure for Management of Equipment and Medical Devices



2.4 Responsibility for Equipment Management

The Trust Board has overall responsibility for the management of Equipment and medical devices.

2.4.1 Director designated as Accountable Officer

The Director designated as Accountable Officer for the Trust is the Medical Director. He will be supported by an overall Medical Devices Steering Group and two operational Medical Devices Committees (In-Patient Medical Devices Committee and Community Medical devices Committee)

2.4.2 Medical Devices Steering Group

This group is chaired by the Medical Director as the executive director with an overall responsibility for equipment and medical devices. They are supported by the operational directors who have a day to day responsibility to ensure the Trust agreed policies and processes are being adhered to.

This group has the overall responsibility for ensuring the strategic direction of the Trust in adherence to the Controls assurance standard for the management of equipment and medical devices, the maintenance of ISO accreditation and for providing assurances to the Trust Board on the management of equipment and medical devices. The terms of reference for this group is included in appendix xx

2.4.3 In Patient Medical Devices Committee

The aim of the In Patient Medical Devices Group is to support the medical devices Steering Group in ensuring a clear and systematic approach to all aspects of the purchase, use and maintenance of medical devices across in patient services within the Trust¹. It will bring together a range of stakeholders from different backgrounds to ensure the safe and effective use of all medical devices within the operational directorates.

This group will develop links with other committees as appropriate including the Trusts Health and Safety Committee, Infection Control Committee and external groups for example Health Estates Regional Group . the terms of reference for this group is included in appendix xx

TOR appendix xx

¹ In patient services are defined as all inpatient services which cut across the operational directorates of the Southern Trust. Namely, Acute hospital sites incorporating children's and neonatal in patient services, non acute hospital sites, mental health and learning disability in patient services.

2.4.4 Community Medical Devices Committee

The aim of the Community Medical Devices Group is to support the medical devices Steering Group in ensuring a clear and systematic approach to all aspects of the purchase, use and maintenance of medical devices within a community setting. It will bring together a range of stakeholders from different backgrounds to ensure the safe and effective use of all medical devices within the community setting including the patient/clients home.

- Develop links with other committees as appropriate including the Trusts Health and Safety Committee, Infection Control Committee and external Groups for example Health Estates Regional Group and the Regional Medical Devices Group
- Ensure that any supporting information and instructions re the safe use of equipment issued to patients/clients and that information is easily understood and complies with relevant standards. (For example Crystal Mark)

TOR for this group is included in appendix xx

2.4.5 Assistant Directors and Associate Medical Directors

All equipment must come under a specified operational directorate, which will include Equipment under Trust or Commercial ownership. The Assistant Directors and Associate Medical Directors have overall responsibility for ensuring the Trust's policy is implemented in relation to the management of equipment within their Directorate.

The Assistant Directors and Associate Medical Directors must ensure that they have in place arrangements to meet the responsibilities of ward/department equipment controllers in relation to equipment management. Responsibilities are set out below and should be met either through operational directorate staff or through the provision of technical and professional support outside of the Directorate.

2.4.6 Department / Ward Manager & Equipment Controller

Each Department / Ward manager is responsible for ensuring that the necessary arrangements are in place to comply with the requirements of the Quality Management system.

Responsibilities are set out in Appendix B.

2.4.7 Head of Operational Services and Medical Technical Officers

The Heads of Operational Services and Medical Technical Officers act in support of Directorates as required in dealing with technical aspects of equipment and co-ordination of external maintenance contracts and all in-house servicing of equipment. This incorporates maintenance, repair and modification of Equipment.

Responsibilities are set out in Appendix B.

2.4.8 Users – (Trust Employees)

Users of Equipment have clear responsibilities which include:

- Ensure the correct use and care of all equipment ensuring that, if required, routine checks or tests are carried out and documented before it is used
- Ensure that they adhere to all procedures relating to decontamination, operation, and maintenance of equipment
- Satisfy themselves that they are trained in the use of equipment and are competent and authorised to use it
- Ensure that the equipment is functioning correctly when in use, particularly life support equipment
- If equipment is not functioning correctly he/she shall withdraw equipment from service and inform the department manager and the technical Services department who will arrange for the equipment to be tested.
- Ensure that all defects and non-conformances are reported immediately to the Ward Manager/Equipment Controller
- Ensure all equipment is checked following servicing, before being put back into operation
- Where an incident has occurred that involves equipment. The equipment should be quarantined with all consumables. The technical services department should be informed and an Incident report form completed.

The term “user” does not refer to the client/patient unless otherwise stated

3.0 PROCEDURES

3.1 Introduction

The following procedures should be followed to ensure uniformity of the management of medical devices and equipment across the Trust in line with the roles and responsibilities of managers and heads of departments. This section is divided into the following areas:

- Selection & Appraisal of medical devices and equipment
- Acceptance of medical devices and equipment prior to their first usage
- Training for professional users of equipment
- Servicing requirements and record keeping
- Other procedures

3.2 Selection and Appraisal of Medical Devices and Equipment

ref: Process Maps

Requests for Equipment EMPM2.1

Equipment Specification Process EMPM2.2

Purchasing Decision Process EMPM2.3

Equipment Procurement Process EMPM2.4

Rationale: To ensure that the agreed selection and appraisal process is in place for the procurement of all medical devices/community equipment. It is important to ensure that;

- new equipment adequately meet the requirements of staff and patients.
- equipment can be easily used and that full training is available
- equipment is basically similar to that already in use
- the variety of similar devices to a minimum
- Consideration is given to the cost of accessories such as giving sets

All medical devices must be prescribed by appropriately qualified staff with suitable experience.

3.3 New Medical Equipment.

(a) Replacement of existing equipment

ref: Process Map

Managing the Return of Equipment Loaned to Patients
(Process Map EMPM2.5)

Consideration to replace medical devices should be done when any of the following criteria apply:

- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliable (check service history)
- Clinically or technically obsolete
- Spare part no longer available
- More cost effective or clinically effective devices have become available
- Unable to be cleaned effectively prior to disinfection and/or sterilisation.

The final decision for condemning a piece of equipment rests with Estates and all equipment should be sent to Estates for that process to start

1. A condemn note is written up
2. A cost for similar replacement is acquired
3. Use the PPQ form to get as much information as possible about the equipment
4. Ask for the loan of equipment so that it can be properly appraised whilst on loan
5. When a device meets any of the criteria and requires replacing a bid to the medical equipment advisory group using the appropriate documentation must be made
6. Complete a Pre Purchase Checklist (PPC) form to accompany the order form.
7. An order is placed

b) New Equipment

Ordered as additional equipment and not as a replacement

Carry out appraisal exercise and complete above documentation

c) Loan Equipment

Definition:

There are three types of loan equipment within the organisation as follows

- (i) equipment loan between departments which is already owned by the Trust
- (ii) equipment on loan or hire by external companies (generally comes from the service company when trust equipment is going for repair.)
- (iii) community equipment loaned by the Trust to patients and clients

An indemnity form should be completed and filed with the technical services department (b) or the community equipment store (C)

Relevant Forms:

Internal Equipment Loan Form STIEL-01

Equipment Loan Indemnity Form STELIF-01

d) Appraisal Trial Equipment

Generally supplied by the companies for appraisal purposes only prior to purchase, an Equipment Loan indemnity form should be completed and filed.

e) Modifications to and Trials of New Equipment

Medical devices and equipment must not be modified without consultation with the Trusts technical officers or the manufacturer.

All equipment on loan or on trial from a manufacturer must be logged with the Trusts Estates Department prior to its use.

3.4 Acceptance Procedures

Acceptance procedures are needed to ensure pre-use checks and verification of equipment before it is used in clinical or social care.

Michael Ross / Jim Crozier / Equipment controller.

Receipt in stores. Technical check and ward /dept acceptance.

More detail

ref: Process Map

Equipment Acceptance Process (Process Map EMPM 2.6)

Equipment Commissioning Process (Process Map EMPM 2.7)

Relevant Form:

Equipment Acceptance/Movements Form STEAM-01

Rationale To ensure All equipment should be checked by the nominated medical devices and equipment officers prior to use for the first time. Nominated equipment officers are as follows:

- a) Estates Technical Officers for acute site equipment; and
- b) Stores Manager for Community Devices/Equipment

All professional users and end-users should be provided with the manufacturers instructions.

3.4.1 Acceptance procedures for in patient sector for Equipment/Device

Pre hand over checks

Before any equipment is passed to the professional **end user** for use it must first be checked by Technical staff. After it has been checked and is fit for use it will be handed over to the ward /department equipment controller.

Technical staff who have checked the device(s) will complete form 'Equipment Acceptance/Movements Form STEAM-01' with the end user receiving the device/equipment.

3.4.2 Acceptance procedures for Community Equipment/device

Pre hand over checks

Before any equipment is passed to the end user (patient or client) for use it must first be checked by the community stores staff. After it has been checked and is fit for use it will be issued from community stores. (additional final checks will be made in the patients home as part of the delivery and assembly procedures).

3.4.3 Community Issues: Installing electrical medical devices and equipment into the patients/clients home

- Equipment will be prescribed by appropriately qualified staff .
- Only approved equipment should be issued.
- Before Community staff issue electrical equipment , the following measures must be taken;
 - a. The clients electrical supply
 - The trust is required to ensure that the clients electrical installation is safe before any electrically powered equipment is issued. (who does this at present)
 - b. The equipment
 - should be correctly unpacked and assembled
 - All leads and or accessories should be in place before connecting to mains supply
 - Should be tested to ensure It is operating safely
 - Must have an agreed service schedule in place before equipment is used
 - Should be labelled appropriately
 - end-users (patients or carers) should be provided with instructions for use and must sign a statement to the effect that they have received instructions on the safe use of the device or equipment provided. (name)

3.5 Training

ref: Process Map

Training in Use of Equipment (Process Map EMPM 2.8)

Relevant Forms:

Versatility / Competence Chart STVCC-01 to 04

Competency Element Review Form STCEARF-01

Individual Training Record Form STTRF-01

Training record Form-Group (the vendors document)

Rationale Anyone who uses medical devices shall have adequate information made available to them in order that they can use the medical device safely.

- Training will enable the staff member to use the medical device without risk of injury or harm to themselves or others. Some medical devices may have written instructions supplied by manufacturers attached to the device and others may require local standard operating procedures to be written.
- The information to be given to the staff member shall also include instructions on decontamination where relevant. Further advice from the decontamination manager must be sought before decontamination protocols are developed
- Any training must include action to be taken in the event of a foreseeable abnormal situation arising.
- Some types of medical devices will require training to be given from an external company in the first instance, which may be cascaded down through the department by specific members of staff who have received training from the company.
- Any medical device that was brought into use by the Trust from 31 December 1992 must conform to the European Community requirements and as such are usually marked by the manufacturer with a CE mark. Any medical device that is purchased must be accompanied by relevant certificates or declarations, carry a CE Marking and should have information about any residual hazards.
- Staff who have not had documented training from an approved person should not be using medical equipment. The guidance is very specific about training. For further information refer to DB9904 (NI) July 1999 & the Controls Assurance Standard for the Management of Medical Devices. First hand training may be given by the vendor's trainer. With critical equipment, the trainer may have to call back on more than one occasion so that all staff are properly trained
- Estates staff will also be given technical training so that they can assist staff with technical problems.

- all training details must be documented and records should be retained
- It is recommended that training provided by the manufacturer should cover the following:
 - why the device is used
 - what the device is intended to do
 - what the device can be reasonably be expected to do.
 - when it is appropriate to use the device
 - how the device should be set up
 - what disposables or accessories should be used
 - the used protocols, operation and interpretation
 - the safety features and the need for them
 - how and why alarms are used
 - how to identify serious and spurious alarms
 - how to deal with and set alarms.
 - how to recognise likely causes of failure
 - how to identify reason for failure
 - identification of common operational mistakes
 - how to consult the operators manual
 - what to do when in difficulty
 - how to recognise an adverse incident
 - how to deal with an adverse incident

Note: the MHRA document “ Devices in Practice” on Trust Intranet Equipment Management section of the Medical Directorate

3.6 Servicing Arrangements

All medical devices must be maintained to a standard where they are safe to use. Equipment Controllers need to ensure that all high risk equipment and medical devices are catalogued correctly and are part of an ongoing maintenance/service programme (this is normally using the Trust asset recording system and Estates maintenance/service programme).

ref: Process Map

Equipment Repair/Service/Maintenance Process (Process MapEMPM 2.9)

Relevant Forms:

Equipment Service Detail (STESD-01)

3.6.1 In patient sector

- an agreed management structure for servicing arrangements with clearly defined responsibilities for nominated staff. Ward and Department managers have an overall responsibility to ensure that the equipment used in

their area of responsibility is properly maintained, serviced and fit for use.

- agreed service contracts must be in place for all equipment so that regular inspections and routine servicing are carried out on a routine and controlled basis. Service contracts are usually agreed at the point of purchase and registered with the technical services department. The technical services department will ensure a log of servicing and maintenance schedules is maintained. (Servicing and maintenance will be completed by either the in house technical services department or external manufacturers or their agent.)
- a reporting system to avoid oversights maintained by the technical services department (use of e-repair request system)
- a procedure for reporting adverse incidents involving equipment /medical devices. This is incorporated into the Trusts single system of reporting adverse incidents.
- a procedure for dealing with decontamination issues.

Permit to Work – Decontamination of Equipment (STPTWF-01)

Rationale All equipment being sent for repair or maintenance must be decontaminated to the standard outlined in the decontamination procedures. This will enable technical staff to work safely and effectively whilst servicing and/or repairing the piece of equipment. This is the responsibility of the ward/department manager and requires the following elements:

3.6.2 Arrangements for servicing medical devices/equipment in in patient sites

- Service contracts will be agreed and processed by estates in agreement with nursing staff.
- Estates staff will maintain all relevant documentation on the servicing and repair of equipment (with exception of Laboratories and Radiology)
- The details held will advise who the service company is, when the service contract is due to begin and the number of visits to be carried out.
- When a service engineer arrives on site he will report to Estates staff and will be issued with a badge / pass. No engineer should be permitted to work at equipment unless he can furnish a current badge.
- The engineer will go to the ward and report to the ward manager or their deputy.

- The schedule and tick sheet should be handed over to the engineer.
- At the end of the visit the engineer will report back to the ward manager. The ward manager will ensure that the tick sheet is fully signed up, sign all service sheets and file copies of all reports in the appropriate section of the folder.
- The person, who is accepting the reports should carefully read all reports before signing them. They should also identify all equipment that is absent and has not been serviced and make arrangements to have it attended to. Any difficulties are to be addressed to Estates staff.
- At the end of the service the engineer shall report back to Estates staff and be signed off.
- When invoices are received for payment they will be forwarded to Estates staff who will authorise payment and file a copy of the service report.

3.6.3 Arrangements for servicing Community Medical Devices

- Community Stores staff will maintain all relevant documentation on the servicing and repair of equipment
- agreed service contracts for all equipment are in place so that regular inspections and routine servicing are carried out on a routine and controlled basis.
- a tracking system is in place to record when equipment leaves the department or store and will identify its destination (MESALS community equipment management system).
- a precise inventory, detailing the name, address & phone number of the patient /client
- a procedure for reporting adverse incidents involving equipment /medical devices. This is incorporated into the Trusts single system of reporting adverse incidents.
- a procedure for dealing with decontamination issues, as per the Trusts decontamination practices
- a system that will ensure that new equipment is logged on to a centrally held inventory and old equipment is logged off (MESALS)
- a protocol to ensure that once equipment is no longer required, that it is removed from the home, decontaminated and serviced and recorded on the register for reissue. .

3.6.3 Arrangements for servicing medical devices/equipment within the patient/clients home

- Service contracts will be agreed and processed by estates in agreement with community staff.
- When a service engineer arrives at the clients home s/he will report to the client or their carer .The service engineer will be issued with a badge / pass. No engineer should be permitted to work at equipment unless he can furnish a current badge.
- The engineer will issue a report to the client or their carer and a second copy to the estates services department.
- At the end of the service the engineer shall report back to Estates staff and be signed off.
- When invoices are received for payment they will be forwarded to Estates staff who will authorise payment and file a copy of the service report.

3.6.4 Repair arrangements

Rationale All equipment being sent for repair must be decontaminated to the standard outlined in the decontamination procedures. Equipment being sent for repair must be clearly labelled with the red equipment do not use label. See appendix xx

3.7 Indemnity ?????

The Chief Executive is the authorised officer whose signature and that of one other Director is required to sign deeds when indemnity agreements are required. However, in day to matters this responsibility is delegated to the Manager of the relevant service who will retain copies of all completed indemnity forms.

3.8 Storage

Equipment, along with relevant accessories, should be stored in a designated safe storage area in each department/ward area and a record kept of medical devices inventory, repairs etc. In the patients home equipment should be stored appropriately and only used for the purpose that it was supplied.

3.9 Decontamination

ref: Process Map & Infection Control Manual

Equipment Decontamination Process (Process Map EMPM 2.10)

Relevant Forms

Permit to Work – Decontamination of Equipment STPTWF-01

The issues on cleaning, decontamination and sterilising are covered in the Decontamination policy. Methods of decontamination of all medical devices must be assessed prior to loan and/or purchase of medical devices to ensure that the Trust can decontaminate all medical devices to the required standard prior to repair internally or externally.

3.10 Single Use Medical Devices

ref: Process Map

Single Use Devices (Process Map EMPM2.11)

- A single use medical device is intended to be used on an individual patient/client during a single procedure and then discarded. It is not intended to be reprocessed and used on other patient/clients. The labelling identifies the device as disposable and not intended to be reprocessed and used again. The Single Use symbol on the packaging of medical devices means that the manufacturer:
 - Intends the device to be used once and then discarded
 - Considers the device is not suitable for use on more than one occasion
 - Has evidence to confirm that reuse would be unsafe.
- Single Use Symbol here
- The MDA defines single patient/client use as more than one episode of use of a medical device on one patient/client only, the device may undergo some reprocessing between each use.
- Single patient/client use devices shall only be used for the period or usage stated by the Manufacturer or for the period indicated by the Trust, whichever is the shorter. Where reprocessing is allowed by the Manufacturer, this shall be in accordance with Manufacturer's instructions. Single patient/client use devices shall not be used on more than one patient/client.

3.11 Patient/Client Equipment Prescribing

See (Process Map EMPM 2.12)

Equipment will only be prescribed by professionally qualified staff. E.g. Occupational Therapists, Physiotherapists, Dietician, Nurse

3.12 Equipment Developments, Modifications & Trials

Note that this process is limited to Biomedical engineers only, and all external requests for research regarding equipment developments, modifications and trials will be processed by the Trust's research

governance committee (for further information see controls assurance standard on Research and Governance)

See (Process Map EMPN 2.13)

3.13 Specific Risks

There are medical devices which pose a significant risk to patient/clients because of the risk of an adverse clinical outcome if it is used inappropriately. In these cases only those staff who have received training specific to the use of such medical devices are permitted to use it.

High risk type of equipment

Moderate risk types of equipment

3.14 Incident Reporting

- Staff should refer to the Procedure on the Management of Adverse Incidents. Any incident that happens involving a medical device must be recorded on the Trust Adverse incident form.
- Equipment and all attachments must be quarantined from further use until such time as it is allowed back into use. Equipment should be placed in a clear plastic bag with a do not use label attached. See Appendix xx Any equipment that is quarantined will be stored in the Estates department.
- Under no circumstances must equipment be given to manufacturers unless there has been authorisation by the risk manager or Estates department. Equipment is not allowed to be given to the manufacturer until such time as the NIAIC, MDA or other relevant body have given permission for the equipment to be released.
- The Trust will only allow equipment to be put back into use once the investigation has been completed and it is deemed safe for the equipment to be used again. In some circumstances and in particular where there is no fault with the equipment this can happen very soon after the event but in other situations where there is a risk of mechanical failure it may take some time. The estates department may require the manufacturer to be involved in the investigation but in any case NIAIC or the MDA are the authorising officer for release of equipment either back into use or to be released back to the manufacturer for their investigation.
- The estates department must be sent a copy of the incident form and if equipment has been involved in an incident or there is a problem with the device estates must be notified. Estates will undertake a non invasive check of the equipment for those devices

that are involved in incidents so that any further tests done by NIAIC, the MDA or Manufacturer are not compromised.

- Where incidents have serious repercussions they must be reported to other agencies such as NIAIC by the Trusts NIAIC Liaison Officer. In these circumstances medical devices must not be discarded but kept in a safe place and only handed over to a member of Trust staff. The incident should be reported immediately to the Central Reporting Unit so that the necessary follow up action is taken.

4.0 TRANSFER and DISPOSAL of USED EQUIPMENT

Note: Once equipment is no longer fit for purpose it should be condemned using the Trust equipment condemn procedures. Equipment cannot be replaced until a condemn note has been issued by the Estates department

ref: Process Map

Equipment Condemns & Disposal Process (Process Map EMPM 3.1)

Relevant Forms:

Equipment Condemns Form (STEC-01)

4.1 Condemning

Where a ward or department wishes to condemn and dispose of Equipment then they should contact the Estates Management Department to have the Equipment inspected.

The Estates Management Department will issue the Condemns/Surplus notice together with the relevant label to attach to the Equipment. The Department Equipment Controller shall remove the Equipment from service. The Department Equipment Controller shall arrange for the Equipment to be removed.

4.2 Decommissioning of complex equipment

Complex equipment may need to be decommissioned (e.g. large Radiology or Laboratory equipment which may contain hazardous substances). This requires the device to be decontaminated, made safe and made unusable so that an inappropriate person does not use the Equipment and expose themselves to potential hazards.

4.3 Disposal

The removal and safe disposal of any device needs to be considered under the Special Waste Regulations.

- Wastes containing metal
- Oil Wastes
- Waste from coolants
- Batteries
- Radioactive waste

- Waste from human or animal healthcare and/or research
- Waste from natal care, diagnosis or prevention of disease in humans

Consideration also needs to be given European Directive on Waste from Electrical and Electronic Equipment and the transport of Equipment prior to disposal i.e. returning to manufacturer.

4.4 Transfer of Old or Obsolete Equipment

The Trust must be indemnified against future liability of Equipment that is of no longer use to the Trust and is being sold or donated. For each device being transferred Directorates must ensure that:

- The Trust's disclaimer letter is completed.
- Transfer information is provided to the prospective purchaser whether for selling or donation.
- Where appropriate and depending on the risk of the device this should include:
 - Documentation of decontamination,
 - User manuals and training requirements,
 - Service history and manual,
 - Quality assurance test details

5.0 PERFORMANCE AND MONITORING AND IMPROVEMENT

Note: This section refers to the arrangements for equipment management performance management and improvement aligned to ISO9001:2000 Quality Management System.

5.1 Document Control

Arrangements for Document Control are set out in Appendix D. This includes procedures to be followed in respect of Equipment specific documentation:

- Manufacturers instructions
- User instructions / Standards Operating Procedures (SOP's)
- Training documentation and records
- Device Alerts (NIAIC)
- MHRA Reports (Medicine & Healthcare Products Regulatory Agency)
- Decontamination documentation and records
- Maintenance procedures and records
- Post Purchase Questionnaires (PPQs)

The following types of document relating to the Quality Management System for Management of Equipment and Medical Devices are also covered :

- Quality policy
- Quality procedures

5.2 Key Performance Indicators for Quality Management

ref: Process Map Process Map 1.4 outlines the process to be followed.

Key Indicators for Quality Management (Process Map EMPM 4.1)

Arrangements with respect to monitoring the performance of the Quality Management System will be determined by the Equipment and Medical Devices Management Steering Group. Where Equipment is to be monitored it will be selected on a sample basis based on Risk. The controls assurance Standard recommends that key performance indicators are developed and measured. The standard outlines the most appropriate indicators for each piece of Equipment as follows:

- Outputs from Process Audits
- Incidents per device
- Breakdowns per device
- Lost hours per device
- % of staff trained per device
- reductions in models for device
- device usage data
- compliance with the Controls Assurance Standard for Medical Devices and Equipment

At present there are no regional performance indicators developed.

5.3 Benchmarking

The Trust should, where appropriate, establish mechanisms to enable the performance of the Quality Management System to be benchmarked against other Trusts. At present there are no benchmarking systems available.

Key benchmarks may include –

- Holdings of Equipment per patient treated
- Maintenance costs as a %age of value of Equipment held

The data will assist the Trust to –

- Determine the cost effectiveness of the arrangements
- Identify best practice
- Identify opportunities for potential financial savings

Action Plans should be developed as appropriate.

5.4 Quality Management System (QMS) Assurance of Performance

The Medical Devices Steering Group will provide assurances, at least annually, to the Governance Committee of the Trust via the senior management team with respect to –

- Accountability arrangements
- Processes, including risk management arrangements
- Capability
- Outcomes
- Internal audit annual assessment of controls assurance standard findings

The Quality Management System is accredited to ISO 9001:2008 for Quality Management Systems and as such audited annually by an external accreditation body. This provides the Trust with independent verification of its performance with respect to Equipment and medical devices.

The Trust has a programme of Process Audits which are used to monitor the performance of the QMS on an on-going basis and identify opportunities for improvement.

Specific aspects of the Quality Management System assessment will also be used by the Internal Audit Department as appropriate to verify the level of compliance with the controls assurance standard

5.5 Quality Management System (QMS)– Continuous Improvement

Continuous improvement is a core principal of the QMS. In order to promote this a number of tools will be utilised which may include:

- Customer and User satisfaction monitoring
- Supplier performance monitoring
- Management focus on improvement
- Analysis of Benchmarking and Key Performance Indicator data
- Process auditing
- Improvement target setting and monitoring

Appendix A: DEFINITIONS AND TERMINOLOGY

The following terms have been defined for the purposes of these procedures

Carer:

Informal carers (i.e. family members or friends who are unpaid) and paid care givers such as home helps, care assistants etc. who provide help and support.

Client:

Someone who enters the community health or social care system and is provided with medical device(s) or Equipment (e.g. bath hoists, walking aids, chair lifts etc.)

Community Healthcare:

Any healthcare provision outside Hospital, including private nursing homes and practices.

Medical Device and Equipment Management Procedure:

A document including policies and responsibilities for purchase, acceptance, issue/recall, decontamination, maintenance, repair, tracking, monitoring and replacement of medical devices and Equipment, training and actions needed in case of breakdown or adverse event. The aim is to ensure that whenever a medical device or Equipment is used, it should be:

- Suitable for its intended purpose – “buy it right”;
- Properly understood by the professional and end-user – “use it right”;
- Maintained in a safe and reliable condition – “keep it right”.

Professional user and end-user knowledge and skills have major implications for safety. Instructions must be clear, concise and readily available. Training should be timely and effective, and include procedures for the routine maintenance of medical devices and Equipment by Professional and end-users. Planned preventative maintenance, carried out following manufacturers guidance by properly trained technicians, is the other key element in ensuring medical devices and Equipment are safe and reliable. Professional users and technicians need to understand the basic principles on which medical devices and Equipment work (generic training) as well as how to use a particular model (specific training). End-users generally need to understand how to use a particular model (specific training). Training programmes should where possible include input from manufacturers. Where appropriate all medical devices and Equipment should be cleaned, disinfected and/or sterilised in accordance with the latest decontamination guidance.

Device Provider:

An organisation which issues Equipment to an end-user (e.g. disablement services centre).

Device Purchaser:

An organisation, which buys or leases products from the supplier.

End-user:

A patient or client who uses a medical device or item of Equipment at home (e.g. wheelchair, chair lift etc.)

Equipment Controller:

For Clinical departments this should be a clinically trained person.

Medical Device:

The term 'medical device' covers a broad range of products including those used every day in most health and social care settings and is defined as: -

Any device, instrument, apparatus, implement, material substance, or other article (used singly or in combination), together with any accessory thereto, which is intended by the manufacturer for:

- i. diagnosis, prevention, monitoring, treatment of alleviation of human disease or injury;
- ii. investigation or modification of human anatomy or of human physiological process; which does not achieve it's principle intended action by pharmaceutical means, but which may be assisted in it's functioning by such means

A more extensive list of products which fall within the definition of medical device is provided on the Northern Ireland Adverse Incident Centre (NIAIC) website at www.dhsspsni.gov.uk/niaic

Non-medical Device:

All Equipment/devices which falls outside the definition of a medical device but which requires to be services, tested or inspected or any Equipment/device which is required to have a service history.

Planned Preventative Maintenance:

Servicing operations carried out at fixed intervals by technical staff.

Prescriber:

A person who decides which is an appropriate medical device or item of Equipment for a given patient or client (e.g. nurse, occupational therapist etc.)

Professional User:

The professional user are trained staff who operate a medical device or Equipment for the benefit of a patient or client. (e.g. doctor, dentist, surgeon, nurse etc.)

Supplier:

The manufacturer, or their agents.

Routine Maintenance:

Inspection and device care operations carried out by end-users and professional users.

Technical Supervisor:

People with technical or managerial roles in device/Equipment management. They can be in charge of acceptance testing, installation, repair and maintenance (e.g. estates officers, biomedical engineering staff).

User organisation:

A device purchaser (either buys or leases the device or Equipment from the supplier) that either uses the medical device or Equipment, issues them to end-users or loans them to end-users (e.g. HSS Trust)

Newly Delivered:

The term “Newly Delivered” refers to any medical device/Equipment used by the organisation whether it is purchased, leased, rented, on loan, on trial, or donated.

Medicines and Healthcare products Regulatory Agency (MHRA):

An Executive Agency of the Department of Health (England) was created on 1 April 2003 from the merger of the Medicines Control Agency and the Medical Devices Agency. The MHRA helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union. As the UK Competent Authority, MHRA has statutory responsibilities and powers under the UK Regulations for medical devices that it exercises across the whole of the UK.

Northern Ireland Adverse Incident Centre (NIAIC):

Part of Health Estates, an Executive Agency of the Department of Health, Social Services and Public Safety (DHSSPS). On behalf of the DHSSPS, NIAIC is the focal point for the reporting of adverse incidents involving medical devices, non-medical Equipment, plant and buildings in Northern Ireland. NIAIC works closely with the MHRA² concerning medical device safety and with NHS Estates for issues concerning estates systems.

The primary objective of NIAIC is to improve the quality of health and care provided to the community by improving safety and effectiveness in using medical devices in the HPSS and wider health and social care community.

² The MHRA is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

Appendix B: Responsibilities

Equipment Management Quality Co-ordinator Responsibilities

The Equipment Management Quality Co-ordinator has a key role in the management of the Quality Management System for Equipment which includes the following tasks:

- Co-ordinating the on-going management and improvement of the Quality Management System
- Meetings – setting up and servicing the Equipment and Medical Devices Management Steering Group
- Information – define information / documentation requirements and ensure that each Directorate has nominated a person/ persons who will keep documents up-to-date, e.g. Equipment manuals, training records, safety notices and device bulletins, text books, etc.
- Risk – ensure arrangements are in place such that Equipment related risk issues are represented on the Trust Risk Management Group and those arrangements cater for identification and management of all such risks at department level. (Arrangements should cover: devise protocols, visit wards, apply protocols, repeat visits to ensure action is taken to reduce risk, etc.)
- User/technical department interface – ensure good lines of communication are maintained between users and maintenance organisations.
- Quality Management System – management of QMS to ensure compliance with: Controls Assurance; External accreditation requirements; Trust requirements.
- External Accreditation Bodies – liaise with external accreditation bodies
- Process Audits – Identify Audit Team; arrange training of auditors; manage audit programme; ensure non-conformances are reviewed and addressed
- Benchmarking the performance of the QMS.

Department / Ward Manager

Each Department / Ward Manager is responsible for ensuring that the necessary arrangements are in place to comply with the safe use of equipment and medical devices from assessment of need through use to disposal. The department /ward manager will also be responsible for maintaining any records in order to meet the requirements of the Quality Management system ISO accreditation inspection and the controls assurance standards.

Responsibilities of the Department / Ward Manager include:

1. Ensuring that all Quality Management System procedures are adhered to in respect of Equipment Management
2. Ensuring the effective management of all records and documentation in respect of Equipment
3. Ensure satisfactory arrangements are in place for the execution of the role of Equipment Co-ordinator and Equipment Controller
4. Identification of Equipment needs / completion of needs assessment
5. Involvement and preparation and submission of Business Cases

6. Ensuring completion of Commissioning Process for new Equipment
7. Ensuring appropriate training in Equipment usage is provided for all staff in respect of Equipment they are required to use
8. Monitor compliance with decontamination procedures
9. Ensuring competence of all users of Equipment addressing deficiencies as appropriate. Maintain records of training and competence in respect of Equipment users
10. Ensuring that all equipment is repaired and maintained as necessary.(with the support of the biomedical engineering departments)
11. Participating in Internal Process Audits and External Audits as necessary
12. Identifying deficiencies and improvement opportunities in respect of the Equipment
13. Identifying deficiencies and improvement opportunities in respect of QMS

Execution of the responsibilities of the Department / Ward Manager may require engagement with other departments and, where appropriate, delegation of some tasks. (In some cases the Department Ward Manager may delegate these duties to a member of their staff who will assume the role of Equipment Controller).

Responsibilities of Equipment Controller

There will be a dedicated equipment controller in each ward or department. their main responsibilities will be to:

1. Maintain an up to date inventory by liaising with the Estates Management Department and advising of any changes (additions; loans; disposals/transfers).
2. Conduct annual reviews of the Asset Register as directed (ensuring all Equipment is asset tagged).
3. Manage of Equipment interdepartmental loans.
4. Provide input to the Equipment Co-Ordinator and Supplies Department from an early stage in the process of selection of new or replacement Equipment.
5. Provide input to the Equipment Co-Ordinator in the preparation and revision of a planned replacement programme.
6. be involved in commissioning equipment and medical devices as appropriate.
7. Conduct initial inspection of new Equipment delivered to department.
8. Liaise with the Equipment Co-Ordinator with respect to all aspects of the maintenance and servicing of Equipment and verify that arrangements made for servicing the Equipment reflect the interest of the user.
9. Ensure that all records pertaining to Equipment are properly managed and maintained.
10. Ensuring that all equipment needing repair or maintenance is brought to the attention of the ward/department manager
11. Participate in Process Audits of QMS.

Estates Department Responsibilities

The estates Department includes the provision of biomedical engineering departments.

The Biomedical engineering departments act in support of ward/department staff as required in dealing with technical aspects of Equipment and medical devices. They also co-ordinate internal and external maintenance arrangements and all in-house servicing of Equipment. This incorporates preventative maintenance, and repair of Equipment. Responsibilities include:-

- Advising ward and department managers, heads of service, assistant directors and directors on the selection, servicing, repair and modification of Equipment
- Input into the suitability of service contractors
- Ensuring “in-house” maintenance and repair systems are in place.
- Advising on the technical content of external maintenance contracts
- Management of effective service/maintenance regimes, through internal and/or external providers

Further responsibilities of the estates department include:

- Ensuring appropriate measures are in place to test the electrical safety of Equipment. (this will also include the training of staff in the community to test electrical safety in the patients home)
- Ensuring that servicing and calibration is carried out where appropriate
- Monitoring of service contracts and supplier performance
- Maintaining inventories and asset registers where appropriate
- Safety of Equipment on loan or trial from equipment and medical device companies.
- Liaison with NIAIC via the Trusts Liaison Officer

Appendix C: TERMS OF REFERENCE

Equipment and Medical Devices Steering Group

In Patient Medical Devices Committee

Community Medical Devices Committee

Appendix F: Equipment Labels

To be used with faulty equipment or equipment involved in an incident

	Equipment Management DO NOT USE THIS EQUIPMENT PLEASE CONTACT THE DEPARTMENT EQUIPMENT CONTROLLER Decontaminated Service Engineer Signed: _____ Date: _____ ☐

Appendix H: Related Documentation

The following related documentation is referenced from within the procedure manual:
Forms

PC Request Form (MD-ITF-01)

Equipment Acceptance/Movements Form STEAM-01

Internal Equipment Loan Form STIEL-01

Equipment Loan Indemnity Form STELIF-01

Versatility / Competence Chart STVCC-01 to 04

Competency Element Review Form STCEARF-01

Training Record Form STTRF-01

Training record Form-Group (STTRFG-01)

Permit to Work – Decontamination of Equipment STPTWF-01

Pre Purchase Checklist (PPC/1)

Equipment Condemns Form (STEC-01)

Equipment Service Detail (STESD-01)

Process Maps

Equipment Management Process Overview (Process Map 1.1)

Capital Request Process (Process Map 1.3)

Key Indicators for Quality Management (Process Map 1.4)

Equipment Specification Process (Process Map 2.1)

Requests for Equipment Process (Process Map 2.2)

Purchasing Decision Process (Process Map 2.3)

Equipment Procurement Process (Process Map 2.4)

Equipment Acceptance Process (Process Map 3.1)

Equipment Commissioning Process (Process Map 3.2)

Equipment Prescribing Process (Process Map 3.3)

Managing the Return of Equipment Loaned to Patients (Process Map 3.4)

Equipment Development, Modifications & Trials (Process Map 3.5)

Single Use Devices (Process Map 3.6)

Training in Use of Equipment (Process Map 4.1)

Equipment Decontamination Process (Process Map 5.1)

Equipment Repair Process (Process Map 6.1)

Equipment Service/Maintenance Process (Process Map 6.2)

Decontamination of Equipment Prior to Repair, Service or Inspection (Process Map 6.3)

Non Conformance (Process Map 6.4)

Equipment Condemns & Disposal Process (Process Map 8.1)

Annual Review of Capital Equipment Requirements (Process Map 11.1)



Managing Medical Devices

Guidance for health and social care organisations

January 2021

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V1.2	November 2020	Minor text changes Update of references Minor text changes to all sections Regulatory updates Removed tables and text boxes
V1.1	April 2015	Minor text changes to: Section 2.5 last paragraph. Section 3.4.2 added point Section 8 Section 8.2 6th paragraph Section 8.7 last paragraph (Note)

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1 Introduction

1.1 Aims of the guidance

The purpose of this document is to outline a systematic approach to the acquisition, deployment, maintenance (preventive maintenance and performance assurance), repair and disposal of medical devices.

It is intended primarily for people in hospital and community based organisations that are responsible for the management of medical devices, to help them set up and develop systems that promote the use of the medical devices for safe and effective health care. Many of the principles of this guidance document may apply to all medical devices. However, not all sections may apply to implantable devices, and in vitro diagnostic (IVD) medical devices are covered in separate documents.

Medical devices play a key role in healthcare, vital for diagnosis, therapy, monitoring, rehabilitation and care. Effective management of this important resource is required to satisfy high quality patient care, clinical and financial governance, including minimising risks of adverse events. Good medical device management will greatly assist in reducing their potential for harm.

This guidance document updates and replaces previous guidelines published in:

- Managing Medical Devices Guidance for healthcare and social services organisations. April 2015
- Managing Medical Devices. Guidance for healthcare and social services organisations DB 2006 (05) November 2006
- Guidance on the safe and effective use of batteries and chargers for medical devices DB 2005 (03) October 2005.

In vitro diagnostic (IVD) medical devices are not within the scope of this document but we have separate guidance in the following publications:

- [Management of in vitro diagnostic medical devices](#)
- [Management and use of IVD point of care test devices](#)

Examples of medical devices are given below

This guidance document aims to:

- help healthcare organisations ensure the provision of adequate quantities of medical devices that are competently used by trained users, properly maintained and effectively managed to provide quality healthcare. The principles are summarised in Outcome 11 of the Care Quality Commission standards [1] CQC Regulation 15
- help healthcare organisations meet the Care Quality Commission's standards [1] (or equivalent) Regulation 15 on prevention of incidents by unsafe or unsuitable devices
- help healthcare organisations to plan and co-ordinate sustainable replacement programmes
- help healthcare organisations optimise cost, risk and performance of medical devices
- address strategies for ownership and use of medical devices
- provide balanced information to help groups developing local policy
- identify relevant legislation

- identify sources of additional guidance.

The main topics cover the life-cycle management of medical devices:

- management of medical devices
- acquiring appropriate devices
- training
- maintenance and repair
- reporting adverse incidents
- decontamination
- decommissioning and disposal.

Examples of medical devices (not an exhaustive list)

Diagnosis or treatment of disease

Diagnostic laboratory device, X-ray machines, magnetic resonance imaging (MRI) scanners, vascular catheters, dressings, surgical instruments, syringes, hip replacement implants, standalone software for diagnosis including apps that are designed to diagnose

Monitoring of Patients

ECG, pulse oximeter

Critical Care

Infant incubators, blood-gas analysers, defibrillators, ventilators, vascular stents

Improve function and independence of people with physical impairments

Hoists, orthotic and prosthetic appliances, pressure care devices, walking aids, wheelchairs

Community-based healthcare

Dressings, domiciliary oxygen therapy systems, urine drainage systems

Emergency services (ambulances)

Stretchers, trolleys, defibrillators

1.2 Role of the MHRA

The role of the MHRA is to protect and promote public health and patient safety.

The MHRA undertakes market surveillance of medical devices on the UK market and takes decisions over the marketing and supply of devices in the UK.

The MHRA is responsible for the designation and monitoring of UK Approved Bodies.

Further guidance is available on [how the MHRA enforces the legislation on medical devices](#)

2 Systems of management

2.1 Management responsibility

Healthcare organisations should appoint a director or board member with overall responsibility for medical device management. There should be systems in place to ensure reporting of device issues including:

- the effectiveness of the medical devices management system
- the condition and performance of medical devices including device failures and issues; utilisation, performance, maintenance; repair and calibration history
- the execution of investment, replacement and disposal plans.

The management structure for medical devices should have clear lines of accountability up to board level. These lines of accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community-based services, independent hospitals providing services for NHS patients, managed care providers, Private Finance Initiative (PFI) organisations and other independent contractors. It is important to establish who is accountable, and where there is a need for joint accountability arrangements.

Healthcare organisations should appoint Medical Device Safety Officers (MDSO). Part of the MDSO role is to report adverse incidents to the MHRA and other official agencies. The lines of accountability should include reference to the appointment of such safety officers [2].

Healthcare organisations should set out a long-term approach and objectives for the management of their medical devices, including strategic replacement and development equipment procurement planning.

This should include an overarching medical devices management strategy setting out medium to long term organisational requirements of assets taking account of cost, performance and risk across the entire equipment lifecycle. This strategic approach should also align with the responsible organisations overarching business / strategic plan.

2.2 Medical devices management group

Healthcare organisations should establish a medical devices management group to develop and implement policies across the organisation.

Membership of the group should depend on the requirements of each healthcare organisation but needs to be broad enough to address all the policy areas (see section 2.3). It needs appropriate representation from among the following groups of staff:

- clinical
- clinical / biomedical engineering
- clinical trainers
- management
- infection control
- decontamination lead
- risk management
- engineering
- maintenance
- IT and data support

- purchasing
- medical device trainers
- medical device users
- MDSOs.

Where appropriate, the medical devices management group should include links with specialist groups dealing with specialised medical devices (for example laboratories, radiology and renal dialysis).

The group's role should be to:

- improve communication about medical devices within the organisation
- ensure involvement of clinicians, technical staff and users in relation to any proposed changes, including configuration settings relating to devices, where appropriate
- define persons responsible for device management tasks, training and safe device operation
- define and review the device management policy
- review incidents including governance issues relating to medical device management.

2.3 Device management policy

A device management policy should help to ensure that risks associated with the use of medical devices are minimised or eliminated. The medical devices management group should ensure that the policy addresses:

- responsibilities in relation to medical device management
- decontamination
- the equipment life cycle (including selection, acquisition, acceptance, maintenance, repair, monitoring, traceability and disposal/replacement) of all medical devices
- risk management including adverse incident reporting and actions required on National Patient Safety Alerts, MHRA safety messages and manufacturers' Field Safety Notices
- training and access to manufacturer's instructions
- records, including device inventory.
- outsourcing
- equipment deployment, tracking and utilisation
- equipment financing.

This policy should be regularly reviewed to ensure that, whenever a medical device is used, it is:

- suitable for its intended purpose
- used in line with the manufacturer's instructions
- traceable, where possible
- maintained in a safe and reliable condition, with associated records kept
- disposed of appropriately at the end of its useful life.

2.4 Records

Good record keeping is essential for the safe management of medical devices. All the aspects of medical device management covered within this guidance document require some degree of record keeping. The records should be maintained within one system wherever possible. For non-centralised records there should be suitable cross references between the various record systems.

Accurate and complete copies of records in paper or electronic form are required to be made available for future inspection, review and copying e.g. for CQC, internal audits, traceability, investigations.

The detail and complexity of the records depend on the type of device and usage during its lifetime. It should also include any specific guidance provided in the manufacturer's instructions and supporting information.

Records must be protected to ensure their accuracy is maintained and that any changes do not obscure previously recorded information. Procedures should include the ability to store securely to enable record retrieval throughout the retention period of records.

NHS Digital provides guidance on record management [3]

The device records should provide evidence of:

- a unique identifier for the device, where appropriate
- the purchase price of the equipment
- a full history, including date of purchase and where appropriate when it was put into use, deployed or installed
- any specific legal requirements and whether these have been met
- proper installation and where it was deployed
- schedule and details of maintenance and repairs
- the end-of-life date, if specified.

Healthcare organisations must ensure records are kept of training of users of medical devices. These should show that users:

- know how to use the device safely
- can carry out routine checks and maintenance
- have been trained and had relevant refresher training
- are confident and/or competent to use devices in their areas of work.

2.5 Deployment

Systems for managing medical devices need to take account of the different ways that the devices can be deployed. For example, devices can be:

- allocated to the department where they are used, which is given the responsibility for managing them. Examples include fixed installations, such as large X-ray machines and smaller critical care devices in some intensive therapy units
- allocated to device stores, pools or libraries, from which they are issued to users, as required. Examples include walking aids and frames issued by community stores and infusion pumps and ventilators in many healthcare organisations
- issued on long-term loan to an individual user for their use only. Examples include artificial limbs and wheelchairs.

Healthcare organisations should monitor equipment utilisation. Where a medical device is being under-used, consider whether it can be re-deployed in the hospital or healthcare organisation, either for the duration of its life or an interim period.

2.5.1 Department control

When the device is allocated to a department, individuals working in the department generally have primary responsibility for the way they treat the device and the state in which it is left. These responsibilities can also include performance checks before use and routine maintenance, such as charging batteries. It is essential that all individuals are aware of the medical device management system and the part that they play within the system to ensure that medical devices are managed correctly.

In many healthcare organisations some important aspects of device management, such as record keeping and scheduling maintenance, are often controlled outside of a department that has the primary responsibility for the use of the equipment. This may be a centralised device management group. It is essential that systems and procedures allow for the relevant details to be passed on to those responsible for the management of records for a device, and that users are aware that different departments within the organisation are responsible for maintenance. There may be significant advantages in terms of expertise and risk management in having a single medical device management group responsible for all types of medical devices and equipment within the organization.

2.5.2 Device stores, pools and libraries

In the community, routine device management may in practice transfer either to the end user or to a community healthcare worker. It is essential that all individuals are aware of the medical device management system and the part that they play within the system to ensure that medical devices are managed correctly.

In the acute setting, medical device libraries are more likely to retain responsibility for device management.

Best practice in the management of an equipment store/pool/library is characterised by a single use and return policy, unless equipment is booked out for multiple cases.

2.5.3 Devices issued individually on long-term loan

Some device management will transfer either to the individual end user or to a healthcare worker or other carer. However, it is essential to be clear about where responsibility lies for each aspect of management. This includes:

- decontamination procedures
- maintenance and associated records keeping
- availability of up-to-date instructions and other information, and passing to end users, where appropriate
- period and type of use
- device identification and traceability
- contact details (users and healthcare establishment).

The healthcare organisation remains accountable for collecting these items when they are no longer needed. It is essential that all individuals are aware of the medical device management system and the part that they play within the system to ensure that medical devices are managed correctly.

2.6 Monitoring and audit

Monitoring the organisation's performance on medical device management is important to minimise or eliminate risks to patients and staff.

Much of this activity should be by internal audit, as part of the organisation's governance arrangements. Healthcare organisations need to review their policies and systems for managing the use of medical devices regularly. This internal audit should be performed by the medical devices management group on a regular basis. An audit report should be submitted to the board.

This audit should also examine the organisation's policies and procedures for the safe acquisition, use, maintenance and repair, decontamination and disposal of medical devices against the checklists set out in this guidance. The audit should also check the storage procedures of records and assess current security measures that protect the integrity of the records. Record retrieval methods should also be audited. Key indicators capable of showing improvements in medical devices management and/or providing early warning of risk should be used. The effectiveness and usefulness of these indicators should be reviewed regularly.

There will in addition be 'external' monitoring and audit components by organisations such as Care Quality Commission (CQC). The CQC will inspect against their Essential standards of quality and safety [1]. Healthcare organisations should consider benchmarking their management of medical devices with other healthcare organisations. This can help sharing of best practices.

2.7 Reporting adverse incidents (includes near misses)

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons. Any known problems associated with product design, documentation and common use related issues should also be reported, for follow up.

Report all adverse events relating to a device including user problems with a device, software failures, or problems with the instructions for use.

Reporting should be in line with the organisation's local policy and procedures. Staff should know who the healthcare organisation's Medical Device Safety Officer (MDSO) is and how they can be contacted. However, reports from individuals will be received by MHRA and investigated as appropriate.

Reporting is essential to ensure that lessons are learnt, and adverse events are not repeated. National reporting is essential to ensure that trends are spotted and appropriate action is taken across the country to help ensure the safe and effective use of medical devices, for example through safety messages. Unless the MHRA receives reports of all adverse events, emerging problems cannot be identified, continuing the risk of repeat events and patient harm.

Information from adverse incident reporting indicates that one of the factors that has the greatest impact on the safety of devices involve the instructions for use issued by the manufacturer, their availability and clarity. Other key safety factors include the design, the quality of training in the appropriate uses of devices and how well they are maintained and prepared.

Adverse incidents can be easily reported online through the Yellow Card scheme:
<https://yellowcard.mhra.gov.uk/>

MHRA

There are different ways for healthcare professionals to report a problem with a medical device if you're in [Scotland](#) or [Northern Ireland](#).

If you are in England or Wales, please report any problems with medical devices online using the [Yellow Card website](#).

Northern Ireland Adverse Incident Centre (NIAIC) niaic@health-ni.gov.uk

Incident Reporting and Investigation Centre (IRIC), nss.irc@nhs.scot

Recommendations for an effective management system

- a comprehensive, organisation-wide policy on the management of medical devices and a system in place, which ensure that all risks associated with the acquisition, deployment, use, monitoring, record integrity, reprocessing, maintenance, record generation and storage, decommissioning and disposal of medical devices are minimised.
- Board-level responsibility for medical devices management is clearly defined and there are clear lines of accountability throughout the organisation, leading to the board
- a medical devices group with representation from a wide range of staff
- a record of the current location of medical devices to facilitate a systematic approach to medical devices management and to target safety communications. or manufacturer's Field Safety Notices. Records of the action taken as a result should be maintained
- mechanisms to distribute manufacturer's Field Safety Notices, and MHRA safety information to the appropriate people in the organisation and to report incidents
- robust procedures to deal with all medical devices loaned within the organisation or to individual users. Independent contractors using medical devices have appropriate risk management systems in place and are aware of the overall policy and systems for medical device management within the healthcare organisation
- connectivity between the healthcare organisation's strategic plan and the 'on the ground' equipment lifecycle management activities
- an evidence-based and methodical decision-making framework to optimise decisions taken within each stage of the equipment lifecycle (see section 6)
- risk management as inherent in the management of medical devices.

3 Appropriate acquisition and selection of devices

3.1 Policy

Every healthcare organisation should ensure there is a policy or other mechanism for the acquisition and selection of appropriate devices for specific procedures.

Healthcare organisations should produce and manage the acquisition of medical devices through a multi-year investment and replacement plan. This plan should include a prioritised schedule of all short to long term medical devices requirements and should be monitored against appropriate risk assessment criteria.

The medical devices management group, or other mechanism, should ensure that local policy for the acquisition of medical devices address:

- safety, quality and performance, as well as all aspects of the acquisition cycle (see section 3.12)
- the need to ensure that the selection process considers care objectives and priorities of the healthcare organisation, and the needs of the patients.
- the process should consider whole life costs and follow national acquisition policy and recommendations, including any regional or national aggregation of procurement where this results in best value for money
- the need to ensure that the agreed acquisition requirement takes account of the needs and reasonable preferences of all interested parties, including those involved in use, commissioning, decontamination, maintenance and decommissioning
- consumables are cost effective for the life of the device, if applicable. This would include the cost of the device and its maintenance and the lifetime costs of consumables
- the mechanism for the acquisition and selection of appropriate devices for specific procedures.

The policy for procuring medical devices should be established in consultation with the professionals who will be prescribing, supplying or using these.

A healthcare organisation could be held responsible, under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage, as a result of inappropriate purchase or prescription of a device.

The MHRA's publication *Devices in Practice* [4] includes a series of checklists that can help in the purchase, use and maintenance of medical devices, and training issues.

3.2 Methods of acquisition

In addition to purchasing and leasing, which are the most common methods of acquisition, there are other ways to acquire medical devices, including loans from manufacturers or other healthcare organisations and in-house manufacturing. Hospitals may loan each other devices to avert temporary problems; manufacturers may loan products as part of an evaluation or as an incentive to purchase associated products. In all cases, it must be clear from the outset who is responsible should a problem arise. The medical devices management group should be made aware of any loans.

Some larger clinical/biomedical engineering departments in healthcare organisations design and build medical devices for their own use. If the devices are supplied to another legal entity, then the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (**UK MDR 2002**) [5] apply. Organisations that manufacture medical devices but do not place them on the market (i.e. they are used only within the organisation or legal entity) should, as a matter of best practice, ensure that those devices are manufactured in accordance with the UK MDR 2002.

3.3 Factors to consider before acquisition

- Agree the requirements for the intended medical procedure and/or needs of the end user.
- Suitability for intended purpose/application by reviewing the manufacturer's description of the intended user, usage and the instructions for use, safety and performance information (including detailed specifications of the medical device), and comparing against the performance specifications contained within the acquisition requirement.
- Safety issues and any limitations on use.
- Software compatibility with archive systems, patient records etc.
- Electronic medical devices which process data need to be secure; the medical device is validated, as appropriate.
- Ease of use. Evaluate the ease of use and consider user experience and manufacturer's compliance with BS EN 62366-1:2015 Medical devices. Application of usability engineering to medical devices' [6] (please note this standard has not been designated to the UK MDR 2002 but represents best practice and therefore MHRA recommends it is adhered to over older versions). Has it been designed to minimise accidental misuse? How easy is it to misuse the device and what precautions are incorporated into the design to guard against misuse? Consider user experience feedback and evaluations from the expected clinical environment.
- Evaluate and assess the readability of manufacturer's instructions. Instructions for use (IFU) should be comprehensive but intelligible. Overly complex IFU may point to poor design that has not incorporated human usability as a key design goal.
- Availability, type and scope of training. What type of training is available e.g. face-to-face, electronic, e-learning, blended? Is it on-going? Is it training for users or maintainers or both? Does training include methods of decontamination?
- Advice and help. What advice services does the supplier offer and/or what user-help guides are incorporated in or with the system to assist the user with the operation of the device and of its suitability for use for specific procedures?
- Ensuring the operating/environmental conditions of the place where the device will be used are compatible with those of the device.
- Decontamination and disposal procedures, including ensuring the healthcare organisation is able to reprocess in line with the manufacturer's instructions (e.g. by trained technicians). The infection prevention team and decontamination lead should be consulted (see section 9).
- Pre-use set up, testing requirements, installation requirements and commissioning procedure (see section 5).
- The projected service life of the product and warranty details. In the long run, it could be cheaper to purchase a device which will last for 10 years but costs twice as much

as a device designed to last for only 3 years, as long as maintenance and replacement parts and consumables are available for the lifetime.

- Whole life costs: acquisition and operational, maintenance and consumable, training, risk, renewal and disposal costs.
- Medical devices may require routine user maintenance, planned preventive maintenance (e.g. by trained technicians) and ad-hoc maintenance, if faults occur. Many require periodic performance checks which may require specialist test equipment. Evaluate the user and planned maintenance recommendations for the device (including frequency and type). Evaluate the ease of breakdown maintenance, particularly in relation to how this will be provided and the response time provided by the supplier for breakdown maintenance. Ensure that all medical devices can be stored, maintained and serviced in line with the manufacturer's instructions for use. Consider all the costs associated with these before buying.
- Using profiles of existing devices. Before acquiring replacement devices, healthcare organisations should consider whether, with improved equipment management e.g. establishment of equipment libraries, they have sufficient inventory of existing devices to meet requirements.
- Rationalising the range of models versus diversity (see section 3.6).
- Reliability and previous performance.

3.3.1 The procedure for accepting new devices should also identify:

- Training needs
- Appropriate planned preventive maintenance and performance checks
- Technical support needs of users
- Whether risks associated with using a model for the first time have been minimised.

Some devices, such as medical gloves, dressings, catheters and syringes are delivered in bulk packs, so it would be inappropriate to check each one on delivery. For such consumable devices key issues are:

- Expiry dates are clearly shown on packaging, as required
- Appropriate marking for tracing lots, if there is a recall or modification required
- Instructions and safety information are available, as necessary
- Packaging is appropriate for storage
- Environmental conditions for storage are clear.

See also section 5.1.2

3.4 Modifying and changing use

Modifying existing devices or using them for purposes not intended by the manufacturer (off-label use) has safety implications. It may also count as manufacture of a new device under the UK MDR 2002 [5]. The original manufacturer's liability is limited and liability may be partly or wholly transferred to the organisation or person making the modifications, if the device is implicated in an adverse incident.

It is essential that modifications outside of the manufacturer's intended use are only considered as part of a fully documented risk management process within the healthcare organisation's risk management policy and procedures.

In specific cases, where it is deemed that using an alternative accessory to that specified by the device manufacturer would give improved benefits, then a risk assessment should be carried out to ensure that all components within a system are compatible and can be used safely, e.g. batteries, chargers, connectors.

If a device fails in use following replacement of a part with one not corresponding to the device manufacturer's specifications and this leads to the death or serious injury of a patient/user, there is a greater likelihood of the organisation responsible for medical device repair/maintenance being held liable for the injuries caused.

3.5 Safety performance and reliability

Points to consider

- Does the medical device have a UKCA, CE or CE UKNI mark? This is a legal requirement for medical devices.
- Is there any local knowledge or history of problems with the device or type of device?
- Do MHRA safety publications, manufacturer's advisory notices or other relevant publications identify issues related to the device?
- Have other users experienced problems and failures? Can the manufacturer provide evidence of reliability from other responsible organisations? Does the manufacturer claim compliance with relevant standards?

3.6 Rationalising the range of models versus diversity

Having a variety of models for the same purpose can increase the risk of operator's confusion, leading to misuse and complicating training requirements. Restricting purchase and stock holding to one type of device reduces these risks and can be financially advantageous.

However, reliance on a single model can also cause problems. The chosen model may prove unreliable or be subject to a manufacturer's recall. Sooner or later, the manufacturer is likely to withdraw the old model, as designs improve or the manufacturer may even cease trading.

There is particular risk of operator's confusion with devices that are superficially similar but have different applications, limitations, settings or operating procedures. If there is a need for different facilities or functions e.g. between infusion pumps for epidural and patient controlled analgesia (PCA) it may be better to choose completely different models.

3.7 Installation support services

- Is the installation to be carried out by manufacturer/supplier?
- What building and utility services are required? The adequacy of services needs to be established (e.g. the suitability of the electrical or piped gas supply).

- Is special decontamination, calibration or other associated equipment needed? Complex devices may need specialists to install and commission them.
- Does the device meet the required IT communication protocols, operating system etc.?
- Does the manufacturer endorse the installation of additional software e.g. virus checker?

3.8 Maintenance support services

Ensure that devices are regularly checked for functionality prior to use by the user in line with the manufacturer's instructions and throughout the expected lifetime of the device.

Points to consider

- Can the desired service provider maintain the device?
- How will the proposed contract or service level agreement deal with continuity of care? For example: on site repair, if needed.
- Are alternative devices available to cover periods when a device is being repaired or serviced?
- Are response times appropriate and guaranteed?
- What are the proposed servicing intervals? (Also, consider the types of checks and calibrations required between servicing intervals.).
- Are spares readily available, and for how long?
- Is service support guaranteed, and for how long?
- What information is available from the device manufacturer, e.g. circuit diagrams, preventive maintenance schedules, trouble-shooting guides, repair procedures, parts list, and special tools list?

3.9 Second-hand medical devices

Usage and service history should always be available for prospective purchasers before sale and then supplied with the device, at the point of sale.

As a minimum, there should be a:

- record of any reconditioning work carried out, including a record of replacement parts
- copy of all maintenance and servicing that have been carried out, including the name of the maintenance/servicing organisation
- record, type and frequency of usage over its working life
- fault log
- record of decontamination status
- date of installation

- tube usage (in the case of X-ray devices)
- helium level (in the case of MRI).
- Technical information supplied by the manufacturer (e.g. IFU, operators manual etc)

3.10 Documentation and monitoring

To reduce the possibility of inappropriate devices being purchased or prescribed it is essential that a full performance specification of the entire system is established before any purchases are made. For example, with battery powered device this must incorporate all elements, such as battery type, charger type, charging process, maintenance and use.

Once the selection process has identified the most suitable medical device, then the final terms and conditions covering all aspects of the acquisition should be agreed by all interested parties and documented. Only then should the contract be awarded, the purchase order raised, or the acquisition otherwise be cleared to proceed.

The acquisition should then be managed in accordance with the terms and conditions agreed, and the results of the acquisition and usage experience fed back into any subsequent acquisitions.

3.11 The acquisition cycle

Recommendations for acquiring equipment:

- Local acquisition policies and processes to be established with the involvement of the medical devices group within the organisation.
- The relevant advisory groups to be established and consulted.
- Safety, quality and performance considerations to be included in all acquisition decisions.
- The recommendations of the MHRA and other appropriate bodies to be considered for selection and acquisition.
- Ensure all acquisitions meet UK regulations.
- All developments, modifications and trials of devices to be carried out in accordance with the relevant legislation, guidance and risk management policy.
- Model ranges to be rationalised, where possible.
- Technical support, maintenance and repair systems, timescales and details of the lifetime of the device to be included.
- User experience to be fed back into the policy, process, future acquisitions and advisory groups.
- Organisations should identify how they can achieve savings through smarter procurement. Examples include identifying opportunities to aggregate spend, utilising national and/or local framework agreements and equipment standardisation.

4 Clinical investigations involving non-UKCA/CE/CE UKNI marked medical devices

The healthcare organisation's medical device management policy should cover situations where that organisation enters into agreements with a medical device manufacturer to take part in a pre-UKCA/CE/CE UKNI marking clinical investigation of a new medical device or wishes to conduct such a trial on a device manufactured in-house. That policy should include consideration of the following factors:

- Has the relevant ethics committee given approval for the study?
- Has the MHRA issued the manufacturer with a letter of no objection?
- Have the relevant healthcare professionals received adequate training?
- Are there arrangements in place to segregate the investigational devices from other UKCA/CE/CE UKNI marked medical devices and to ensure that the only healthcare professionals to use the investigational device are those named as clinical investigators in the application to the MHRA?
- Have patients who agreed to take part in the investigation done so only after providing fully informed consent?
- Has provision been made, where relevant, for decontamination, reprocessing, servicing, maintenance and disposal in conjunction with the sponsoring manufacturer?
- Does the agreement include criteria for stopping or curtailing the investigation or use?

5 Receiving a new device

5.1 Acceptance checks

Healthcare organisations should check that the specification of newly delivered devices matches the purchase order detail or tender specification.

Simple checks on delivery can save time and avoid trouble. Finding out that a device is broken or inappropriate, only when someone tries to use it for the first time, can delay or interrupt treatment, make it harder to establish when and where the problem arose and invalidate warranties.

5.1.1 Record keeping

The healthcare organisations should keep records of the order, the results of the delivery inspection, the individual device or batch identifier and any safety or functional tests.

It should always be recorded who carried these out, when and how, because:

- health and safety inspectors require records to be available
- a defence in a negligence case based on good device management can only be effective if records are available for the device involved
- recording the individual device or batch details on a validated and secure database means it can subsequently be traced for maintenance or for a manufacturer's recall/field correction, if necessary.

This should be part of the device life cycle that includes maintenance and traceability.

5.1.2 Skills required for, and scope of, checks and tests

Delivery checks should include:

- checking that the correct product, complete with usage and maintenance information and any relevant accessories, has been supplied
- ensuring that devices have been delivered in good condition and, where relevant, in good working order
- the manufacturer's instructions may specify particular testing, calibration or adjustment before a medical device is used for the first time. It may also be desirable to generate baseline data for comparisons, for example to show calibration drift during subsequent maintenance and to measure and record 'as new' reference values for electrical safety parameters.

Note: The tests listed in product safety standards, such as BS EN 60601-1 [7], are designed for type-testing and may damage the device under test, hence some are not suitable for pre-use or maintenance tests.

Checks and tests can only be effective if everyone carrying them out has appropriate training.

below is some basic guidance on what checks and tests should cover, and the skills required to carry them out. These checks will be dependent on device type.

See also section 3.4.3

Table 5.1 Basic guidance on delivery checks

Paperwork / database

- Is the device compatible with specification set out in the purchase order?
- Have the user, repair and maintenance information, compliance and calibration certificates, as well as test results been included, where relevant?
- Add device details, asset number and serial number on to device management records.
- Does the device (or any component part or accessory) need decontaminating before first use?
- Are the instructions for use appropriate?
- Does the device require validation?
- Are the Decontamination instructions appropriate?

Knowledge required

- Ordering system
- Inventory system
- Names and appearances of common medical devices
- Medical device documentation (Instructions for Use, certificates etc)
- Serial numbers and model identification codes

Visual inspection

- Check outer packaging is intact and undamaged
- Check for any damage apparent to the device on inspection
- Look for an appropriate expiry date, UKCA/CE/CE UKNI mark, UK Approved Body/Notified Body number, electrical class, lot number, quantity in pack, storage information for unopened pack

Knowledge required

- Knowledge of areas to check for damage
- Familiarity with the appearance of product in good condition, common defects
- Knowledge of medical devices and their use
- Knowledge of electrical class symbols.

Configuration

- Configure the medical device to clinical requirements and ensure compatibility with all other equivalent medical devices in the healthcare organisation
- Agree configuration with clinical manager or director, documenting the decision with reasons, where appropriate.

Knowledge required

- Knowledge and understanding of the medical device and its clinical application
- Knowledge and understanding of the impact of configuration changes on clinical care
- Knowledge of how to configure this device.

Basic guidance on safety and calibration checks**Functional**

This may require more extensive checks by specialist staff for complex or specialist device.

- Does the device function in line with the manufacturer's information?
- Are accessories/parts included and compatible?
- Do indicators and displays function correctly in line with the manufacturer's information when powered up?*
- When powered up, does the device start when it should and do the dials and switches do what they say?*

Knowledge Required:

- For some devices, the skills required will be little more than basic training to allow the manufacturer's information to be followed.
- In cases where the manufacturer's instructions specify specialist assembly or manipulation, familiarity with the functions of the device and its components and accessories is required.

Electrical

- Are the mains leads, plugs and other connectors undamaged?
- Are the mains plugs compatible with the sockets used in the UK (BS 1363/A)? (Mains adapters should not be used on medical devices.)

Knowledge required:

Training in visual electrical safety inspection techniques.

Calibration and Measurement

Where appropriate, use test device to check:

- Accuracy of physiological measurements
- Dose delivery*
- Energy delivery*
- Accuracy of other outputs*

Knowledge required:

Tests should be carried out by an adequately trained and appropriately qualified person.

*only for active devices

For simple devices, bought with an adequately specified purchase order or tender system, pre-use testing may not be appropriate. Organisations may, however, wish to carry out random testing of samples at the delivery stage, as well as subsequent periodic checks.

5.1.3 Safety test limits

Acceptance tests should not exceed the bounds of normal use. They should not be type tests.

- Disassembly should be restricted to what is necessary for normal use and cleaning.
- Currents or voltages applied during tests should not exceed those occurring in normal use.
- Refer to BS EN 62353:2014* [8] for further information (please note this standard has not been designated to the UK MDR 2002 but represents best practice and therefore MHRA recommends it is adhered to over older versions).

Any test, in addition to those intended by the manufacturer and involving an abnormal stress, such as loading a hoist above its stated maximum working load, carries an unacceptable risk of causing permanent damage. It should not be carried out.

5.2 Special considerations**5.2.1 Risk assessment before first use**

Healthcare organisations should have standard configuration sets for equipment, signed by a lead clinician and that equipment configuration is always verified before being put into service.

There may be additional risks associated with devices in the following categories which should be considered in the assessment process:

- Devices manufactured in-house
- Second-hand devices
- Devices lent by another responsible organisation
- Devices reissued to second or subsequent users
- Custom made devices for named patients
- Devices under clinical investigation

Risk assessment may mean local testing and the issue of a local safety certificate. A local safety certificate is intended to:

- Confirm that a device is safe and effective
- Set any necessary limits on its use.

5.2.2 Devices on loan from manufacturers

All devices on loan from manufacturers should be subject to a written agreement which defines the device management requirements, responsibilities and liabilities, including decontamination if applicable. See NHS Master Indemnity Agreement [9]. Delivery receipt and pre-use procedures for loan device should be the same as those for purchased device, unless otherwise specified in this written agreement.

5.2.3 Home use

Where the ownership and management of the device remain with the supplier, such as enteral feeding pumps, the manufacturer's pre-dispatch tests, combined with simple pre-use checks by those responsible for the care of the end user in the community, (e.g. community nurse), should provide adequate safety assurance. In this situation, record-keeping is the supplier's responsibility with input from the end user, as appropriate. For devices owned by healthcare services and loaned to end users in the community for use at home, the responsibility for ensuring that the device is delivered and is safe to use is the responsibility of the healthcare service. However, this may include an agreement for the end user to carry out basic assembly or safety checks before use.

For devices in the home and owned by the supplier, incident reporting to the MHRA is the responsibility of the supplier, once alerted by the user/carer. The local health provider that has purchased the service should also be notified by the supplier.

5.2.4 Installed devices

When a device needs to be installed, there should be a procedure in place for commissioning the installation, which has been agreed with the supplier and the healthcare organisation responsible for carrying it out. Installed devices need to take account of connecting to IT network, ensuring connectivity, configuration etc.

Particular attention should be given to connection to electrical power supplies. The electrical power installation should conform to the 18th Edition of the IET Wiring Regulations (in particular Section 710) [10].

Installation is required when any of the following occurs:

- Substantial assembly work will be required on-site
- There are permanent plumbing, electrical and gas pipeline connections
- The device needs to be permanently fixed in place.

Under the UK MDR 2002 [5], suppliers must provide instructions for installing a device and bringing it into use. Where appropriate, these instructions should include specifications for safety and performance checks.

A designated member of staff should oversee the commissioning process and take responsibility for deciding that it has been completed satisfactorily.

5.3 Legal requirements in relation to electrical safety testing

The Electricity at Work Regulations (EWR) [11] and the Health and Safety at Work etc. Act (HASAWA) [12] form the basis of programmes used by hospital technical staff for the regular electrical testing or inspection of portable electrical equipment. Carrying out a risk assessment may determine the need for either an inspection or electrical testing.

HASAWA imposes a duty on employers for:

- the provision and maintenance of plant and systems of work that are so far as is reasonably practicable, safe and without risks to health
- the provision of such information, instruction, training and supervision, as necessary.

The Electricity at Work Regulations state:

- 'no electrical equipment shall be put into use where its strength and capability may be exceeded in such a way as may give rise to danger'

- 'all systems shall be maintained so as to prevent, so far as is reasonably practicable, such danger'.

Healthcare organisations must have procedures to comply with the legislation. There is no specific legal obligation, or even guidance, requiring healthcare organisations to carry out any particular test, but there is a general duty to take necessary steps to protect staff and patients from danger. Healthcare organisations should implement electrical safety schedules to comply with this legislation. Risk assessments should be done to ensure that the tests carried out are appropriate or reasonably practical. These include pre-use testing of new devices (see section 5.1.3) in addition to subsequent maintenance tests.

6 Training

Healthcare professionals working for the organisation, as employees or contractors, have a professional duty to ensure their own skills and training remain up to date. The healthcare organisation should ensure that continuous professional development and training activities include the safe use of medical devices during annual staff appraisal.

Users, carers and prescribers need to carefully consider the content of all warnings of risks and the device should only be used and maintained in line with the manufacturer's instructions. If the manufacturer's instructions do not fully cover these points then please report to the MHRA, using the details in section 2.7.

The need for training depends on many factors including the device, and can involve end users, carers, professional users or other staff:

- Will it be required for all anticipated users, carers or staff?
- Will it be required for maintenance, repair and decontamination staff to enable them to carry out all their duties?
- Is the same model already in use and registered on a database for medical devices?
 - > If so, will refresher or update training be needed?
 - > If not, are new training and records needed?

6.1 Policy on training

A training policy should be developed by the medical devices management group.

Points to consider

- The need for adequate training programmes which may include generic and specific training and periodic review or retraining, as required.
- How will training be delivered (face-to-face, e-learning)?
- Is it competency based?
- Who should receive the training offered by the manufacturer or supplier? How will everyone else be trained, and by whom, and when?
- Inclusion of new staff, agency, on-call and locum staff and contractors and those involved in maintenance and repair services as appropriate.

- Continuing professional development.
- Training for service end users and carers. This may include written guidance and that the necessary checks and actions are taken in the event of failures or faults.
- Planned training before a new medical device is introduced to the organisation.
- Appropriate record keeping of training both centrally and by individuals.
- Access to manufacturer's instructions for all users.
- Have you considered future training needs for when those trained directly by the manufacturer/supplier change jobs?
- How will training updates be managed for device/software upgrades?
- How will end users or staff in the community be trained?

6.2 Training for device users

Any user of a device needs to understand how the manufacturer intends the device/equipment to be used, and how it normally operates to be able to use it effectively and safely. Training should include

- differences between models, compatibility with other products and any contraindications or limitations on use
- accessories and how they may increase or limit the use of the device
- use of controls
- displays, indicators, alarms etc.
- requirements for maintenance and decontamination, including cleaning, in line with the manufacturer's instructions and relevant local procedures
- be able to show end users how to use the device
- troubleshooting, including potential issues including those identified in safety advice from the MHRA, manufacturers and other relevant bodies
- be able to recognise device defects or when a device is not working properly and know what to do
- understand the importance of **reporting device-related adverse incidents** to the MHRA and be familiar with the organisations' reporting procedure (see section 2.7).

6.3 Training for repair and maintenance service providers

Individuals providing repair and maintenance services need to be adequately trained and appropriately qualified. This applies to directly employed staff, contracted services or others.

The training records of individuals involved should identify that they are appropriately trained to a level proportionate to the activities they are undertaking. See section 8.4.

6.4 Documentation

Evidence that suitable instructions and training were provided are needed, should a legal case be brought. Users of device should be asked to sign / electronically confirm statements confirming that they have received and understood written and / or oral instructions.

Details of training given should also be recorded. A simple test at the end of training to check that the information has been understood may also be included.

7 Instructions for use

7.1 The importance of effective instructions

Good clear instructions for use have a crucial role in the safe and effective use of devices. The manufacturer is responsible for supplying appropriate instructions, considering the knowledge and training of the intended user(s).

Clear responsibilities should exist for ensuring that the manufacturer's instructions are passed on to all users and, where appropriate, carers. The manufacturer's instructions may need to be supplemented with training.

When manufacturers update their information, healthcare organisations should have a protocol for keeping track of all sets of instructions they hold or have issued to users to enable replacement of existing instructions with revised versions. Consideration should be made to updating the content of relevant training.

Any shortcomings in the instructions should be reported to the MHRA as an adverse incident (see section 2.7).

7.2 Instructions for the end user

All necessary information on storage, pre-use checks, use, maintenance and cleaning should be passed on to the end user, including when the device is issued to a second or subsequent user.

A failure to pass on to the end user the manufacturer's original instructions may compromise the end user's ability to use the device safely, and may lay the healthcare organisation open to legal liability under:

- The Consumer Protection Act 1987 [13] (in the case of a medical device)
- The General Product Safety Regulations 2005 [14] (in the case of a consumer product not covered by other specific legislation)
- The Common Law of Negligence [15].

Some users or carers with particular disabilities or medical conditions may need additional instructions or training. For example, people who are visually impaired may not be able to easily read some forms of written information.

The healthcare organisation may also need to supply its own information to explain any additional administrative arrangements e.g. contact details for maintenance, consumables or spare parts.

Instructions may need to be written locally to cover whole systems where devices are used together with other device, such as connecting a blood analyser to a computer, to permit automatic updating of patient records.

If healthcare organisations draft their own instructions to supplement the manufacturer's instructions, consider consulting the manufacturer/supplier on their accuracy and suitability, before issue.

7.3 Documentation

Evidence that suitable instructions and training were provided will be needed, should a legal case be brought. Records should be kept of who has received written device instructions.

- All users and prescribers should have access to the manufacturer's instructions.
- Records should be kept of who has received written device instructions.
- There must be a process for recording, tracking and updating the manufacturer's instructions.
- Any updates must be distributed to all relevant users of the device.
- Any manufacturer's instructions considered to be inadequate or ineffective should be reported to the MHRA (see section 2.7)

8 Maintenance and repair

8.1 Management policy for medical devices

The healthcare organisation's medical device management policy must cover the provision of maintenance and repair of all medical devices, including reconditioning and refurbishment. The healthcare organisation is responsible for ensuring their medical devices are maintained appropriately.

This includes:

- How each device should be maintained and repaired, and by whom
- Arrangements for maintenance and repair to be included as part of the assessment process
- Arrangements for the most suitable persons/providers to carry out the work
- Arrangements to ensure items subject to inspection, maintenance, repair or disposal should be decontaminated beforehand (see section 9)
- The timescale for planned maintenance
- The timescale for repairs to be completed
- Maintenance databases are validated for their intended use and functionality.

Where other regulations apply, Ionising Radiations Regulations 2017 [16] and The Lifting Operations and Lifting Equipment Regulations 1998 [17] for example, the tests therein should be carried out in addition to the maintenance and testing recommended in the manufacturer in the instructions for use (IFU) supplied with the device, not instead of.

The frequency and type of planned preventive maintenance should be specified, in line with the manufacturer's instructions and taking account of the expected usage and the environment in which it is to be used.

8.1.1 Audit and review

Random audits should be carried out on all elements of maintenance, repair, record generation and storage to ensure that the correct procedures are in place and being adhered to. Audits should be carried out by staff with appropriate knowledge and experience of managing medical devices.

The healthcare organisation should also ensure that there is a mechanism to obtain regular feedback from all users of the device on the repair and maintenance process.

This should include the reporting of even apparently minor problems as these might lead to major failure unless remedied.

8.2 Choosing appropriate maintenance and repair services

The UK MDR 2002 [5] require a manufacturer to provide:

'all the information needed to verify whether the device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times'.

The following organisations and individuals can have a role in ensuring that medical devices are adequately maintained and repaired:

- manufacturer service organisation
- authorised service agents
- generic/third-party service providers
- in-house maintenance departments
- users.

The healthcare organisation should carry out a risk-benefit analysis before finalising the specification of any maintenance and repair services. Cost alone should not be the determining factor.

Where available, use a service provider or third-party repairer who complies with relevant quality system standards, such as European Standard BS EN ISO 13485: (2016) [18] or BS EN ISO 9001:(2015) [19]. These standards ensure their work is consistently of the nature and quality intended.

When selecting external maintenance contracts (OEM or third-party repairer), healthcare organisations should take time to fully consider which service level is the most appropriate to meet requirements. Consideration should be made against risk, performance and cost criteria.

A manufacturer may wish to supply and maintain devices exclusively to guarantee the standard of repair. Alternatively, a manufacturer may stipulate strict criteria on the training, equipment and resources of an in-house department or any third-party repairer. If these criteria are changed, it should be done so on the basis of a risk assessment.

Note: The term 'third-party repairer' does not apply to in-house healthcare maintenance facilities.

Points to consider:

- Do service providers have access to the necessary equipment and up-to-date and detailed maintenance records? Otherwise they may not be able to carry out the tasks safely and effectively.
- The track record of the service provider. How quickly can they provide a service? Will they loan devices whilst maintenance or repair is being carried out?
- What level of detail is needed in the records? It will vary with the type of device and may include, for example: calibration, preventive maintenance and trouble-shooting.
- Are full details of the repair and maintenance procedures and spare parts available?
- Are consumable materials, such as adhesives or thread locking compounds, included?

Comparison of in-house maintenance with an external provider**External provider****Advantages:**

- Predictable costs.
- Possible to specify response times.
- Possible to specify equipment down times.
- Loan equipment.
- Often cheaper than manufacturer.
- Possible to have an on-site engineer to cope with breakdowns.
- Fewer external organisations to deal with.

Disadvantages:

- Hard to maintain fast response cover for critical care or high dependency breakdowns without additional costs.
- Equipment may need to be sent away for repair and servicing.
- Equipment loans may be required.
- May only be able to cover certain devices.
- Some devices may be excluded.
- Ensure manufacturers can train staff where appropriate.
- Possible lack of manufacturer's information.

In house maintenance**Advantages:**

- Fast response possible for problem solving and breakdowns.
- In-house teams may be flexible in accessing equipment for scheduled preventive maintenance thus reducing down times.
- In-house equipment management departments can co-ordinate and manage an appropriate mix of in-house, manufacturer and third-party service

Disadvantages:

- Hard to maintain adequate stocks of spare parts across a wide range of devices.
- Special tools and test equipment may not be available.

- Specialist training costs can be high.
- Manufacturers are sometimes reluctant to provide training

Manufacturer

Advantages:

- Same build standard as
- original device, with modifications and updates incorporated.
- Assured access to spares.
- Remote diagnostics via computer network sometimes available.
- No problems with warranty/liability.
- Assured access to spares.
- Remote diagnostics via computer network sometimes available.
- No problems with warranty/liability.
- Availability of training for professional users.

Disadvantages

- Contracts with many separate manufacturers need to be negotiated and updated.
- Response times may be long, depending on the contract.
- Users may need long lists of helpline numbers.
- Problems with co-ordinating multiple contracts from the same manufacturer.

Note: If using an outside organisation, you need in-house expertise to monitor, audit and manage contracts.

8.3 The service contract

Any contractual agreement with a maintenance and / or repair service provider should specify the level and type of service required by the healthcare organisation and should include, where appropriate:

- reference to manufacturer's written instructions
- availability, source and traceability of spare parts
- notification of any changes, including the use of alternative spare parts or methods
- training of staff
- quality management systems
- requirement for adequate record keeping
- who is responsible under information governance when third parties and manufacturers are taking patient data from the premises
- use of sub-contractors
- response times
- loan devices
- disposal of obsolete devices, parts and waste.

Take specialist advice in drawing up contracts where specific legislation covers the process e.g. the radiation protection adviser in the preparation of service contracts for diagnostic X-ray device, as required by the Ionising Radiation Regulations 2017 [16] and

for hoists or lifting device the Lifting Operations and Lifting Equipment Regulations 1998 [17]. See section 11, for other examples of legislation.

Guidance on a range of repair and maintenance contracts is available through the [NHS Supply Chain](#) and other frameworks.

8.4 Training and experience of repair and maintenance staff

Health and safety law [12] require employers to ensure employees are adequately trained. All service staff should be adequately trained and competent on devices and have sufficient work experience of the devices they repair and maintain.

Those without adequate training should not be allowed, nor should they attempt, to repair or maintain medical devices and equipment.

All those undertaking repair and maintenance should be able to produce written evidence of appropriate and up-to-date training, preferably as part of the documentation required by a quality management system. They should also be able to show that they are up to date on new maintenance techniques, consistent with the devices they are servicing.

8.4.1 Contracts with the manufacturer

Where contracts are placed with the manufacturer for repair and maintenance, the healthcare organisations should ensure that they are made aware of any changes in circumstances that may affect the repair or maintenance of their devices.

For example, if a manufacturer merges with, or is taken over by another organisation, the responsibility for repair and maintenance may transfer to the new organisation.

If the manufacturer ceases trading and an alternative service provider is not able to undertake the work in line with the manufacturer's instructions, the device may need to be disposed of. However, there may be circumstances where it is essential to keep a device in use. If this happens, a risk assessment of its continued use with service backup from another provider in line with the manufacturer's instructions must be completed, set against the consequences of the device not being available in the short or longer term.

Regularly review the situation to see if alternative arrangements can be made, including acquiring new or replacement devices and subsequent disposal of the original ones.

8.4.2 Subcontracted repair and maintenance

If any aspect of the repair or maintenance process is subcontracted, the healthcare organisation should ensure that:

- they are aware of those aspects of the repair that are being subcontracted
- the main service provider and the subcontractor have a contract, detailing the responsibilities of each party
- the service provider audits the subcontractor frequently to establish that it has the necessary expertise and resources, and that the work level meets the standard agreed between the service provider and the healthcare organisation
- they are notified of any changes in these arrangements.

8.5 Updating changes to manufacturers' instructions

Whoever provides maintenance and repair services should ensure that they are automatically alerted of any changes to repair or maintenance instructions and other essential safety information issued by the manufacturer, such as Field Safety Notices.

There may be changes to the design, or other information, which could affect safety or change the requirements for repair or maintenance, including recalls or safety measures and mandatory upgrades.

The records of the healthcare organisation and the service provider must show the version of the device currently in use and whether it has been upgraded, modified or repaired since it was supplied. This includes integral computer software.

This system should include all relevant guidance issued by the MHRA.

8.6 Spare parts and other components

There are several sources of spare parts:

- the device manufacturer
- other manufacturers
- healthcare organisations
- service providers
- pre-used.

8.6.1 Quality and compatibility with the device

Before purchasing equipment the purchaser should clarify with the manufacturer if there are any conditions imposed by them before they are willing to supply any spare part.

The contract between the healthcare organisation and the maintenance and / or repair service provider should clearly define the terms 'spare parts' and 'consumables' and ensure that their quality and compatibility match those supplied by the original device manufacturer.

To ensure that replacement parts are of the correct specification, purchase them either directly from the manufacturer or to the same specification.

When obtaining replacement spare parts from sources other than the manufacturer, you must take care to ensure that all aspects of the technical specification are met, including, for example: physical dimensions, material strength, mechanical properties and compatibility.

Any agreements to supply parts from sources other than those recommended by the manufacturer should be properly risk assessed, costed and documented, before a decision is made to buy them.

This should also include any effects on whole life costs: a cheaper part requiring more frequent maintenance may not be cost-effective in the longer term. There also may be legal consequences for the healthcare organisation if a device failure, associated with the fitting of such a spare part, causes an injury or incident.

8.6.2 Reusing spare parts

Under normal circumstances, pre-used parts should not be used to repair a device. They may be acceptable in exceptional circumstances after a fully documented risk assessment.

The stresses and strains that the part has undergone will depend on many factors, such as: the length of time in service, age and repair or maintenance history. Pre-used parts may therefore increase the need for maintenance checks or reduce the overall life cycle of the device.

The failure of a part can have severe consequences for the end user. The part should not be reused if its previous history is unknown.

8.6.3 Traceability of spare parts

The healthcare organisation should ensure that they or the repair and maintenance service provider can:

- identify all spare parts replaced during the maintenance or repair of a device
- trace all critical parts back to the supplier.

This will permit ready identification of those devices containing parts that need to be repaired or recalled.

Not all spare parts are critical and the extent to which they need to be identified and related to the original piece of device will depend on several factors.

As a guide, a critical part is a component that might reasonably be expected to cause the failure of a piece of equipment, in such a way that affects its safety or effectiveness and consequently results in death or injury to a user, should it stop working.

8.6.4 Replacement batteries (see also Appendix)

Replacement batteries must provide the same power and lifecycle as those provided with the original device. If an inappropriate replacement battery is used, the device may not function or recharge properly, leading to increased risk to users or healthcare staff. The device manufacturer's specifications should always be followed with respect to replacement. Replacement battery packs may have to incorporate specific features such as active memory, current-limiting or capacity-indicating elements that interface with the medical device.

Note: The device manufacturer may upgrade the specification of the battery or pack during the lifetime of the device to allow improved performance. The latest instructions from the manufacturer of the specific device should be followed.

An organisation could be held responsible under health and safety law [12] and civil liability if a patient or member of personnel died or suffered personal injury or damage as a result of inappropriate replacement of batteries.

8.7 Repair and maintenance methods

The maintenance and repair service provider should have all the necessary testing, measuring and repair equipment and ensure that this is adequately maintained and calibrated, as required.

Test equipment, such as jigs, templates, and computer service and validated diagnostic software should be checked regularly to ensure that they can adequately demonstrate device safety.

Make sure that the service provider has identified and documented all risks, implemented a strategy to manage them, and has documented procedures in place detailing the repair and maintenance methods to safeguard device malfunctions and facilitate tracing of any subsequent parts recall.

Before bringing a device back into service, it should be adequately tested for electrical safety where applicable and for performance. The user should be informed of the results and any changes made to the settings of the device.

Professional users should be told, where applicable, about pass / fail criteria or anything that may adversely affect the treatment of a patient, for example increased radiation dose.

Note: A 'SERVICED' label should also include a due service date as clinical staff need to know the expected next service date in order to maintain patient safety. Service intervals for devices should range between 1 month and 2 years, depending on the device.

Planned preventive maintenance checklist

Initial inspection

- Is the device clean?
- Does it need decontaminating?
- Note settings of controls.
- Inspect each element in line with manufacturer's instructions.

Parts replaced

- Note each item/part to be replaced.
- Record each items/part replaced, including details of source manufacturer and method of fitting.

Calibration

- Establish if any element/part requires calibration or re-calibration.
- Calibrate in line with the manufacturer's instructions.

Performance and safety

- Carry out performance tests against the manufacturer's specifications before and after maintenance.
- Consider if handover procedure is required.

Return to use

- Input all details on individual equipment record in the maintenance database.
- Check the device has its accessories, where appropriate, and is properly assembled.
- Return controls either to zero or to the settings noted at initial inspection.
- Stick on a dated, 'SERVICED' label noting the next date due and a note of any alterations in control settings

8.8 Routine maintenance by users

Routine maintenance by the user should ensure that the device continues to function correctly.

It entails regular inspection and care, as recommended in the manufacturer's user information or in local procedures. This should clearly show the routine tasks and how they should be carried out. Instructions for user maintenance of medical devices should be provided to the users. These will include:

- checking that it is working correctly before use
- regular cleaning
- specific daily/weekly checks
- noting when it has stopped working properly or when obvious damage has occurred, and then discontinuing use
- contacting the relevant servicing organisation.

Any problems the user finds can then be referred to a repair service. Minor changes that do not affect the safe working of the device can be recorded for attention during the preventive maintenance sessions.

Users may need to be trained to carry out routine maintenance. For example, they may require training on how to remove, change and insert batteries correctly in line with the manufacturer's instructions. They may also need to be warned about the dangers of substituting different battery types. See also Appendix.

8.9 Breakdowns

Even with comprehensive maintenance schedules, breakdowns may still occur.

To restore function as quickly as possible, it is often easiest to substitute a similar device, although this may require increased stock levels especially if equipment is not centrally managed. Substitution is not always possible for items such as large X-ray machines and specially adapted wheelchairs.

Increased stock levels can be set against the likely costs of, for instance, paying an external service provider or providing a similar in-house service for response cover 24 hours per day. Decisions will also depend on the level of service the healthcare provider wishes to provide for their patients and any associated costs for re-arranging clinic appointments etc.

Wherever possible, temporary repairs should be avoided but, if needed, the temporary repair should be carried out and all concerned should be informed of any special precautions or limitations on use, until a permanent solution is available. This should be documented on the device records.

The device should be replaced or withdrawn from service as soon as possible and properly repaired, before it is used again.

8.10 Legal liabilities and Insurance

The healthcare organisations should take all reasonable steps to ensure that medical devices are repaired and maintained to a suitable standard. The extent of liability will depend on the specifics of the case, and what steps are taken to ensure that adequate repair and maintenance are carried out.

Healthcare organisations that modify devices and subsequently transfer them to another legal entity, such as another healthcare organisation, will also need to comply with the UK MDR 2002 [5].

Particular types of devices / equipment are covered by specific legislation and this may affect their maintenance requirements. Health and Safety legislation usually refers to the responsibilities of the employer, rather than the term 'healthcare organisation' used throughout this document. See section 11 for a list of relevant legislation.

The healthcare organisations should ensure that provider has adequate insurance or indemnity in place.

9 Decontamination

Healthcare organisations should keep patients, staff and visitors safe and have policies and systems in place to ensure that all reusable medical devices are properly decontaminated prior to use or maintenance, and that the risks associated with decontamination facilities and processes are well managed.

Decontamination requirements should be considered before reusable medical devices are acquired to ensure they are compatible with the decontamination procedures and equipment available. Decontamination pre-purchase questionnaires can be invaluable for auditing device decontamination issues, prior to purchase. The [Institute of Decontamination Sciences](#) have an example and information on how it can be accessed.

If the manufacturer's instructions appear inappropriate or incomplete, the organisation should report this to the MHRA as an adverse incident (see section 2.7).

Medical devices should be decontaminated and stored in accordance with legislation and best practice requirements, whilst following validated procedures. For further guidance see the Department of Health's document 'Management and decontamination of surgical instruments used in acute care' [20]. Devolved administrations may have their own guidance and should be contacted directly for advice.

Items subject to inspection, maintenance, repair or disposal, either on site or at the manufacturer's or agent's premises, should be decontaminated beforehand. Any loaned items being returned to a manufacturer or supplier should also be decontaminated. Devices intended for single-use only do not require decontamination, except where they are implicated in an adverse incident and may need to be sent to the manufacturer for investigation. In this situation, contact the manufacturer to find out the most appropriate method of decontamination.

Once decontamination has been completed, the items should be labelled accordingly, and a declaration of contamination status form/label completed (or sent electronically). This should be readily accessible to the recipient of the device.

10 Decommissioning and disposal of devices

10.1 Planning for replacement

A policy on removal from service is an essential part of device management. At some point, all devices will need to be replaced.

The expected life cycle of a device or piece of equipment should be held in the inventory record where appropriate, and regularly reviewed against the usage, maintenance and repair record, to see if the end date needs to be adjusted.

Heavy use or irregular maintenance may reduce the life cycle of a device but limited use may extend it.

A manufacturer's recall of a device will take precedence over other considerations.

10.1.1 Replacement criteria

Factors to consider include:

- whether the device is damaged or worn out beyond economic repair
- its reliability (check service history)
- clinical or technical obsolescence
- disposal due to contamination
- changes in local policies for device use
- absence of manufacturer/supplier support
- non-availability of correct replacement parts
- non-availability of specialist repair knowledge
- end users' opinions
- possible benefits of new model (features, usability, more clinically effective, lower running costs)
- lifecycle of the medical device
- redeployment
- utilisation profile – are additional units of equipment required or does the existing supply meet demand?
- equipment downtime
- disposal costs / revenue generation potential
- changes in clinical recommendations/standards
- new equipment technologies and / or technological obsolescence
- changes in service provision.

10.2 Decommissioning

Decommissioning aims to make devices safe and unusable, while minimising damage to the environment. Any device deemed unfit for use should be decommissioned.

It is advisable to contact the manufacturer at this stage for information on decommissioning. The manufacturer should be able to provide details of any

environmental, disposal, recycling or structural requirements. If the manufacturer has ceased trading, contact the MHRA for further guidance.

Decommissioning should include decontamination, making the device safe and unusable. This is to ensure that an inappropriate person does not use the device and expose themselves and / or others to hazards.

For devices that are mobile or housed in general facilities, safety checks, such as power disconnection and cooling system disconnection, should be carried out.

Decommissioning larger installations often involves removal from a purpose-built room or surroundings. Decommissioning of device incorporating radioactive sources must be carried out in accordance with the Ionising Radiations Regulations [16].

10.2.1 Erasing stored data

If a device stores patient identifiable data, this should be certified as securely erased to an appropriate standard, such as BS ISO/IEC 15408 [21] and British HMG Infosec Standard 5, or IS5 [22], before disposal. Data on any device should be forensically unrecoverable, i.e. patient data must be over-written.

10.3 Disposal

Consult the manufacturer for the best methods of waste disposal. They should be able to provide details of the current techniques and processes applicable to their products.

The [Waste Electrical and Electronic Equipment Regulations](#) (WEEE) [23] primarily impose duties on 'producers', i.e. manufacturers and importers.

10.3.1 Examples of special waste

Some waste products need specialised disposal. Examples include:

- wastes containing certain metals (e.g. mercury above 3%, some batteries)
- oil wastes (including polychlorinated biphenyls – PCBs)
- wastes from coolants
- radioactive waste
- healthcare wastes from human or animal origin
- human waste from natal care, diagnosis, treatment or prevention of disease.

Where applicable, devices should be decontaminated before disposal or transfer to a third party, and supplied with a certificate of decontamination.

10.3.2 Transport of devices before disposal

When returning medical devices to the manufacturer at end of life, or when transporting devices, ensure that they are appropriately packaged and secured. Issues that should be addressed include: strength of packing materials, protecting sharp edges, ensuring the device is not damaged in transit etc.

Legislation applies to the transport of goods by road and rail:

- The Carriage of Dangerous Goods by Road Regulations [24]
- The Carriage of Dangerous Goods by Rail Regulations [25]

- Chemicals (Hazard Information and Packaging for supply) Regulations [26]
- The Radioactive Material (Road Transport) (Great Britain) Regulations [27].

Guidelines on transport by post are also provided by Royal Mail on their website: Prohibited goods – business customers [28].

10.4 Sale or donation for reuse

The UK MDR 2002 [5] apply to medical devices being sold for the first time. There is no legislation which specifically covers the resale or reuse of medical devices or equipment.

Note that devices not deemed to be safe for current patient use are therefore not safe for use by anybody to whom the device is donated. If the device is risk assessed as safe to use and working according to specification, it must be supplied with all relevant documentation (e.g. IFU, service history etc).

However, used medical devices are still required to be safe under other national provisions, including:

- Consumer Protection Act (Consumer Safety and Product Liability) [13]
- Sale and Supply of Goods Act [29]
- Health and Safety at Work Act [12]
- Trade Descriptions Act [30]
- The Electrical Equipment (Safety) Regulations [31]
- Unfair Contract Terms Act [32].

10.4.1 Liability issues

Before sale or transfer of ownership of medical devices, both parties should be clear about their legal liabilities. Legal advice should be obtained concerning general device types, such as walking frames or wheelchairs, and more specific advice for individual, larger devices such as X-ray machines.

Essential requirement 13b in Part II of the UK MDR 2002, Annex I (as modified by Part 2 of Schedule 2A to the UK MDR 2002) [5] requires the manufacturer to provide: 'all the information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all

It is good practice to apply this principle to the sale of used device or transfer of ownership, to ensure safety.

This information should be available for a prospective purchaser to view before sale and be supplied with the device on its completion.

On selling or donating used devices, as much as possible of the following information should be supplied with the device to the purchaser:

- a clear statement that the device is being resold/donated
- a certificate of decontamination
- the user manuals and training requirements
- full details of maintenance and servicing requirements
- service history and manual

- usage history
- quality assurance test details
- safety updates, including MHRA and manufacturer's documents that have been released since the medical device was first supplied.

If instructions, training and maintenance/repair information are not available, It is not recommended to pass the device to a new user until the appropriate documentation becomes available.

10.4.2 Refurbishment

A medical device supplied to a new owner after full refurbishment is covered by the UK MDR 2002 [5]. A new UKCA/CE/CE UKNI mark has to be affixed by the person or organisation that carries out the refurbishment.

The term reconditioning or 'refurbishment' is often used for the process of routine cleaning and maintenance, which precedes the re-issue of an item. This process is not generally considered 'full' refurbishment.

Full refurbishment

This term is used in the UK MDR 2002 [5] and applies to the re-manufacture and placing on the market of a device 'as new'. Devices that are fully refurbished and placed on the market are covered by the Medical Devices Regulations.

Full refurbishment will vary for a given device, but is generally considered to consist of:

- stripping into component parts or sub-assemblies
- checking their suitability for reuse
- replacement of components / sub-assemblies not suitable for reuse
- assembly of the replacement components or sub-assemblies, testing of the assembled devices against either original or revised release criteria
- the identification of the fully refurbished device, by appropriate means.

Additional guidance on what constitutes 'full refurbishment' of medical devices is given [here](#).

11 Legislation

This section gives examples of legislation that might apply to your organisation. It is not an exhaustive list.

- [Consumer Protection Act 1987](#) (Consumer Safety and Product Liability) [13]
- [Health and Safety at Work etc. Act](#) (HASAWA) 1974 [12]
- [Ionising Radiation \(Medical Exposures\) Regulations 2017](#) IR(ME)R
- [Ionising Radiations Regulations 2017](#)(IRR) [16]
- [Management of Health and Safety at Work Regulations](#) 1999
- Medical Devices Regulations 2002 (SI 2002 No 618, as amended) [5]
- Sale and Supply of Goods Act 1994 (Chapter 35) [29]
- The Common Law of Negligence: Law Reform (Contributory Negligence) Act 1945 [15]
- The Control of Substances Hazardous to Health Regulations 2002
- The Electrical Equipment (Safety) Regulations 1994 [31]
- The Electricity at Work Regulations 1989 [11]
- The Employers' Liability (Compulsory Insurance) Regulations 1998
- The General Product Safety Regulations 2005 [14]
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. Regulation 16 Safety, availability and suitability of equipment
- The Lifting Operations and Lifting Equipment Regulations 1998 [17]
- The Pressure Systems Safety Regulations 2000
- The Provision and Use of Work Equipment Regulations 1998
- The Waste Electrical and Electronic Equipment Regulations 2006 and The Waste Electrical and Electronic Equipment (Amendment) Regulations 2007 [23]
- Trade Descriptions Act 1968 [30]
- Unfair Contract Terms Act 1977 [32]

12 References and further information

12.1 References

A list of standards designated to the relevant legislation, including the UK MDR 2002, can be found here: <https://www.gov.uk/guidance/designated-standards>

1. Care Quality Commission. [Essential standards of quality and safety](#). 2010
2. NHS England and MHRA. [Improving medical device incident reporting and learning](#).
3. NHS Digital <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/records-management-code-of-practice-for-health-and-social-care-2016>
4. MHRA. [Devices in Practice](#)
5. [Medical Devices Regulations 2002](#) (SI 2002, No 618, as amended)
6. BS EN 62366-1:2015 Medical devices. Application of usability engineering to medical devices
7. BS EN 60601-1-8:2007+A11:2017, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. 2007
8. BS EN 62353:2014 Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment. *Please note - this standard has not been designated under the UK MDR 2002*
9. Department of Health. [NHS Master Indemnity Agreement](#) July 2010
10. The 18th Edition. Requirements for electrical installations. IET Wiring Regulations.
11. [The Electricity at Work Regulations 1989](#)
12. [Health and Safety at Work etc. Act 1974](#)
13. [Consumer Protection Act 1987 \(Consumer Safety and Product Liability\) \(Chapter 43\). Part I: Product Liability, Part II: Consumer Safety](#)
14. [The General Product Safety Regulations 2005](#)
15. [The Common Law of Negligence: Law Reform \(Contributory Negligence\) Act 1945](#)
16. Ionising Radiations Regulations 2017
17. [The Lifting Operations and Lifting Equipment Regulations 1998](#)
18. BS EN ISO 13485:2016 Medical devices. Quality Management Systems. Requirements for regulatory purposes
19. BS EN ISO 9001:2015 Quality management system requirements

20. Department of Health. [Management and decontamination of surgical instruments used in acute care](#). 2013
21. [BS ISO/IEC 15408-1:2009](#) Information technology. Security techniques. Evaluation criteria for IT security Introduction and general model
22. HMG Information Assurance Standard No. 5 - Secure Sanitisation. Part of a larger family of IT security standards published by [CESG](#). If you have an nhs.net email address you can [register on the CESGIAP site](#) to access their policy and guidance documents.
23. [The Waste Electrical and Electronic Equipment Regulations 2006](#) as [amended in 2007](#)
24. [Carriage of Dangerous Goods by Road Regulations 1996](#)
25. [Carriage of Dangerous Goods by Rail Regulations 1994](#)
26. [Chemicals \(Hazard Information and Packaging for supply\) Regulations 2009](#)
27. [The Radioactive Material \(Road Transport\) \(Great Britain\) Regulations 2002](#)
28. Royal Mail. [Prohibited goods – business customers](#)
29. [Sale and Supply of Goods Act 1994](#) (Chapter 35)
30. [Trade Descriptions Act 1968](#)
31. [The Electrical Equipment \(Safety\) Regulations 1994](#)
32. [Unfair Contract Terms Act 1977](#)

12.2 Further reading

[The Special Waste Regulations 1996, SI1996 No. 972](#)

[The Management of Health and Safety at Work Regulations 1999 No. 3242](#)

Lee P, Thompson F & Thimbleby H (2012). 'Analysis of infusion pump error logs and their significance for healthcare,' British Journal of Nursing, 21(8):S12–S22 (IV Supplement)

BS EN 12182:2012, Assistive products for persons with disability. General requirements and test methods. 2012.

BS EN 12184:2014, Electrically powered wheelchairs, scooters and their chargers. Requirements and test methods

BS EN ISO 14971:2019, Medical devices. Application of risk management to medical devices

BS EN ISO 17664:2017, Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices

BS EN 62353:2014 Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment

IPEM. Report 95 Risk Management and its Application to Medical Device Management 2007, IPEM: York. ISBN 978 1 903613 33 7

IPEM. Report 97 Guide to Electrical Safety Testing of Medical Equipment: the how and why 2009, IPEM: York. ISBN 978 1 903613 36 8

12.3 Useful websites

Care Quality Commission

www.cqc.org.uk

Department for Business Innovation & Skills (BIS)

<https://www.gov.uk/government/organisations/department-for-business-innovation-skills>

European Association of Notified Bodies for Medical Devices

<http://www.team-nb.org>

Health and Safety Executive

<http://www.hse.gov.uk/>

NHS Supply Chain

<http://www.supplychain.nhs.uk/>

The Institute of Asset Management

<http://theiam.org/>

National Association of Medical Device and Equipment Trainers (NAMDET)

www.namdet.org

Computers and Human Interfacing with Medical Devices (CHI+MED)

<http://www.chi-med.ac.uk/>

The Institute of Physics and Engineering in Medicine

www.ipem.ac.uk

BSI shop website (for standards)

<http://shop.bsigroup.com/>

Websites accessed January 2021

Appendix – batteries

A1 Battery maintenance

Batteries will naturally discharge over time. If they are not tested and regularly replaced or recharged, they may not operate correctly when required and may even become damaged, due to extensive discharge. For example, some patient monitors and infusion pumps have battery capacity indicators. If the batteries have not been charged in line with the manufacturer's instructions, the indicator itself may not give an accurate reading. This can result in the device shutting down unexpectedly. It should be used for guidance only.

The most important parts to maintaining battery function and life are:

- charging rechargeable batteries correctly in line with the device manufacturer's instructions
- using the correct charger
- keeping the terminals clean and free from debris
- checking connector cables, plugs and sockets.

This is particularly relevant for devices that are infrequently used, for example defibrillators.

Non-rechargeable batteries cannot be repaired if damaged, and should be replaced. Repairs to the outer case of a rechargeable battery may be possible in some circumstances, but should only be carried out by appropriately trained personnel. This may involve the battery being returned to the original manufacturer.

All devices with rechargeable batteries should be maintained and serviced in line with the manufacturer's instructions. This may require regular charging and discharging of the battery and use of specialist test equipment to check the output and condition of the battery or straightforward maintenance suitable for the end user to undertake.

Common issues

Batteries which no longer have any useable life should be removed from the device and replaced in line with manufacturer's instructions. When a device is not going to be used for a significant time, it may be beneficial to remove the batteries from the device.

All batteries must be treated with care to avoid physical damage.

Batteries should be subjected to as little environmental stress as possible. This includes storage or use outside the temperature range intended by the manufacturer, e.g. storage in vehicles or unheated outdoor storage. Batteries, wiring and connectors in medical devices which are left outdoors must be protected from damp to avoid corrosion of the case, contacts, terminals or connections. High ambient temperatures will reduce the capacity and life of the battery; low temperatures will reduce the ability of most batteries to deliver their rated output. Batteries should be stored in line with the manufacturer's instructions.

Batteries in implantable medical devices, such as pacemakers, require no specific maintenance other than voltage monitoring by the clinician in line with the pacemaker manufacturer's instructions, since they are sealed within the implant.

Incorrect output from a charger or an incomplete charging cycle could result in the battery being undercharged. This may result in a reduced time of operation of the device between charges. In other cases, incorrect output from the charger may result in overcharging with consequent deterioration of the battery performance and of the battery itself. The frequency with which batteries are charged depends on use.

Freestanding chargers should be positioned to allow a free flow of air into and out of the case venting or heat sinks. Chargers should not be covered or placed on long pile carpets. During the operation of charging, the charger should be close enough to the batteries and the mains socket to avoid strain on either of the leads. All usage should be in line with the manufacturer's instructions.

Chargers especially designed for non-rechargeable batteries are being marketed in the UK. Users should be aware that this charging process could be hazardous, and the recharged batteries have an extremely short shelf life. Batteries recharged in this way are not generally suitable for use in medical devices because of their unreliability.

An organisation could be held responsible under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage as a result of supplying an inappropriate charging system.

Planned preventive maintenance should include inspections of:

- batteries
- chargers
- connector cables
- plugs
- sockets.

A2 Compatibility of power sources

During their design processes, manufacturers of medical devices set the specification of the battery, charger, all leads and connectors and the charging process, to ensure that the device operates correctly during normal use.

Manufacturers will also establish the detailed specification for maintenance and future replacements.

Batteries, chargers or processes that do not meet the specification set by the manufacturer can lead to incorrect operation or failure of the device. The user or others may be put at risk of:

- fire
- shock
- inhalation of fumes
- inappropriate treatment (e.g. misadministration of intravenous fluids via an infusion pump)
- malfunction of a device (e.g. patient hoist which does not operate as expected and leads to injury).

For applications where the chargers, batteries and leads are constantly disconnected and reconnected, it is essential that the plugs, leads and sockets have been designed to cope with multiple uses. Where repair services replace cables, plugs and sockets, it

should be in line with the manufacturer's instructions – the correct cable wiring configuration and plug or socket should be used.

If in a specific case it is deemed that the benefit of not using the battery, charger, connectors or charging process specified by the device manufacturer would give improved benefits then a risk assessment should be carried out and documented to ensure that all components within a system are compatible and can be used safely.

If a device fails in use following replacement of a part with one not corresponding to the device manufacturer's specification and this leads to the death or serious injury of a patient / user, there is a greater likelihood of the organisation responsible for setting up the components being held liable for the injuries caused. This liability is likely to be mitigated if a thorough, valid and documented risk assessment has been carried out.

The manufacturer's information should include, as a minimum:

- how to access the batteries
- how and when to charge
- how connections are marked to prevent incorrect fitting
- how to connect, disconnect and reconnect
- how to maintain and if necessary how to clean the connectors
- how to test the output of a battery or charger to ensure its performance is adequate
- when to replace batteries
- details of any fuses, overloads, circuit protection and what to do if any of these are activated
- guidance on battery replacement
- battery voltage and capacity
- battery type
- time to charge batteries depending on conditions of use or storage
- what maintenance is required including frequency for batteries, chargers, cables and connectors.

Philips ventilator, CPAP and BiPAP devices: Potential for patient harm due to inhalation of particles and volatile organic compounds

Date of Issue:	23/06/2021	Reference No:	NatPSA/2021/005/MHRA
This alert is for action by: all Hospital Trusts and Health Boards providing NHS and private healthcare, including community care.			
This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by a senior member of staff such as the Head of Respiratory Medicine and head of Procurement/supplies or equivalent roles			

Explanation of identified safety issue:	Actions required 
Philips have issued 2 FSNs about selected ventilators and CPAP and BiPAP devices: See additional information section for affected models. These devices are primarily used in patients with Obstructive Sleep Apnoea (OSA) and type 2 respiratory failure There is a risk of patient harm from degradation of the sound abatement foam found in these devices. Reports of incidents related to this issue are rare, and no incidents of harm have been reported in the UK. There are 2 identified issues: - Degradation of foam causing particles to be blown into the patient's airway. There have been a small number of reports outside the UK of this causing minor, short-term effects such as: irritation to the skin, eye, and respiratory tract; an inflammatory response; headaches; asthma. Inappropriate use and decontamination can worsen the foam degradation. Devices should be used and decontaminated as stated in the manufacturer's instructions for use. - Release of volatile organic compounds (VOC) including Dimethyl diazene and Phenol. Evidence suggests these gases dissipate after 24 hours from first 'out of box' use. There is a risk of short-term effects such as: headache/dizziness; irritation of the eyes, nose, respiratory tract and skin; hypersensitivity; nausea and vomiting. There have not been any reports of this to date. Patients with known allergies or sensitivities to these VOCs should be prioritised for an alternative device if available. There is currently no definitive data showing long-term harm to patients, but VOCs and degradation of the foam are associated with possible long-term effects such as: genotoxicity; mutagenic and carcinogenic effects; hepatotoxicity; nephrotoxicity; neurotoxicity.	NOTE: Do not advise patients to stop using the devices unless a risk assessment has concluded that the risks outweigh the benefits. Actions to be complete by 21 February 2022 - Identify whether you have any of the affected devices in your organisation, or if you have provided them to patients under your care. - Send the FSNs to all relevant departments. Ensure clinicians read and follow the manufacturer's FSNs for each device within 2 days. - Implement and document a risk assessment process to determine the suitability of the continued use of these devices within 1 month. Refer to additional information section below for more information. Clinicians should: - Determine whether risk assessments should be based on individual patients or patient groups and - Contact affected patients and have a risk–benefit conversation about continued use. Advise that they can register their devices on the manufacturer's website. - Source alternative devices where clinically appropriate. Guidance will be available through NHS Supply Chain in England (or national procurement services for Devolved Administrations). - Train staff and patients, and verify competency, in using the alternative devices. Ensure training records are updated.

Additional information:

Risks involved in stopping treatment

Stopping treatment suddenly could have an immediate and detrimental effect on patient health. BiPAP devices are primarily used by patients with established type II respiratory failure. Withholding treatment may worsen the respiratory failure, resulting in the underlying condition getting worse and possible hospitalisation.

CPAP devices are primarily used by patients with Obstructive Sleep Apnoea (OSA), enabling them to carry out activities of normal daily living e.g. driving a vehicle, that they would be unable to do if they were to stop treatment. Withholding treatment could increase their risk of stroke, heart disease and high blood pressure. This could require hospital admission and a more invasive method of treatment and have long-term health consequences.

Filters for ventilator systems (not applicable to CPAP/BiPAP)

Inserting an inline filter into the breathing system of a ventilator between the patient and the device will greatly reduce the risk of patients inhaling particulates, due to the size of the particles released during degradation (2.69UM-724UM). The use of filters is only validated by Philips for the ventilator system and is recommended in the instructions for use.

The use of filters is not validated by Phillips for their CPAP/BiPAP machines and is considered off-label use. The effect of introducing a filter to the breathing system on patient treatment is unknown.

Biological safety risk assessment (based on the currently available data)

The available evidence suggests:

- Volatile organic chemicals of concern (Dimethyl Diazine and Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)) are not detectable 24 hours after the first 'out of box' use of the device.
- Levels of diethylene glycol detected were within an acceptable margin of safety.
- The degradation by-products Toluene Diamine and Toluene Diisocyanate are classified by IARC as Group 2B carcinogens. This category is used for chemicals where there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals.
- Laboratory analysis found that as the foam degraded it tended to stick to nearby surfaces as well as itself. This reduces the risk of respirable particles entering the breathing circuit.
- Degradation of the polyurethane foam can be accelerated by off-label use of ozone decontamination or use in environments with high humidity and temperature, neither of which apply in the UK.
- Available evidence suggests that most degraded foam particles are too big to be inhaled.
- Diisocyanate is associated with isocyanate-induced asthma in a very small number of patients. For sensitised patients even low concentrations can cause adverse effects.

The available evidence suggests that the risks to patients of ceasing to use these devices significantly outweigh the biological safety risks if patients do not have ready access to an alternative.

Affected devices: All devices manufactured before 26 April 2021 are affected. This includes all device models and serial numbers listed below.

CPAP/BiPAP DreamStation ASV, DreamStation ST AVAPS, SystemOne ASV4, C-Series ASV, C-Series S/T and AVAPS, Dreamstation Go, DreamStation SystemOne (Q-Series), Dorma 400, Dorma 500, REMstar SE Auto, OmniLab Advanced+

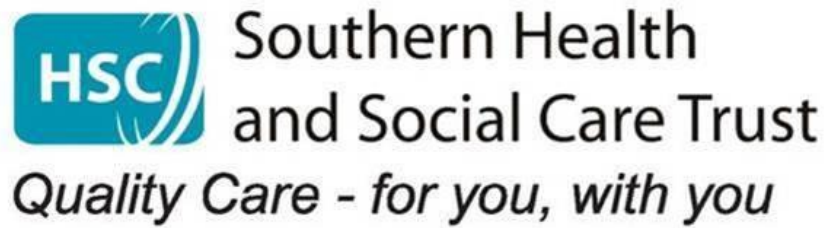
Mechanical ventilators

Trilogy 100, Trilogy 200, Garbin plus, Aeris, LifeVent, A-Series BiPAP Hybrid A30, A-Series BiPAP V30 Auto, A-Series BiPAP A40, A-Series BiPAP A30.

Stakeholder engagement:

DHSC Supply resilience
NHSE/I – including National Clinical Director for Respiratory Disease
Devolved Administrations
Cross-system Incident Management Team
International regulators

Report any suspected or actual adverse incidents involving these devices through your healthcare institution's local incident reporting system and/or your national incident reporting authority as appropriate: [England](#), [Scotland](#), [Northern Ireland](#), [Wales](#).



Blood Transfusion Policy

Lead Policy Author & Job Title:	Trust Transfusion Team
Directorate responsible for document:	Acute Services, Children & Young People Services, Mental Health and Disability, Older People and Primary Care
Issue Date:	April 2018
Review Date:	April 2020

Policy Checklist

Policy name:	Blood Transfusion Policy
Lead Policy Author & Job Title:	Trust Transfusion Team
Director responsible for Policy:	All Operational Directors
Directorate responsible for Policy:	Acute Services, Children & Young People Services, Mental Health and Disability, Older People and Primary Care
Equality Screened by:	Click here to enter text.
Trade Union consultation?	Yes ☒ No ☐
Policy Implementation Plan included?	Yes ☐ No ☐
Date approved by Policy Scrutiny Committee:	Click here to enter a date.
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Policy circulated to:	Eg Directors, Assistant Directors, Heads of Service for onward distribution to line managers, Global email, Staff Newsletter
Policy uploaded to:	Eg SharePoint, Trust website

Version Control

Version:	Version 4		
Supersedes:	Blood Transfusion Policy 2012		
Version History			
Version	Notes on revisions/modifications and who document was circulated or presented to	Date	Lead Policy Author
<i>Eg Version 1_0</i>	Click here to enter text	Click here to enter a date.	Click here to enter text
<i>Eg Version 2_0</i>	Click here to enter text	Click here to enter a date.	Click here to enter text

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1.0 Introduction

The Southern Trust is committed to supporting all staff who are involved in the blood transfusion process to deliver safe, high quality, evidence based care to all patients/clients.

Errors in the prescribing, requesting, collecting and administration of blood components (red cells, platelets, Fresh Frozen Plasma - FFP, cryoprecipitate) lead to significant risks for patients. These are documented in the Serious Hazards of Transfusion (SHOT) voluntary reporting scheme

www.shotuk.org/home

The National Patient Safety Agency (NPSA), the National Blood Transfusion Committee (NBTC) and SHOT have collaborated to develop an initiative to ensure blood transfusions are carried out safely.

The Southern Health and Social Care Trust Blood Transfusion Policy incorporates guidance from SHOT recommendations, Blood Safety and Quality Regulations (BSQR) and the NPSA Safer Practice Notice 14, "Right Patient Right Blood". This NPSA Safer Practice Notice 14 identifies competencies certifiable for a 3-year period. These have been implemented in Trusts in NI and were the subject of an RQIA inspection visit 20-24/04/09.

There is a separate requirement in the Blood Safety and Quality Regulations (BSQR) 2005: Statutory Instrument 2005/50 <http://www.opsi.gov.uk/si/si2005/20050050.htm> 2005 that all staff involved in the distribution and collection of blood components should receive annual update training and there should be an effective practical assessment of their competency every three years.

All registered nurses/midwives/medical staff have a duty of care to provide safe and effective care to all patients/clients and are personally accountable for ensuring that their practice is based on the best available evidence. They are also responsible for ensuring their knowledge and skills are up to date and for participating in appropriate learning and practice activities that maintain and develop competence.

Staff are accountable for their practice and should adhere to guidance set out by their professional regulatory body.

This policy has been developed in accordance with the Trust's key principles for policy development and in consultation with appropriate internal stakeholders.

2.0 Purpose

This policy has been developed to ensure compliance with the requirements of the National Patient Safety Agency (NPSA) Safer Practice Notice 14, "Right Patient, Right Blood" relating to safe blood component transfusion.

3.0 Policy Statement

The Trust will ensure that all staff involved in the Blood Transfusion process will adhere to the NPSA Safer Practice notice (14).

4.0 Scope of the Policy

This policy applies to all staff that prescribe, supply or administer blood components.

5.0 Responsibilities

5.1 Responsibility of the Chief Executive

As Accountable Officer the Trust Chief Executive has overall responsibility for ensuring that staff are compliant with this policy.

5.2 Responsibility of Senior Management.

All Trust Directors, Assistant Directors, Heads of Service and Senior Managers have responsibility for the effective implementation of this policy.

Hospital Trust Management is responsible for the following:

- ensure that there is senior management commitment to all Department of Health Circulars pertaining to blood transfusion
- ensure appropriate membership and function of the Trust Transfusion Committee.
- ensure compliance with the UK Blood Safety and Quality Regulations.
- ensure compliance with the NPSA Safer Practice Notice 14 (2006)
- ensure appropriate composition and function of the Trust Transfusion Team.
- ensure appropriate blood transfusion policies are implemented and reviewed.

Heads of Service / Team Mangers

This Southern HSC Trust policy supersedes all legacy Trust policies referring to Blood Transfusion. Heads of Service / Team Managers must ensure the removal of all related legacy trust policies no later than 4 weeks after the date this policy is ratified by the Senior Management Team (SMT).

5.3 Definition of responsibilities

All staff must adhere to the procedures (Appendix 2) which support this policy.

Medical staff and Registered nurses/midwives who have successfully obtained their certificate of competence for the written authorization of blood components are responsible for appropriately prescribing blood components and for ensuring adequate documentation of blood transfusion in the medical case note record. They are responsible for reporting of transfusion reactions or other incidents related to transfusion. In addition, medical staff are responsible for informing the patient of

- the indication for the blood transfusion.
- its risks and benefits.
- his or her right to refuse the blood transfusion.
- alternatives to a blood transfusion if available.
- the consequences of transfusion – exclusion from the donor panel
- retrospective information

Please refer to the SaBTO final guidance on consent

Medical and/or nursing staff/midwifery may carry out the following:

- request blood components
- obtain blood samples for pre transfusion testing
- carry out the procedure for pre transfusion checks
- monitor patients during the blood transfusion, and carry out appropriate actions in the event of adverse events.
- report transfusion reactions or other incidents related to transfusion.

Phlebotomists, Trauma Aids, Medical Assistants and Maternity Assistants are responsible for the following:

Obtain blood samples for pre transfusion testing.

Biomedical Scientist staff have the authority to challenge any request for blood component/product that appears inappropriate with established best practice.

Staff in the blood bank in addition to their designated roles and responsibilities are responsible for ensuring compliance with Trust Standard Operating Procedures.

Trust Transfusion Committee is responsible for the following:

- promote best practice based on regional and national guidelines; developing and implementing trust policies, protocols and guidelines in all practice related to transfusion

- lead multi-professional audit of the use of blood components within the Trust.
- audit the practice of blood transfusion against local, regional and national standards
- disseminate audit findings to all relevant hospital staff
- promote the education and training of all clinical, laboratory and support staff involved in the blood transfusion process.
- facilitate competency based training and assessment to comply with requirements of NPSA Safer Practice Notice 14 'Right blood, Right patient'.
- have the authority to modify and improve existing blood transfusion protocols and to introduce appropriate changes to practice.
- be a focus for local contingency planning for and management of blood shortages.
- report regularly to NI Regional Transfusion Committee.
- participate in the activities of the NI Regional Transfusion committee.
- consult with local patient representative groups where appropriate.
- develop annual objectives and provide strategic direction to the Trust Transfusion Team
- report to the Trust Chief Executive.

Trust Transfusion Team is responsible for the following:

- lead the implementation of the Hospital Transfusion Committee's objectives.
- promote and provide advice and support to clinical teams on the appropriate and safe use of blood.
- actively promote the implementation of good transfusion practice.
- promote and facilitate education and training for all staff involved in the blood transfusion process.
- monitor and review all transfusion reactions and transfusion related incidents.
- report Serious Adverse Reactions and Serious Adverse Events to SABRE and SHOT.

Haemovigilance Practitioners are responsible for the following:

- ensure quality improvement in transfusion.
- review, implement and disseminate policies, procedures and guidelines pertaining to transfusion.
- promote and provide advice and support to clinical teams on the appropriate and safe use of blood.
- facilitate transfusion training and education to clinical and support staff involved in the transfusion process
- facilitate competency based training and assessment to comply with

NPSA Safer Practice Notice 14 'Right patient, right blood'.

- act as a clinical specialist to advise individuals, clinical teams, and patients and outside agencies.

Hospital Porters are responsible for the following:

- collect samples and the blood component collection forms from the clinical ward/ departments.
- collect blood or blood components from blood bank and delivering them to clinical wards/departments
- return blood or blood components from wards/departments and ensure their prompt return to blood bank.
- be aware of their role in the emergency transport of samples and blood components

6.0 *Legislative Compliance, Relevant Policies, Procedures and Guidance and references.*

Staff must take cognisance of relevant legislations and guidance, including:

- Better use of Blood in Northern Ireland, guidelines for Blood transfusion Practice (GAIN, 2009)
www.gain-ni.org
- British Committee for Standards in Haematology (BCSH) (2009) Guidelines on the administration of blood components
http://www.bcsghguidelines.com/documents/Admin_blood_components_bcsgh_05012010.pdf
- British Committee for Standards in Haematology (BCSH) (2012) Guideline on the investigations and management of Acute Transfusion Reactions.
http://www.bcsghguidelines.com/documents/ATR_final_version_to_pdf.pdf
- Health Service Circular 2007/001 Better Blood Transfusion. Safe and Appropriate Use of Blood.
- United Kingdom Blood Services (2013) Handbook of Transfusion Medicine McClelland, DBL 5th (ed), The Stationery Office, London.
www.transfusionguidelines.org.uk
- UK Blood Safety and Quality Regulations (BSQR)
www.opsi.gov.uk/si/si2005/20050050.htm
- NPSA Safer Practice Notice 14.'Right Patient, Right Blood'
- SaBTO (2011) Patient Consent for Blood Transfusion
www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_130716?ssSourceSiteId=ab
- Nursing and Midwifery Council (2015), *The Code Standards of Conduct, Professional Standards of Conduct for Nurse and Midwives.*

www.nmc.org.uk/standards/code

- The Royal Marsden Hospital (2015) Manual of Clinical Nursing Procedures, 9th edition.

7.0 *Equality and Human Rights Considerations*

Equality Considerations

This policy has been screened for equality implications as required by Section 75, Schedule 9, of the Northern Ireland Act, 1988. Equality Commission of Northern Ireland Guidance states that the purpose of screening is to identify those policies that are likely to have a significant impact on equality of opportunity so that greatest resources can be targeted at them. Using the Equality Commission's screening criteria no significant equality implications have been identified. This policy will therefore not be subject to an equality impact assessment.

Human Rights Considerations

This policy has been considered under the terms of the Human Rights Act, 1998, and was deemed to be compatible with the European Convention of Human Rights contained in that Act. This policy will be included in the Trust's register of screening documentation and maintained for inspection whilst it remains in force.

- 8.0 This document can be made available on request in alternative formats, for example Braille, disc, and audio-cassette and in other languages to meet the needs of those who are fluent in English.

9.0 *Copyright*

The supply of information under the Freedom of Information does not give the recipient or organization that receives it the automatic right to re-use it in any way that would infringe copyright. This includes, for example, making multiple copies, publishing and issuing copies to the public. Permission to re-use the information must be obtained in advance from the Trust.

10.0 *Sources of advice and further information*

Further advice and information regarding this policy can be obtained from the Trust Blood Transfusion Committee.

Appendix 1

1.0 Training and assessment of staff involved in the blood transfusion process

- 1.1 All staff involved in clinical aspects of the blood transfusion process of transfusion must receive training at induction and every *three years thereafter within their area of responsibility.
- 1.2 All staff involved in clinical aspects of the blood transfusion process must have completed relevant NPSA core competencies and be recertified every three years.
* There is a separate requirement in the Blood Safety and Quality Regulations (BSQR) 2005: Statutory Instrument 2005/50 that all staff involved in the distribution and collection of blood components should receive annual update. The Porters are the staff group specified to undertake this role in this Trust.
- 1.3 In order to ensure that all staff involved in the blood transfusion process are competency assessed, it is imperative that there are approximately 3 or 4 trained assessors in each clinical area. It is the responsibility of each Division to ensure that their relevant staff are assessed and competent and their competency maintained. It is also the responsibility of each Division to maintain records of competency assessment for external inspection. All Trained Assessors must receive an update of training every 18 months for assessors.

Appendix 2 Procedures

2.0 Prescription of Blood Components.

2.1 Prescription of blood components is the responsibility of a Medical staff and Registered nurses/midwives who have successfully obtained their certificate of competence for the written authorization of blood components

2.2 Blood components must be prescribed on the appropriate Trust documentation. An integrated blood component prescription and transfusion record combines the prescription sheet, blood transfusion observation, blood transfusion incident report form and information/guidance for staff.

2.3 The prescription must include:

- the blood component to be administered
- quantity to be given
- duration of the transfusion
- any special requirements e.g. gamma irradiated, CMV antibody negative.
- date and time
- prescribers signature

2.4 The prescriber must inform the patient of:

- indication for the blood transfusion.
- Its risks and benefits.
- his/her right to refuse the blood transfusion.
- alternatives to a blood transfusion.
- an opportunity to ask questions.
- retrospective patient information- when the clinical circumstance has precluded patient consent being obtained prior to transfusion of a blood component.

Please refer to the SaBTO final guidance on consent

<http://vsrintranet.southerntrust.local/SHSCT/HTML/PandP/documents/SaBTOfinalguidanceonconsentDec2011.pdf>

2.5 *Use must be made of information leaflets for patients explaining risks and benefits of blood transfusion where appropriate.

http://hospital.blood.co.uk/library/pdf/2011_Will_I_Need_English_v3.pdf

**Will I Need a Blood Transfusion' leaflet in Ten Languages

<http://vsrwebapps02/QPulseDocumentService/Documents.svc/documents/active/attachment?number=INTRANET-54>

3.0 Completing the Pre-Transfusion Request Form.

3.1 The recommended pre transfusion request form is the NI Hospital Transfusion Request form.

<http://shsctintranet.hpss.n-i.nhs.uk/HTML/PandP/documents/Regionalrequestformversion09.pdf>

The following details must be completed for an identified patient:

- patient's surname
- patient's first name
- date of birth
- *health and care number
- gender of patient
- location of patient at time of request and where blood must be sent to if different.
- number and type of blood components including any special requirements e.g. gamma irradiated, CMV antibody negative and the date and time they are required.
- information about transfusion history and obstetric history.

*Regarding unique patient identification

Please note the unique identification number to be used is the Health and Care number (H&C). If the patient does not have an H&C number (i.e. not registered with a General Practitioner in Northern Ireland) the Hospital Number can be used and blood bank must be informed of these situations.

3.2 The pre-transfusion request form requires the signature of the member of staff who took the sample and this staff member will sign a declaration that he/she has achieved NPSA core competency assessment 'obtaining a venous sample for pre-transfusion testing.'

3.3 Addressograph labels may be used on the pre transfusion request form

3.4 If the pre transfusion request form is completed inadequately or inaccurately, the sample will be rejected for testing by the laboratory.

3.5 Telephone requests.

3.5.1 Hospital blood bank must have a policy for receiving and documenting telephone requests.

4.0 Obtaining a Venous Sample for Pre Transfusion Testing

4.1 Positive identification of the patient is essential:

- for patients who are competent and can give an accurate, reliable response, the patient should verbally state his or her first name, surname, date of birth.
- where the patient is unconscious or cannot give an accurate, reliable response the patient's carer, relative or another staff member should be asked to state the patient's first name, surname and date of birth and this must be verified confirmed as identical with the patients wristband.
- in the case of unidentified patients following the agreed Trust policy check identification wristband to verify patient's identity.
- check the patient's details on the patient's identification wristband match those on the request form and the answers to the questions above.
- all patients must have a patient identification number and identification wristband (or validated and risk assessed alternative)
- for an unidentified patient the patient identification number and gender are minimum patient identifiers. The blood bank must be informed when identification details have been confirmed.

4.2 Venepuncture

4.3. The sample tube must be hand written by the person taking the sample immediately after blood has been dispensed. This must be done at the patient's bedside.

4.3.1 Sample tubes must be hand written with the minimum patient identification

- first name
- surname
- date of birth
- health and care number
- signature of the person taking the sample.

4.3.2 Addressograph labels are not permitted on sample tubes. Details must be handwritten.

4.3.3 A final check must be made of the wristband and label on sample tube and the pre-transfusion sample form.

4.3.4 The person taking the sample should record in the patient's notes why the sample was taken, when it was taken, and sign this entry in the notes.

4.3.5 The sample must be sent to the laboratory as per local agreed procedure.

- 4.4 In the case of samples taken within the Outpatient/Treatment room setting the patient must be asked to clarify their first name, surname and date of birth and this must be verified confirmed as identical with the patient's notes and/or hospital appointment letter.
- 4.5 A final check must be made of the details on the sample tube with the patient's notes and/or hospital appointment letter.

5.0 Requesting and Collection of Blood Components from the Hospital Blood Bank and Delivery to the Clinical Area.

- 5.1 Ensure the component is ready for collection
Staff members who are involved in the requesting and collection of blood components will sign a declaration that he/she has achieved the relevant NPSA core competency assessment of 'Organising a Request for a Blood Component for Transfusion' or 'Collecting a Blood Component for Transfusion'.
- 5.1.2 Transfusion should only take place if there are sufficient staff available to adequately monitor the patient throughout the transfusion episode and manage any adverse events or reactions (BSH, The Administration of Blood Guidelines 2017)
- 5.1.3 Positive identification of a patient is essential before the blood component collection form is completed. Ask the patient to state their first name, surname and date of birth. Check that these details and the patient's health and care number correspond with the patient's identification wristband and the details on the blood component collection form.
<http://vsrwebapps02/QPulseDocumentService/Documents.svc/documents/active/attachment?number=1BBBLOODCOLLECTION>
- 5.1.4 Check the prescription chart for the signed prescription for the blood component and any pre-transfusion instructions.
- 5.1.5 The blood component collection form should specify patient's first name, surname, date of birth, health and care number, ward and blood component required.
- 5.1.6 The staff member removing a blood component from appropriate storage must check that the patient's first name, surname and requesting ward correspond with the details on the accurately completed blood component collection form for checking the component before removal. The label on the traceability record is then placed on the appropriate section of the blood component collection form. The blood component collection form should be signed by the staff member removing the component and the date and time of collection recorded.

- 5.2 When blood is delivered to the clinical area the staff member receiving the component should check delivery of correct component for correct patient by checking the component details against the appropriate documentation in the presence of the staff member delivering the blood component. The expiry date and the integrity of pack must be checked.

N.B. The member of staff collecting blood components from the blood transfusion laboratory fridge only checks the patients name and area for delivery. The responsibility for ensuring the correct component has been delivered is the responsibility of the member of staff receiving the component in the clinical area.

- 5.2.1 The time of receipt must be recorded to comply with traceability requirements.

- 5.3 Only one unit of blood should be collected at a time for routine transfusion.

- 5.4 If more than one unit of blood component is required it is essential that clinical staff communicate requirements to the blood bank staff prior to the Porter being asked to collect the blood components.

- 5.4.1 In an emergency a Registered nurse/midwife or Registered medical practitioner must communicate the patients' first name, surname, date of birth, health and care number and number and type of components required to the biomedical scientist in the blood bank.

- 5.4.2 Blood bank staff will document this information and the name of the requesting staff member onto the blood component collection form and this form will be packaged with the blood components.

- 5.4.3 When blood is delivered to the clinical area the staff member receiving the component should check delivery of the correct components for correct patient by checking the component details against the blood component collection form.

- 5.4.4 Staff member receiving the blood components must complete the relevant sections of the blood component collection form.

- 5.5 Red cells must only be stored in blood transfusion refrigerators certified for use and not in ward or other domestic refrigerators, or in appropriately packed and labelled cool boxes which are validated for maintaining the "cold chain".

6.0 Pre Transfusion Identification Checks

- 6.1 It is essential that any patient having a blood transfusion has an identification wristband (or validated alternative) with the patient's first name, surname, gender, date of birth and health and care number.

- 6.2 Positive identification of the patient is essential and must be based on the following,

- ask the patient to state his/her first name surname, date of birth in the case of patients who are competent of giving an accurate reliable response.
- where the patient is unconscious or cannot give an accurate reliable response the patient's carer or relative or another staff member should be asked the patient's first name, surname and date of birth and this should be checked and confirmed as identical against the patients wristband.
- in the case of an unidentified patient follow the Trust Identification Policy.
- check that details of the patient's wristband correspond with the patient identification details on the integrated blood component prescription and transfusion record, the blood bag compatibility label and the transfusion traceability record.
- check that the blood group and donor number put by the Northern Ireland blood transfusion service on the unit of blood component is identical to that on the blood transfusion compatibility label attached by the hospital transfusion laboratory.

- 6.3 Check any special requirements contained on the prescription sheet correspond with special requirements indicated on the blood component label attached by the Blood Transfusion Service.
- 6.4 The blood component must be checked to ensure that it has not expired.
- 6.5 Two members of staff who must be Registered Nurses/Midwives or Registered Medical staff are required to perform the pre-transfusion identification checks. These two staff members must check the identity of the patient and the unit of blood separately. These are double independent checks. Both members of staff will perform the checks separately and independently and agree the result.
- 6.5.1 A final check must include the patient, wristband, blood component and integrated blood prescription record.
- 6.5.2 If checking by two members of staff is not possible e.g. in an emergency situation or patient bleeding in theatre, one member of staff, who must be a Registered Nurse/Midwife or Registered Medical staff may carry out the pre-transfusion checks.
- 6.6 For out of hospital transfusions it is permissible for one person to perform the pre transfusion identification checks provided they have completed NPSA core competency "preparing and administering of transfusion of blood components"

- 6.7 The relevant section of the integrated blood component prescription record and the traceability record should be completed with the following details - start time, finish time and signature of two members of staff.
- 6.8 If any discrepancies are found during the above checking procedure the component must not be transfused. The blood bank must be informed and the component, blood component collection form and the traceability record must be returned to the blood bank.
- 6.9 If no discrepancies are found during the above procedures, the blood component can be erected. This must be done by the staff involved in the above pre transfusion checking procedure.

7.0 Technical Aspects in the Administration of Blood Components

- 7.1 Blood is only permitted to be out of temperature control for maximum time 30 minutes. When blood is received in the clinical area transfusion must commence as soon as practical (within 30 minutes).
This is a BSQR requirement
- 7.2 Maximum infusion time for a red cell unit is 4 hours after removal from the blood fridge.
- 7.3 Blood must be transfused through a sterile blood administration giving set. A standard blood or platelet administration set must be used for the transfusion of platelet concentrates. Platelets must not be transfused through giving sets which have been used for blood or plasma products. Fresh Frozen Plasma (FFP) and cryoprecipitate must be transfused using a blood administration set.
- 7.4 There is no minimum or maximum size of cannula for transfusion. The size of the cannula chosen should depend on the size of the vein and the speed at which the blood is to be transfused.
- 7.5 Blood is not routinely warmed. Blood must only be warmed using a specifically designed commercial device with a visible thermometer and audible warning by staff who have received training to use this equipment.
- 7.6 Blood for transfusion must be stored in a designated blood fridge at a stable temperature 2-6°C. Blood throughout its transportation and storage should be maintained at 2-6°C using validated “cool boxes” which are required to maintain the “cold chain”. If a unit of blood has been out of temperature control for more than 30 minutes and there is no prospect of its imminent transfusion the unit must be returned to blood bank and blood bank informed of this.

7.7 Drugs must not be added to blood under any circumstance.

7.8 Glucose solutions must never be administered immediately before or after a unit of blood is given as they may cause formation of aggregates.

7.9 A new giving set must be used:

- after 12 hours of continuous transfusion in order to prevent bacterial growth.
- if another infusion is to continue after the transfusion.

7.10 Completing the Transfusion.

- empty blood bags must be spiggoted and placed in the clear plastic bag provided before returning to the blood transfusion laboratory. The blood component collection form and traceability record must also be returned to the blood transfusion laboratory with the empty blood bag within 24 hours of the transfusion.
- any unused blood components must be returned to the blood bank as soon as possible.
- if the transfusion runs over in excess of its prescribed time the Doctor must be informed.
- Nurses/midwives must ensure that the blood component collection form and traceability record is returned with the blood bag to the hospital blood bank.

7.11 Platelet transfusion technical aspects

Platelets must never be stored in a refrigerator

- a standard blood or platelet administration set must be used for the transfusion of platelets. Platelets must not be transfused through giving sets which have been used for blood or plasma products.
- platelets must be administered immediately upon arrival to the ward area.
- maximum infusion time 30 minutes.
- N.B: Extended life platelets have an expiry TIME and date.

7.12 Fresh Frozen Plasma (FFP) and Cryoprecipitate (Cryo) transfusion technical aspects.

- FFP and Cryo must be transfused through a sterile blood administration set.
- start infusion immediately upon arrival to the ward/clinical area.
- maximum infusion time 30 minutes.

8.0 Care and Monitoring of Transfused Patients

- 8.1 Registered Nursing/ Midwifery staff are responsible for the care and monitoring of patients receiving a transfusion. In addition they are responsible for measuring and recording the patient's vital signs throughout the transfusion.
- 8.2 A Registered Medical Practitioner and/or Registered Nurse /Midwife is responsible for informing the patient about possible adverse effects of transfusion and the importance of reporting immediately any adverse effects. Adverse effects include:
- pyrexia
 - shivering
 - rashes
 - flushing
 - shortness of breath
 - tachycardia
 - headache
 - chest tightness
 - hypotension/hypertension
 - anxiety/restlessness
 - pain in the extremities and loins.

Please refer to APPENDIX 3

Flow chart guidance for staff Recognition, initial Management and Investigations of an Adverse Transfusion Reaction and Table 1-Investigations of Moderate and Severe Transfusion Reactions

<http://vsrwebapps02/QPulseDocumentService/Documents.svc/documents/active/attachment?number=INTRANET-52>

- 8.3 Visual observation of the patient throughout transfusion is an essential assessment.
- 8.4 Further observations during the transfusion of each unit of blood or blood component are at the discretion of each clinical area and will depend on the clinical condition of the patient.

- 8.5 The start and finish times of the infusion of each unit must be clearly indicated on the observation chart contained in the integrated blood component prescription transfusion record.
- 8.6 The minimum observations required are measuring and recording before the start of each unit of blood or blood component, at 15 minutes after commencement of the transfusion and at the end of each transfusion episode are temperature, pulse blood pressure and respirations. (vital signs).
- 8.7 Vital signs related to the transfusion must be recorded separately from routine observations and clearly dated, and recorded in the integrated blood component and transfusion record.
- 8.8 In the emergency situation vital signs can be recorded on the MEWS chart or anaesthetic record and it should be documented clearly on the integrated blood prescription record where the observations are recorded. **The observations do not need to be duplicated.**
- 8.9 Throughout the transfusion observations must be carried out as follows:
- temperature, pulse, blood pressure and respirations at the start and at the end of each transfusion episode.
 - temperature, pulse, blood pressure and respirations 15 minutes after the start of each unit of blood component.
 - further observations during the transfusion of each unit of blood component are at the discretion of each clinical area and will depend on the clinical condition of the patient.
 - unconscious patients are more difficult to monitor for signs of transfusion reactions. Routine observation patterns should continue. Transfusion reactions should be considered when assessing a change or deterioration in the patient's condition, particularly during the first 15- 20 minutes following the start of a unit of blood component.
- 8.10 Be aware that the patient may experience a delayed transfusion reaction and all patients discharged within 24 hours of receiving a transfusion of blood components should be given an Advice for Patients following a Blood Transfusion Leaflet.

<http://vsrintranet.southerntrust.local/SHSCT/HTML/PandP/documents/AdviceforPatientsfollowingaBloodTransfusiononDischarge.pdf>

9.0 Management and Reporting of Adverse Events

- 9.1 Adverse blood reactions and events are required to be reported by law to Medicines and Health Care Products Regulatory Agency (MHRA). The MHRA has a web based system for reporting known as SABRE (acronym for Serious Adverse Blood Reactions and Events).

9.2 In the event of an adverse incident or 'near miss' relating to blood transfusion, complete the IR1 form on DATIX. In the event of a suspected transfusion reaction complete the IR1 form on DATIX and also complete the Blood Transfusion Incident Report form and send to the hospital blood bank within 24 hours. The Transfusion Team receives all transfusion related DATIX incidents and will communicate and report to SABRE/SHOT if appropriate. The incident will then be reviewed by the Trust Transfusion Team, corrective action formulated and timescales defined. Incidents of high or moderate severity will be reported to the Trust Transfusion Committee and where necessary reported to the Pathology and Laboratory Clinical Governance Committee and to the Trust Director Risk Co-ordinator. All SHOT/SABRE incidents are discussed at the Hospital Transfusion Committee meetings

9.3 Reporting of Serious Adverse Event (SAE) – definition:

'any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to death or life threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity' (UK Blood safety and Quality Regulations 2005)

9.4 Reporting of Serious Adverse Reactions (SAR) – definition:

'an unintended response in a donor or a patient that is associated with the collection, testing, processing, storage and distribution, of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity' (UK Blood Safety and Quality Regulations).

9.5 Reporting of near miss events- definition:

A near miss event is defined as any error which, if undetected could result in the determination of a wrong blood group, or issue of an incorrect or inappropriate component, but which is recognised BEFORE transfusion occurred. (SHOT 2004).

9.5.1 Essentially a 'near miss' is where an error has occurred but a transfusion has not taken place.

9.6 If a severe transfusion reaction is suspected:

- the transfusion must be stopped and urgent medical advice obtained.
- the blood administration set must be changed and venous access maintained using 0.9% normal saline, running slowly to keep the vein open.
- the reaction must be reported immediately to the hospital blood bank.
- the unit and patient identification details must be re-checked to ensure that the correct unit of blood was being transfused.

- any blood remaining in the component and the administration set must be returned to the blood transfusion laboratory for testing. Blood and urine samples from the patient will be required by the laboratory.
- the registered Nurse/Midwife is responsible for ensuring that vital signs are monitored. The Doctor must issue instructions on their frequency.
- the volume and colour of any urine passed must be recorded.

9.7 Reporting of Adverse Events.

9.8 All adverse events related to blood transfusion must be reported according to the appropriate local arrangements as described in section 9.2

9.9 If a severe reaction is suspected, medical advice from a haematologist must be sought.

Please refer to Appendix 3 and Table 1

10.0 Documentation of Transfusions

10.1 Medical notes

10.2 A permanent record of the transfusion of blood components and the administration of blood products must be kept in the medical notes. This policy recommends this should be the integrated blood component prescription and transfusion record.

The following items must be included:

- prescription sheets for blood components
- the indication for the use of blood components, the date, the number and type used, whether or not it achieved the desired effect, the occurrence and management of any adverse effect, and a record that risks and benefits have been explained to the patient
- clinical observations measured and recorded during the transfusion.

10.3 Nursing notes

A permanent record of the transfusion of blood components and the administration of blood products must be kept in the nursing notes.

The following items must be included:

- start time, finish time, number and type transfused.
- the occurrence and management of any adverse event.

11.0 Monitoring and Evaluation

- 11.1 Monitoring and evaluation of all clinical aspects of the blood transfusion process will be managed through the Trust Transfusion Team reporting to the Trust Transfusion Committee and will be subject to periodic audit and regular review.
- 11.2 The Blood Safety Quality Regulations EU Directive (Statutory Instrument 05/50) requires a full audit trail from vein to vein, donor to patient.
- 11.3 All clinical aspects of the blood transfusion process should be subject to periodic audit and regular review.

12.0 Transferring and Receiving of patients receiving a Blood Transfusion.

12.1 Receiving Blood Components from another Hospital.

- The patient will finish any unit which is already being transfused on their arrival to hospital (if the condition of the patient permits)
- If blood is received from another hospital a member of the blood bank staff must be contacted immediately and the additional blood components returned to the blood bank.
- Any blood which has been appropriately packaged by the blood bank staff and which is accompanied by the relevant documentation will be re-crossmatched by the Craigavon or Daisy Hill blood bank. A fresh sample will be required.
- When it is suspected that the correct transport conditions for the blood have not been adhered to then the cross matched components must be discarded and a crossmatch with a fresh patient sample will be performed using donor units stored in Craigavon or Daisy Hill blood bank.

12.2 Transferring Blood Components with a patient to another hospital.

- If blood components are required to be transferred with a patient the blood bank must be contacted immediately.
- Blood bank staff must be provided with full patient identification details, the destination of the patient and the expected time of transfer.
- Blood bank staff will ensure that the blood components are packaged appropriately and complete the relevant documentation.

- Blood bank staff will communicate with the blood bank staff of the receiving hospital and provide information regarding the blood components and patient identification details.
- Only staff who have completed NPSA core competency “preparing and administering transfusion of blood components” can transfuse a patient with full adherence to the Trust Blood Transfusion Policy.
- If the blood components are not transfused during the transfer of the patient, the blood components must be sent to the blood bank of the receiving hospital as soon as possible after arrival.

**Appendix 3- Flow chart for recognition, initial management and investigations of adverse transfusion reactions and
Table 1- Investigation of Moderate and Severe Transfusion Reactions**

Recognition, initial management and subsequent management and investigations of Acute Transfusion Reactions
(adapted 2017 from BCSH, 2012)

Patient exhibiting possible features of an acute transfusion reaction, which may include Fever, chills, rigors, tachycardia, hyper or hypotension, collapse, flushing, urticarial, pain (bone, muscle, chest, abdominal), respiratory distress, nausea, general malaise

STOP THE TRANSFUSION – undertake rapid clinical assessment, check patient ID/blood compatibility label, visually assess unit
Evidence of:
Life threatening **A**irway and/or **B**reathing and/or **C**irculatory problems and/or wrong blood given and/or evidence of contaminated unit

YES

SEVERE LIFE-THREATENING

- Call for urgent medical help
- Initiate resuscitation – ABC
- Is haemorrhage likely to be causing hypotension? If not – discontinue transfusion (do not discard implicated unit/s)
- Maintain venous access
- Monitor patient eg RR, HR, BP, Temp, urinary output, oxygen saturations

- If likely anaphylaxis/severe allergy – follow anaphylaxis pathway
- If bacterial contamination likely start antibiotic treatment
- Use BP, pulse, urine output (catheterise if necessary) to guide intravenous physiological saline administration
- Inform Blood Bank and return unit (with administration set) to Blood Bank
- If bacterial contamination suspected, contact Blood Service to discuss recall associated components
- Perform appropriate investigations (and complete the blood transfusion incident form and document in the patient notes)

Transfusion Team will discuss and if necessary report to SABRE/SHOT

NO

Inform Medical Staff

MODERATE

- Temp $\geq 39^{\circ}\text{C}$ or rise $\geq 2^{\circ}\text{C}$ and/or
- Other symptoms/signs apart from pruritus/rash only

- Consider bacterial contamination if the temperature rises as above and review patient's underlying condition and transfusion history
- Monitor patient more frequently e.g. TPR, BP, oxygen saturations, urinary output

- Not consistent with condition or history
- Discontinue (do not discard implicated unit/s)
- Perform appropriate investigations

- If consistent with underlying condition or transfusion history consider continuation of transfusion at slower rate and appropriate symptomatic treatment

Transfusion-related event

Transfusion unrelated

MILD

- Isolated temperature $\geq 38^{\circ}\text{C}$ and rise of $1-2^{\circ}\text{C}$ and/or
- Pruritus/rash only

- Continue transfusion
- Consider symptomatic treatment
- Monitor patient more frequently as for moderate reactions
- If symptoms/signs worsen, manage as moderate/severe if symptoms indicative of MILD

Continue Transfusion

Document in Notes-Blood Transfusion Incident from NOT required

Appendix 3- Table 1

Table 1 Investigation of Moderate or Severe Acute Transfusion Reactions (for detailed guidance and references see Appendix 2 of the full guidance
http://www.bcsghguidelines.com/documents/ATR_final_version_to_pdf.pdf)

Symptoms	Investigations
Fever $\geq 2^{\circ}\text{C}$ rise or $\geq 39^{\circ}\text{C}$, and/or chills, rigor, myalgia, nausea or vomiting and/or loin pain	Standard investigations* Take samples for repeat compatibility testing, DAT, LDH and haptoglobin Take blood cultures from patient Coagulation screen Do not discard implicated unit If febrile reaction sustained , return unit to laboratory, repeat serological investigations (compatibility testing, antibody screen and DAT), haptoglobin and culture unit If loin pain , perform serological investigations as above
Mucosal swelling (angio-oedema)	Standard investigations* measure IgA level (EDTA sample)- if $<0.07\text{g/L}$, and no generalised hypogammaglobulinaemia, perform confirmatory test with sensitive method and check for IgA antibodies
Dyspnoea, wheeze, or features of anaphylaxis	Standard investigations* Check oxygen saturation or blood gases. Chest X-ray (mandatory if symptoms severe) If severe or moderate allergy suspected measure IgA level. If severe allergy/anaphylaxis suspected, consider measurement of serial mast cell tryptase (plain tube) (immediate, 3 h and 24 h)
Hypotension (isolated fall systolic of $\geq 30\text{ mm}$ resulting in level $\leq 80\text{ mm}$)	Investigate as for fever If allergy suspected measure IgA level. If severe allergy/anaphylaxis consider measurement of serial mast cell tryptase, as above

DAT, direct antiglobulin test; Ig, immunoglobulin; LDH, lactate dehydrogenase;

* Standard investigations: full blood count, renal and liver function tests, and assessment of urine for haemoglobin

Appendix 4**Blood Ordering Schedule**Blood Ordering

The intention behind a blood ordering schedule is to relate ordering of blood to the likelihood that a transfusion will be required. However one should always take into account individuals' risk factors, e.g. age, sex, weight, height and every opportunity should be taken to optimise the pre-transfusion haemoglobin e.g. use of iron.

Guidelines for Prescription of Red Blood Cells
**Northern Ireland Regional Transfusion Committee recommendations
and GAIN guidelines 2009**

There is no 'universal' trigger for blood transfusion.

Appropriateness of Transfusion

Age <65years Hb<70g/l usually transfuse,

Age > 65 years Hb <80g/l usually transfuse

Hb>100g/l Usually do not transfuse

**Individual decision (assess symptoms &
cardiopulmonary reserve)**

Transfusion given at any haemoglobin level can cause morbidity and mortality.

1. Appropriately symptomatic: Symptoms such as dyspnoea, angina palpitations, tachycardia, orthostatic hypotension and syncope that is documented and likely to be due to anemia (Tiredness alone is not an appropriate symptom for transfusion)

2. Ongoing bleeding causing symptoms as listed in 1 or bleeding > 500ml/hr and not stopping

- *Generally allow increase of Hb result by 10.2 g/l – 10.5 g/l per unit of red cells

Post transfusion check must be taken after each unit of red blood cells transfused before decision is made regarding further transfusion.

***Above upper limit is classed as over transfusion**

MAXIMUM SURGICAL BLOOD ORDERING SCHEDULE (MSBOS)

The ratio of the number of units of cross-matched red cells for a given operation to the number of units actually transfused – the C:T ratio – should not exceed 2:1

By following this MSBOS patients for whom the likelihood of blood transfusion is less than

- 30% do not have blood cross-matched but instead have their blood group established and their plasma checked for alloantibodies. This “group and screen” allows rapid blood delivery in an emergency.

Guidelines for Ordering Blood

- Most patients undergoing elective surgery do not require blood
- Transfusion may be required in the post-op period if individual patient assessment indicates this and if the haemoglobin falls below the transfusion trigger.
- If transfusion is required, contact the blood bank and order the appropriate number of units to achieve the criteria target. Ensure the patient is not over-transfused.
- Patients with anaemia pre-operatively may require blood transfusion before anaesthesia – discuss with the anaesthetist and transfuse if indicated.
- Cross-matched blood can be available within 40 minutes if a current group and hold sample is with the blood bank.
- Likewise Group Specific blood can be issued in 10 minutes in an emergency

PROCEDURE	MSBOS
Obstetrics	
Caesarean Section	G&S
Removal of Placenta	G&S
Major Placenta Praevia	2 units
Significant acute Antepartum, Intrapartum or Postpartum haemorrhage	2 – 4 units
Ectopic Pregnancy	G&S
Anaemia in Labour (Hb < 10)	G&S
Previous PPH	G&S
Trial of Vacuum / Forceps in theatre	G&S
3 rd Degree tear	G&S
Multiple birth	G&S
Breech presentation	G&S
Gynaecology	
Hysterectomy	G&S
Myomectomy	2 units
Vaginal Repair	G&S
Salpingectomy/Oophorectomy	G&S
Colposuspension	G&S
Evacuation of Uterus	G&S
Operative Laparoscopic Procedure	G&S

Orthopaedic Surgery	
Fixation fractured neck of femur (Hb < 10.4)	2 units
Fixation fractured neck of femur (Hb > 10.4)	G&S
Total Hip Replacement	G&S
Fractured Tibia	G&S
Total Knee Replacement	G&S
Revision of THR	2 units
Revision Knee Replacement	2 units
ENT / Oral Maxillofacial Surgery	
Thyroid/Parathyroid Surgery	G&S
Parotid Surgery (with potential for complications)	G&S
Parotid Surgery (involving reconstruction or splitting of mandible)	2 units

General Surgery	
Amputation	G&S
Mastectomy	G&S
Excision of Breast Lesion	G&S
Cholecystectomy (Open or Laparoscopic)	G&S
Total Gastrectomy	2 units
Partial Gastrectomy	G&S
ERCP	G&S
Liver Biopsy	G&S
Splenectomy	G&S
Emergency Laparotomy (Discuss with senior clinician as cross match X 2 units may be required)	G&S
Abdominal-Perineal resection of Rectum	G&S
Right Hemi - Colectomy	G&S
Sigmoid Colectomy	G&S
Abdominal Colectomy	2 units
Anterior Resection	G&S
Urology	
Radical Cystectomy	2 units
Nephrectomy (Open or Laparoscopic)	2 units
Percutaneous Renal Surgery (PCNL)	G&S
Prostatectomy (TURP)	G&S
Resection of Bladder Tumour	G&S
Radical Prostatectomy	2 units
Urethroplasty	G&S
Renal Biopsy	G&S

Appendix 5**Procedure for receipt of Blood Components at South Tyrone and Lurgan Hospitals****1. Introduction**

- 1.1. The Blood Safety and Quality Regulations 2005 transpose the European Blood Directive into United Kingdom law. This new law imposes significant new requirements on hospital transfusion laboratories and the clinical transfusion process.
- 1.2. The Regulations require “unambiguous traceability” of all blood and blood components from donor to patient and vice versa or final date if not transfused.
- 1.3. The law demands that evidence of the final fate of every blood component be retained and accessible for 30 years.
- 1.4. The procedure described in this Standard Operating Procedure (SOP) has been designed to allow a signed record of the staff that witnessed the transfusion to be returned to the blood transfusion laboratory that issued the blood component and for the laboratory to complete the computer audit record of the transfusion.
- 1.5. This SOP describes the basic use of the blood collection form and the Blood Traceability Record.

2. Objective

- 2.1. The initial of a formalized and documented procedure, which allows the Blood Transfusion Laboratory to fully trace the movement of blood components from the blood bank storage refrigerator through to its final fate.
- 2.2. To ensure that all nursing and medical staff are aware of their responsibilities with regard to the receipt of blood components at South Tyrone and Lurgan Hospital.

3. Procedure for the receiving Hospital

- 3.1. Staff should contact the Transfusion Laboratory to enquire if the requested blood is ready for collection.
- 3.2. Blood components when ready for issue must be transported in an approved and validated cool box, with fresh cool pack inserted. The blood bank staff are responsible for the packing of the cool box and ensuring that the correct blood component as detailed on Section A of the Blood Collection Form has been packed.
- 3.3. The staff at the requesting hospital are responsible for the transport arrangements.

- 3.4. On arrival, a registered nurse or medical officer must check the integrity of the cool box and complete the blood collection form. Blood must not be accepted if the cool box seal (yellow tag) has been tampered with.
- 3.5. A blood collection form will accompany each unit of blood delivered to the satellite hospital. This form must be completed to ensure a complete audit trail.
- A member of the laboratory staff will have completed sections A, B and C
 - Section D to be completed by a Registered Nurse or Doctor at the receiving hospital.
- 3.6. Continue checking procedure as described in the Southern Health and Social Care Blood transfusion Policy
- Any discrepancy must be investigated and resolved *before* proceeding.
- 3.7. When a cool box has been opened and the transfusion has not been started within the '30 minutes transfusion rule' (as per Southern Health and Social Care Blood transfusion Policy) the blood must be returned to the laboratory for disposal. The blood bank staff must be contacted and the completed blood collection form returned with the unused blood unit clearly marked 'Blood for Disposal out of temperature control'
- 3.8. If blood is not required for a patient and the tamper proof seal is intact the blood bank staff must be contacted and the cool box returned directly to the hospital transfusion laboratory.
- 3.9. Following a successful transfusion the completed blood collection form, Blood traceability record and the used blood unit, that has had a spigot inserted to prevent any leakage sealed in the returnable over-wrap bag, and returned to the blood bank.

4. **AUDIT Non Return of Collection Forms**

The Laboratory blood recording system (Plumtree) is checked for components that have been assigned for use but do not have an entry recording the final fate of the blood component. Non-return reports are produced and followed up by blood bank staff or the Haemovigilance Practitioners. An agreed corrective action plan will be developed with any department found to be non-compliant with this protocol. Offending departments that continue to be non-compliant will be referred on to the Trust Clinical Governance committee.

Appendix 6

TACO Checklist

Transfusion-Associated Circulatory Overload (TACO)

- An adverse outcome of transfusion characterised by respiratory distress as a result of pulmonary oedema following blood component transfusion due to excessive volume and/or transfusion rate and/or when pre-disposing co-morbidities are present (Grey, SHOT, 2016)
- The leading cause of blood transfusion related patient morbidity and death (SHOT, 2016)
- Must be suspected where there is respiratory distress that improves with treatment for circulatory overload e.g. diuretics, morphine and nitrates (SHOT, 2016)
- If TACO suspected, report immediately to Blood Bank

TACO Checklist

CLINICAL ASSESSMENT (BSH, 2012)	YES	NO	CLINICAL ASSESSMENT (SHOT, 2016)	YES	NO
Patient ≥ 70 years of age			Severe aortic stenosis		
Low Body Weight State Weight Kgs			Moderate to severe left ventricular dysfunction		
Cardiac Failure			On a regular diuretic		
Renal Impairment			History of pulmonary oedema		
Hypoalbuminaemia			Respiratory symptoms of undiagnosed cause		
Fluid Overload			On concomitant fluids (or has been in past 24 hrs)		
If 'YES' to any of the above, the patient is at high risk of TACO.					
☐ Review the need for transfusion (do the benefits outweigh the risks?) ☐ Can the transfusion be safely deferred until the issue is investigated, treated or resolved? If transfusion is required: ☐ Transfuse one unit of Red Cells, showing the transfusion duration to 3.5 hours ☐ Review symptoms of anaemia (single unit transfusions are recommended where possible, especially in non-bleeding patients) ☐ Consider giving a prophylactic diuretic ☐ Vital signs must be monitored closely (every 30 minutes) during the transfusion ☐ Fluid balance must be monitored and recorded accurately					

Acknowledgement to:
WH SCT Trust Transfusion Team 2017



UK Haemovigilance

User guide for mandatory and professionally mandated
haemovigilance reporting in the UK

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Overview and aims

The MHRA and SHOT (Serious Hazards of Transfusion) have collaborated to improve haemovigilance reporting by producing an integrated single SHOT and MHRA incident reporting process by linking the SABRE and SHOT online reporting systems.

The main aims of this system are:

- a. A reporting system that avoids duplication of reporting, by the reporter, whilst maintaining the reporter's regulatory and professionally mandated obligations to report, as defined under the Blood Safety and Quality Regulations 2005 (as amended) (BSQR), to the competent authority and to SHOT.
- b. Maintain MHRA as the UK's competent authority (CA) for Serious adverse reaction (SAR) and Serious adverse event (SAE) reporting.
- c. Provide a system that maximises the clinical scrutiny of reports, by SHOT, to ensure that they are correctly classified and imputability ratings identified as directed by BSQR.
- d. Ensure that the data collected accurately reflect the number, type and imputability score of all UK SAR and SAE reports annually.
- e. That both MHRA and SHOT have the appropriate access to the reporter for clarification of SAR and SAE data.
- f. Maintain the legal requirement that ALL SARs and SAEs must be reported to the CA as soon as known.

This guide provides the legal framework for reporting all haemovigilance incidents in the UK and guides the reporter through the key steps for reporting on SABRE and the SHOT online reporting systems.

1 WHY – the legal framework in the UK

1.1 UK legislation and the blood safety and quality regulations

Quality and safety of human blood and blood components from 1 January 2021

From 1 January 2021, you should continue to work to the same quality and safety standards as you do now. You will not need to change your current practice.

This is because the UK will maintain the existing quality and safety standards for the collection, testing, processing, storage and distribution of human blood and blood components.

Before importing or exporting blood and blood components from the EU, Norway, Iceland or Liechtenstein you should [consult with the MHRA](#).

The Blood Safety and Quality Regulations 2005 No. 50 [1] and the Blood Safety and Quality (Amendment) (No.2) Regulations 2005 No. 2898 [2] became effective for the purposes of regulation in the United Kingdom (UK) on 08 November 2005.

The Blood Safety and Quality Regulations apply to **blood establishments** and to **hospital blood banks**. The 2006 Amendment Regulations [3] introduce requirements for a quality system in blood establishments and hospital blood banks. They also extend traceability and record-keeping requirements to ‘facilities’ which may receive blood and blood components (care homes, independent clinics, hospitals and other NHS facilities and services, manufacturers of medicines and medical devices and biomedical research.) Further additional amendments to the BSQR have been made to incorporate minor changes and amendments to fees. Collectively they are referred to as the Blood Safety and Quality Regulations 2005 (as amended).

1.2 Reporting to the MHRA and SHOT

The reporting requirements for MHRA and SHOT are similar but not the same. These requirements are detailed below. The joint reporting system is designed to allow reporters to report all incidents which need to be reported to either MHRA or SHOT. Reports which are not required by either organisation can be excluded or withdrawn as appropriate.

This document will assist reporters in knowing how and when to report adverse events and reactions. It also includes guidance to help identify what constitutes a serious adverse reaction and a serious adverse event and, therefore, what is or is not reportable to the CA. However, this document does not provide a definitive list of what does and what does not constitute a reportable incident. You may also need to contact the MHRA and/or SHOT for advice. In cases of doubt, a report should be submitted.

To ensure that all SAR reports are captured and classified correctly SHOT and the MHRA have combined their efforts to produce a single reporting arrangement which is detailed below.

1.3 Annual summary reports

The CA is required to submit an annual report to the UK Competent Authority by 30 June of each year to include all reports for the 12 month period January to December of the preceding year. The MHRA haemovigilance team will generate and email a summary report, or a nil-report, to each reporter to review in January each year. In addition to the summary data, each reporter is required to complete a table notifying the CA of the number of units of each component issued, the number of recipients and the number of units transfused. Once completed, this must be returned before March 31.

1.4 Annual haemovigilance fees

The Regulation 22 of the BSQR requires fees to be paid to the CA for maintenance of the haemovigilance reporting system. These fees are required to be paid by the person who is responsible for the management of a hospital blood bank or a blood establishment. As the fees are payable by the person responsible for the management of the hospital blood bank, this means they are the responsibility of the Chief Executive of the hospital trust, or the responsible officer of a private organisation. Where transfusion activities are undertaken by a 3rd party provider, it is the trust's responsibility to make local arrangements for payment to the MHRA. The MHRA will not directly invoice the 3rd party provider.

Invoices are raised by the Finance Division of the MHRA on behalf of the Secretary of State for Health and payment is required within 30 days. They will be raised during the first or second quarter of the financial year and cover the period of 1st April to 31st March.

The fee payable is reviewed annually.

Please note that a fee is payable for every blood bank within a trust. Where services are merged onto one central site it is important to advise us of this in writing so that we can ensure correct invoicing.

1.5 Confidentiality

Personal information about patients, donors or staff involved in an investigation is not required to be submitted to the MHRA as part of a notification or confirmation of a SAE or SAR. The link between any submitted report and the traceability records held by the reporting organisation will be made through a local incident reference number that you associate with your report and that you record on the report source section of the report form. The local incident reference number can be any reference used to identify a report locally but must **not** be the patient ID number, NHS number, donation number, donor number or any other reference that can be linked directly to personal details.

Any personal data that has been supplied in your registration or in your submitted reports of adverse events or reactions will be held on our database and will be used in accordance with the **Data Protection Act** [3]. This could be for statistical analysis, management, planning or in the provision of services by the Agency. The MHRA and SHOT will treat all personal information as confidential. Whilst details of reported events or reactions may be disclosed, personal identifying details of patients and/or reporters will not.

Since 01 January 2005 the **Freedom of Information Act** [4] obliged the MHRA to respond to requests for information which it holds and is recorded in any form, and creates a right of access to that information. The Agency will carefully consider its obligations to reporters under the Act prior to any release or non-release of information.

If you are concerned that, as a result of having disclosed information, you may be penalised by your employer or that your actions may lead to your dismissal you may wish to consider whether the provisions of **The Public Interest Disclosure Act (PIDA)** [5] will protect your employment position.

PIDA protects workers who make a protected disclosure of information, concerning certain types of matters relating to their employment, from being dismissed or penalised by their employers as a result of the disclosure. The Act also has the effect of making confidentiality clauses unenforceable where there is a protected disclosure.

The General Data Protection Regulation (GDPR) came into effect as of May 2018 and states;

‘where parties must obtain permission from the data provider, if the information provided such as email addresses, to provide those people with details about what the parties are using their data for, where this relates to direct marketing sent electronically (email, SMS or social media direct message), the parties must seek the data providers consent in advance and respect their wishes should they want to stop receiving this information.’

The MHRA collect data solely for the use of regulatory compliance and therefore do not use any mailing list information for any purpose outside the regulatory framework of the BSQR.

2 WHAT – legal definitions and guidance

2.1 Serious adverse reactions (SAR)

MHRA

Definitions

All italicised quotes are from the BSQR.

A serious adverse reaction (SAR) is:

*‘an unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is **fatal, life-threatening, disabling or incapacitating**, or which results in or prolongs hospitalisation or morbidity’*

The reporting requirements are:

‘blood establishments and the person responsible for the management of a hospital blood bank shall notify the Secretary of State (Competent Authority) of any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components –

- (i) collected, tested, processed, stored or distributed by the blood establishment, or*
- (ii) issued for transfusion by the hospital blood bank’*

Notifications of SARs should be submitted on SABRE **as soon as known**.

All SAR reported under BSQR are also reportable to SHOT, as the reporting requirements for SAR are very similar. However, in addition, SHOT also accepts reports of reactions to solvent-detergent fresh frozen plasma (FFP) (Octaplas) which are not reportable under BSQR.

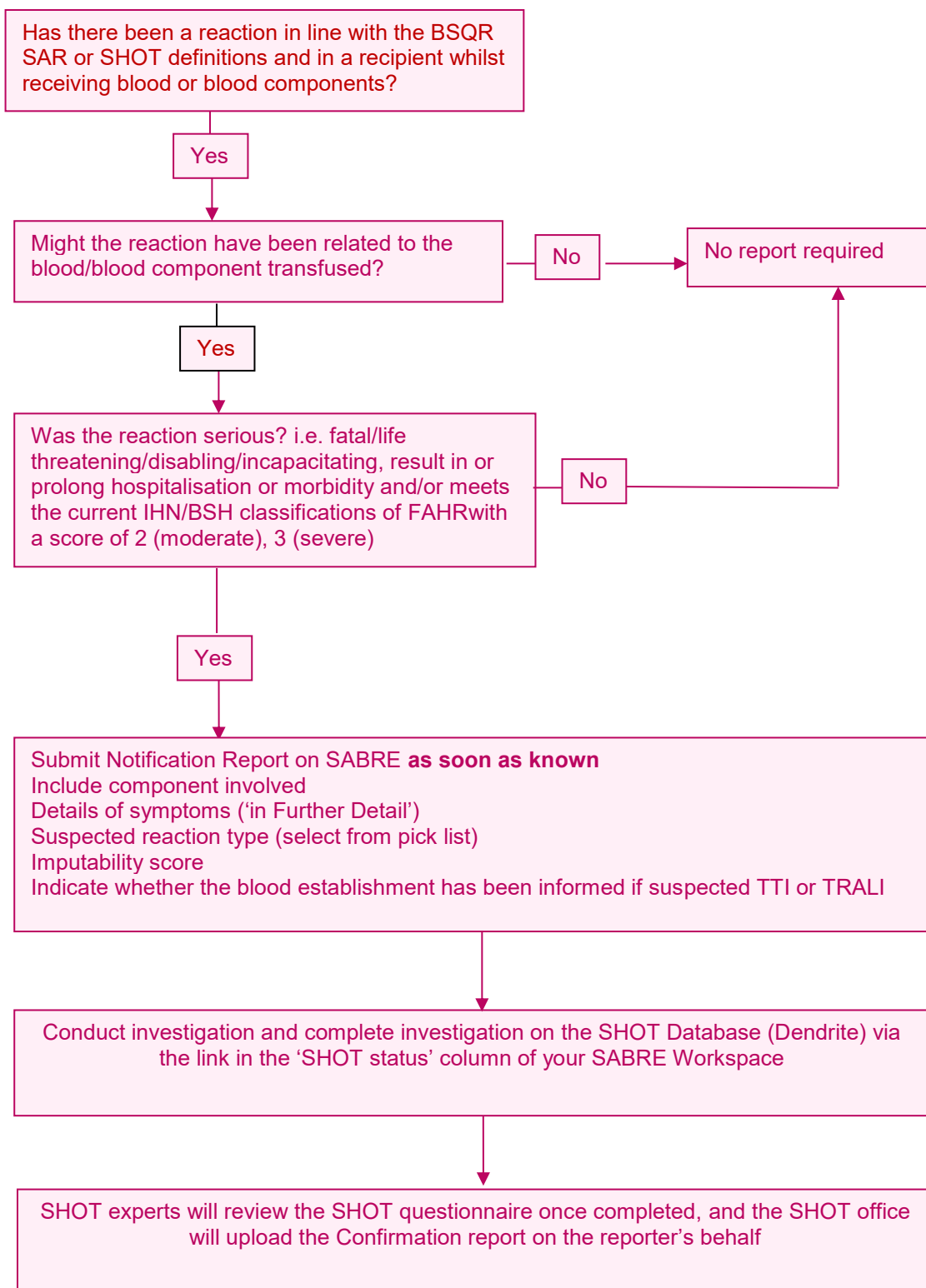
Please report these to SHOT via the SAR page, however they will be excluded by the MHRA.

For further information about reporting definitions, please see the SHOT Definitions Document which is available on the SHOT website (www.shotuk.org).

International Society of Blood Transfusion (ISBT) definitions, clinical and laboratory features of reaction types.

The table in Annex A reproduces the ISBT internationally agreed definitions of the serious adverse reactions terms listed in Part 7, Section A of the BSQR.

An easy to follow flow diagram is located at Figure 1 below

Figure 1 SAR reporting flow chart

2.2 Serious adverse events (SAE)

MHRA

Definitions

All italicised quotes are from the BSQR

A serious adverse event (SAE) is:

'Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.'

The reporting requirements are:

'Blood establishments shall notify... any serious adverse events related to the collection, testing, processing, storage and distribution of blood or blood components by the blood establishment which may have an influence on their quality and safety, and;

'the person responsible for the management of a hospital blood bank shall notify... any serious adverse events related to the collection, testing, processing, storage and distribution of blood or blood components by the hospital blood bank which may have an influence on their quality and safety,'

Notifications of SAEs should be submitted on SABRE **as soon as known**.

Distribution

'the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusion'

Issue

'the provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient'

The following terms, though used, are not defined in the BSQR. Reporters in the UK should be guided by the following definitions to help in determining the need to report an SAE.

'Collection' means the collection of whole blood or apheresis components from the donor.

'Testing' means the mandatory or discretionary testing of the donation by the blood establishment. It also includes tests done by the blood bank on processed components or the recipient sample to determine compatibility.

Note: for SABRE reporting the event category 'testing of donations' should only be used by blood establishments. For laboratory testing errors use the event category 'other'.

'Processing' means manipulation of the blood donation or other blood components for further manufacturing or subsequent administration to humans.

Note: for SABRE reporting the event category 'processing' should only be used by blood establishments. For laboratory processing errors use the event category 'other'.

‘Storage’ means safe management of the blood at all stages of the cold chain and is undertaken by both blood establishments and by hospital transfusion laboratories. Blood leaves the control of the hospital transfusion laboratory at the point where it is issued for transfusion or transferred to a satellite refrigerator that is not within the control of the laboratory (it is arguable that all blood storage refrigerators should be within laboratory control).

An additional category, **Donor Selection**, has been added to collect data on collections from Donors who should have been deferred.

The reporter is NOT now expected to decide at Notification if an event qualifies as an SAE, this will be left to the MHRA and SHOT. All previously defined SAEs, other laboratory errors, clinical errors and near misses should be reported via the SAE Notification form. It will be MHRA’s responsibility to decide whether your report qualifies as an SAE under the BSQR and SHOT’s responsibility if it qualifies as reportable under their definitions.

In the case where a reported event falls outside of the BSQRs the MHRA will contact the reporter via E Mail to exclude the report from the annual summary

Reporters are reminded that the MHRA only has responsibility for acting upon reports that are SAEs, as defined by the BSQR, and they will not take action regarding any clinical error, near miss or laboratory error that is outside of the scope of the BSQR and therefore scrutiny of these reports will solely lie with SHOT.

A decision-making flow diagram which MHRA use to assess SAEs is located at Figure 2 below.

2.2.1 Definitions of reportable SAE

The table in Annex B provides examples of serious adverse events and how they should be classified according to the format in Part 8, Section A of the BSQR.

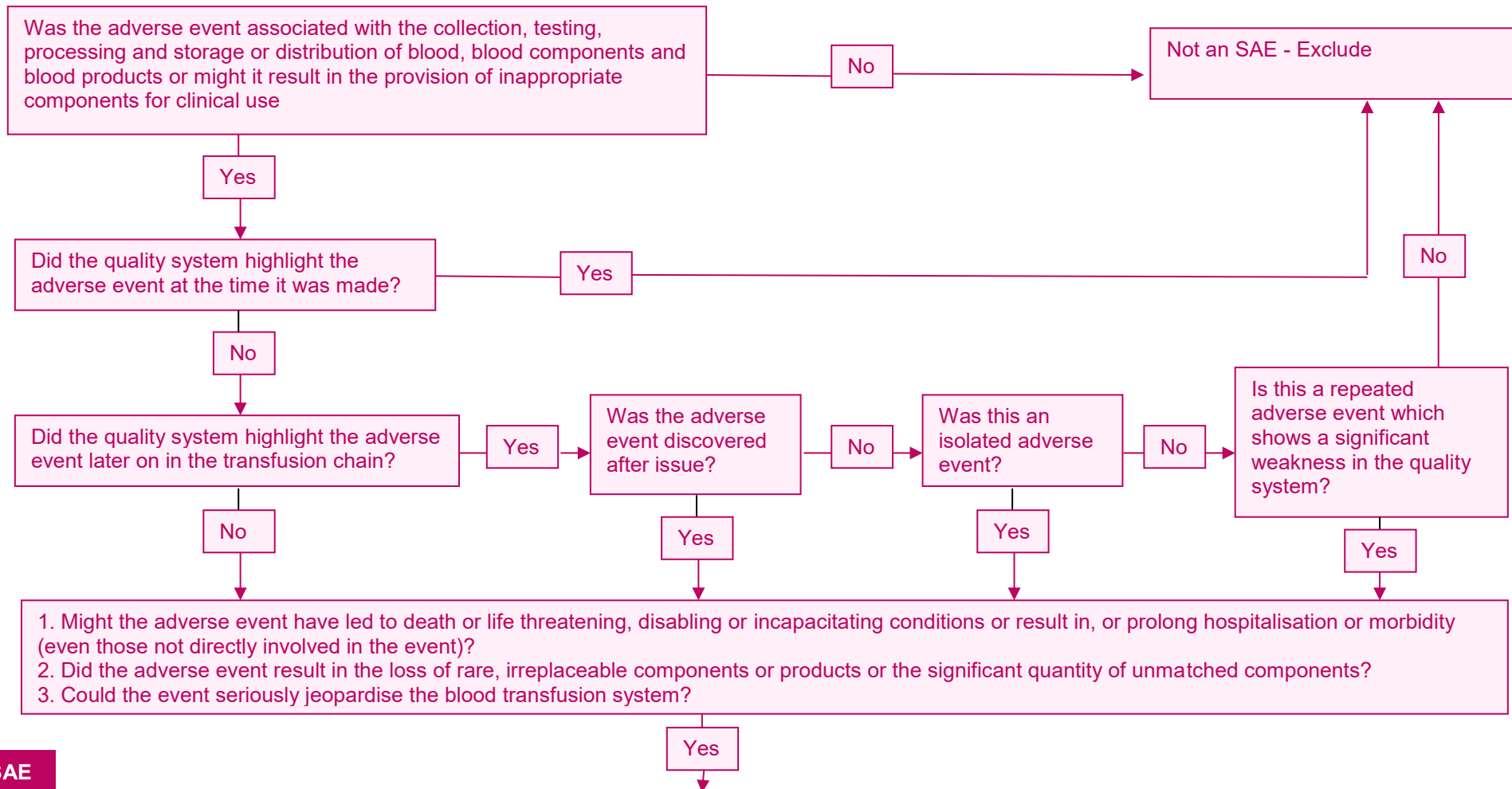
2.2.2 Reporting error-related reports to SHOT

Any report that does not involve a reaction in the patient should be reported via the SAE route of the SABRE workspace.

This includes any non-BSQR reports, for example wrong blood in tube, avoidable transfusions, delays in transfusion, and any incorrect blood component reports where the error originated in the clinical area.

Reports relating to errors in anti-D immunoglobulin (Ig) or PCC administration, and new anti-D immunisations should also be reported here.

For further information about SHOT reporting definitions, please see the SHOT Definitions Document which is available on the SHOT website (www.shotuk.org).

Figure 2 MHRA SAE decision making flow chart**SAE**

Send out first email reminder no sooner than one month.
 Send out second email reminder no sooner than two months.
 Telephone reminders no sooner than after 3 months at no greater than one month intervals.

Assess Confirmation report to verify root cause and contributory factors have been identified and addressed. Amend categories if required to reflect the Event category and Specification. Contact reporter for further detail if required.

Reports which are not confirmed and closed out by the MHRA within 6 months of initial Notification may be referred to the MHRA Inspectors. Reporters can add a Footnote

2.3 Reporting adverse incidents involving medical devices or licensed medicinal products

The Yellow Card Scheme is run by the MHRA and the Commission on Human Medicines (CHM), and is used to collect information from health professionals and the general public on suspected side effects or adverse drug reactions (ADRs) to a medicine. Its continued success depends on the willingness of people to report suspected ADRs.

We collect Yellow Card reports from anyone in the UK on both licensed and unlicensed medicines including:

- i. prescription medicines
- ii. blood products such as anti-D Ig, IVIg and Octaplas
- iii. vaccines
- iv. over-the-counter (OTC) medicines
- v. herbal remedies
- vi. swine flu antiviral medicines (Tamiflu or Relenza)
- vii. swine flu vaccines (Pandemrix, made by GSK or Celvapan, made by Baxter).

Reporters are also reminded that adverse incidents involving failures or problems with medical devices (e.g. blood bags, syringes and needles, blood testing kits, refrigerated blood storage, blood salvage devices, irradiators, etc.) should also be reported to the MHRA Adverse Incident Centre – preferably using the Yellow Card online reporting system <https://yellowcard.mhra.gov.uk/>.

Further information on this aspect of incident reporting may be obtained from the Adverse Incident Centre (telephone: 020 3080 7080) or from guidance documents on adverse incident reporting available on the MHRA website:

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

3 HOW – using the UK Haemovigilance online reporting system

SABRE can be accessed via the following link:

<https://aic.mhra.gov.uk/mda/sabresystem.nsf/Login?Open>

and the SHOT Database can be accessed via the link in the 'SHOT Status' column of the Workspace.

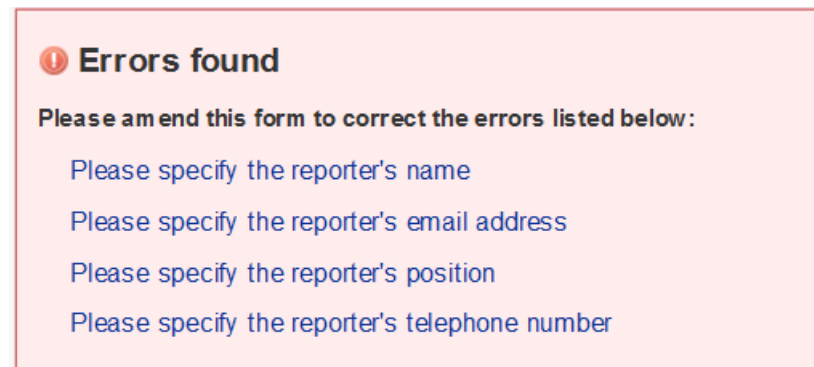
To register for an account please use the following link:

<https://aic.mhra.gov.uk/mda/sabresystem.nsf/Registration?Open>

The system is secure and provides access only to registered users. Once registered, users have access to an electronic report form and to a workspace containing a library of their previously drafted and/or submitted reports. Draft reports can be edited online and may have electronic files (e.g. images, documents) attached for submission.

At all stages of the SABRE reporting process, you will need to have completed all required fields before progressing to the next stage. If there is missing information, error messages will be displayed. Clicking on these messages will take you directly to the field which needs to be provided.

Figure 3 Errors found



3.1 Help

Online help is available at every stage and every level when using the SABRE system. Not only does every page (registration, log in etc.) and every section of the report form have general help text (accessed via a button at the top of the page), but each individual item on those pages has its own help information (accessed by clicking the help icon adjacent to that item).

Practical advice on the use of the UK Haemovigilance system is available from the following sources:

SHOT team – shot@nhsbt.nhs.uk or 0161 423 4208

MHRA SABRE helpdesk – sabre@mhra.gsi.gov.uk or 020 3080 7336

3.2 Registration

Before using the UK Haemovigilance reporting system reporters must first register on SABRE with the MHRA helpdesk.

To register for an account for the UK Haemovigilance reporting system please use the following link:

<https://aic.mhra.gov.uk/mda/sabresystem.nsf/Registration?Open>

Registration is a simple process requiring the completion of a straightforward online form on which you are asked to provide basic details of who you are, the name and type of organisation that you work for, and how we can contact you. In this and the other sections of the form, there are certain fields that you must complete prior to submission. These mandatory fields are marked with a red asterisk.

You are also asked to create and enter a password of your choice. This will be used each time you wish to log in to SABRE. Separate registration for SHOT is not required as a link will be provided to the SHOT system in the SHOT Status column of the SABRE workspace.

When you have completed the registration form, just click the 'submit' button to send your details to the MHRA helpdesk. A member of the MHRA team will then validate your request and send you an email containing your registration number. In certain circumstances staff on the helpdesk may wish to speak to you in person as part of the validation process.

Figure 4 Registration form

The MHRA anticipates that many reporters will continue to operate as part of a haemovigilance team and may therefore choose to register using a shared email address. The MHRA recommends this approach. Once an account has been created, individual reporters can be added to the main account (see 3.2.2).

It will, however, still be possible for reporters to register individually. However, should individual SABRE accounts be registered, individual account holders will not be able to view reports made from other accounts.

For reasons of security and confidentiality, we recommend that you take care to ensure that your chosen password is carefully guarded within your team, but that it is accessible to more than one person so that reports can always be made as soon as possible even in the event of sickness or absence of the main reporter.

3.2.1 Updating registration details

You can change your password, email address, office address or telephone number. Simply log in to SABRE (see 3.3) using your existing registration details and from your workspace click the 'Update Registration' button from the top navigation bar. Amend your details as necessary and submit.

If you change your email address or organisation name, your original account will be temporarily suspended pending validation of the new one by the MHRA team. Until the account has been reactivated, you will not be able to log in using either your old details or your new ones.

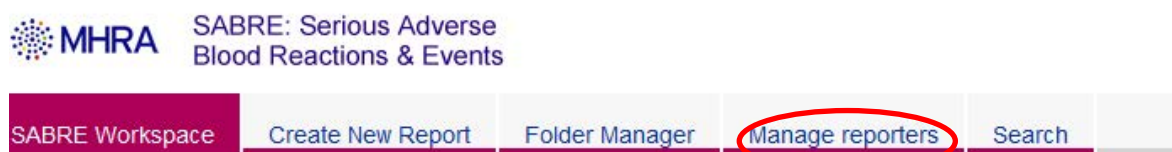
If you have forgotten your log-in details, then telephone the SABRE helpdesk on 020 3080 7336.

3.2.2 Registering reporters on an individual account

Once logged into SABRE, the main account details will automatically be filled into any subsequent SAE or SAR report made. A SABRE account can contain a list of other reporters' details, which can be selected when that reporter makes a report.

- From the Workspace click the 'Manage reporters' button

Figure 5 Manage reporters



- Enter the details
- To add reporters, click the 'Add Reporters' button

Figure 6 Add a reporter

Jump to main content.

Incident Reporting Home Contact us.

SABRE Workspace Create New Report Folder Manager Manage reporters Search Update registration Help Back to MHRA

Add a reporter to your account You are logged in as John Noakes of MHRA Log out

Registered reporter					
Name	Email	Position	Telephone	Fax	
Mr John Noakes	m.d@mhra.com		01294 274191		

Current reporters					
Name	Email	Position	Telephone	Fax	
Chris Robbie	chris.robby@mhra.gsi.gov.uk	SEO	6104	n/A	Delete
Debbi Poles	debbi.poles@nhsbt.nhs.uk	SHOT Research Analyst	0161 423 4233		Delete

Name

Email

Position

Telephone number

Fax number

Freedom of information
Adverse Incident Centre: 020 3080 7336 sabre@mhra.gsi.gov.uk
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- Changes to individual reporter details will need to be deleted and re-added individually

3.3 Log in

Access UK Haemovigilance via the appropriate link on SABRE and the reporter will be presented with the following log in page see below:

Figure 7 Log in page

Login Help Back to MHRA

In SABRE Login Registration form Forgotten Password

Login

Welcome to SABRE – *Serious Adverse Blood Reactions and Events* – the MHRA's online system for reporting blood safety incidents.

SABRE has been specifically designed to provide registered reporters with a simple electronic means of submitting haemovigilance reports to the MHRA and to SHOT.

Registered Reporters - Registered Reporters may log in below.

IMPORTANT: Your password is 'Case Sensitive'. Please ensure that you remember to use the same combination of upper and lower case letters as you entered on your Registration Form.

Not yet registered? - If you have not yet registered as a SABRE Reporter, click the link above and submit the requested details. Please note that the provision of certain information is compulsory for registration.

For security reasons, new Registrations will not be activated until registration details have been checked and verified by the MHRA.

If you are unable to complete your Login successfully please contact the Adverse Incident Centre for assistance and advice:
sabre@mhra.gsi.gov.uk or **020 3080 7336**

Email Address:

Registration No:

Password:
(Case sensitive)

Freedom of information
Adverse Incident Centre: 020 3080 7336 sabre@mhra.gsi.gov.uk
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Simply enter these three items and click 'Login'

- an email address (the one submitted on your registration request)
- a registration number (sent to you by the MHRA SABRE helpdesk)
- your password (chosen by you when registering)

If you have forgotten your password then please call the SABRE helpdesk to have it reset.

3.4 Workspace

After successfully logging in, your workspace will be displayed as shown below.

Figure 8 Workspace

Report type	Reaction / Event related to	Incident Date	Local Ref No	MHRA Ref No	Reporter action	MHRA status	SHOT status
1 N Event	IBCI	24/12/2016 00:00:00	1402 04	2017-02-08-1953	To be Assigned	Submit Notification	Not received
C Event	Other / WBIT	02/02/2014	Weds 3	2017/002/02	2 Submit Footnote	Pending MHRA review	Open N-3
C Event	other test	06/02/2015	Weds 2	2017/002/02	No action	Closed	Open N-3
N Reaction	Red blood cells, - Granulocytes	03/03/2014	Weds 1	2017/002/022/HV1/126	No action	Confirmation required	Open N-3
N Event	Testing of donations	02/02/2015	#dsalf	2017/002/021/HV1/125	No action	Excluded	N-3
N Event	Storage / HSE	04/04/2014	test 210217	2017/002/021/HV1/125	5 Submit Confirmation	Confirmation required	Open N-3
N Reaction	Red blood cells	03/03/2016	2017-02-20-1412 evtl (will rb to Reac)	2017/002/021/HV1/125	No action	Confirmation required	6 Open N-3

1. Indicates a draft SAE Notification report which requires submission as MHRA and SHOT have not received the report
2. Indicates that a Footnote has been requested
3. Indicates that MHRA has closed the report
4. Indicates MHRA has excluded the report
5. Indicates an SAE where Confirmation is required on SABRE and action required by the reporter and an SAR where Confirmation is required by SHOT, but no action is required by the reporter on SABRE
6. Indicates the status of the SHOT report and the web link or N3 link to access the SHOT database directly (see section on 'SHOT status' 3.4.1).

The workspace serves two primary functions:

- as a searchable library of all your draft and submitted reports
- as the platform from which you can
 - create a new report
 - open, read, and/or edit an existing report
 - search the content of all draft and submitted reports and their attachments
 - create folders so that you can organise and manage your reports.

On your first visit your workspace will be empty. Each time you save a draft or submit a report (whether a notification or a confirmation, an event or a reaction report) identifying details of that report will appear in the workspace.

Your workspace is **not** visible to the MHRA or SHOT. However, report details are visible to both organisations once the report has been submitted.

The columns of summary information in the workspace are clearly labelled. The icons that will appear on the left hand side describe the type of report and its status. The icons contain the letters N or C.

N identifies a Notification, C a Confirmation.

The yellow background colour indicates the report's current status as draft, and the blue background indicates that you have submitted that report.

There are columns containing key identifying information from your notification and confirmation.

Table 1

Column header	Explanation	Expected values
Report type	Indicates if it is a reaction or event, a Confirmation or a Notification and a draft or submitted report	Event or reaction, N or C, yellow or blue
Reaction/event related to	Describes the components related to the reaction reported or the Event category. This information may be changed by MHRA on review	Reaction related to field (SAR) or Event involving (SAE)
Incident date	The date the incident occurred	User defined
Local reference number	Local reference number	User defined
MHRA Reference no	The reference number assigned to the report once submitted. A draft report will state 'To be assigned'	In the format YYYY/MMM/DDD/HVX/NNN Where Y= year, M = month, D = Day, X = 1(online report) or = 2 (input by MHRA), N = sequential number in order of receipt
Reporter action	Describes the action expected to be taken next by the reporter, in relation to the MHRA report only.	• Submit Notification • Await MHRA review • Submit Confirmation • Submit Footnote • No action
MHRA Status	Describes the status of the report for MHRA	• Not received • Review pending (for Notifications) • Confirmation required • Pending MHRA review (For Confirmations) • Excluded • Closed
SHOT Status	Describes the status of the SHOT questionnaire	• Open • Closed • Withdrawn

3.4.1 SHOT status

This column shows the reporter the status of the corresponding report on the SHOT Database. Also, this column provides a link directly to the SHOT Database without the need for a separate log-in.

The link to the SHOT database will not be instantaneous, but should be generated within a few minutes of submitting the SABRE notification. You may need to refresh the screen (press 'F5') if the link does not appear automatically.

There are two choices, 'Open' (or any other status) for a link via the general internet or 'N-3' for those reporters who require an N3 connection (the internal NHS network). The different statuses are:

- Open: The SHOT report is open and requires completion by the reporter
- Closed: The SHOT report has been completed and closed by the reporter
- Withdrawn: The SHOT report has been reviewed and withdrawn by the SHOT Team

It is hoped that the addition of these columns will give each reporter more feedback from MHRA and SHOT with regard to the assessment of each report and the expected next steps without having to keep records of 'Excluded reports', 'Outstanding Confirmations' and records of 'additional Footnotes required'.

Please review your Workspace regularly so as to be pro-active in addressing outstanding action statuses.

3.4.2 Folder management

SABRE allows you to organise and store your reports in folders. You can create folders and sub-folders using the folder manager option that is available from your workspace. All folders are displayed alphabetically. You can name and rename folders and also delete them.

There is an online help text for this section that will guide you through the creation and management of folders. Further assistance can be obtained from the SABRE helpdesk.

3.4.3 Searching

SABRE incorporates an internal search facility that is accessible from the workspace. This allows you to search the content of all saved reports and questionnaires – whether they have been submitted or are still in draft form.

3.4.4 Printing

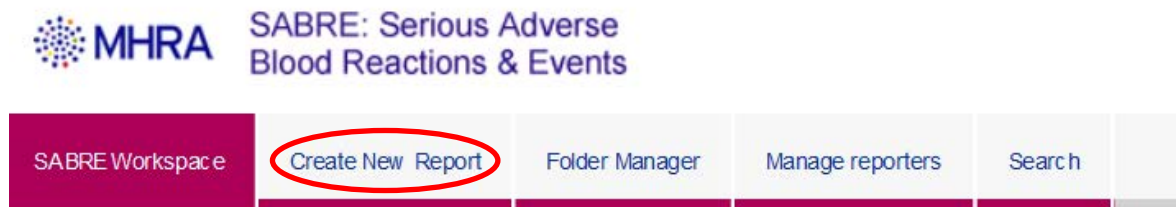
Each section within SABRE includes a button at the top of the screen that enables you to access a 'Printer Friendly Version' of your form should you need a hard copy for your local records.

On the SHOT database clicking the 'Data Summary' button from within any report will display a printable summary of all data entered within the SHOT questionnaire.

3.5 Creating a new report

To create either an SAR or an SAE report to be viewed by both MHRA and SHOT, click Create New Report on the Workspace to open the SABRE Report Source page.

Figure 9 Create new report



Much of this section of the report form will be pre-populated with information submitted on your registration form.

 This is a detailed screenshot of the 'SABRE Report Source' form. The form is titled 'SABRE Report Source' and shows the user is logged in as 'Chris Robbie of MHRA Competent Authority'. The form is divided into two main sections: 'Report Source' and 'Report Details'. The 'Report Source' section includes fields for 'Reporting Organisation' (pre-filled with 'MHRA Competent Authority'), 'Reporting Organisation Address' (pre-filled with '151 BPR, London, England, SW1W 9SZ'), 'Reporter's Name' (pre-filled with 'Mr Chris Robbie'), 'Reporter's Email' (pre-filled with 'chris.robbie@mhra.gsi.gov.uk'), 'Telephone Number' (pre-filled with '020 3080 7306'), 'Fax Number' (pre-filled with 'none'), 'Position / Occupation' (pre-filled with 'Haemovigilance specialist'), 'MHRA Ref No' (pre-filled with 'To be Assigned'), 'Local Reference Number(s)', 'Hospital Consultant', 'Incident Location' (with a dropdown menu), and 'Hospital / Establishment where incident occurred' (with a dropdown menu). The 'Report Details' section includes 'Report type' (with radio buttons for 'Serious Adverse Reaction' and 'Serious Adverse Event'), 'In addition, email this report to', 'Reported locally' (with radio buttons for 'Yes' and 'No'), a red box stating 'Suspected TTI and TRALI must be reported promptly to the Blood Establishment', 'Has this been reported to a Blood Establishment?' (with radio buttons for 'Yes' and 'No'), 'If so, which Blood Establishment', and 'Blood Establishment Consultant'. A 'Next' button is located at the bottom right of the form.

3.5.1 Local incident reporting

Your local incident reference number is also required in this section. This (coupled with the MHRA reference number assigned upon submission of your completed report form) is vital in avoiding potential confusion between incident reports. The local incident reference number can be any reference used to identify a report locally but must not be the patient ID number, NHS number, donor number or any other reference that can be linked directly to personal details.

The MHRA and SHOT are very keen to ensure that reporting to the UK haemovigilance system does not interfere with, or replace, existing local reporting systems (e.g. local risk management reporting systems). To ensure that you are able to advise your colleagues promptly and clearly when you submit a report form, SABRE allows you to enter email addresses for report copies. Any email address correctly entered will receive an electronic copy of your report when you click submit. You may find this useful for ensuring that colleagues, including local risk managers, clinical governance leads etc. are kept aware of your reports of such events and reactions. If more than one email address is entered, each must be separated by a comma.

3.5.2 Blood establishment notification

As well as indicating whether you have made a local report, you must also indicate whether you have submitted a report to the relevant blood establishment. This is of particular importance in TTI (transfusion-transmitted infections) and TRALI (transfusion-related acute lung injury) cases, or in any other circumstances where it is possible that the blood establishment will have to take prompt action to ensure the safety of blood or blood components that have been distributed elsewhere.

3.5.3 Changing the reporter details

To use the details of the added reporters, certain mandatory questions must first be completed before a different reporter can be selected.

- Enter the local reference number
- Select report type serious adverse reaction or serious adverse event
- Click select reporter

Figure 10a Selecting a different reporter

MHRA SABRE: Serious Adverse Blood Reactions & Events

SABRE Workspace **Create New Report** Folder Manager Search

SABRE Report Source

Text marked with an * indicates a required field.

Report Source	Attachment
Report Source ? Reporting Organisation: * MHRA Reporting Organisation * Ayrshire Central Hospital, Kilwinning Road, Irvine, , Scotland, KA12 8SS Address: Reporter's Name: * ? Mr John Noakes Reporter's Email: * ? m.d@mhra.com Telephone Number: * ? 01294 274191 Fax Number: ? Position / Occupation: * ? Clinician Select reporter MHRA Ref No: * ? To be Assigned Local Reference Number * ? Incident 123 (S): Hospital Consultant: ? Incident Location: * ? Transfusion lab Hospital / Establishment where incident occurred ? Crosshouse Hospital Next	Report Details In addition, e n Suspected TTI and TRALI If so, whic Establi Blood Estab Cor

- Select the reporter's details by selecting the radio button adjacent to the reporter's details

Figure 10b Selecting a different reporter

MHRA SABRE: Serious Adverse Blood Reactions & Events

SABRE Workspace Create New Report Folder Manager **Manage reporters** Search

Incident Reporting Home Contact us

You are logged in as John Noakes of MHRA Log out

Select reporter

Registered reporter				
Name	Email	Position	Telephone	Fax
Mr John Noakes	m.d@mhra.com	01294 274191		Clinician

Current reporters				
Name	Email	Position	Telephone	Fax
Chris Robbie	chris.robby@mhra.gsi.gov.uk	SEO	6104	n/A
Debbi Poles	debbi.poles@nhs.uk	SHOT Research Analyst	0161 423 4233	

Selecting reporters

If the reporter you wish to select does not appear in the list above or if the information requires updating, please make the changes using [Manage reporters](#)

Use selected reporter **Cancel**

- Click Use selected reporter

3.5.4 Completing the report source page

Complete the rest of the mandatory fields and any of the additional fields as required

- Incident location is the area or department of the hospital where the error occurred
- Hospital/ Establishment where the incident occurred is a list of hospitals and facilities pre-determined by SHOT particular to your original reporting location. If any changes are required to the list of hospitals, please contact the SABRE helpdesk

Click next to proceed to the SAR or SAE report form.

3.6 Serious adverse reactions – notification and confirmation

3.6.1 Notification report

Once the reporter has correctly completed the 'Report Source details' and selected the 'SAR option' and clicked on the 'Next' button they will be directed to the following SAR Notification screen:

Figure 11 SAR notification report

MHRA SABRE: Serious Adverse Blood Reactions & Events

SABRE Workspace **Create New Report** Folder Manager Search

Serious Adverse Reaction

Text marked with an * indicates a required field

Notification

Date of transfusion *
Day Month Year

Time transfusion started
HH MM (if unknown, leave values as --)

Date reaction started
Day Month Year

Date reaction ended
Day Month Year

Adverse Reaction related to:
☐ Whole blood
☐ Red blood cells
☐ Platelets
☐ Plasma
☐ Other
 If other, please state here:

Type of adverse reaction(s): *
Please Select

Further Detail:
 If other, please state here:

Imputability Level: *
Please Select

Attach file:
 Attach a file
 File Name & Comment Date Actions

Patient/Donor Details

Date of birth *
Day Month Year or Age years

Gender:
☐ Male ☐ Female

Complete the data fields in the Notification section of the SAR where appropriate.

- Use the drop-down lists to record the date and time fields.
- Select the most likely imputability. The imputability is the level at which the blood was likely to have caused the reaction (see section 3.6.5). It is recognised that at this stage, without having completed the investigation, the imputability may have to be an estimate.
- Select all blood components involved in the suspected reaction. Multiple selections are allowed.
- The drop down list for 'Type of adverse reaction' has been designed so that the reporter can add a reaction type that is relevant to both MHRA and SHOT categories. See screen below:

Figure 12 Type of adverse reaction

Reporters can select 'Other/ xxxx' as the reaction type from the drop down list without having to enter free text into the 'If Other, please state here' box. If the reaction type is not specified in the drop down list, reporters should select the lone 'Other' selection and then specify the reaction type as they do currently in the 'If Other, please state here' box.

The 'Type of adverse reaction(s)' field will determine the category of report that is pre-populated on the SHOT database. From the screenshot above, the category name after the last '/' denotes the equivalent SHOT category. Where there is no SHOT category specified, then the category is the same, or in the case of 'Non-immunological haemolysis' there is no specific SHOT equivalent.

- Add a full description of the reaction to allow a third party without access to your local records to fully understand the nature of the reaction being reported.

- Locally written documents are allowed to be attached containing details of the reaction and supporting evidence instead of detailing in the Further Detail section. Please remember, any attachments should NOT contain any patient identifiable information, and must be fully anonymised. To attach a file, click on the 'Attach a file' button as highlighted below:

Figure 13a Attach a file

The screenshot shows the 'Notification' section of the SABRE reporting form. It includes fields for 'Date of transfusion', 'Time transfusion started', 'Date reaction started', 'Date reaction ended', 'Adverse Reaction related to', and 'Imputability Level'. There are also checkboxes for 'Whole blood', 'Red blood cells', 'Platelets', 'Plasma', and 'Other'. A dropdown menu for 'Type of adverse reaction(s)' is set to 'Anaphylaxis / hypersensitivity'. The 'Further Detail' section contains a text area with 'XXXXXXXXXXXXXXXXXXXX'. The 'Attach a file' button is highlighted with a red circle. Below it, a table shows the attached file 'I hope this is attached.doc' with a 'Delete' button.

File Name & Comment	Date	Actions
I hope this is attached.doc XXXXXXXXXXXX	17/08/2015	Delete

Reporters will then be directed to the following screen:

Figure 13b Attach a file

The screenshot shows the 'Attach a file' screen in the SABRE system. It includes a navigation bar with links: 'SABRE Workspace', 'Create New Report', 'Folder Manager', 'Search', 'Update registration', 'Help', and 'Back to MHRA'. The user is logged in as 'Michael Dawe of MHRA Competent Authority'. The main section has a 'Comments:' text area, a 'Date:' field set to '17 Sep 2015', and a 'File:' field with a 'Browse...' button. Below the 'File:' field are 'Attach File' and 'Cancel' buttons. The footer contains 'Freedom of information', 'Adverse Incident Centre' contact details, and the MHRA logo.

Reporters can add a comment, browse from their documents and attach an appropriate file from their document library. Once the appropriate file has been located and is highlighted in

the 'Browse' field click on the 'Attach File' button. (Attachments added here will transfer across to the SHOT Database when the report is submitted).

- Add the patient details

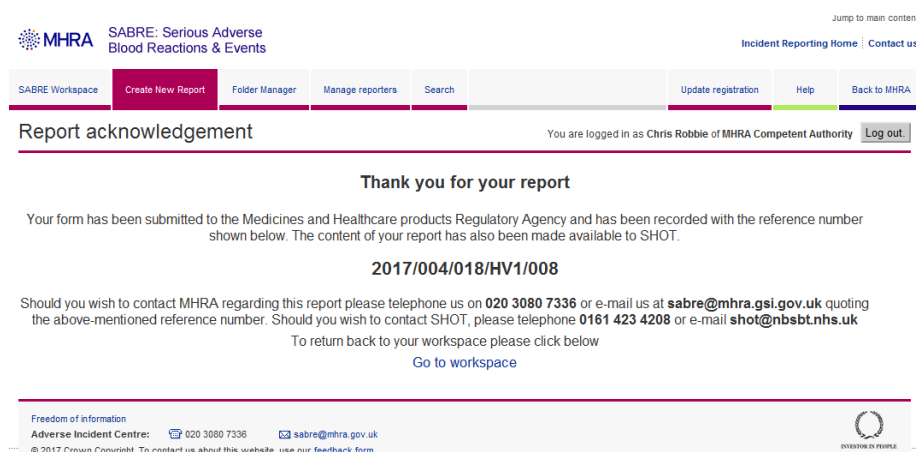
Reporters can 'save', 'save and close', 'discard' the report at any stage by clicking on the appropriate button as highlighted below:

Figure 14 Submitting the report



- The 'save' function will allow the reporter to save the Notification report at any stage as you complete it i.e. like a word document.
- The 'save and close' option will allow you to save and close the report so you can return to it later for completion.
- A draft report i.e. ('to be assigned') can now be deleted in its entirety if it is no longer required. A submitted report (i.e. with an MHRA reference number) cannot be deleted.
- Once reporters have completed the SAR Notification report click on the Submit button. Clicking the Submit button is the only way MHRA and SHOT will have access to your report.

Figure 15 Acknowledgement screen



Once the investigation is complete, the reporter must complete the questionnaire on the SHOT online reporting system. Access this by clicking the link in the 'SHOT status' column of the workspace. Please see section 5 for more details about completing the SHOT questionnaire.

Figure 16 SHOT questionnaire

SHOT
status
Open N-3.

SAR confirmations will be undertaken by SHOT (following completion of the SHOT questionnaire by the reporter) and will be submitted as soon as possible after SHOT subject matter experts have collated all the required information and their expert assessment is complete.

3.6.2 Donors

For serious adverse reactions in a donor, the blood establishment must notify the Competent Authority only where the quality and safety of the blood may be compromised.

3.6.3 Reportable reaction types

Under the new SAR reporting arrangements, at the notification stage, reporters are requested to enter a reaction type which includes:

- Immunological haemolysis due to ABO incompatibility / IBCT
- Immunological haemolysis due to other alloantibody / HTR
- Non-immunological haemolysis
- Transfusion-transmitted bacterial infection
- Anaphylaxis / hypersensitivity / Allergic / ATR
- Transfusion-related acute lung injury
- Transfusion-transmitted viral infection (HBV)
- Transfusion-transmitted viral infection (HCV)
- Transfusion-transmitted viral infection (HIV-1/2)
- Transfusion-transmitted viral infection - Other - Specify in Further Details
- Transfusion-transmitted parasitological infection (Malaria)
- Transfusion-transmitted parasitological infection - Other - Specify in Further Details
- Post-transfusion purpura
- Graft versus host disease
- Other / Febrile ATR
- Other / Mixed febrile / allergic ATR
- Other / Hypotensive ATR
- Other / ATR
- Other / Hyperhaemolysis
- Other / TACO
- Other / TAD
- Other / UCT
- Other / Cell salvage
- Other / Haemosiderosis
- Other / HSE
- Other

NOTE: Please see the SHOT Definitions Document which is available on the SHOT website (www.shotuk.org) or contact SHOT directly for help with a reaction type – listing symptoms is not appropriate in this field, but should be supplied under 'Further details' along with the results of any follow-up tests undertaken as part of the transfusion reaction investigation.

For ISBT definitions with clinical and laboratory features of reaction types please see Annex A.

3.6.4 Patient/donor information

Although some patient or donor information is required, this is only age or date of birth and gender. Your local records will, of course, require further detail for fulfilling traceability requirements.

Confirmation reports will not be carried out by the reporter but by SHOT. MHRA and SHOT will undertake regular consolidation exercises to ensure that the number of reports submitted are accurate by number, classification and imputability score.

The confirmation process will be undertaken by SHOT who will have access to the confirmation area of the SAR in SABRE so it can be populated after the appropriate clinical expert input.

Once SHOT has submitted the final SAR confirmation report the Confirmation report will appear on the Workspace.

Once the reporter has logged into their SABRE account they will be able to view the completed SAR confirmation report, including attached files and Footnotes.

Reporters may be asked to complete a Footnote after they have submitted the SAR Notification report. This can be done as follows:

Access the appropriate SAR report via the SABRE 'workspace' and you will be directed to the following screen:

Figure 17a Adding a footnote

Serious Adverse Reaction You are logged in as Michael Dawe of MHRA Competent Authority [Log out.](#)

Text marked with an * indicates a required field. [Save](#) [Save & Close](#) [Submit](#) [Discard](#)

Report Source **Serious Adverse Reaction** **Foot Notes**

Serious Adverse Reaction
Report Type: Notification and Confirmation

Notification

Date of transfusion: 05 Aug 2015
Time transfusion started
HH:MM (24 Hrs):
Date reaction started: 05 Aug 2015
Date reaction ended: 05 Aug 2015
Adverse Reaction related to: Red blood cells
If other, please state here:
Type of adverse reaction(s): Anaphylaxis / hypersensitivity
If other, please state here:
Further Detail: xxxxxxxxxxxx
Imputability Level: 2
Attach file:

File Name & Comment	Date	Actions

Patient/Donor Details

Patient/Donor Details

Date of Birth (dd/mm/yyyy): or Age: 44 years
Gender: Male

Click on the footnotes tab and you will see the following screen:

Figure 17b Adding a footnote

SABRE Workspace **Create New Report** Folder Manager Search [Update registration](#) [Help](#) [Back to MHRA](#)

SABRE Footnotes You are logged in as Michael Dawe of MHRA Competent Authority [Log out.](#)

Text marked with an * indicates a required field. [Save](#) [Save & Close](#) [Submit](#) [Discard](#)

Report Source Serious Adverse Reaction **Foot Notes**

Create Footnote

Description	Comment	Attachment	Status	Author	Date Submitted
Freedom of information Adverse Incident Centre: ☎ 020 3080 7336 ✉ sabre@mhra.gsi.gov.uk © 2013 Crown Copyright. To contact us about this website, use our feedback form.					

Click on the Create Footnote function, and the reporter will be directed to the following screen:

Figure 17c Adding a footnote

Complete the 'Description', 'Comments' and or 'browse' to attach a file and then click on 'Submit Footnote' button. Reporters can cancel the footnote at any time before clicking on the 'Submit Footnote' button by clicking on the 'Cancel' button.

Once you have clicked on the 'Submit Footnote' button reporters will see the following screen:

Figure 17d Adding a footnote

Click on the Return to Report option and you will now see an overview of the footnote you have just submitted. SHOT will also receive a copy of the footnote and attachment.

SHOT will be the primary contact for reporters for SARs. Reporters can contact SHOT for confirmation of their decision and/or for any further information.

The MHRA adverse incident haemovigilance team will liaise with SHOT to ensure that the SARs meet the BSQR reporting requirements and are appropriately classified.

Adverse reactions that do not fall within the BSQR definition of an SAR will be excluded from the MHRA database but not necessarily from SHOT. Reporters will be informed by e mail that the report has been excluded and the reasons why.

3.6.5 Imputability levels

This is an essential part of the data sets that are reported, therefore the confirmation report that is submitted by SHOT will have an imputability score assigned. This will be transferred to the SABRE database when the confirmation report has been completed.

Imputability means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process. The table below defines the imputability levels:

Table 2 Imputability levels

N/A	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components.
0	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing the adverse reaction either to the blood or blood component or to alternative causes.
2	Likely	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

Although imputability levels are defined by the reporter at the notification stage of the report this may be changed at the confirmation stage following review by the SHOT expert. If further information is required relating to the confirmation report decision, please contact the SHOT office.

3.7 Serious adverse event notification and confirmation

3.7.1 Notification report

Once the reporter has correctly completed the 'Report Source details' and selected the 'SAE option' and clicked on the 'Next' button they will be directed to the following SAE Notification screen:

Figure 18a SAE notification report

Test marked with an * indicates a required field.

Report Source: **Serious Adverse Event**

Change this report to: **Notification & Confirmation**

Report Type: Notification

Notification

Date of event: Day [] Month [] Year []

Event involving: [Please Select]

Specification: [Please Select]

Implicated Component: []

Blood component transfused: [Please Select]

Further Details: []

Attach file

File Name & Comment Date Actions

Patient/Donor Details

Date of birth: Day [] Month [] Year [] or Age [] years

Gender: [] Male [] Female

The SAE reporting process is a two-step processing requiring a Notification report and then a Confirmation report. The SAE reporting requirements request you report a notification of an SAE as soon as known. Usually this will be before the investigation has been completed. However, in some circumstances, it is acceptable to report the Notification and Confirmation reports simultaneously. Consistently late submission of reports is an indicator of problems within the quality management system and may prompt referral to the MHRA's Inspection, Enforcement and Standards Division (IE&S).

To report a Notification and Confirmation simultaneously, click the button labelled 'Change this report to: Notification & Confirmation'. This will then change the report to a Notification and Confirmation report and the button will display as

Figure 18b SAE notification report

Serious Adverse Event ?

Change this report to: **Notification Only**

To convert the report back to a Notification report only, then click on the button 'Change this report to: Notification only'. The Confirmation section will then disappear, and the button will be displayed as

Figure 18c SAE notification report

Serious Adverse Event ?

Change this report to: **Notification & Confirmation**

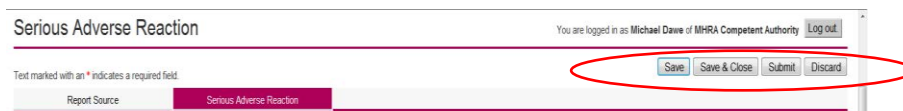
Complete the data fields in the Notification section of the SAE where appropriate.

- Use the drop-down lists to record the date fields.
- Select the most appropriate '*Event involving*' category to determine the correct SHOT questionnaire. If the event is not in the drop down list, the reporter should select the lone 'Other' selection and then specify in the 'If other, please state here' box.
- Select the most appropriate Specification category. This is a broad description of the main root cause of the SAE. If the Specification is not in the drop down list, the reporter should select the lone 'Other' selection and then specify in the 'Other, please state here' box.
- MHRA may change these two categories on review to reflect the most appropriate BSQR categories.
- Select all blood components involved in the suspected reaction. Multiple selections are allowed.
- State whether a blood component was transfused using the drop-down list. This will help SHOT determine the correct questionnaire is assigned to your report.
- If a patient or donor was involved, enter the data in the Patient/Donor Details section.

SAE reports that fall outside the MHRA remit such as Wrong Blood in Tube (WBIT), Anti D etc. must be reported via the UK Haemovigilance system as normal. The MHRA Adverse Incident Team will exclude these reports from the MHRA database and inform the reporter by email.

SABRE allows you to save reports in draft whilst you collect the information required to complete all sections of the report form.

Figure 19 Submitting the report



- The 'save' function will allow the reporter to save the Notification report at any stage as you complete it i.e. like a word document.
- The 'save and close' option will allow you to save and close the report so you can return to it later for completion.
- A draft report i.e. ('to be assigned') can now be deleted in its entirety if it is no longer required. A submitted report (i.e. with an MHRA reference number) cannot be deleted.
- Once reporters have completed the SAE Notification report click on the Submit button. Clicking the Submit button is the only way MHRA and SHOT will have access to your report.

3.7.2 Event categorisation

Under the terms of Directive 2005/61/EC [5] the activities of hospital blood banks are limited to storage, distribution (to external satellite sites only) and other (serious failures of the quality management system). Sites which process blood and blood components (e.g. irradiation process) will need to be registered as blood establishments and may also report processing errors.

SAEs that occur within the hospital blood bank scope of responsibility as monitored by their quality system (i.e. training of staff, security of equipment and premises, adherence to policies and procedures) should be reported when one or more of the following criteria apply:

- inappropriate blood/blood components have been issued/distributed for clinical use, even if not used
- the adverse event resulted in the loss of any irreplaceable autologous blood/blood component (e.g. rare blood group) or any highly matched (i.e. recipient specific) allogeneic blood/blood component
- the adverse event resulted in the loss of a significant quantity of unmatched blood or blood components
- the adverse event could have implications for other patients or donors because of shared practices, services, supplies or donors (i.e. repeated event inside or outside the BE/HBB)
- the adverse event could have a significant impact on the blood transfusion system e.g. by jeopardising the confidence of blood donors or recipients in the system.

The SAE section has been designed to primarily collect the data that is required by the BSQR and SHOT. In order to collect the data in a consistent manner that is suitable both for SHOT and for MHRA summary analysis, standard pick-lists are provided for a number of areas. The available '*Event involving*' categories are:

Table 3 Event involving categories

'Event involving' category	Correct use
Whole blood collection	Blood establishment only relating to collection of blood from a donor
Apheresis collection	Blood establishment only relating to collection of apheresis components from a donor
Testing of donations	Blood establishment only relating to testing of donor blood
Processing	Blood establishment only relating to processing or secondary processing of donor blood
Storage / HSE	Storage including 30minute rule, Miscellaneous, Component expiry, Failure to action alarm, Incorrect storage of component, Return to stock error, Sample expiry, Security, Storage temperature deviation
Distribution / HSE	The act of transporting blood from one legal entity to another. Not for internal stock transfers.
Materials	Errors relating to the materials used in the transfusion service
Other / BSQR event	Any other SAE covered by BSQR that is not also SHOT reportable
Other / IBCT - WCT	Wrong component transfused
Other / IBCT - SRNM	Specific requirements not met
Other / ADU	Avoidable, delayed or undertransfusion
Other / RBRP	Right blood, right patient
Other / WBIT	Wrong blood in tube
Other / Near Miss	Near miss
Other / Anti-D administration	Anti-D administration
Other / Anti-D immunisation	Anti-D immunisation
Other / Cell salvage	Cell salvage
Other / Prothrombin Complex Concentrate (PCC) administration	Prothrombin complex concentrate administration (PUCT)
Other / HSE	Handling and storage errors not covered by Storage / HSE or Distribution / HSE
Other	Any SAE or SHOT-reportable incident not covered by the above
Other / Acknowledging Continuing Excellence (ACE)	To report examples of good practice only to SHOT – this option should not be selected for reporting a serious adverse event

Annex B gives examples of serious adverse events and how they should be classified according to the proposed format in part 8, section C (annual notification format for serious adverse events) of the BSQR.

The '*Event involving*' field in combination with the 'Blood component transfused' field will determine the category of report that is pre-populated on the SHOT database.

From the table below, the category name after the last '/' denotes the equivalent SHOT category. Those with no SHOT category listed are generally not SHOT reportable, and would only be reportable to the MHRA under the BSQR. These reports will still transfer across to the SHOT database, but will have no SHOT category pre-selected.

If the report does not fulfil the SHOT reporting criteria, then please e-mail the SHOT team at shot@nhsbt.nhs.uk and request that the report be withdrawn.

The second field that determines the SHOT category is '*Blood component transfused*'. This is a mandatory field unless the '*Implicated component*' question is answered as 'No implicated component'.

If answered 'Yes', a full incident report will be generated on the SHOT database. If answered 'No' a Near Miss report will be generated regardless of the SHOT category selected in the '*Event involving*' field. This question only has an impact on 'Labile component' categories.

Figure 20 Blood component transfused

So, for example the combinations of data entry below would result in the following SHOT categories (this table is not an exhaustive list):

Table 4 Examples of how SABRE categories map to SHOT questionnaires

Event involving	Blood component transfused	SHOT Category
Other / IBCT-WCT	Yes	IBCT-WCT
Other / IBCT-WCT	No	Near Miss
Storage / HSE	Yes	HSE
Storage / HSE	No	Near Miss
Other / Anti-D administration	Yes	Anti-D
Other / Anti-D administration	No	Anti-D
Other / Anti-D administration	N/A (if 'no implicated component')	Anti-D

If the incorrect SHOT category is chosen, this can be amended in the SHOT database. See section 5.5 on Changing SHOT categories.

3.7.3 Confirmation reports and SHOT questionnaires

Log into SABRE as described in Para 3.3 above and the reporter will then be directed to their workspace, see Para 3.4 above.

Select the appropriate SAE report from your workspace and you will be directed to the completed SAE 'Report Source' page relevant to the SAE report accessed.

Figure 21a SAE confirmation report

Text marked with an * indicates a required field.

Save Save & Close Submit

Report Source **Serious Adverse Event** Foot Notes

Report Source	Report Details
Reporting Organisation: MHRA Competent Authority	Report type: Event
Reporting Organisation Address: 151 BPR, , London, , England, 67576t	In addition, email this report to:
Reporter's Name: Mr Chris Robbie	Reported locally: No
Reporter's Email: chris.robby@mhra.gsi.gov.uk	Suspected TTI and TRALI must be reported promptly to the Blood Establishment.
Telephone Number: 0207 0843336	Has this been reported to a Blood Establishment? No
Fax Number: none	If so, which Blood Establishment:
Position / Occupation: test 3 24 feb	Blood Establishment Consultant:
MHRA Ref No: 2017/006/006/HV1/012	
Local Reference Number(s): jyfgkjh	
Hospital Consultant:	
Incident Location: Coronary care unit (CCU)	
Hospital / Establishment where incident occurred: Ayrshire General	

Now click on the 'Serious Adverse Event' Tab above

You will now have access to the confirmation section of the selected SAE report as shown below:

Figure 21b SAE confirmation report

Serious Adverse Event Confirmation

Confirmation report submitted by: ?

☒ Original Reporter ☐ Other

Please enter your contact information, if you are not the original reporter.

Confirmation
Reporter's Name:

Email Address:

Telephone Number:

Position / Occupation:

Confirm date of Serious Adverse Event ?

Day Month Year

Confirmation of Serious Adverse Event ?

☐ Yes
☐ No

Root cause analysis ?
(outcome of investigation):

Corrective measures ?
taken (details):

Attach file: ?

Attach a file

File Name & Comment	Date	Actions

Attach file: ?

Attach a file

File Name & Comment	Date	Actions

Complete all the mandatory fields.

- If you are the original reporter **do not** complete the four reporter details fields
- If you are **not** the original reporter select 'Other' in the 'Confirmation report submitted by' field and complete the four reporter fields below
- Enter the date of the completion of the investigation in the 'Date of confirmation' field
- Enter the date of the SAE
- Confirm if the reported event was an SAE or not
- Complete the Root cause analysis and Corrective measures boxes (see 3.7.4 and 3.7.5). These 2 fields will also transfer across to the associated SHOT questionnaire and be displayed on the 'Procedural review' page.
- Click the submit button to submit the report to MHRA for review. An incompletely submitted Confirmation report cannot be viewed by MHRA.

Note: Because SHOT and MHRA review SAE reports from a clinical and a BSQR point of view, SHOT may additionally require a separate questionnaire to be completed to address the clinical and/or laboratory errors involved in the report. For example, if a wrong unit is collected from a fridge, and a failure of the administration checks results in the wrong patient being transfused, MHRA will assess the report at the point of collection, and SHOT will assess the report at the point of administration.

3.7.4 Root causes

This is where you must enter details of the outcome of your local investigation into the event that has occurred. The term *root cause analysis* is taken directly from the BSQR. It is not intended that SABRE reporters must undertake specialist root cause analysis training in order to complete this section of the report form.

In this section, you must provide enough detail to describe not just **how** the event occurred, but **why** the incident occurred. It will benefit your corrective and preventive action to identify all the human factors involved. Write this section with enough detail so a third party without access to your local incident system can fully understand the root cause. You may attach files with an internal report or supporting evidence.

3.7.5 Corrective measures

Enter details of any actions taken to ensure that the circumstances that led to the occurrence of this SAE will not be repeated. Please ensure that all human factors and contributory factors identified are addressed.

Successful CAPA may involve re-designing critical processes, re-writing procedures, re-training staff or otherwise improving the overall Quality Management System such as managing distractions or addressing workload or staffing issues. Do not rely on CAPA which simply reminds staff of the correct procedure, or employs additional checking for errors instead of preventing the error from occurring. Write this section with enough detail so a third party without access to your local incident system can fully understand the corrective measures. You may attach files with an internal report or supporting evidence.

Both MHRA and SHOT are concerned of the effects of resourcing, staffing and workload on the root causes of SAEs. It is vital that if these factors result in the events reported, that these are detailed and addressed in the report to allow us to properly categorise and analyse the data collected.

3.7.6 Changes made by MHRA to SABRE reports

Once a reporter has submitted a SABRE report, the MHRA will sometimes amend categories and data within those reports on the MHRA SABRE HITS database. Previously, these changes were not reflected on SABRE and MHRA notified reporters by email to changes made that would be reflected in the next Annual summary report. Now, when changes are made following assessment by the MHRA haemovigilance team, or additional information from the reporter or SHOT, these changes will be reflected in your report. Reporters will still receive notification emails from MHRA and you will still have the opportunity to discuss any changes made.

3.7.7 Referral to the MHRA inspectors

Some reports may be referred to the MHRA Inspection, Enforcement and Standards division (IE&S) for further action where we are concerned that there may be a risk to patient safety e.g.

- death due to ABO incompatible transfusion

- multiple pre-transfusion testing errors
- recurrent failures of the quality management system/ineffective corrective and preventative actions
- late reports
- unusual recalls due to processing errors
- issuing of wrong components/ incorrect special requirements.

3.8 Logging out

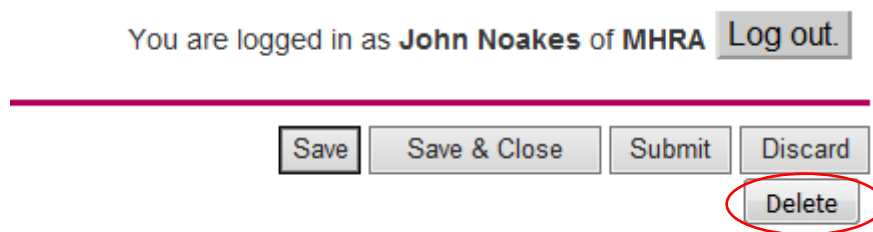
It is important that you remember to log out after every session. Failing to log out may cause difficulties on the next occasion that you (or your colleagues) log in.

4 Additional information

4.1 Deleting draft reports

Previous versions of SABRE have not allowed you to delete reports in case one reporter accidentally deleted the wrong report. However, this has often resulted in a number of blank reports which clutter up the Workspace. SABRE now allows you to delete draft reports only. To do this, simply open the report to be deleted and click the delete button.

Figure 22 Delete button



4.2 Amending report types (rollback)

If a reporter incorrectly reported an SAE instead of an SAR, or vice versa, previously the reporter was required to report the incident again in the correct format, while the original report was excluded. **New functionality will allow MHRA to change the Report type of Notification reports only.** Once this has been done, the reporter is required to then re-submit the amended form.

In the image below, 2017/003/001/HV1/164 has been submitted as an SAE.

Figure 23a Amending report types (rollback)

Report type	Reaction / Event related to	Incident Date	Local Ref No	MHRA Ref No	Reporter action	MHRA status	SHOT status
N Reaction			2017-02-27_1111 Rn	To be Assigned	Submit Notification	Not received	
N Event			test	To be Assigned	Submit Notification	Not received	
N Event	Processing	04/04/2013	2017-02-08-1953	2017/003/001/HV1/164	Submit Confirmation	Confirmation required	

If this is incorrect, contact MHRA or MHRA will contact you to arrange the change of report type. Once MHRA have made the change, your report will appear in the Workspace as below.

Figure 23b Amending report types (rollback)

Report type	Reaction / Event related to	Incident Date	Local Ref No	MHRA Ref No	Reporter action	MHRA status
N Reaction			2017-02-27_1111 Rn	To be Assigned	Submit Notification	Not received
N Event			test	To be Assigned	Submit Notification	Not received
N Reaction			2017-02-08-1953	2017/003/001/HV1/164	Submit Notification	Not received

The Report type has now changed from a submitted SAE Notification report to a draft SAR with the original MHRA reference number. You are required to complete the new form and submit as usual.

4.3 Troubleshooting

Reports of serious adverse events and serious adverse reactions should only be submitted to the MHRA via SABRE.

Other means of submission should only be considered if SABRE is temporarily unavailable and the report is urgent. In such cases the MHRA Adverse Incident Centre should be contacted for guidance on how to report.

5 Completing the SHOT questionnaire

5.1 Documentation & help

Further information about the SHOT reporting categories is available in the SHOT Definitions Document which can be accessed via the SHOT website under the Current Resources section. <https://www.shotuk.org/resources/current-resources/>

Full details of the data required for each reporting category are available for download from the Documents section of the SHOT database (Dendrite). These datasets contain a flowchart of questionnaire pages, and a list of questions and answer options on each page.

To access them go into a SHOT questionnaire via SABRE. This questionnaire must be either completed, or at least have the mandatory questions on the registration page completed or you will be unable to move off the page until those fields are completed.

- Click either 'Save & Exit' or 'Patient Search' buttons to go back to the SHOT workspace
- Click 'Main Menu' button
- Click 'Documents' button

Documents available:

- SHOT Dendrite Database User Manual
- Reporting FAQs (SHOT Bite No. 6)
- Dataset of questions and answer options for each SHOT reporting category

5.2 Completing the SHOT database record

Once a report has been submitted on the SABRE system, a link will be generated on the SABRE workspace which will lead directly to the associated SHOT report on the SHOT database.

Figure 24 SHOT link



On clicking this link, the SHOT Database will be opened and the **Registration Details** page for that specific report will be displayed. Most fields will be pre-populated from the information entered onto SABRE but the remaining fields will need to be completed as far as possible.

Fields populated directly from SABRE where data is present:

- Date event reported
- Date and time of event
- Gender
- Reporter name
- Reporter telephone number
- Local reference number
- Patient date of birth
- Patient age (auto-calculated from date of birth and date and time of event fields)
- Reporting organisation
- Reporting hospital
- Description of the adverse event or reaction
- Is this event related to (and subsequent question if applicable)
 - Was a component transfused (Labile components only)

The database has been designed so that the response to certain questions will determine which questionnaire pages are generated.

If the incident is related to Anti-D Ig administration, Anti-D immunisation, Cell Salvage or Acknowledging Continuing Excellence (ACE) the relevant pages for these reporting categories only will be available to complete.

If 'Anti-D' is selected, there is an additional question before the main Anti-D Ig questionnaire pages are generated. 'Was Anti-D omitted, administered late or administered incorrectly'.

The purpose of this question is to determine whether the report is a full Anti-D Ig incident, or whether it was an Anti-D Ig 'near miss':

- Answering 'Yes' to this question will generate the Anti-D incident pages
- Answering 'No' will generate the Near Miss incident pages (for example where an error was discovered before anti-D Ig was administered to the wrong woman)

If the report is for an incident related to blood and blood components (labile components), the next question is: Was a component transfused.

Figure 25 Labile components

Is this event related to	☒ Labile component	☐ Anti-D	☐ Cell salvage	☐ Anti-D immunisation
Was a component transfused	☐ No	☐ Yes		

If the answer is 'Yes' the following pages will need to be completed:

Implicated Component
Indication for Transfusion
Transfusion
Transfusion Event

Some of these pages may contain data that has been pre-populated from SABRE. The **Transfusion Event** page determines the reporting category for all labile component

reports where a component has been transfused. The choice of reporting category made here will determine which pathway the report is taken down. In most cases these selections will be pre-populated based on the initial data entered on SABRE.

If the answer is 'No', a new question will be generated 'Was there a delay which resulted in no component being transfused'.

- Answering 'Yes' to this question will generate the usual labile component pages (listed on the previous page). This option should only be used to report a delay in transfusion (ADU) that meant no component was transfused which resulted in harm or potential harm to the patient.
- Answering 'No' will generate the Near Miss incident pages i.e. no component was transfused because the error was identified prior to transfusion

5.3 Entering data and navigating the database

Please note any patient or staff-identifiable information must not be included in the record or in any documents that you upload.

5.3.1 Navigating the database and saving records

To navigate through the database, use the Previous Page and Next Page which are situated at the top and bottom of every page. When clicking on these buttons the data on the screen will be saved and the next page or the previous page will be displayed. The data on the screen will also be saved if the Save and Exit button is clicked.

Figure 26a Navigation



There is also the facility to navigate directly to another page within the questionnaire by using the drop down list of pages next to the buttons at the top of the page.

Figure 26b Navigation

Save & Exit	Transfusion event	Page
	Registration details	
	Implicated component	
	Indication for transfusion	
	Transfusion	
	Transfusion event	
Transfusion incident	Overall morbidity and mortality	
	Incident details	
	Other fluids	
	Patient history	
Adverse reaction	Reaction	
	Investigations	
	Treatment / Support	
	Outcome	
	Procedural review	

5.3.2 Interactive questions

Most questionnaire pages contain some interactivity, which means that certain questions are hidden until they become relevant. For example, on the **Implicated component** page. Further questions are displayed when different options are selected.

Figure 27a Interactive questions

Implicated component			
Implicated component/s	☐ Red cells components ☐ Other	☐ Platelets	☐ Plasma components ☐ Granulocytes

Implicated component			
Implicated component/s	☒ Red cells components ☐ Other	☐ Platelets	☐ Plasma components ☐ Granulocytes
Implicated red cell component/s	☐ Red cells ☐ CMV negative ☐ For neonatal use	☐ Irradiated ☐ Washed ☐ For exchange transfusion	☐ For intra-uterine transfusion ☐ HEV negative

Implicated component			
Implicated component/s	☒ Red cells components ☐ Other	☒ Platelets	☐ Plasma components ☐ Granulocytes
Implicated red cell component/s	☐ Red cells ☐ CMV negative ☐ For neonatal use	☐ Irradiated ☐ Washed ☐ For exchange transfusion	☐ For intra-uterine transfusion ☐ HEV negative
Implicated platelet component/s	☐ Pooled	☐ Apheresis	
Platelet component specific requirements	☐ Irradiated ☐ HPA matched ☐ HEV negative	☐ CMV negative ☐ Hyperconcentrate for neonatal use	☐ HLA matched ☐ Pathogen inactivated (PI)

Once data are entered in one of the sub questions, the primary question cannot be changed.

Trying to do this will result in the error message below.

hostn3.e-dendrite.com says:

You can not change the value of this field because the following target fields contain data.
Implied red cell component/s

☐ Prevent this page from creating additional dialogues.

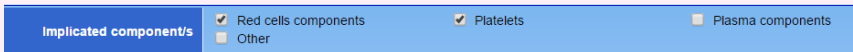
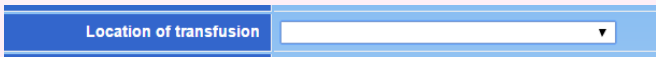
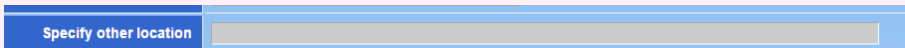
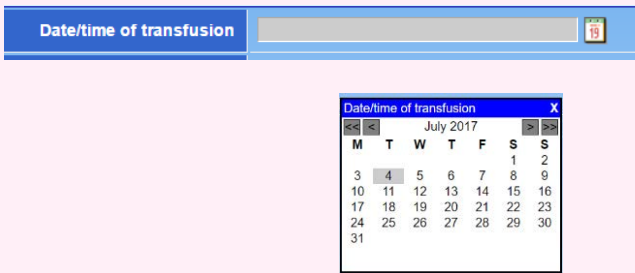
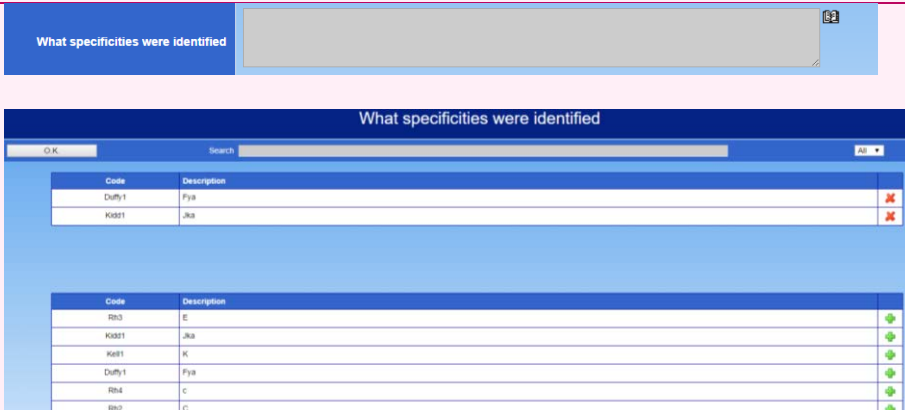
OK

The same principles apply to any primary and sub questions throughout the database.

5.3.3 Question types and entering data

The SHOT questionnaire pages are made up of different question types:

Table 5 Question types and data entry

Multiple choice More than one option can be selected. Tick all options that apply, and click once on a checkbox to remove its entry.	
Single choice Only one option can be selected. Clicking on a different option will change the selection, unless there is dependant data entered further down the page. To remove a selection completely, double click on it to 'de-select' the entry.	
Drop down list Click the arrow on the right hand side of the box to open the drop down list. Choose an item from the list, and click to select it.	
Free text fields Any text can be entered in these fields, but avoid using symbols or quotation marks " where possible.	
Date/time Click on the calendar symbol on the right hand side and select a date from the pop up calendar. Alternatively, the date and time can be typed directly into the box. This must be a valid date format to be accepted e.g. dd/mm/yyyy.	
Table list Select multiple items from a list. Click on the 'open book' icon at the right hand side of the text box. This will open a new window with the list of options. Click on the options required and they will move to the top of the screen. When all items have been selected click the 'OK' button.	

5.3.4 Completing and closing a record

It is extremely important to include the outcome of the final local review before closing the report, as this is essential for SHOT to appropriately analyse and assess the case.

When all the data necessary have been entered and the record is complete, please ensure that the report is closed by answering 'Yes' to the question below. This is the last question on the **Procedural Review** page.

Figure 28a Completing and closing a record

Is the questionnaire complete? Click Yes to close the report	☐ No	☒ Yes

When clicking 'Save and Exit', the record will turn green on the workspace, which indicates that it is complete. The record is now locked as 'read only' so the completed data can be reviewed by the SHOT Team. If any changes are required after completion, please contact the SHOT Office.

Figure 28b Completing and closing a record

21031	18 November 1997	Female	26 November 2015	2015/011/026/HV1/001		Transfusion associated circulatory overload (TACO)	T

5.4 General SHOT database features

5.4.1 Hover prompts

Some fields will show what is known as a 'hover prompt' when the cursor is rested on them. They contain definitions or details of what information is required to complete the field. While the cursor rests on them they will persist, and will only disappear when the cursor is moved on. See below.

Figure 29 Hover prompts

Transfusion event	
Transfusion incident	- Serious adverse event - Serious adverse reaction - Transfusion Transmitted Infection
Serious adverse event	- IBCT - Wrong component transfused - IBCT - Specific requirements not met - Avoidable, delayed and undertransfusion - Right blood / right patient - Handling and storage errors

Prescription of components that are not required or where another therapy or component would have been clinically appropriate or prescription at an incorrect dose or rate, or for an inappropriate indication, including over transfusion or under transfusion.

If the hover prompt does not disappear when the cursor is moved, then clicking on the hover prompt text will remove the message.

5.4.2 Uploading documents

There is a document upload facility on the **Procedural Review** page which enables relevant documents to be uploaded, such as Root Cause Analyses. SHOT would encourage this so that a thorough analysis can be undertaken for the SHOT Annual Report.

From 2021 there will be restrictions on the type of files that can be uploaded on the SHOT database. Permitted file types are: .pdf, .docx, .xlsx, .pptx, .txt.

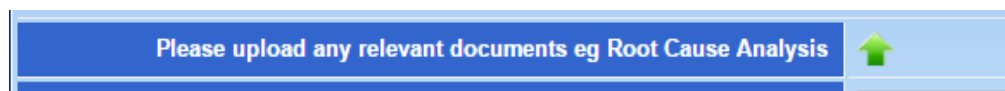
The preferred, and most secure format for any document upload is pdf.

Please ensure any documents uploaded are anonymised so that there is no identifiable patient or staff member data included

In addition, any documents uploaded to SABRE will transfer across to the SHOT database and will be held on a new page called **Footnotes**. This page will only exist in the record if an attachment has been transferred across from SABRE.

To upload a document on the **Procedural Review** page, click on the green arrow (shown below).

Figure 30a Uploading documents



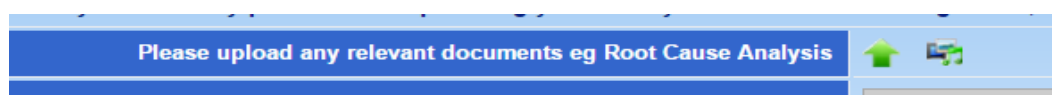
Add a description in the 'Media Description' field, for example 'Root cause analysis' or 'Investigation report' etc.

Then click the 'Choose file' button and select the file to upload. Once there is a file selected, click 'Upload'. The filename will be displayed in place of the text 'No file chosen'.

Figure 30b Uploading documents

Click the back button to return to the **Procedural Review** page. There will be an additional media icon displayed to the right of the green arrow, which indicates that there is an attachment now available to view.

Figure 30c Uploading documents



5.4.3 Reminder e-mails

SHOT will send reminder e-mails for any report that is still incomplete (i.e. 'Open' on the SABRE workspace, or 'yellow' on the SHOT workspace) one month or more from the date the report notification was submitted.

Monthly reminder e-mails will continue to be sent until the report is either completed, or the report is more than 6 months old. After a report is 6 months old, SHOT will need to consider whether the report should be withdrawn from the analysis. However, SHOT will not withdraw any report without first attempting to contact the reporter to discuss by telephone.

If there is a particular reason why the report cannot be completed, for example, awaiting the results of an investigation or root cause analysis etc. then please contact the SHOT office to arrange for the report to be kept open longer. Alternatively, if the report is not SHOT reportable, then please e-mail the SHOT office and request that it is withdrawn.

SHOT reports are only reviewed by the team once completed, so you may still receive reminders for non-SHOT-reportable incidents. In these cases, please let the SHOT office know and the report can be withdrawn to prevent further reminders.

Reminders for Anti-D Ig immunisation reports will be sent once the expected date of delivery (EDD) has passed so please ensure this date is added on page 2 of the new report on the SHOT database.

5.5 Changing SHOT categories

On occasion, it may become necessary to change the category of a report, usually following review by the SHOT Incident Specialists.

To do this, any data entered on the **Transfusion event** page must first be 'de-selected' by double clicking on the selected options, starting from the bottom of the page and working upwards.

Example steps have been provided below for 3 example category changes, however, the same principles will apply for all category amendments. The original category selection must be removed first before trying to select a new category.

Example 1: Changing from TACO (SAR) to ADU (SAE)

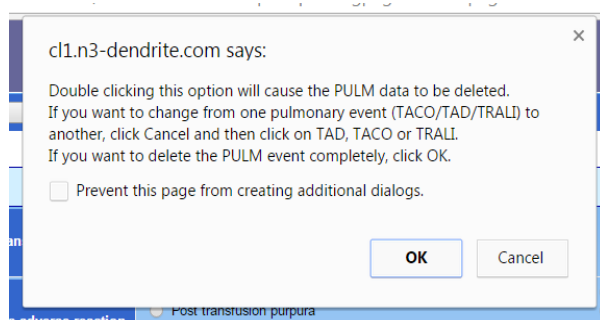
1. **Double click** 'Transfusion associated circulatory overload (TACO)' in the last question 'Pulmonary complication of transfusion' to de-select it.

Figure 31a Changing SHOT categories

Transfusion event	
Transfusion incident	☐ Serious adverse event ☐ Serious adverse reaction ☐ Transfusion Transmitted Infection
Serious adverse reaction	☐ Acute (non-haemolytic) transfusion reaction ☐ Post transfusion purpura ☐ TA Graft vs Host Disease ☐ Previously uncategorised complication of transfusion ☐ Haemolytic (acute and delayed) transfusion reaction ☐ Pulmonary complication of transfusion ☐ Haemosiderosis (optional)
Pulmonary complication of transfusion	☒ Transfusion associated circulatory overload (TACO) ☐ Transfusion associated dyspnoea (TAD) ☐ Transfusion related acute lung injury (TRALI)

- This will produce a warning message from the system to inform you that any data entered in the TACO pages will be deleted.

Figure 31b Changing SHOT categories



- Click 'OK' and the TACO entry will be de-selected.
- Next, double click 'Pulmonary complication of transfusion'

Figure 31c Changing SHOT categories

Transfusion event	
Transfusion incident	☐ Serious adverse event ☐ Serious adverse reaction ☐ Transfusion Transmitted Infection
Serious adverse reaction	☐ Acute (non-haemolytic) transfusion reaction ☐ Post transfusion purpura ☐ TA Graft vs Host Disease ☐ Previously uncategorised complication of transfusion ☒ Haemolytic (acute and delayed) transfusion reaction ☒ Pulmonary complication of transfusion ☐ Haemosiderosis (optional)
Pulmonary complication of transfusion	☐ Transfusion associated circulatory overload (TACO) ☐ Transfusion associated dyspnoea (TAD) ☐ Transfusion related acute lung injury (TRALI)

- Click once on 'Serious adverse event'

Figure 31d Changing SHOT categories

Transfusion event	
Transfusion incident	☐ Serious adverse event ☒ Serious adverse reaction ☐ Transfusion Transmitted Infection
Serious adverse reaction	☐ Acute (non-haemolytic) transfusion reaction ☐ Post transfusion purpura ☐ TA Graft vs Host Disease ☐ Previously uncategorised complication of transfusion ☐ Haemolytic (acute and delayed) transfusion reaction ☐ Pulmonary complication of transfusion ☐ Haemosiderosis (optional)

6. Click once on 'Avoidable, delayed and undertransfusion' and then click 'Next page' to continue with entering the ADU data.

Figure 31e Changing SHOT categories

Transfusion event	
Transfusion incident	☐ Serious adverse event ☐ Serious adverse reaction ☐ Transfusion Transmitted Infection
Serious adverse event	☐ IBCT - Wrong component transfused ☐ IBCT - Specific requirements not met ☒ Avoidable, delayed and undertransfusion ☐ Right blood / right patient ☐ Handling and storage errors

Example 2: Changing from IBCT-WCT (SAE) to Near Miss (if no component transfused)

1. Starting from the **Transfusion event** page, **double click** 'IBCT – Wrong component transfused' to de-select it.

Figure 31f Changing SHOT categories

Transfusion event	
Transfusion incident	☐ Serious adverse event ☐ Serious adverse reaction ☐ Transfusion Transmitted Infection
Serious adverse event	☒ IBCT - Wrong component transfused ☐ IBCT - Specific requirements not met ☐ Avoidable, delayed and undertransfusion ☐ Right blood / right patient ☐ Handling and storage errors

2. **Double click** 'Serious adverse event' to de-select. Following this step, there should be no questions completed on this page.

Figure 31g Changing SHOT categories

Transfusion event	
Transfusion incident	☒ Serious adverse event ☐ Serious adverse reaction ☐ Transfusion Transmitted Infection
Serious adverse event	☐ IBCT - Wrong component transfused ☐ IBCT - Specific requirements not met ☐ Avoidable, delayed and undertransfusion ☐ Right blood / right patient ☐ Handling and storage errors

3. Navigate back to the **Registration details** page. (Either by clicking on the 'Previous page' button or by using the drop down list of pages at the top.)
4. Click 'No' to change the answer to the question 'Was a component transfused'

Figure 31h Changing SHOT categories

Is this event related to	☒ Labile component ☐ Anti-D
Was a component transfused	☐ No ☒ Yes

5. Click 'No' to new question 'Was there a delay which resulted in no component being transfused'

Figure 31i Changing SHOT categories

Is this event related to	☒ Labile component ☐ Anti-D
Was a component transfused	☒ No ☐ Yes
Was there a delay which resulted in no component being transfused	☐ No ☒ Yes

6. Click 'Next page' and continue to answer the near miss incident questions.

Example 3: Changing from Near Miss (if no component transfused) to a Labile component category (i.e. SAE or SAR where a component was transfused)

1. Starting from the **Registration details** page, double click 'No' on the question 'Was there a delay which resulted in no component being transfused' to de-select it.

Figure 31j Changing SHOT categories

Is this event related to	☒ Labile component	☐ Anti-D
Was a component transfused	☒ No	☐ Yes
Was there a delay which resulted in no component being transfused	☒ No	☐ Yes

2. Click once on 'Yes' to the question 'Was a component transfused'. This changes the report to a transfused labile component report, and the following pages should be completed and a new category selected on the **Transfusion event** page.

Figure 31k Changing SHOT categories

Is this event related to	☒ Labile component	☐ Anti-D
Was a component transfused	☒ No	☒ Yes
Was there a delay which resulted in no component being transfused	☐ No	☐ Yes

Enquiries, advice and feedback

For any further advice or assistance with regards to haemovigilance reporting, or anything contained in the guide, please contact the relevant organisation below.

MHRA

Tel: 020 3080 7336

Email sabre@mhra.gsi.gov.uk

SHOT

Tel: 0161 423 4208 Fax: 0161 251 4395

Email shot@nhsbt.nhs.uk

Annex A ISBT table of reportable serious adverse reactions (SAR)

Directive 2005/61/EC [5] categories	ISBT Definitions	
	Clinical features	Laboratory features
Immunological Haemolysis due to ABO incompatibility	Fever, chills/rigors, facial flushing, chest pain, abdominal pain, back/flank pain, nausea/vomiting, diarrhoea, hypotension, pallor, jaundice, oligoanuria, diffuse bleeding, dark urine, decreased haemoglobin levels. Reactions may occur within 24 hours (acute) or may not manifest for up to 28 days (delayed)	Haemoglobinaemia, haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels. Blood group serology shows ABO incompatible mismatch between recipient and donor.
Immunological Haemolysis due to other alloantibody NOTE – Delayed serologic transfusion reactions (alloimmunisation) without clinical or laboratory signs of haemolysis are not reportable to SABRE.	As above.	As above but blood group serology shows either alloantibodies to donor red cells or auto-antibodies in the recipient.
Non-immunological haemolysis	As above	As above but due to non-immunological, possibly mechanical factors such as malfunction of a pump or blood warmer, or the use of hypotonic solutions etc.
Transfusion-transmitted bacterial infection. Note – MUST be reported to the supplying Blood Establishment as soon as possible	Fever, rigors and joint pain with no evidence of symptoms pre-transfusion or alternative source of infection.	Positive blood cultures from recipient and donor pack (matching organisms) or at least one component received by the infected recipient shown to contain the agent of infection.
Anaphylaxis/hypersensitivity NOTE – minor allergic reactions which respond quickly to symptomatic treatment like anti-histamine or steroid medications are NOT reportable to SABRE	Mucocutaneous signs and symptoms including urticaria, rash, pruritus, localised angioedema, oedema of lips, tongue, uvula and conjunctivae with airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). Respiratory symptoms may be laryngeal (throat tightness, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia) Usually occurs during or very shortly after transfusion.	Rising mast cell tryptase levels or IgA deficiency and/or anti-IgA in the recipient.
Transfusion-related acute lung injury	Hypoxaemia ($\text{PaO}_2/\text{FiO}_2 < 300$ mm Hg or O_2 sats $< 90\%$ on room air), bilateral infiltrates on frontal chest X-ray, no evidence of TACO, no temporal relationship to an alternative risk factor for ALI during or within 6 hours of completion of transfusion. Usually acute onset.	Evidence of anti-HLA or anti-HNA antibodies in recipient with incompatibility between donor and recipient.

Directive 2005/61/EC [5] categories	ISBT Definitions	
	Clinical features	Laboratory features
Transfusion-transmitted viral infection (HBV)		Include if the recipient shows evidence of infection post-transfusion and there was no evidence of infection prior to transfusion or any alternative source of the infection, PLUS either at least one component received by the infected recipient was shown to contain the agent of infection or at least one component received was donated by a donor who has evidence of the same transmissible infection.
Transfusion-transmitted viral infection (HCV)		As above
Transfusion-transmitted viral infection (HIV 1/2)		As above
Transfusion-transmitted viral infection - other		As above
Transfusion-transmitted parasitical infection (Malaria)		As above
Transfusion-transmitted parasitical infection – Other, specify. NOTE: All suspected TTIs must be reported to the Blood Services.		As above
Post transfusion purpura	Bruising, severe haemorrhage, oozing wounds. Usually occurs 5-12 days post transfusion.	Thrombocytopenia (5-12 days post transfusion) and anti-HPA antibodies present.
Graft versus host disease	Fever, rash, liver dysfunction, diarrhoea. Usually occurs 1-6 weeks after transfusion.	Pancytopenia, characteristic histological appearances on bone marrow biopsy, bone marrow hypoplasia, chimerism.
Other serious reaction(s) - specify	E.g. Febrile non-haemolytic transfusion reactions (FNHTR) where fever $\geq 39^{\circ}\text{C}$ oral or equivalent and a change of $\geq 2^{\circ}\text{C}$ from pretransfusion value, chills, rigors, headache, nausea. Usually occurs within 4 hours of transfusion and without any evidence of haemolysis, bacterial contamination or underlying condition. E.g. Cases of TACO characterised by any four of the following which occur within six hours of transfusion • Acute respiratory distress. • Tachycardia. • Increased blood pressure. • Acute or worsening pulmonary oedema. • Evidence of positive fluid balance. E.g. Transfusion associated dyspnea (TAD) – respiratory distress occurring within 24 hours of transfusion but without the symptoms of TRALI, TACO or allergic reactions and not explained by any underlying condition.	

Annex B Table of reportable serious adverse events (SAE)

Serious adverse event, affecting quality and safety of blood component due to a deviation in:	Specification			
	Product defect	Equipment failure	Human error	Other (specify)
Definitions	Serious adverse event which is mainly linked to a defect of the blood or blood components. Product defect: blood or blood component which does not meet the quality and safety requirements set in annex V of the Directive 2004/33/EC [4], or which contain (remaining) contaminating agents despite screening, testing and processing having been undertaken properly (e.g.: product discarded after positive infection test result following a window period). Example: Clotting factor rates not compliant with specifications for fresh frozen plasma.	Serious adverse event which is mainly linked to a failure of the equipment. Equipment: any material used at any stage from the collection to the distribution of blood and blood components, such as whole blood collection machines, blood bags, aphaeresis kits and machines, production sets, reagents, test kits, bags for platelets or plasma storage, filters for leukocyte reduction, labelling machines, IT systems, etc. Note: Failures of the equipment – whether or not causing a Serious Adverse Event - should also be reported under the devices reporting procedure (e.g. pack check reveals a faulty seal and bag is discarded during processing: not a SAE but should be reported under the device reporting procedure).	Serious adverse event which is mainly linked to a human error. Human error: An inappropriate or undesirable human decision or behaviour that reduces, or has the potential for reducing, effectiveness, quality, safety, or system performance. It can be e.g. an omission: (forgetting to do something, or just leaving it out), a commission (performing an act incorrectly), a problem in sequence (right action, wrong order) or timing (too fast or too slow).	Any serious adverse event which cannot be classified in the already listed specifications.

Annex C Terms and conditions of use for the SABRE platform

Account management terms and conditions

Definitions

Medicines & Healthcare products Regulatory Agency

The Medicines and Healthcare Products Regulatory Agency (or simply ‘the Agency’) is an Executive Agency of the Department of Health protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance, and effectiveness, and are used safely. The Agency is comprised of three regulatory centres: MHRA, CPRD and NIBSC.

MHRA

The MHRA is the UK’s Competent Authority for Medical Devices and Medicines.

Registration for the collection of blood safety incident data

The MHRA’s responsibility is to ensure there is an accessible mechanism for the reporting and recording of serious adverse blood reactions and events. To facilitate this reporting requirement the MHRA has developed SABRE, an online system that allows the drafting, editing, saving and submission of notifications and subsequent confirmations of blood related adverse events and adverse reactions. This is a joint haemovigilance reporting system for both the MHRA and the serious Hazards of transfusion (SHOT).

The UK Legal Framework

The legal framework is based on the following regulations however they only apply to data collected by the MHRA as the UK Competent Authority.

The Blood Safety and Quality Regulations 2005 No. 50 and the Blood Safety and Quality (Amendment) (No.2) Regulations 2005 No. 2898.

The Blood Safety and Quality Regulations apply to **blood establishments (BE)** and to **hospital blood banks (HBB)**. The 2006 Amendment Regulations introduce requirements for a quality system in blood establishments and hospital blood banks. They also extend traceability and record-keeping requirements to ‘facilities’ which may receive blood and blood components (care homes, independent clinics, hospitals and other NHS facilities and services, manufacturers of medicines and medical devices and biomedical research.)

Registration

With regards to the SABRE registration service, “registration” refers to the requirements under the UK legal framework as described above.

User

A person, who is authorised by the MHRA to use SABRE provided by the Agency. The MHRA reserves the right to refuse access to the Devices registrations service and to terminate an account, or service access at its absolute discretion.

Authorised representative

The natural or legal entity which is explicitly designated by the HBB, BE, care home, independent clinic, hospitals and other NHS facilities and services, manufacturers of medicines and medical devices and biomedical research, acts on behalf of the organisation and which may be addressed by the MHRA or other authorities and bodies instead of the organisation regarding the latter's obligations under the relevant UK legislation.

Service

The online systems made available to eligible entities and their Users by the Agency and/or the MHRA.

Account organization

An organisation who has setup an Agency account. Designated users are able to access the account for the organisation.

Confidentiality and protection of personal data

Directive 2005/61/EC [5] traceability requirements and consequent UK legislation, section 1(1) Data Protection Bill 2017 2019 and the Data Protection Act 2018 Part 1 section 2, also require that identifying information on donors and recipients should be recorded by blood establishments and by those to whom the blood or blood components may be delivered. However, this information is not required to be submitted to the MHRA as part of a notification or confirmation of a SAE or SAR. The link between any submitted report and the traceability records held by the reporting organisation will be made through a local incident reference number that you associate with your report and that you record on the report source section of the SABRE form. The MHRA will treat all personal information as confidential. Whilst details of reported events or reactions may be disclosed, personal identifying details of patients and/or reporters will not.

Since 01 January 2005 the **Freedom of Information Act** [9] obliged the MHRA to respond to requests for information which it holds and is recorded in any form and creates a right of access to that information. The Agency will carefully consider its obligations to SABRE reporters under the Act prior to any release or non-release of information.

The Agency is bound by its obligations under these regulations and It endeavours to ensure that its employees, representatives, and agents comply with the relevant legislation meeting all obligations under the act which arise under these Terms and Conditions of Use.

Agreement

The Agency agrees:

- a) that eligible stakeholders of the Agency are granted an account to allow for the accessing and use of services offered by the Agency;
- b) to provide Secure Socket Layer ("SSL"), Username and Password protection to meet the requirement in the Medical Device Directives to observe confidentiality;

By creating an account to use the Devices registration service the User agrees:

- c) That submission of an account request to the Agency is not the fulfilment of any regulatory obligation applicable to you as a stakeholder of the agency;

d) That if notified that information that it has sent to the MHRA is incomplete, inaccurate, or corrupted, it must take prompt action to submit a corrected registration;

e) To be responsible and accountable for all use of its Username and Password. The User must take sensible measures to protect these if they wish to protect the data it places in the system. To submit data to the MHRA using the system the User may only use the access provided by these details;

f) Any unauthorised attempt to access or modify computer system information or to interfere with normal system operations, whether on MHRA computer systems or on networks accessible from the MHRA website, may result in the suspension or termination of the User's access. Access by any persons other than those authorised by the manufacturer and the MHRA is prohibited. Depending on the nature of any such activity the MHRA, or any other body with the power to do so, may initiate legal proceedings of whatever kind are appropriate;

Without prejudice to point 4(f) above, the User shall not:

g) resell or make commercial use of the system or its contents;

h) make a collection of and use any product listings, descriptions, or prices;

i) make any derivative use of the service or its contents;

j) download or copy any account information for the benefit of a third party [save where the User is an Authorised Representative and is downloading or copying such account information relating to a Manufacturer, under the terms or in fulfilment of the agreement under which it has been designated an Authorised Representative];

k) knowingly download any worm, cancelbot, Trojan horse, virus or any other malware onto the system;

l) The User may not reproduce, duplicate, copy, sell, resell, visit or otherwise exploit for any commercial purpose the system or any portion of the system without the MHRA's express prior written consent.

The User shall only use the system for lawful purposes. The User shall not use the system for:

m) fraudulent purposes, or in connection with a criminal offence or other unlawful activity;

n) to send, use or reuse any material that is illegal, offensive, abusive, indecent, defamatory, obscene or menacing;

o) or in breach of copyright, trademark, confidence, privacy or any other right;

p) or otherwise injurious to third parties;

q) or objectionable;

r) or which consists of or contains political campaigning, commercial solicitation, chain letters, mass mailings or 'spam' to cause annoyance, inconvenience, or needless anxiety;

Whilst authorized Users have the ability to nominate a person to become an additional User for their organisation account, the Agency reserves the right to deactivate any User access to its systems and services.

Limitation of liability

a) The MHRA reserves the right without notice to disable or discontinue the service as required. This may be for the purposes of routine maintenance or other reasons, or as part of an emergency termination of electronic computer connections designed to protect resources from illegal access or other damage.

b) The MHRA reserves the right to reject submissions to the service on the basis that the incidents reported, which are the subject of the submission, are not recognised by MHRA as either meeting the definition of a Serious Adverse Reaction (SAR) and or Serious Adverse Event (SAE) as defined within the relevant UK Blood Safety legislation.

c) In the case of an unanticipated service failure the MHRA and/or its agents will endeavour to restore the service to normal operating conditions as quickly as possible. Temporary disruption of the service will not constitute termination of the Agreement or relieve the User from their general obligations to the MHRA.

d) The MHRA accepts no responsibility for any loss, damage, or inconvenience of any kind, except for death or personal injury which is the result of the negligence of the MHRA that the User of this service may suffer as a result of its use. By using this service, the User specifically accepts all legal and general liability for any loss that may arise from such use.

e) In the event of a contact being deactivated the Agency accepts no responsibility for any loss, damage, or inconvenience of any kind.

Copyright

a) All content included on the MHRA SABRE platform, such as text, graphics, logos, button icons, images, audio clips, digital downloads, data compilations, and software, is the property of the MHRA and is protected by United Kingdom and international copyright, authors' rights and database right laws. The compilation of all content on the MHRA website is the exclusive property of the MHRA and is protected by United Kingdom and international copyright and database right laws.

b) The User may not systematically extract and/or reutilise parts of the MHRA website without the MHRA's express prior written consent. In particular, the User may not utilise any data mining, robots, or similar data gathering and extraction tools to extract (whether once or many times) for reutilisation any substantial parts of the MHRA website, without the MHRA's express prior written consent. The User may not create and/or publish its own database that features substantial parts of the MHRA website without the MHRA's express prior written consent.

Communications

When we refer, in these Terms, to "in writing", this will include email.

Any notice or other communication given by you to us, or by us to you, under or in connection with the Contract shall be in writing and shall be delivered personally, sent by prepaid first-class post or other next working day delivery service or email.

A notice or other communication shall be deemed to have been received: if delivered personally, when left at our registered office; if sent by prepaid first-class post or other next working day delivery service, at [9.00 am] on the [second] business day after posting or if sent by email, one business day after transmission.

In proving the service of any notice, it will be sufficient to prove, in the case of a letter, that such letter was properly addressed, stamped and placed in the post and, in the case of an email, that such email was sent to the specified email address of the addressee.

The provisions of this clause shall not apply to the service of any proceedings or other documents in any legal action.

Alternative dispute resolution

The Agency and the Service User agree that in the event of a dispute or disagreement as to the effect of any term or condition, or the consequences of the application of any such term or condition, they will jointly seek to resolve the dispute or disagreement by mediation using the services of a mediator appointed by the Centre for Dispute Resolution (CEDR) prior to the initiation of any proceedings in the Courts.

Use of collected Data within the Joint Haemovigilance reporting agreement with SHOT

MHRA and SHOT acknowledges and agrees that only authorised users are permitted to have access to and use of the data. Each party, and in particular their respective Lead Investigator, will be responsible for independently maintaining their own register of authorised users and for ensuring that the data is used solely for undertaking the Joint UK Reporting Arrangement and for MHRA within the regulatory framework of the Blood Safety and Quality Regulations (BSQRs) and shared with SHOT, for a legitimate purpose, to improve patient safety within the clinical and laboratory areas of haemovigilance and not for any other purpose.

The information shared through this agreement may not be shared with any other organisation not party to these terms and conditions without the prior written consent of the organisation deemed the original provider of that data and with a clear indication of what the information, if shared, will be used for.

Each party will undertake to make no attempt to link the data to other datasets held by different recipients not party to these terms and conditions or for different projects without the prior written consent from the relevant data provider, or to use the data to identify data subjects or further information about them of a confidential nature other than for purposes of carrying out the requirements of UK Joint Haemovigilance reporting and within the regulatory framework of the BSQR's.

Each party will hold and use the data in accordance with:

- i. the IG requirements of the relevant data provider;
- ii. all other applicable laws and relevant regulations; and
- iii. If the data constitutes personal data within the legislation of section 1(1) Data Protection Bill 2017 2019 and the Data Protection Act 2018 Part 1 section 2.
- iv.

Each party shall hold the data as Data Controllers, for each reporter and subject to the legal responsibilities as laid out in the relevant legislation and within the terms and conditions of this agreement.

As an Agency the MHRA collect and store data in accordance with BSQR's, Directive 2002/98 Article 14.3, but with reference to the General Data Protection Regulation (GDPR) MHRA will not use reporter's data for anything other than for a regulatory purpose and within the BSQR regulatory framework. A consequence of the Joint haemovigilance reporting platform allows SHOT to have access to the reporters mailing list.

MHRA have a legitimate reason to share the collected data with SHOT to help maximise the analysis of data to ensure its correct interpretation and therefore help with safe transfusion practice methods. SHOT use this data to send out SHOT-related communications, for example advertising the SHOT symposium, surveys related to SHOTs work and SHOT newsletters. To comply with the GDPR regulations SHOT are responsible for obtaining reporters consent, in advance, to use their data for direct marketing sent electronically (email, SMS or social media direct message) and respect their wishes should they want to stop receiving the information from SHOT.

Each party undertakes not to use data or derived data for any commercial purpose or any purpose that is subject to consulting or licensing obligations to third parties without prior written consent from the relevant data provider and will consult their respective Data Protection Officers before processing the data for any new purpose.

Governing Law and Jurisdiction

These Terms and Conditions of Use shall be governed by and construed in accordance with the Laws of England and Wales, the MHRA and the User expressly agree to submit to the exclusive jurisdiction of the Courts of England and Wales.

Price and payment methods

There is no direct payment levied for the use of SABRE as this is included in the fees collected as part of a organisation regulation fees as laid out in the BSQR.

Other important terms

The Agency reserves the right to change its Terms and Conditions at any time and whilst it will endeavour to advise Users beforehand this may not always be possible. Users should regularly check these Terms and Conditions regularly to ensure they are current.

In providing this service the Agency may direct Users to other websites outside of its control. In such cases Users should not assume that the Agency Terms and Conditions still apply. You may only transfer your rights or your obligations under these Terms to another person if we agree in writing.

This Contract is between Users of the Haemovigilance service and the MHRA. No other person shall have any rights to enforce any of its terms, whether under the Contracts (Rights of Third Parties) Act 1999 or otherwise.

Each of the paragraphs of these Terms operates separately. If any court or relevant authority decides that any of them are unlawful or unenforceable, the remaining paragraphs will remain in full force and effect.

If we fail to insist that you perform any of your obligations under these Terms, or if we do not enforce our rights against you, or if we delay in doing so, that will not mean that we have waived our rights against you and will not mean that you do not have to comply with those obligations. If we do waive a default by you, we will only do so in writing, and that will not mean that we will automatically waive any later default by you.

This Contract and any dispute or claim arising out of or in connection with it or its subject matter or formation (including noncontractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.

We both irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with a Contract or its subject matter or formation (including noncontractual disputes or claims). The Agency reserves the right to change its Terms and Conditions at any time and whilst it will endeavour to advise Users beforehand this may not always be possible. Users should regularly check these Terms and Conditions regularly to ensure they are current. In providing this service the Agency may direct Users to other websites outside of its control. In such cases Users should not assume that the Agency Terms and Conditions still apply.

Contact Details

SABRE Helpdesk Tel 020 3080 7336

SABRE E Mail: Sabre@mhra.gov.uk

References

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INVESTIGATION AND REPORTING OF TRANSFUSION RELATED SERIOUS ADVERSE REACTIONS AND EVENT

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1.0 INTRODUCTION

1.1 The Blood Safety and Quality Regulations 2005 No.50 and the Blood Safety and Quality (Amendment) (No.2) Regulations 2005 No. 2898 became effective for the purposes of regulation in the United Kingdom on 08 November 2005. These regulations implement the requirements of the following European Union (EU) directives:

- **DIRECTIVE 2002/98/EC – SETTING STANDARDS OF QUALITY AND SAFETY FOR THE COLLECTION, TESTING, PROCESSING, STORAGE AND DISTRIBUTION OF HUMAN BLOOD AND BLOOD COMPONENTS**
- **DIRECTIVE 2004/33/EC – REGARDING CERTAIN TECHNICAL REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS.**

Two further technical directives were adopted by the European Commission on 30 September 2005. These are:

- **DIRECTIVE 2005/61/EC REGARDING TRACEABILITY REQUIREMENTS AND NOTIFICATION OF SERIOUS ADVERSE REACTIONS AND EVENTS**
- **DIRECTIVE 2005/62/EC REGARDING COMMUNITY STANDARDS AND SPECIFICATIONS RELATING TO A QUALITY SYSTEM FOR BLOOD ESTABLISHMENTS.**

1.2 These directives were transposed into UK legislation by the Blood Safety and Quality (Amendment) Regulations 2006 No. 2013, which came into force on 31 August 2006.

The Blood Safety and Quality Regulations apply to hospital blood banks. The 2006 Amendment Regulations introduce requirements for a quality system in hospital blood banks. They also extend traceability and record-keeping requirements to 'facilities' which may receive blood and blood components (care homes, independent clinics, hospitals and other NHS facilities and services, manufacturers of medicines and medical devices and biomedical research.)

2.0 REPORTING OF BLOOD RELATED SERIOUS ADVERSE REACTIONS AND EVENTS

2.1



SABRE: Serious Adverse
Blood Reactions & Events

Directive 2005/61/EC introduces the legal requirement for serious adverse reactions (SARs) and serious adverse events (SAEs) occurring within EU member states to be reported to the relevant Competent Authority. The Department of Health has designated the MHRA as the UK Competent Authority. It is, therefore, the MHRA's responsibility to provide a mechanism for the reporting and recording of these incidents. For this purpose the MHRA has developed the fully accessible online reporting system: SABRE (Serious Adverse Blood Reactions & Events).

- 2.2 Implementation of the Directive 2005/61/EC with the mandatory requirement for reporting to the MHRA has provided an opportunity to strengthen and further develop haemovigilance in the UK.
- 2.3 This document describes the requirements of the directives and also, in order to assist in the reporting of adverse events and reactions, includes guidance and flow charts to help identify what constitutes a serious adverse reaction and a serious adverse event and, therefore, what is or is not reportable to the Competent Authority (MHRA) under the Directive 2005/61/EC and UK legislation. However, this does not provide a definitive list of what does and what does not constitute a reportable incident. As a general rule, in cases of doubt, a report should be submitted.
- 2.4 The document also describes the requirements of the local reporting system for Blood Transfusion related incidents.

3.0 REPORTING TO SHOT (SERIOUS HAZARDS OF TRANSFUSION)

3.1



Reports to SHOT to be submitted by the TTT only
Reporting to SHOT remains voluntary, but is required for compliance with HSC/2007/001 'Better Blood Transfusion' - safe and appropriate use of blood and is a standard for the NHS Litigation Authority. A number of blood safety initiatives depend on continuity of SHOT data for monitoring and evaluation and it is therefore important that reporters use the SABRE system to initiate a report to SHOT at the notification stage. When reporting select either 'Share this report with SHOT' or select the 'SHOT only report' box. SABRE will then prompt the SHOT

Dendrite database to create a record and send you an automated email link to the database. You will then be asked to log in separately to the SHOT Dendrite system and complete their online form.

Refer to the SHOT Dendrite database user manual for details of how and what to report to SHOT and the laboratory document 1BBSHOTCATEGORIES

- 3.3 Joint SHOT/ MHRA Reporting: from the 5th October 2015 a fully integrated on-line MHRA and SHOT reporting facility that avoids duplication of reporting for the reporter meet the reporters regulatory requirements for reporting to the MHRA all Serious Adverse Reactions (SAR), Serious Adverse Events (SAE) and Corrective and Preventative Actions (CAPA) as defined under the Blood Safety and Quality Regulations (BSQR) meet the professionally mandated requirements for reporting to SHOT

4.0 SERIOUS ADVERSE REACTIONS (SAR)

- 4.1 Definition: 'an unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity.

5.0 SERIOUS ADVERSE EVENT (SAE)

- 5.1 Definition: 'any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.' (UK Blood Safety and Quality Regulations 2005)

6.0 'NEAR MISSES'

- 6.1 Definition: Any error, which if undetected, could result in the determination of a wrong blood group, or issue, or administration of an incorrect, inappropriate or unsuitable component but which was recognised BEFORE transfusion took place. (SHOT 2004)

7.0 USING THE SABRE ONLINE REPORTING SYSTEM

7.1 REPORTS TO SABRE TO BE SUBMITTED BY THE TTT ONLY

SABRE can be accessed via the MHRA website: www.mhra.gov.uk

MHRA SABRE: Serious Adverse Blood Reactions & Events

Incident Reporting Home | Contact us

Login

Welcome to SABRE – Serious Adverse Blood Reactions and Events – the MHRA’s online system for reporting blood safety incidents.

SABRE has been specifically designed to provide registered reporters with a simple electronic means of submitting haemovigilance reports to the MHRA and to SHOT.

Registered Reporters - Registered Reporters may log in below.

IMPORTANT: Your password is 'Case Sensitive'. Please ensure that you remember to use the same combination of upper and lower case letters as you entered on your Registration Form.

Not yet registered? - If you have not yet registered as a SABRE Reporter, click the link above and submit the requested details. Please note that the provision of certain information is compulsory for registration.

For security reasons, new Registrations will not be activated until registration details have been checked and verified by the MHRA.

If you are unable to complete your Login successfully please contact the Adverse Incident Centre for assistance and advice:
sabre@mhra.gsi.gov.uk or 020 3080 7336

Freedom of information
 Adverse Incident Centre: 020 3080 7336 sabre@mhra.gsi.gov.uk
 © 2014 Crown Copyright To contact us about this website, use our [feedback form](#).

The system is secure and provides access only to registered users. Once registered, users have access to an electronic report form and to a workspace containing a library of their previously drafted and/or submitted reports. Draft reports can be edited online and may have electronic files (e.g. images, documents) attached for submission.

- 7.2 Online help is available at every stage and every level when using SABRE. Not only does every page and every section of the report form have general help text, but each individual item on those pages has its own help information.

PRACTICAL ADVICE ON THE USE OF SABRE IS AVAILABLE BY EMAIL (SABRE@MHRA.GSI.GOV.UK)

7.3 LOG IN

Simply enter these three items and click ‘Login’

- An email address (the one submitted on our registration request)
- A registration number (sent to us by the MHRA SABRE helpdesk)
- Our password (chosen by us when registering).

7.4 WORKSPACE

After successfully logging in, the workspace will be displayed.

The workspace serves two primary functions:

- As a searchable library of all draft and submitted reports
- As the platform from which to
 - 1) Create a new report
 - 2) Open, read, and/or edit an existing report
 - 3) Search the content of all draft and submitted reports and their attachments
 - 4) Create folders so that you can organise and manage your reports.

On the first visit the workspace will be empty. Each time a draft is saved or a report submitted (whether a notification or a confirmation, an event or a reaction, or a SHOT only report) identifying details of that report will appear in the workspace.

THE WORKSPACE IS NOT VISIBLE TO THE MHRA OR SHOT.

The columns of summary information in the workspace are clearly labelled. The icons that appear on the left hand side describe the type of report and its status.

- **N IDENTIFIES A NOTIFICATION,**
- **C A CONFIRMATION,**

The **YELLOW** background colour indicates the report's current status as draft.

The **BLUE** background indicates that the report has been submitted.

There are columns containing key identifying information from the notification and confirmation, and a separate column to indicate, where relevant, the date that a link to SHOT was established.

7.5 REPORT SOURCE

Much of this section of the report form will be pre-populated by SABRE with information submitted on the registration form.

The MHRA recognises that in some circumstances the person completing a report form may not be the registered SABRE user but part of the Transfusion Team. For this reason the reporter name and email fields in this section remain editable, i.e. if you are not the person in whose name the registration was made, you can enter your own name and contact details. This will ensure that any communications from the MHRA or SHOT are directed to the correct person.

The SHOT MHRA reporting system is a joint system from 5th October 2015. A joint system provides a fully integrated on-line MHRA and SHOT reporting facility that avoids duplication of reporting for the reporter meet the reporters regulatory requirements for reporting to the MHRA all Serious Adverse Reactions (SAR), Serious Adverse Events (SAE) and Corrective and Preventative Actions (CAPA) as defined under the Blood Safety and Quality Regulations (BSQR) meet the professionally mandated requirements for reporting to SHOT. All reports logged on this system will be available to both authorities.

8.0 LOCAL INCIDENT REPORTING

- 8.1 The local incident reference number created in QPulse is also required in this section. This (coupled with the MHRA reference number assigned upon submission of your completed report form) is vital in avoiding potential confusion between incident reports. The MHRA is very keen to ensure that reporting to SABRE does not interfere with, or replace, existing local reporting systems (e.g. local risk management reporting systems).

9.0 SERIOUS ADVERSE REACTIONS

9.1 NOTIFICATION REPORT

The first decision to make is whether the incident was serious i.e. was it associated with the collection or transfusion of blood or blood components and was it fatal, life-threatening, disabling or incapacitating, or did it result in or prolong hospitalisation or morbidity.

Then decide is it a serious adverse event (SAR) or a serious adverse reaction (SAE) – and to tick the appropriate box.

If the serious adverse reaction (SAR) is ticked on the report source section, SABRE will automatically allow access to this section and the serious adverse event (SAE) section will not be available. The report will automatically be submitted as a notification only report. If all the information required to complete the report is available it is possible to change the report type to notification and confirmation and submit both at the same time.

9.2 NOTIFICATIONS OF SARS SHOULD BE SUBMITTED TO THE MHRA AS SOON AS POSSIBLE

Confirmations should be submitted as soon as possible after all the required information has been collated and the local investigation complete. Where the report has been made available to SHOT, both the MHRA and SHOT recommend that appropriate account be taken of the SHOT analysis of the incident when concluding the local investigation. The MHRA will send email reminders to reporters where a confirmation report has not been received within a reasonable time period. The time allowed will vary according to the nature of the reaction reported, but is generally one month.

Remember – SABRE allows reports to be saved in draft whilst information required to complete all sections of the report form is obtained.

The SAR section has been designed by the MHRA primarily to collect only that data required by the EU Haemovigilance system. In order to collect this data in a consistent manner suitable for summary analysis across Europe, standard pick lists are provided for a number of areas. Choose from these lists when reporting:

- Which blood component the serious adverse reaction is related to
- Type of serious adverse reaction
- Imputability level
- Clinical outcome

10. PATIENT/DONOR INFORMATION

- 10.1 Although some patient or donor information is required, this is only age and gender. Our local record in QPulse will, of course, require further detail for fulfilling traceability requirements.

11. CONFIRMATION REPORT

- 11.1 When completing the confirmation section first indicate whether you are the person that submitted the Notification. If not, you will be asked to enter your own name and contact details.

Next indicate whether the original assessment was correct: i.e. which component type was implicated, whether there was a serious adverse reaction and whether that reaction was correctly described in the notification (and, if not, what the reaction actually was). Report the clinical outcome.

PLEASE NOTE THAT THIS RELATES ONLY TO THE CLINICAL OUTCOME OF THE REACTION.

- 11.2 Deaths associated with a patient's underlying condition or any other cause should not be included. Therefore, if the eventual outcome for the patient is death but the cause of death is not due to the transfusion reaction, then the clinical outcome of the reaction is most likely to be either complete recovery, minor sequelae or serious sequelae.

Death should only be selected as a reporting option where the patient failed to recover from the transfusion reaction before dying. In these instances the imputability level will assign the likelihood that the reaction can be attributed to the transfused blood or blood component. If any associated components, products or reagents were required to be recalled and/or investigated as a result of the serious adverse reaction, the report should also include explicit reference to their fate and to any subsequent actions taken to ensure the future safety of the supply chain.

- 11.3 Lastly, a further assessment of the imputability level is required, as the assessment may have altered following review of the results of the local investigation. Where the final imputability level is 2 or 3, a report of the local investigation is required. Where the imputability level is considered to be ≤ 1 , it is useful to explain to what else the reaction could be attributed.

12. IMPUTABILITY LEVELS

Imputability means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process. The table below defines the imputability levels:

N/A	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components.
0	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
2	Likely	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

13. SERIOUS ADVERSE EVENTS

NOTIFICATION REPORT

- 13.1 If serious adverse event (SAE) is ticked on the report source section, SABRE will automatically allow access to this section and the serious adverse reaction (SAR) section will not be available. The system directly opens the notification only section but if all the information

required for both notification and confirmation is available the report type can be changed in order to submit both at the same time.

- 13.2 Notifications of SAEs should be submitted to the MHRA **as soon as possible**. Consistently late submission of reports is an indicator of problems within the quality management system and **may prompt referral to the MHRA's Inspection**, Enforcement and Standards Division.

EVENT CATEGORISATION

- 13.3 Under the terms of Directive 2005/61/EC the activities of hospital blood banks are limited to storage, distribution (to external satellite sites only) and other (serious failures of the quality management system).

THE CLINICAL ACT OF TRANSFUSION IS OUTSIDE THE SCOPE OF THE DIRECTIVE 2005/61/EC WHICH APPLIES ONLY UP TO THE ISSUE OF THE BLOOD COMPONENT FOR TRANSFUSION.

- 13.4 SAEs that occur within the hospital blood bank scope of responsibility as monitored by their quality system (i.e. training of staff, security of equipment and premises, adherence to policies and procedures) should be reported when one or more of the following criteria apply:

- Inappropriate blood/blood components have been issued/distributed for clinical use, even if not used
- The adverse event resulted in the loss of any irreplaceable autologous blood/blood component (e.g. rare blood group) or any highly matched (i.e. recipient specific) allogeneic blood/blood component
- The adverse event resulted in the loss of a significant quantity of unmatched blood or blood components
- The adverse event could have implications for other patients or donors because of shared practices, services, supplies or donors (i.e. repeated event inside or outside the BE/HBB)
- The adverse event could have a significant impact on the blood transfusion system e.g. by jeopardising the confidence of blood donors or recipients in the system.

- 13.5 Although there is a space for patient or donor information (age and gender) this is not mandatory as the blood or blood component involved may not have reached a patient. The MHRA does not need or want patient or donor identifying information (e.g. patient/hospital identification number or name) to be reported on SABRE.

CONFIRMATION REPORT

- 13.6 When completing the confirmation section indicate whether you are the person that submitted the notification. If not, you will be asked to enter your own name and contact details.
Next indicate whether the original assessment was correct i.e. whether there was a serious adverse event and whether that event was correctly described in the notification (and, if not, what the event actually was).

ROOT CAUSES

- 13.7 Provide what is described in the legislation as a 'root cause analysis'.
 What the MHRA requires here is simply details of the outcome of the local investigation into the SAE with evidence that as far as possible all root causes and contributory factors have been considered. This should help ensure that corrective and preventative measures are targeted effectively.
 Serious adverse events are most frequently caused by human error. It is important that you do not report this as the root cause but investigate further into why the error was made e.g. distraction, recent process change, lack of knowledge/training, complexity of task etc.

CORRECTIVE MEASURES

- 13.8 Finally, provide details of any corrective measures and preventative actions taken as a result of your investigation. Again provide information to explain what immediate action has been taken to deal with the serious adverse event and then explain what processes have subsequently been implemented to ensure that the situation does not recur; e.g. an expired unit of blood has been discovered, recalled and discarded and in future units due to expire at midnight will be held in the laboratory stock fridge and will only be issued up to 8 pm for immediate use.

SAVING/SUBMITTING REPORTS

- 13.9 When completed, the notification and/or confirmation sections and all the information provided is both correct and complete, click submit to send the report to the MHRA.

ACKNOWLEDGEMENTS AND REFERENCE NUMBERS

- 13.10 As soon as submitted, SABRE will provide us with an electronic acknowledgement and an automatically generated, unique MHRA reference number.
 Cross-reference the MHRA reference number with the local QPulse records.
 The reference number will appear in this format: 2010/011/008/HV1/001
 It shows, from left to right, the year, month and day that the report is submitted. The reference number is automatically entered onto the saved report form and onto the workspace listing, and is retained when a confirmation report is submitted. The same numbering system is used for SHOT only reports.

LOGGING OUT

- 13.11 It is important to log out after every session. Failing to log out may cause difficulties on the next occasion that you log in.

14.0 LOCAL REPORTING PROCESS

- 14.1 In order to fulfil the requirements of this Directive, if a blood transfusion incident occurs or is suspected the incident must be logged onto DATIX (IR1) and/or a Blood Transfusion Incident form (page 7 of the Integrated Blood Transfusion and Prescription Record) must be completed and sent to the Hospital Blood Bank OR the Haemovigilance Practitioners as soon as possible.

- 14.2 The Blood Transfusion staff or the Haemovigilance Practitioner must contact the Trust Transfusion Team as soon as possible, if appropriate.
- 14.3 The Haemovigilance Practitioner or (Trust Transfusion Team member) must record the incident on the Trust Datix (IR1) incident reporting form if not already done so by the initial reporter and on the Q- Pulse system. If reportable to -SABRE and/ or SHOT report within 24 hours (as detailed above)
- 14.4 A Non-conformance identified during the audit process will be brought to the attention of the Ward/Department manager by the Haemovigilance Practitioner and it is the responsibility of the Ward/Department manager to document this incident on the Trust Datix system.
- 14.5 An incident will be investigated as outlined in the process map.
- 14.6 The Trust Transfusion Team must review the incident; the remedial action taken and the corrective action proposed.
- 14.7 The Trust Transfusion Team must assess the effectiveness of the corrective action of SHOT/SABRE incidents formally record outcomes within the Trust Transfusion Team minutes
- 14.8 The TTT must review incidents for trends and initiate preventative action where appropriate
- 14.9 The Trust Transfusion Team must assess the effectiveness of the preventative action of SHOT/SABRE and formally record outcomes within the Trust Transfusion Team minutes
- 14.10 All SABRE/SHOT incidents reported to HTC /AD irrespective of risk rating. They are also reported to the Pathology and Laboratory Services Committee under the set agenda item; Governance. The incidents are fed up to the Acute Governance Forum by the Assistant Director for Cancer and Clinical Services.
- 14.11 Incidents that may impact on patient safety or the safe delivery of service, though rated as low risk, are also reported to the Acute Governance Forum by the Assistant Director for Cancer and Clinical Services. .

15.0 RESPONSIBILITIES FOR INVESTIGATING INCIDENT

- 15.1 All Staff groups involved in the transfusion process have a responsibility to report transfusion related incidents and to take part in subsequent investigations.
- 15.2 Staff involved or aware of any type of incident concerning blood transfusion practice must contact a member of the blood transfusion laboratory immediately and also inform the relevant ward/department /site manager.
- 15.3 The ward/department /site manager must confirm that contact has been made with the Haemovigilance Practitioner and/or a member of the Trust Transfusion Team.
- 15.4 The member of Staff involved or aware of an incident must complete a DATIX (IR1) form and Blood Transfusion Incident form (page 7 of the Integrated Blood Transfusion and Prescription

Record). The Line manager should approve the incident report, date, and sign and then forward the report to the Blood Transfusion Laboratory or Haemovigilance Practitioners.

- 15.5 The TTT must review the incident; decide if the remedial action was appropriate and if provided that the proposed corrective action is appropriate. The incident is then recorded on Q Pulse if SHOT/SABRE reportable and on the Trust DATIX system (if not already done so by the initial reporter) and forwarded to the person deemed responsible for further investigation and reporting back to the TTT.

TRANSFUSION TEAM RESPONSE TO INCIDENTS SHOULD BE COMPLETED WITHIN 10 WORKING DAYS. THIS RESPONSE TIME WILL ONLY APPLY TO THE TEAM

- 15.6 The TTT review the time scales set for any corrective action to ensure prompt and timely resolution to incidents. Incidents that are considered SABRE/SHOT reportable should be completed within 1 month.

16.0 ACTIONS TO BE TAKEN IF NOT CLOSED IN THE DEFINED TIME

- 16.1 The Trust Transfusion Team will communicate all delayed responses and/or actions to the relevant Assistant Directors/Associate Medical Directors

17.0 PROCESS FOR LOOKING FOR TRENDS

- 17.1 All transfusion related incidents are analysed through the CAPA module quarterly. Any required action resulting from trends to be instigated by the Trust Transfusion Team: All resulting actions to be monitored by the Trust Transfusion Team.
- 17.2 When reviewing incidents the TTT, where appropriate, propose preventative action: The proposed preventative action to be forwarded to the relevant Assistant Directors.

18.0 SUMMARY REPORT

- 18.1 The SABRE summary report must be reviewed and verified by the Trust Transfusion Team in Feb each year. This report is issued by SABRE and contains the summary of the year's inputs to the SABRE system. This is scheduled as **AUD2224** In addition to this aspect of the report; totals of the units that have been received by the trust must be imputed. SABRE list these as issues however the figures from BSO business services do not accurately reflect the definition of issues in this case. Data can be acquired as follows:

18.2 ISSUE TOTALS

RED CELL ISSUES: Data to be extracted from reporting function in BSMS (BSO data includes repeat issues so is not accurate for the SABRE report)

FOR EXAMPLE RED CELL: IN THE REPORTING YEAR 2015 THE TOTAL ISSUE OF RED CELLS FROM NIBTS WERE 6766

FFP: This data can be directly transcribed from BSO data as FFP cannot be recycled

PLATELETS: This data can be directly transcribed from BSO data as platelets are not generally recycled

OTHER: SHSCT generally do not have 'other products' to issue

USAGE AND WASTAGE can be extracted from BSO.

NOTE: At present we cannot identify the number of recipients without duplication due to repeat transfusion of a number of patients so this should be marked as 'unavailable'

19.0 TRUST TRANSFUSION TEAM

Dr Don Hull, Consultant Haematologist, Ext 2816
Mr Graham Scott, Blood Bank Manager, Ext 2666
Mrs Patricia Watt, Area Haemovigilance Practitioner, Ext 3740.

SOUTHERN HEALTH AND SOCIAL CARE TRUST

THE REPORTING OF SERIOUS ADVERSE REACTIONS, SERIOUS ADVERSE EVENTS AND 'NEAR MISSES' RELATING TO THE TRANSFUSION OF BLOOD/BLOOD COMPONENTS.

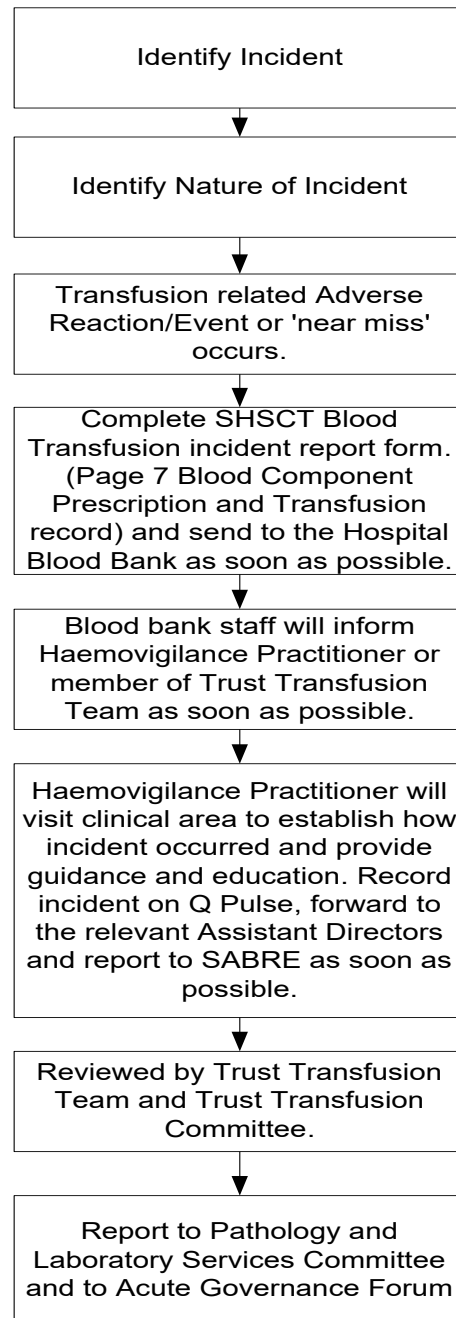
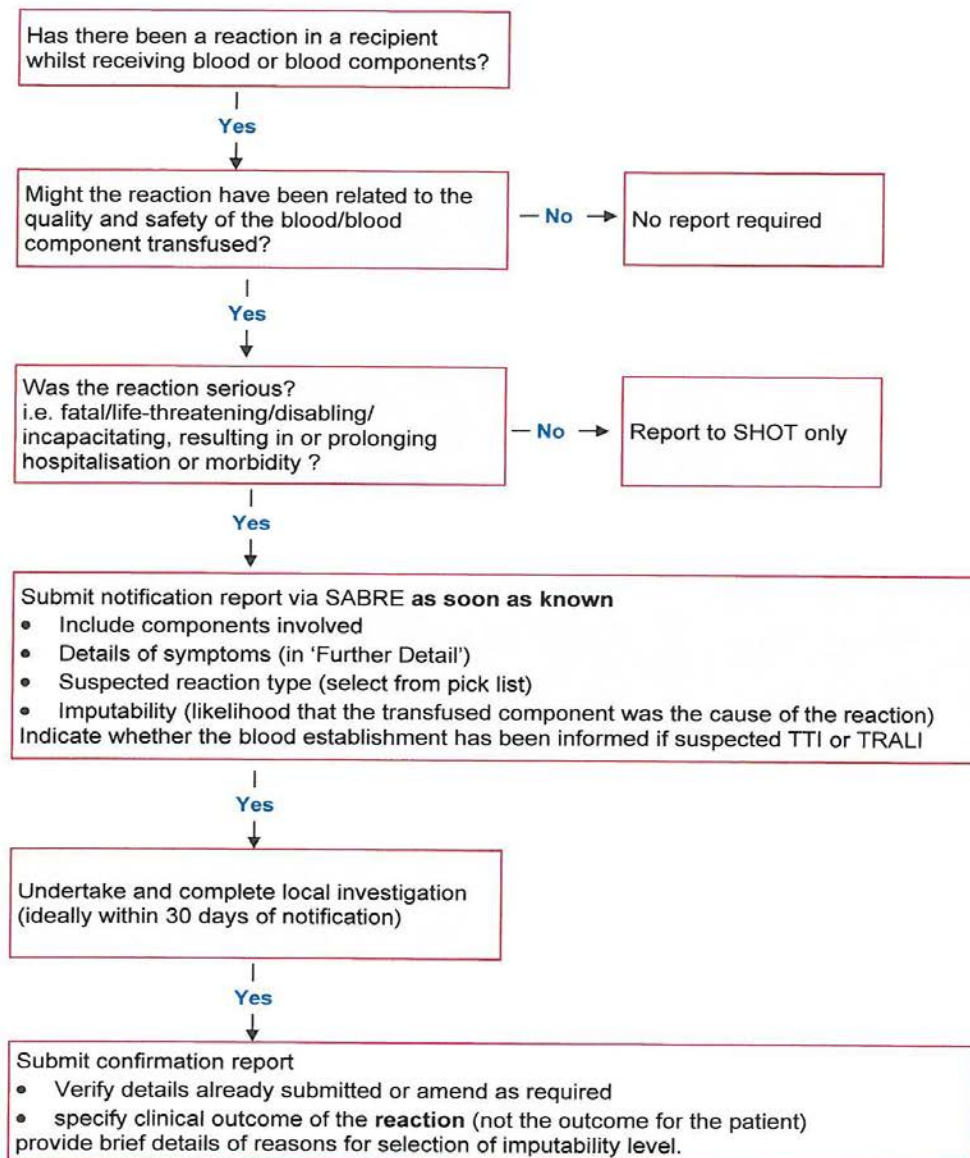


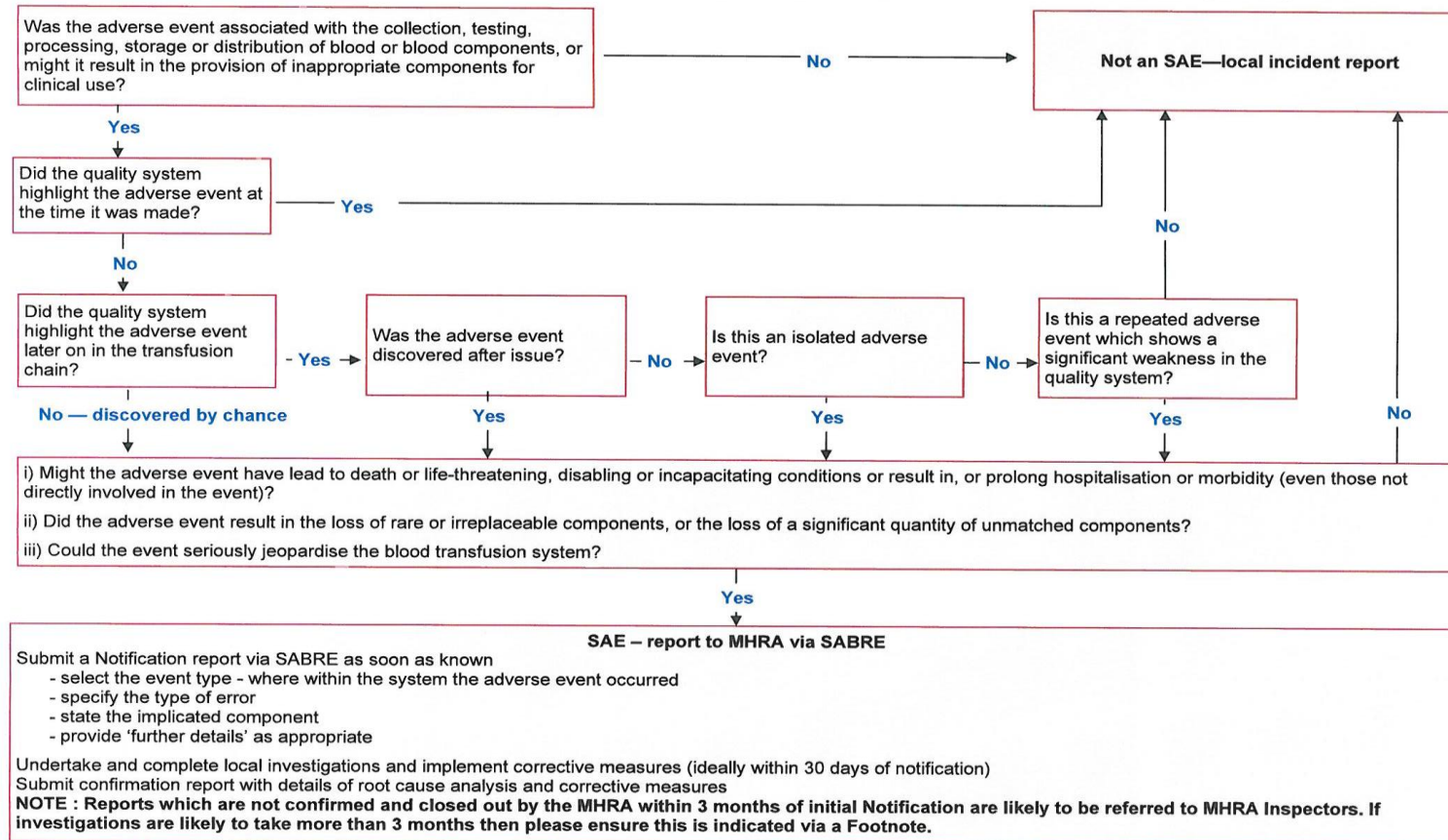
Figure 1 SABRE reporting flow chart for serious adverse reactions (SARs)



Note: Reports which are not confirmed and closed by the MHRA within 3 months of initial notification are likely to be referred to MHRA inspectors. If investigations are likely to take more than 3 months then please ensure this is indicated via a footnote.

Figure 2 SABRE reporting flow chart for serious adverse events (SAE)

Has there been an adverse event which occurred within the organisation's scope of responsibility as monitored by their quality management system?



Definitions of current SHOT reporting categories & what to report

SHOT accepts reports on serious adverse reactions and events related to blood components, including any novel components such as convalescent plasma and whole blood. Where blood components are being used in clinical trials this must be recorded in the SHOT submission.

Serious adverse reaction (SAR):

MHRA Definition: an unintended response in a patient that is associated with the transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating or which results in or prolongs hospitalisation or morbidity

All transfusion transmitted infections (TTI) must be reported to MHRA.

Serious adverse events (SAE):

MHRA Definition: Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to **death or life threatening, disabling or incapacitating** conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

SAR and SAE must be submitted for all transfusion settings, including pre-hospital (ambulance/helicopter), home and community transfusion.

Note:

SHOT does not accept reports on adverse reactions or events related to manufactured blood products except those relating to anti-D Ig, prothrombin complex concentrates (PCC), solvent detergent fresh frozen plasma (Octaplas) and lyophilised plasma (LyoPlas). All serious adverse reactions and adverse events related to manufactured blood products should be reported on the Yellow Card scheme. (<https://yellowcard.mhra.gov.uk/>).

Examples included under 'What to Report' are for illustrative purposes and are not an exhaustive list. Please email shot@nhsbt.nhs.uk if you need any further information or clarification.

Summary of Changes 2022

Chapter	Date of Change
General page 1: Included requirement for reporting novel blood components in clinical trials	December 2021
General page 1: Included reporting for pre-hospital, home and community settings	December 2021
IBCT-WCT and SRNM: Incorrect specification of red cells provided as a result of errors in sex/gender allocation	December 2021
ADU - PCC reporting moved to ADU category	December 2021
ADU: Clarification around reporting delays due to lack of availability of stock – local or national	December 2021
HSE: Clarification of reporting category where there has been an error in the rate of transfusion	December 2021
Anti-D Ig: Clarification of reporting anti-D Ig use where D-positive blood components have been given to D-negative patient with child-bearing potential	December 2021

ACKNOWLEDGING CONTINUING EXCELLENCE

TERM	DEFINITION	WHAT TO REPORT
ACE (Acknowledging Continuing Excellence)	Exceptional transfusion practice by a team or department, that was above and beyond routine practice and has widespread learning opportunities. Please do not name individuals within reports, the staff group (e.g., BMS, or Transfusion Practitioner) should be used where required. All reports should have been discussed and agreed at the Hospital Transfusion Team/Committee (HTT/HTC) level before submitting to SHOT. <i>NB – SHOT encourage local processes to be put in place to recognise excellent contributions by individuals and sharing best practices between teams. Please focus on team or departmental excellence and avoid individual compliments unless they have widespread learning opportunities.</i> Reporting in this category will not be included in participation data for SAE and SAR. All SAE/SAR must also be reported to SABRE and SHOT as normal.	This category currently includes excellence within: • Transfusion Practice - Clinical • Transfusion Practice – Laboratory • Education & Research • Audit • Patient or public engagement • Team work and collaboration Examples include: • Innovative solutions to previous adverse events (all SAE/SAR must also be reported to SABRE and SHOT as normal) • Implementation of new procedures with positive patient outcomes • Multidisciplinary collaboration and communication • Patient involvement in agreeing individual transfusion treatment plans For illustrative examples of ACE reports please visit https://www.shotuk.org/reporting/ace-reporting/

ADVERSE EVENTS		
TERM	DEFINITION	WHAT TO REPORT
IBCT – WCT (Incorrect Blood Component Transfused – Wrong Component Transfused)	Where a patient was transfused with a blood component: a) of an incorrect blood ABO/D group b) which was incompatible with the recipient c) which was intended for another patient but was fortuitously compatible with the recipient d) other than that prescribed, e.g. platelets instead of red cells NB – Cases involving failure to provide patient-specific requirements such as extended phenotype, irradiated or CMV-seronegative components should be reported in the IBCT-SRNM category. <i>Samples that are rejected by the laboratory at booking in, as a result of the quality management system checks, are not reportable to SHOT.</i>	This category currently includes: • Patients receiving a blood component intended for a different patient • Patient transfused a component of an incorrect group due to clinical and/or laboratory errors in the transfusion process Examples of errors include: • Wrong blood in tube (WBIT) associated with group & screen phlebotomy errors • Failure to provide appropriate blood group following allogeneic haemopoietic stem cell transplant or solid organ transplant • Testing and procedural errors associated with ABO/D grouping • Component selection errors • Collection & administration errors • Incorrect component selected from stock. (Includes adult units to neonates) • Failure to supply high titre negative group mismatched platelets or plasma components • D-positive component given inadvertently to D-negative patient as a result of incorrect sex/gender allocation

ADVERSE EVENTS		
TERM	DEFINITION	WHAT TO REPORT
IBCT – SRNM (Incorrect Blood Component Transfused – Specific Requirements Not Met)	Where a patient was transfused with a blood component that did not meet their specific transfusion requirements. Do NOT report if a clinical decision has been taken to knowingly transfuse components not meeting specification in view of clinical urgency. <i>N.B. Occurrences where pathogen inactivated plasma components or apheresis platelets are not supplied for those born after 1996 or with TTP are no longer SHOT reportable. SaBTO (the advisory committee on the Safety of Blood, Tissues and Organs), review on this matter can be found here.</i>	Transfusion of a blood component of inappropriate specification or that did not meet the patient's individual requirements Examples currently include <i>failure to transfuse</i>: • Cytomegalovirus (CMV)-negative components • Irradiated components • Human leucocyte antigen (HLA)-matched platelets • Antigen-negative red cells for patients with known irregular red cell antibodies • Incorrect specification of component transfused to patient as a result of incorrect sex/gender allocation (e.g., K negative not provided) • Red cells of correct phenotype in accordance with national guidelines e.g., haemoglobinopathy, patients with childbearing potential Also: • Testing or release of components when the status of the sample does not comply with the guidelines • Release of components prior to completion of laboratory testing (including internal quality control) • Failure to use blood warmer when clinically indicated • Inappropriate use of electronic issue



Serious Hazards
of Transfusion

ADVERSE EVENTS		
TERM	DEFINITION	WHAT TO REPORT
ADU (Avoidable transfusion, Delayed transfusion or Under- or Over-transfusion, including PCC)	Failure to transfuse when indicated, under or over-transfusion, avoidable transfusion and significant delays in transfusion, whether caused by the laboratory or the clinical area. This includes all errors relating to the order, issue or administration of prothrombin complex concentrate (PCC). AVOIDABLE: Where the intended transfusion is carried out, and the blood component itself is suitable for transfusion and compatible with the patient, but where the decision leading to the transfusion is flawed. DELAYED: Where a transfusion of a blood component was clinically indicated but was not undertaken or non-availability of blood components led to a significant delay (e.g., that caused patient harm, resulted in admission to ward or return on another occasion for transfusion). UNDER (OR OVER) TRANSFUSION: A dose inappropriate for the patient's needs, excluding those cases which result in TACO (see TACO section).	This category includes: • Components that are not required or are inappropriate as a result of erroneous laboratory results, transcription errors or faulty clinical judgement • Components that are for an inappropriate indication • Transfusion of asymptomatic patient with haematinic deficiency • Inappropriate volume transfused • Infusion pump errors leading to under or over transfusion with clinical consequences (if no clinical consequences please report as HSE) • Avoidable use of emergency group O blood (O D-negative or positive) where group-specific or crossmatched blood was readily available for the patient or the laboratory could have supplied a more suitable component, including use of group O when time would allow a more appropriate group to be remotely allocated from a remote release refrigerator system Delays • Situations where transfusion would have been clinically appropriate but could not be given due to lack of availability of a suitable component (e.g., rare component, recognised blood shortage) • Delays in provision of blood components in an emergency, including delays in clinical recognition of major haemorrhage or need for blood components (e.g., transfusion in sickle cell patients) • Delays where specialist testing is required (e.g., monoclonal antibody therapy, complex antibodies) • Cases where a delay in transfusion affected the patient's health/wellbeing, for example: - o An out-patient who must return to hospital the next day as components were not available at the allotted time - o Delayed treatment

SHOT Definitions active January 2022



ADVERSE EVENTS		
TERM	DEFINITION	WHAT TO REPORT
HSE (Handling and Storage Errors)	Transfusion of the correct blood component to the intended patient, where handling or storage errors may have rendered the component less safe for transfusion. Do NOT report events where there is failure to complete collection paperwork, but the blood component was transfused safely to the correct patient. Do NOT report events where the blood is available for issue but has not been collected to be transfused to the patient (including blood in temperature-controlled boxes and satellite refrigerators). <i>Blood available and incorrectly handled/stored in the clinical area but not transfused IS REPORTABLE as a near miss HSE, except where the component has not been collected from a remote storage device.</i>	Cases of potentially 'unsafe' blood component where there were handling, or storage errors involved such as: • Cold chain errors such as transfusion of a unit that has been out of controlled temperature storage (CTS) for times exceeding national guidance or stored inappropriately, including equipment failure • Transfusion of a time-expired unit • Improperly prepared component/product e.g., cryoprecipitate issued before fully thawed • Transfusion of a unit of red cells that should have been cleared from the issue refrigerator and re-crossmatched • Excessive time to transfuse (> 5h from removal from cold storage to completion of transfusion) • Technical administration errors e.g., using an inappropriate giving set or setting an infusion pump incorrectly leading to incorrect transfusion rate or time (if this led to patient harm then is reportable under ADU, if resulted in TACO then report as TACO) • Transfusion of a component that has had a drug added, or co-administration of a blood component and drug through the same venous access • Component transfused despite the component being visibly damaged, or having been tampered with



ADVERSE EVENTS		
TERM	DEFINITION	WHAT TO REPORT
RBRP (Right Blood Right Patient)	Incidents where a patient was transfused correctly despite one or more serious identification (ID) or prescription errors which in other circumstances might have led to an IBCT. <i>NB – Cases involving reactions should be reported under the appropriate SAR category.</i>	This category includes errors associated with labelling and patient ID such as: • Administration with incorrect/incomplete details on the component label • Transposition of labels between units intended for the same patient • Absence of patient ID band or equivalent risk-assessed alternative identification system • Transfusion of a blood component that was intended for the patient, but was not formally prescribed/authorised • Pre-administration check not being performed correctly • Access cards being used inappropriately



Serious Hazards
of Transfusion

ADVERSE EVENTS		
TERM	DEFINITION	WHAT TO REPORT
Near Miss	A near miss is an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrong transfusion or a reaction in a recipient if transfusion had taken place. Do NOT report failures of the laboratory quality system which are not linked to a transfusion request for a specific named patient. Do NOT report events where the blood is available for issue but has not been collected to be transfused to the patient (including blood in temperature-controlled transport boxes and satellite refrigerators). These events are reportable to the MHRA but not SHOT. Blood for potential transfusion and available in the clinical area IS REPORTABLE, except where components have not been collected from storage devices in clinical areas.	For near miss incidents not related to wrong blood in tube (WBIT): - The incident is only reportable if the blood component has been collected from a blood fridge and taken to the clinical area. If laboratory QMS processes have picked up the error or a component has not been ordered or collected, then it is not SHOT-reportable For near miss WBITs: Do report - Cases where the sample was tested, and group or antibody testing found to be discrepant with historic results - Samples or tests rejected following a communication from the clinical area to inform the laboratory of an actual or potential error (e.g., patient misidentified) - Cases where a WBIT was discovered by other fortuitous circumstances e.g., two samples apparently from the same patient arriving close together and discovered to be erroneous Do NOT report - Incidents where samples have been rejected by the laboratory QMS before testing, i.e., zero tolerance labelling

SERIOUS ADVERSE REACTIONS

TERM	DEFINITION	WHAT TO REPORT
FAHR (Febrile, allergic and hypotensive reactions formerly known as Acute Transfusion Reactions – ATR)	Allergic/febrile transfusion reactions occurring at any time up to 24 hours following a transfusion of a blood component. NB – Acute reactions due to the following causes should be reported under the appropriate heading: • Incorrect blood component being transfused (IBCT-WCT or IBCT-SRNM) • Haemolytic transfusion reaction (HTR Acute or HTR Delayed) • Transfusion-related acute lung injury (TRALI) • Transfusion-associated circulatory overload (TACO) • Transfusion-associated dyspnoea (TAD) • Suspected bacterial contamination of the component (TTI)	This category includes: • Febrile-type reaction (simple febrile reactions associated with chills and/or rigors or other inflammatory symptoms, or involving a 2°C temp rise over baseline, or an absolute temp of 39°C) • Allergic-type reaction • Reactions with both febrile and allergic features • Hypotensive reactions Note that the reactions reported in patients with selective IgA deficiency – both allergic and acute non-allergic reactions will be included here. Please note that further features of these reactions and how to classify them in SABRE are provided in the classification of acute transfusion reactions table, which should also be used to grade and report the severity of the reaction. Please note that those graded as 'Mild' are NOT SHOT reportable. Do not report cases of apparent transfusion reactions that are consistent with, and explained by, the patients underlying condition.

SERIOUS ADVERSE REACTIONS

HTR Acute (Haemolytic Transfusion Reaction)	Acute HTRs are defined as fever and other symptoms/signs of haemolysis within 24 hours of transfusion; confirmed by one or more of the following: • Failure to increment or Hb drop to lower than pre-transfusion levels • Rise in LDH • Rise in bilirubin • Positive DAT • Incompatible crossmatch not detectable pre-transfusion NB – Cases of haemolytic reactions due to the following should be reported under the appropriate heading: - ABO-incompatible RED CELLS are reported under Incorrect Blood Component Transfused (IBCT-WCT) - ABO-incompatible PLATELETS are reported under haemolytic transfusion reaction (HTR)	Cases with relevant features should be reported together with results of all laboratory investigations including antibody identification if available. Please include Blood Service reference laboratory investigation number where possible. Specific HTR acute or delayed related to failures in the processing of samples from patients prior to or undergoing treatment with monoclonal antibody therapy.
HTR Delayed (Haemolytic Transfusion Reaction)	Delayed HTRs are defined as fever and other symptoms/signs of haemolysis more than 24 hours after transfusion; confirmed by one or more of the following: • Fall in Hb or failure of increment • Rise in bilirubin • Incompatible crossmatch not detectable pre-transfusion NB – Simple serological reactions (development of antibody with or without a positive DAT but without clinical or laboratory evidence of haemolysis) are no longer reportable.	Cases with relevant features should be reported together with results of all laboratory investigations including antibody identification if available. This category includes cases of suspected hyperhaemolysis. Please note the SHOT expert will use the information given in the report to categorise the Severity Grades for Haemolytic Transfusion Reactions, so please refer to this table and include adequate information.



**Serious Hazards
of Transfusion**

SERIOUS ADVERSE REACTIONS

TERM	DEFINITION	WHAT TO REPORT
PTP (Post-Transfusion Purpura)	Thrombocytopenia arising 5 – 12 days following transfusion of cellular blood components (red cells or platelets), associated with the presence in the patient of alloantibodies directed against the HPA (Human Platelet Antigen) systems.	Cases where the platelet count drops more than 50% following transfusion should be investigated and reported if complete or partial serological evidence is available to support PTP.
UCT* (*Uncommon and new Complications of Transfusion not fitting into any of the other categories)	Pathological reaction or adverse effect in temporal association with transfusion which cannot be attributed to already defined side effects and with no risk factor other than transfusion and do not fit under any of the other reportable categories, including cases of transfusion-associated hyperkalaemia.	This category includes • Cases of transfusion-associated necrotising enterocolitis (NEC) i.e., NEC occurring within 48h of red cell transfusion in pre-term infants • Cases of transfusion-associated hyperkalaemia, where it is noted that a patient has an unexpectedly high potassium level following transfusion. An example is hyperkalaemia following rapid transfusion of red cells NB – Please contact the SHOT office to discuss any UCT cases to get clarification prior to reporting on 0161 423 4208 or email shot@nhsbt.nhs.uk
TA-GvHD (Transfusion-Associated Graft versus Host Disease)	Characterised by fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow hypoplasia occurring less than 30 days after transfusion. The condition is due to engraftment and clonal expansion of viable donor lymphocytes in a susceptible host.	All cases where diagnosis is supported by skin/bone marrow biopsy appearance or confirmed by the identification of donor-derived cells, chromosomes or DNA in the blood and/or affected tissues. Cases with a very high index of clinical suspicion.

SHOT Definitions active January 2022


SERIOUS ADVERSE REACTIONS

TERM	DEFINITION	WHAT TO REPORT
TACO (Transfusion-Associated Circulatory Overload)	* Required criteria (A and/or B) A. Acute or worsening respiratory compromise and/or B. Evidence of acute or worsening pulmonary oedema based on: • clinical physical examination, and/or • radiographic chest imaging and/or other non-invasive assessment of cardiac function Additional criteria C. Evidence for cardiovascular system changes not explained by the patient's underlying medical condition, including development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema D. Evidence of fluid overload including any of the following: a positive fluid balance; clinical improvement following diuresis E. Supportive result of a relevant biomarker, e.g., an increase of B-type natriuretic peptide levels (BNP) or N-terminal-pro brain natriuretic peptide) NT-pro BNP to greater than 1.5 times the pre-transfusion value	Patients classified with TACO (surveillance diagnosis) should exhibit the following during or up to 12 hours after transfusion* • At least one required criterion (i.e., A and/or B) • With a total of at least 3 or more criteria (A to E) *SHOT continues to accept cases where patient's symptoms have started up to 24 hours after transfusion.

SERIOUS ADVERSE REACTIONS

TERM	DEFINITION	WHAT TO REPORT
TAD (Transfusion-Associated Dyspnoea)	TAD is characterised by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI , TACO or allergic reaction . Respiratory distress in such cases should not be explained by the patient's underlying condition.	Cases with relevant features (see definition) should be reported together with, wherever possible, information on oxygen saturation/arterial blood gases and chest X-ray appearances.
TRALI (Transfusion-Related Acute Lung Injury)	Acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within six hours of transfusion - not due to circulatory overload or other likely causes - in the presence of human leucocyte antigen (HLA) human neutrophil (HNA) antigen antibodies cognate with the recipient	Suspected cases should be discussed with a Blood Service Consultant (who can arrange appropriate investigations) and reported to SHOT if there is a high index of suspicion, even if serological investigations are inconclusive.

SERIOUS ADVERSE REACTIONS

TERM	DEFINITION	WHAT TO REPORT
TTI (Transfusion-Transmitted Infections)	(Reporters should explore all possible risk exposures in parallel with the Blood Service investigations, in order to determine the patient's most likely source of infection. This includes checking records prior to the implicated transfusion(s) to check that the recipient was not infected prior to transfusion). Include as a TTI if, following investigation the recipient had evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion, and no evidence of an alternative source of infection. Plus: Either at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection. Or at least one component received by the infected recipient was shown to contain the agent of infection.	Cases currently include: - Bacterial transmission from blood components, where cultures from the patient's blood match cultures from the component bag and/or from the donor - Transmissions of viruses, whether routinely tested for by the Blood Services or not - Transmissions of other agents such as prions, protozoa and filarial Please note that the joint NHSBT/UK Health Security Agency (UKHSA) staff support SHOT by acting as the national infections' coordinator. The unit works across both NHSBT and UKHSA the epidemiology database containing information on possible, probable, and confirmed transmissions hosted at UKHSA. The unit collates data from all the four UK Blood Services. Additional information for reporting TTI to the blood services: - If a TTI is suspected in England, then the webpage below provides guidance how to report an adverse event https://hospital.blood.co.uk/diagnostic-services/reporting-adverse-events/ - If a TTI is suspected in Wales, then the webpage below has a request form for the investigation of suspected contamination of blood components and/or a clinician at WBS can be contacted https://wbs-intranet.cymru.nhs.uk/bht/wp-content/bht-uploads/sites/4/2019/11/QAL-Templates-196-Request-form-for-the-Investigation-of-Suspected-Contamination-of-Blood-Components-1.pdf - If a TTI is suspected in Northern Ireland, then this should be discussed at the hospital level by the haemovigilance team and the Consultant Haematologist in charge of transfusion and then discussed with the medical consultant in NIBTS to guide and coordinate investigation - If a TTI is suspected in Scotland, then this should be reported to the on-call patient services consultant, via the local transfusion laboratory / blood bank. The on-call consultant should then notify the donor services consultant via the Donor Services (DS) medical team who will liaise with the national reference laboratory.

OTHER REPORTING CATEGORIES

TERM	DEFINITION	WHAT TO REPORT
ANTI-D	Events relating to the requesting and/or administration of anti-D immunoglobulin (Ig) and RAADP during pregnancy and after delivery. Please note that this category now includes events relating to the administration of anti-D Ig following inadvertent transfusion of D-mismatched red cells or platelets, as per national guidance. NB – Cases of near misses relating to anti-D Ig should be reported under the Near Miss category rather than as anti-D Ig errors. NOT SHOT REPORTABLE • Cases of pathological reaction (e.g., allergy) to anti-D Ig are not reportable to SHOT, but are reportable via the MHRA 'Yellow Card' system for medicines • Cases of omission or late administration where the primary reason is patient non-compliance are not reportable to SHOT • Due to inevitable variation in local practice, SHOT has defined late administration of RAADP as after 34 weeks of gestation IMMUNE ANTI-D Cases of D-negative women who become sensitised and are found to have developed immune anti-D which is detected during pregnancy, either at booking or later in pregnancy, should be reported as SAE via SABRE by selecting 'Other/Anti-D immunisation' for 'Event involving'.	This category currently includes anti-D Ig and RAADP during pregnancy and after delivery that has been: • Omitted or administered late • Administered to a D-positive woman • Administered to a woman with immune anti-D • Administered erroneously to a mother of a D-negative infant • Given to the wrong woman (failure of pre-administration ID check) • Incorrect dose of anti-D Ig given according to national policy, due to erroneous selection of wrong dose or misinterpretation of Kleihauer/quantification results • Failure to perform Kleihauer following potentially sensitising event/delivery • Handling and storage errors associated with anti-D Ig, including issue of expired anti-D Ig, inappropriately stored anti-D Ig, where batch numbers on the vials do not match with issue paperwork, or inappropriate route of administration • Errors associated with cell free fetal DNA (cffDNA) testing, including false negative and false positive results, failure to confirm results • Inadequate follow up of fetal cell clearance post sensitising event or post delivery Failures in requesting or administration of anti-D Ig to D-negative females with childbearing potential, including paediatric, following transfusion of D-positive blood components.

OTHER REPORTING CATEGORIES

TERM	DEFINITION	WHAT TO REPORT
Cell Salvage	Events and reactions in relation to the use of intraoperative and postoperative cell salvage.	This category currently includes: • Adverse events due to operator error, where the event impacts on the care of the patient • Adverse events due to machine or disposable failure where the event impacts on the care of the patient • Adverse events related to the availability of trained staff which impact on the patient • Adverse clinical events during the cell salvage process, such as hypotensive events • Pathological reactions to reinfused blood



**Serious Hazards
of Transfusion**

MAJOR MORBIDITY

Intensive care or high dependency admission and/or ventilation, renal dialysis and/or renal impairment:

- Transfusion induced coagulopathy in association with treatment for major haemorrhage (due to the dilution of haemostatic factors following unbalanced resuscitation or overuse of crystalloid/colloid)
- Evidence of acute intravascular haemolysis e.g., haemoglobinaemia, gross haemoglobinuria
- Life-threatening acute reaction requiring immediate medical intervention
- Persistent viral infection
- Acute symptomatic confirmed infection
- Sensitisation to D or K in a woman of childbearing potential
- Reaction resulting in a low or high haemoglobin (Hb) level of a degree sufficient enough to cause risk to life unless there is immediate medical intervention

IMPUTABILITY

N/A	Not assessable	When there is insufficient data for imputability assessment
0	Excluded or Unlikely	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components or where the evidence is clearly in favour of alternative causes
1	Possible	When the evidence is indeterminate for attributing the adverse reaction either to the blood or blood component or where there may be alternative causes
2	Likely / Probable	When the evidence is clearly in favour of attributing the adverse reactions to the blood or blood component
3	Certain	When there is conclusive evidence beyond reasonable doubt attributing the adverse reactions to the blood or blood component

CURRENT IHN/SHOT/B(C)SH CLASSIFICATION OF ACUTE TRANSFUSION REACTIONS				SABRE Classification
	1=Mild (not SHOT reportable)	2=Moderate	3=Severe	
Febrile type reaction	A temperature $\geq 38^{\circ}\text{C}$ and a rise between 1°C and 2°C from pre-transfusion values, but no other symptoms/signs	A rise in temperature of 2°C or more, or fever 39°C or over and/or rigors, chills, other inflammatory symptoms/signs such as myalgia or nausea which precipitate stopping the transfusion	A rise in temperature of 2°C or more, and/or rigors, chills, or fever 39°C or over, or other inflammatory symptoms/signs such as myalgia or nausea which precipitate stopping the transfusion, prompt medical review AND/OR directly results in, or prolongs hospital stay	Other/Febrile FAHR
Allergic type reaction	Transient flushing urticaria or rash	Wheeze or angioedema with or without flushing/urticaria/rash but without respiratory compromise or hypotension	Bronchospasm, stridor, angioedema or circulatory problems which require urgent medical intervention AND/OR, directly result in or prolong hospital stay, or Anaphylaxis (severe, life-threatening, generalised or systemic hypersensitivity reaction with rapidly developing airway AND/OR breathing AND/OR circulation problems, usually associated with skin and mucosal changes)	Anaphylaxis /Hypersensitivity /Allergic /FAHR
Reaction with both allergic and febrile features	Features of mild febrile and mild allergic reactions	Features of both allergic and febrile reactions, at least one of which is in the moderate category	Features of both allergic and febrile reactions, at least one of which is in the severe category.	Other /Mixed febrile /Allergic FAHR*
Hypotensive reaction		Isolated fall in systolic blood pressure of 30 mm Hg or more occurring during or within one hour of completing transfusion and a systolic blood pressure 80 mm or less in the absence of allergic or anaphylactic systems. No/minor intervention required	Hypotension, as previously defined, leading to shock (e.g., acidemia, impairment of vital organ function) without allergic or inflammatory symptoms. Urgent medical intervention required	Other /Hypotensive FAHR

* This category may include mild symptoms/signs of one reaction type providing the other category is either moderate or severe

SEVERITY GRADES FOR HAEMOLYTIC TRANSFUSION REACTIONS

1=DAT without haemolysis	2=Mild	3=Moderate	4=Severe
Not SHOT reportable	<i>2 of the following:</i> - Falling haemoglobin - Positive DAT - Spherocytes	- Falling haemoglobin - Rise in bilirubin $\pm$ positive DAT $\pm$ spherocytes	- Falling haemoglobin - Rise in bilirubin - Renal impairment $\pm$ positive DAT $\pm$ spherocytes

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Policy for Reporting of Early Alerts to the Department of Health (DoH)

Lead Policy Author & Job Title:	Stacey Hetherington, Corporate Clinical and Social; Care Governance Co-Ordinator Nicole O'Neill, Corporate Clinical and Social Care Governance Manager
Directorate responsible for document:	Medical
Issue Date:	28 July 2022
Review Date:	Click here to enter a date.



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Policy Checklist

Policy name:	Policy for the Reporting of Early Alerts to the Department of Health (DoH)
Lead Policy Author & Job Title:	Stacey Hetherington, Corporate CSCG Co-Ordinator Nicole O'Neil, Corporate CSCG Manager
Director responsible for Policy:	Dr Damian Gormley, Interim Medical Director
Directorate responsible for Policy:	Medical
Equality Screened by:	Click here to enter text.
Trade Union consultation?	Yes ☐ No ☒
Policy Implementation Plan included?	Yes ☒ No ☐
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Date approved by SMT:	Click here to enter a date.
Policy circulated to:	Operational Directorate Governance Co-Ordinators
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<i>Eg Version 2_0</i>	Click here to enter text	Click here to enter a date.	Click here to enter text

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Introduction

The Early Alert System was introduced on 01 June 2010 to coincide with the transfer of responsibility for the Serious Adverse Incident (SAI) system from the Department of Health (DoH) (formerly known as the Department of Health, Social Services & Public Safety) to the Department of Health Strategic Planning and Performance Group (SPPG) (formerly known as the Health & Social Care Board (HSCB))/ Public Health Agency (PHA).

The Early Alert system outlines the requirements for Chief Executives and their senior staff in Health & Social Care (HSC) to notify the Department in a prompt and timely way of events or incidents which have occurred in the services provided or commissioned by their organisations, which may require urgent attention by the Minister, Chief Professionals or policy leads, and/or require urgent regional action by the Department.

Purpose and Aims

The purpose of this policy is to ensure the Southern Health and Social Care Trust (SHSCT) adheres to the Early Alert guidance which have been in effect from 1 June 2010 (and subsequent updates) to ensure that the DoH/SPPG (and thus the Health Minister) receive prompt and timely details of events (these may include potential serious adverse incidents), which may require urgent attention or possible action by the DoH/SPPG including those of media interest.

Objectives of this Policy

To support staff involved in the procedure for reporting Early Alerts to the DoH.

Policy Statement

Department of Health (DOH): Department of Health (previously known as the Department of Health, Social Services and Public Safety [DHSSPS]). Also referred to as the 'Department'.

Early Alert: an incident or an event which has occurred in the services provided or commissioned by the organisation and which may require immediate attention by the Health Minister, Chief Professional Officers or policy leads and/or requires urgent regional action by the Department.

Strategic Planning and Performance Group (SPPG) (formerly known as the Health & Social Care Board (HSCB)): department within the Department of Health responsible for the receiving, review and escalation of Early Alerts from the Trust. SPPG will advise the Trust if any further action is required on receipt of an Early Alert.

The Early Alert system (see Appendix 1) provides a channel which enables the Chief Executive and senior staff (Director level) to notify the DoH/SPPG, in a prompt and timely manner, of events or incidents which have occurred in any service provided by the Trust and which may require immediate attention by the Health Minister, Chief Professional Officers or policy leads and/or require urgent regional action by the Department.

It is important to note that this reporting system is intended to complement, not replace, existing channels of communication, both formal and informal.

Whilst it is likely that some of the notifications reported as Early Alerts will also require to be managed as Serious Adverse Incidents (see Policy and Procedure for the Reporting of Serious

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Adverse Incidents to the Health & Social Care Board, November 2016) many Serious Adverse Incidents will NOT require to be reported through the Early Alert channel.

Where an Early Alert is identified out of hours, Directors should make contact with the relevant senior member of staff at Department level by telephone (Appendix 2). The completed proforma to the DoH/SPPG by the Corporate Governance office will follow as soon as possible thereafter.

Scope of Policy

This policy is applicable to incidents within all service areas across the SHSCT.

Responsibilities

Chief Executive: is responsible for ensuring that a system is in place to notify the DoH/SPPG in a prompt and timely way of events or incidents which have occurred in the services provided or commissioned by their organisations, which may require urgent attention by the Health Minister, Chief Professionals or policy leads, and/or require urgent regional action by the DoH/SPPG.

Corporate Clinical and Social Care Governance: have responsibility for centrally managing the Trust's Early Alert's (through the mailbox: [REDACTED] Personal Information redacted by the UST) ensuring queries are raised with Directorate Clinical and Social Care Governance teams in a timely manner and that Early Alert Proformas are submitted to the DoH/SPPG as per the timeframes stipulated in the reporting process (Appendix 1).

Directors: are responsible for making a decision as to whether an incident meets the criteria for an Early Alert and if so to make contact with the relevant senior member of staff at Department level by telephone, including out of hours (using the phone numbers at Appendix 2). They are responsible for agreeing with SPPG any follow-up action as required.

Directors are responsible for ensuring the initial telephone contact is followed up in writing (using the Early Alert proforma, Appendix 3) within the timescales set out by DoH.

Assistant Directors: are responsible for ensuring that incidents which may fall within the criteria for Early Alerts within their areas of responsibility are reported to the relevant Director as a matter of urgency to allow for a decision by their respective Director as to the merits of reporting to the DoH/SPPG. In addition, they may also have to make the telephone call to the DoH in the event the Director is not available.

Directorate Governance Co-Ordinators: are responsible for the coordination of the Early Alert process within their Directorates, ensuring Assistant Directors/Directors have reviewed and approved prior to submitting the proforma to Corporate Governance for onward submission. Directorate Co-Ordinators will ensure relevant updates to Early Alerts submitted are escalated for approval and submission.

Senior Managers: are responsible for making staff aware of this policy and ensuring discussion with the Assistant Director of any incident which may fall within the criteria for reporting as an Early Alert.

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Staff (including permanent, temporary, locum, agency, bank, contractors and voluntary): are responsible for making themselves aware of, and adhering to, the content of this policy when involved with raising an Early Alert at service level.

Dissemination

Following approval, this policy will be disseminated widely to all Governance staff within the Trust but particularly Directorate Governance Co-Ordinators, Senior Managers, Assistant Directors and Directors within the organisation. Staff at service level involved in Early Alerts will be made aware of this Policy as required.

Resources

Within the Medical Directorate, the Corporate Clinical and Social Care Governance (CSCG) Department is responsible for ensuring all relevant staff detailed in 5.1 have an awareness of this policy, delivering bespoke training sessions as and when required.

Exceptions

This policy indirectly applies to all staff across all service areas within the Trust and there are no exceptions to its application.

Monitoring

Audit of the policy will be undertaken, to ensure adherence to the principles and procedures outlined within the document.

Legislative Compliance, Relevant Policies, Procedures and Guidance

Policy Circular HSC (SQSD) 64/16 – Early Alert System dated 28 November 2016 (Superseded)
 Policy Circular HSC (SQSD) 10/10 – Establishing an Early Alert System dated 28 May 2010
 Policy Circular HSC (SQSD) 5/19 – Early Alert System dated 27 February 2019
 Regional Working Group consult
 HSC (SQSD) circulars

Equality & Human Rights Considerations

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out.

The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact. ☒

Sources of Advice & Further Information

Appendix 1: Process for the Reporting of Early Alerts to the Department of Health

Appendix 2: Early Alert System Department Officer Contact List – March 2022

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Appendix 3: Early Alert Proforma
Appendix 4: SHSCT Process Flowchart for the Reporting of Early Alerts

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Process for the Reporting of Early Alerts to the Department of Health Strategic Planning and Performance Group (SPPG) (formerly known as the Health & Social Care Board (HSCB))

1.0 Introduction

The purpose of this guidance is to make staff aware of the arrangements which should be followed to ensure that the DoH/SPPG (and thus the Health Minister) receive prompt and timely details of events (these may include potential serious adverse incidents), which may require urgent attention or possible action by the DoH/SPPG including those of media interest.

1.0 Criteria for Reporting an Incident as an Early Alert

- 1.1 The established communications protocol between the DoH/SPPG and HSC organisations emphasises the principles of 'no surprises', and an integrated approach to communications. Accordingly, the Trust is required to notify the DoH/SPPG promptly (**within 48 hours of the event**) of any event which has occurred within Trust services which meets one or more of the following criteria:
- a) Urgent regional action may be required by the DoH/SPPG, for example, where a risk has been identified which could potentially impact on the wider HSC service or systems;
 - b) The Trust is going to contact a number of patients or clients about harm or possible harm that has occurred as a result of the care they received. Typically, this does not include contacting an individual patient or client unless one of the other criteria is also met;
 - c) The Trust is going to issue a press release about harm or potential harm to patients or clients. This may relate to an individual patient or client;
 - d) The media have inquired about the event;
 - e) The PSNI is involved in the investigation of a death or serious harm that has occurred in the Trust's Services, where there are concerns that a Trust service or practice issue (whether by omission or commission) may have contributed to or caused the death of a patient or client. This does not include any deaths routinely referred to the Coroner, unless:
 - (i) There has been an event which has caused harm to a patient or client and which has given rise to a coroner's investigation; or

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- (ii) Evidence comes to light during the Coroner's investigation or inquest which suggests possible harm was caused to a patient or client as a result of the treatment or care they received; or
- (iii) The Coroner's inquest is likely to attract media interest.

f) The following should always be notified:

- (i) The death of, or significant harm to, a child and abuse or neglect are known or suspected to be a factor;
- (ii) The death of, or significant harm to, a Looked After Child or a child on the Child Protection Register;
- (iii) Allegations that a child accommodated in a children's home has committed a serious offence; and
- (iv) Any serious complaint about children's home or person(s) working there.

g) There has been an immediate suspension of staff due to harm to patient/client or a serious breach of statutory duties has occurred.

2.0 Operational Arrangements

- 2.1 The **Assistant Director** should advise the relevant Director as soon as they are made aware of the incident having occurred within their area of responsibility.
- 2.2 The Director should consider the incident description against the criteria set out for reporting under the Early Alert system and make an assessment as to whether it is reportable.
- 2.3 The Director (or nominee) should communicate by telephone with the senior member of staff in the Department (i.e. the Permanent Secretary, Deputy Secretary, Chief Professional Officer or Assistant Secretary) and the Public Health Agency, as appropriate and any other relevant bodies regarding the event.
- 2.4 Appendix 2 provides the contact details of a range of senior Departmental staff together with an indication of their respective areas of responsibility. The senior officers are not listed in order of contact. Should a senior officer with responsibility for an area associated with an event not be available, please proceed to contact any senior officer on the list. The list of names is up to date as at March 2022 but contact details should not change even if individual staff members do.
- 2.5 The next steps should be agreed during the call and appropriate follow-up action taken by the relevant parties.
- 2.6 The Director (or nominee) will arrange for the follow-up proforma to be fully completed as soon as possible after the event but no later than **24 hours** from the original telephone report (Appendix 3) and forwarded to the Corporate CSCG department at [REDACTED] and email marked 'important' for processing.

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- 2.7 The Corporate CSCG office will insert the appropriate reference number, anonymise the content and issue to the DoH/SPPG early alerts mailbox within 24 hours of the initial telephone notification at 3.3. At no time should the completed proforma be forwarded to the DoH/SPPG by anyone other than Corporate CSCG Department staff.
- 2.8 The report will be issued simultaneously by the Corporate CSCG office to the Chief Executive, the Chair, Directors, Non-Executive Directors, the relevant Assistant Director, the Communications Manager, CSCG staff including the Assistant Director for CSCG and any other relevant officers as deemed appropriate by the Corporate CSCG department.
- 2.9 The SPPG will provide an update and decision on whether the file can be closed or further follow up is required to the Corporate CSCG department Personal Information redacted by the USI within 4 weeks of receipt of Early Alert. Details of this update will be shared with CSCG staff within the relevant Directorate. ** Early Alerts in relation to reduced cover within GP Out of Hours will not be followed and an automatic update of "the issue in relation to reduced cover within GP Out of Hours continues, Early Alerts will continue to be submitted when the Director feels appropriate.*
- 2.10 There may be occasions when Directors feel it is appropriate to provide updates to the DoH/SPPG on an Early Alert which has already been reported, and where there has been a considerable passage of time since the initial report, with possible Ministerial changes. It may be appropriate, therefore, for the Director (or nominee) to communicate with a senior member of staff in the Department of Health (i.e. the Permanent Secretary, Deputy Secretary, Chief Professional officer or Assistant Secretary) regarding the update. This is not mandatory, however it is considered to be good practice. Any telephone update should be advised to the Corporate CSCG Department to allow for a written update to be provided also.
- 2.11 It is the responsibility of the Trust to comply with any other possible requirements to report or investigate the event being reported in line with any other relevant applicable guidance or protocols [e.g. Police Service for Northern Ireland (PSNI), Health & Safety Executive (HSE(NI)), Professional Regulatory Bodies, the Coroner etc. This should include compliance with GDPR requirements for information contained in the Early Alert proforma and the mandatory requirement to notify the Information Commissioner's Office (ICO) about any reportable personal data breaches. The information contained in the proforma should relate only to the key issue and it should not contain any personal data.

Early Alert System Departmental (DoH) Officer Contact List

The following information provides the contact details of a range of senior Departmental staff together with an indication of their respective areas of responsibility. **The senior officers are not listed in order of contact. Should a senior officer with responsibility for an area associated with an event not be available, please proceed to contact any senior officer on the list. Voicemails must not be left.**

EARLY ALERT SYSTEM: DEPARTMENTAL OFFICER CONTACT LIST MARCH 2022

HEALTHCARE POLICY GROUP

Deputy Secretary

Jim Wilkinson

Personal Information redacted by the USI

General Dental, Ophthalmic Services & Criminal Justice Healthcare

Robbie Davis

Personal Information redacted by the USI

Primary Care/Out of Hours Services

Gearoid Cassidy

Personal Information redacted by the USI

Secondary Care

Ryan Wilson

Personal Information redacted by the USI

Workforce Policy/Human Resources

Philip Rodgers

Personal Information redacted by the USI

Transformation/EU Exit

Patricia Quinn Duffy

Personal Information redacted by the USI

Hospital Services Reform

Tomas Adell

Personal Information redacted by the USI

Regional Health Services Transformation

Peter Jakobsen

Personal Information redacted by the USI

RESOURCE AND CORPORATE MANAGEMENT GROUP

Infrastructure Investment

Preet Miller

Personal Information redacted by the USI

Finance Director

Brigitte Worth

Personal Information redacted by the USI

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Director of Public Inquiries and Public SafetyLa'Verne Montgomery Personal Information redacted by the USI**Director of Corporate Management**Paul Montgomery Personal Information redacted by the USI**CHIEF DIGITAL INFORMATION OFFICER****Chief Digital Information Officer**Dan West Personal Information redacted by the USI**SOCIAL SERVICES POLICY GROUP****Chief Social Services Officer**Sean Holland Personal Information redacted by the USI**Child Protection/Looked After Children (LAC's)**Eilis McDaniel Personal Information redacted by the USI**Mental Health**Peter Toogood Personal Information redacted by the USI**Disability and Older People**Mark McGuicker Personal Information redacted by the USI**Social Services**Aine Morrison Personal Information redacted by the USI**CHIEF MEDICAL OFFICER GROUP****Chief Medical Officer**Dr Michael McBride Personal Information redacted by the USI**Deputy Chief Medical Officers**Dr Naresh Chada Personal Information redacted by the USIDr Lourda Geoghegan Personal Information redacted by the USI**Population Health Director**Liz Redmond Personal Information redacted by the USI**Director Quality, Safety and Improvement**Andrew Dawson Personal Information redacted by the USI**Early Alerts Policy - June 2022**

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Chief Dental Officer

Caroline Lappin

Personal Information redacted by the USI

Chief Pharmaceutical Officer

Cathy Harrison

Personal Information redacted by the USI

Chief Environmental Health Officer

Nigel McMahon

Personal Information redacted by the USI

Senior Medical Officers

Dr Carol Beattie

Personal Information redacted by the USI

Dr Monica Hughes (Primary Care)

Dr Mark Roberts (Acute Care)

Personal Information redacted by the USI

CHIEF NURSING OFFICER**Chief Nursing Officer**

Maria McIlgorm

Personal Information redacted by the USI

Deputy Chief Nursing Officer

Lynn Woolsey

Personal Information redacted by the USI

Chief AHP Officer

Suzanne Martin

Personal Information redacted by the USI

Midwifery

Dale Spence

Personal Information redacted by the USI

Early Alerts Policy - June 2022

Working together



Excellence



Openness & Honesty



Compassion

✕ Initial call made to (DoH) on DATE

Datix Reference (if applicable)

Follow-up Pro-forma for Early Alert Communication:

Details of Person making Notification:

Name Organisation
 Position Telephone

Criteria under which event is being notified (mark as appropriate)

1. Urgent regional action
2. Contacting patients/clients about possible harm
3. Press release about harm
4. Regional media interest
5. Police involvement in investigation
6. Events involving children/young people in care or receiving after care support
7. Suspension of staff or breach of statutory duty

Brief summary of event being communicated: * *If this relates to a child please specify DOB, legal status, placement detail If there have been previous events reported of a similar nature please state dates and reference number. In the event of the death or serious injury to a child - Looked After or on CPR - Please confirm report has been forwarded to Chair of the Safeguarding Board for Northern Ireland (SBNi).*

.....

.....

.....

Appropriate contact within the organisation should further detail be required:

Name of appropriate contact:

Contact details:

Email address (work or home)

Mobile (work or home) Telephone (work or home)

Forward pro-forma to the SPPG at and DoH at

FOR COMPLETION BY DoH:

Early Alert Communication received by: Office:

Forwarded for consideration and appropriate action to: Date:

Detail of follow-up action (if applicable)

Early Alerts Policy - June 2022



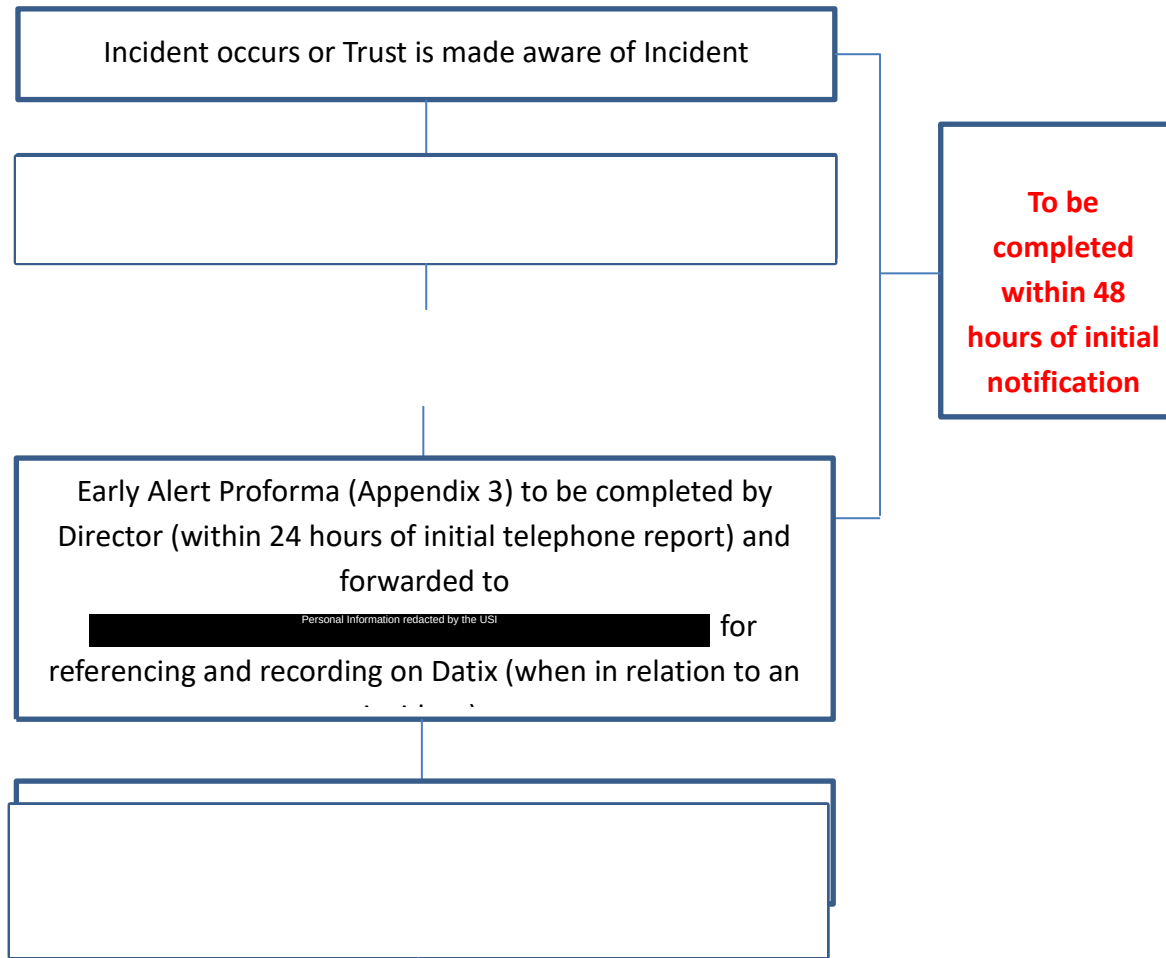
Working together

Excellence

Openness & Honesty

Compassion

Early Alerts Flowchart



Reference: HSC (SQSD) 5/19

Date of Issue: 12 November 2020

EARLY ALERT SYSTEM

For Action:

Chief Executives of HSC Trusts
Chief Executive, HSCB for cascade to:

- *General Medical Practices*
- *Community Pharmacy Practices*
- *General Dental Practitioners*
- *Ophthalmic Practitioners*

Chief Executive, PHA

Chief Executive NIAS

Chief Executive RQIA

Chief Executive NIBTS

Chief Executive NIMDTA

Chief Executive NIPEC

Chief Executive BSO

Related documents

HSC (SQSD) 10/10: Establishment of an Early Alert System

<https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2010-10.pdf>

HSC (SQSD) 07/14: Proper use of the Early Alert System

<https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2007-14.pdf>

Superseded documents:

HSC (SQSD) 64/16: Early Alert System

<https://www.health-ni.gov.uk/sites/default/files/publications/health/HSC-SQSD-64-16.pdf>

Implementation: Immediate

For Information:

Distribution as listed at the end of this Circular.

DoH Safety and Quality Circulars can be accessed on:

<https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars>

Issue

This updated circular advises on the use of the Early Alert System with respect to COVID 19 incidents/outbreaks and also serves as a reminder to the operation of the Early Alert system. COVID 19 incidents/outbreaks that are being managed as part of a normal operational response (usual business) should not be routinely reported through the Early Alert system. Such outbreaks/incidents should continue to be reported to Health Protection Team in the PHA as notifiable disease and HSC organisations should continue to provide regular updates to HSCB through established SITREP arrangements.

Action**Chief Executives of HSCB and PHA should:**

- Disseminate this circular to all relevant HSCB and PHA staff for consideration through the normal HSCB/PHA processes for assuring implementation of safety and quality circulars.
- Disseminate this circular to Community Pharmacies, General Medical, General Dental and Ophthalmic Practitioners.

Chief Executives of HSC Trusts, NIAS, NIBTS, NIPEC and BSO should:

- Disseminate this circular to all relevant staff.

Chief Executive, RQIA should:

- Disseminate this circular to all relevant staff and all relevant independent sector providers.

Chief Executive of NIMDTA should:

- Disseminate this circular to all relevant staff and doctors and dentists in training in all relevant specialities.

Background

In June 2010, the process of reporting Early Alerts was introduced. The Early Alert protocol is designed to ensure that the Department of Health (DoH) is made aware in a timely fashion of significant events, which may require the attention of the Minister, Chief Professional Officers and/or policy leads. The purpose of this circular is to clarify arrangements with respect to COVID 19 incidents/outbreaks and re-issue updated guidance for the procedure to be followed if an Early Alert is appropriate.

This updated circular will also serve as a reminder to HSC organisations to ensure that the Department (and thus the Minister) receive prompt and timely details of events (these may include potential serious adverse incidents), which may require urgent attention or possible action by the Department. The protocol, criteria and operational arrangements for the Early Alert system are provided at **Annex A**, an updated summary of departmental contact numbers is provided at **Annex B**, amendments to these guidance documents, last issued 27 February 2019, are highlighted in yellow for your attention.

During this current surge of COVID-19 incidents/outbreaks have become more prevalent across all HSC organisations, and the handling and management of many of these has become embedded in usual operational business arrangements across HSC organisations. Healthcare outbreaks that are being actively managed as part of an organisation's normal operational response should not be routinely reported

through the Early Alert System. These incidents/outbreaks in health and social care settings should instead continue to be reported to the Health Protection Team within the PHA through established processes for notifiable diseases. Such incidents/outbreaks will subsequently be notified to the Department via daily SITREPs collated by HSCB and via daily update reports shared by PHA's Health Protection service with the Chief Medical Officer's office.

It is important to note that certain COVID-19 incidents/outbreaks, including where there is a serious impact on service delivery, that are not being handled through normal operational response may fall within some of the criteria listed below in **Annex A** and therefore they may warrant an Early Alert. HSC organisations should assess events as they occur/emerge and should they determine that one or more of the criteria listed in Annex A is met they should report through the Early Alert system as appropriate.

You are asked to ensure that this circular is communicated to relevant staff within your organisation.

Enquiries:

Any enquiries about the content of this circular should be addressed to:

Mr David Wilson
Safety Strategy Unit
Department of Health
Castle Buildings
Stormont
BELFAST
BT4 3SQ

qualityandsafety@health-ni.gov.uk

Yours sincerely

Personal information redacted by the USI

Dr Lourda Geoghegan
Deputy Chief Medical Officer

Distributed for information to:

Director of Public Health/Medical Director, PHA
 Director of Nursing, PHA
 Director of Performance Management & Service Improvement, HSCB
 Director of Integrated Care, HSCB
 Head of Pharmacy and Medicines Management, HSCB
 Heads of Pharmacy and Medicines Management, HSC Trusts
 Safety and Quality Alerts Team, HSC Board
 Governance Leads, HSC Trusts
 Professor Donna Fitzimmons, Head of Nursing & Midwifery, QUB
 Professor Pascal McKeown, Head of Medical School, QUB
 Professor Donald Burden, Head of School of Dentistry, QUB
 Professor Carmel Hughes, Head of School of Pharmacy QUB
 Dr Neil Kennedy, Acting Director of Centre for Medical Education, QUB
 Professor Sonja McIlfatrick, Head of School of Nursing, UU
 Professor Paul McCarron, Head of Pharmacy School, UU
 Staff Tutor of Nursing, Open University
 Director, Safety Forum
 Lead, NI Medicines Governance Team
 NI Medicines Information Service
 NI Centre for Pharmacy Learning and Development
 Clinical Education Centre
 NI Royal College of Nursing

ANNEX A

Purpose of the Early Alert System

The Early Alert System provides a channel which enables Chief Executives and their senior staff (Director level or higher) in HSC organisations to notify the Department in a prompt and timely way of events or incidents which have occurred in the services provided or commissioned by their organisations, and which may require immediate attention by Minister, Chief Professional Officers or policy leads and/or require urgent action by the Department.

Criteria for using the Early Alert System

The established communications protocol between the Department and HSC organisations emphasises the principle of 'no surprises', and an integrated approach to communications. Accordingly, HSC organisations should notify the Department promptly (within 48 hours of the event in question) of any event which has occurred within the services provided or commissioned by their organisation, or relating to Family Practitioner Services, and which meets one or more of the following criteria:

1. *Urgent regional action may be required by the Department, for example, where a risk has been identified which could potentially impact on the wider HSC service or systems;*
2. *The HSC organisation is going to contact a number of patients or clients about harm or possible harm that has occurred as a result of the care they received. Typically, this does not include contacting an individual patient or client unless one of the other criteria is also met;*
3. *The HSC organisation is going to issue a press release about harm or potential harm to patients or clients. This may relate to an individual patient or client;*
4. *The event may attract media interest;*
5. *The Police Service of Northern Ireland (PSNI) is involved in the investigation of a death or serious harm that has occurred in the HSC service, where there are concerns that a HSC service or practice issue (whether by omission or commission) may have contributed to or caused the death of a patient or client. This does not include any deaths routinely referred to the Coroner, unless:*
 - i. *there has been an event which has caused harm to a patient or client and which has given rise to the Coroner's investigation; or*
 - ii. *evidence comes to light during the Coroner's investigation or inquest which suggests possible harm was caused to a patient or client as a result of the treatment or care they received; or*
 - iii. *the Coroner's inquest is likely to attract media interest.*
6. *The following should always be notified:*

- i. the death of, or significant harm to, a child, and abuse or neglect are known or suspected to be a factor;
 - ii. the death of, or significant harm to, a Looked After Child, a child on the Child Protection Register or a young person in receipt of leaving and after care services;
 - iii. allegations that a child accommodated in a children's home has committed a serious offence; and
 - iv. any serious complaint about a children's home or persons working there.
7. There has been an immediate suspension of staff due to harm to patient/client or a serious breach of statutory duties has occurred.

Family Practitioner Services should notify the HSC Board about events within the services they provide that meet one or more of these criteria. The HSC Board will then notify the Department.

Operational Arrangements

It is the responsibility of the reporting HSC organisation to ensure that a senior person from the organisation (Director level or higher) communicates with a senior member of staff in the Department (i.e. the Permanent Secretary, Deputy Secretary, Chief Professional Officer, Assistant Secretary or professional equivalents) regarding the event, and also an equivalent senior executive in the HSC Board and the Public Health Agency, as appropriate, and any other relevant bodies.

To assist HSC organisations in making contact with Departmental staff, **Annex B** attached provides the contact details of a range of senior Departmental staff together with an indication of their respective areas of responsibility. **The senior officers are not listed in order of contact. Should a senior officer with responsibility for an area associated with an event not be available, please proceed to contact any senior officer on the list.**

It is the responsibility of the reporting Family Practitioner Service practice to ensure that a senior person from the practice **speaks in person** to the Director of Integrated Care (or deputy) in the HSC Board regarding the event.

The next steps will be agreed during the call and appropriate follow-up action taken by the relevant parties. In **all** cases, however, **the reporting organisation must arrange for the content of the initial contact to be recorded on the updated pro forma attached at Annex C**, and forwarded, within **24 hours** of notification of the event, to the Department at Personal Information redacted by the USI and the HSC Board at Personal Information redacted by the USI

It is important that, when completing the proforma, the information about the person making the notification to the Department, the person who received the information within the Department and the date on which the information is exchanged, is accurate (for recording purposes).

It is the responsibility of the reporting HSC organisation to comply with any other possible requirements to report or investigate the event they are reporting in line with any other relevant applicable guidance or protocols (e.g. Police Service for Northern Ireland (PSNI), Health and Safety Executive (HSE), **the Safeguarding Board for Northern Ireland**, Professional Regulatory Bodies, the Coroner etc.) **including compliance with GDPR requirements for information contained in the Early Alert proforma and the mandatory requirement to notify the Information Commissioner's Office (ICO) about any reportable personal data breaches. The information contained in the proforma should relate only to the key issue and it should not contain any personal data.**

There will be occasions when reporting organisations feel it is appropriate to provide updates on an Early Alert which has already been reported. Given that a passage of time may have elapsed and Ministerial/personnel changes, this is good practice. It may be appropriate, therefore, for a senior person from the organisation (at Director level or higher) to communicate with a senior member of staff in the Department (i.e. the Permanent Secretary, Deputy Secretary, Chief Professional Officer, or Assistant Secretary) regarding the update. This is not mandatory but reporting organisations will wish to exercise judgement as to whether there has been a substantive change in the position which would warrant a call.

ANNEX B

EARLY ALERT SYSTEM: DEPARTMENTAL OFFICER CONTACT LIST NOVEMBER 2020

HEALTHCARE POLICY GROUP

Deputy Secretary

Jackie Johnston

Personal Information redacted by the USI

Primary Care/Out of Hours Services

Chris Matthews

Personal Information redacted by the USI

Secondary Care

Ryan Wilson

Personal Information redacted by the USI

Workforce Policy/Human Resources

Preeta Miller

Personal Information redacted by the USI

RESOURCES AND PERFORMANCE MANAGEMENT GROUP

Deputy Secretary

Deborah McNeilly

Personal Information redacted by the USI

Infrastructure Investment

Andrew Dawson

Personal Information redacted by the USI

Information Breaches/Data Protection

La'Verne Montgomery

Personal Information redacted by the USI

Finance Director

Brigitte Worth

Personal Information redacted by the USI

SOCIAL SERVICES POLICY GROUP

Chief Social Services Officer

Sean Holland

Personal Information redacted by the USI

Child Protection/Looked After Children (LAC's)

Eilis McDaniel

Personal Information redacted by the USI

Mental Health Learning Disability/Elderly & Community Care

Mark Lee

Personal Information redacted by the USI

Social Services

Jackie McIlroy

Personal Information redacted by the USI

CHIEF MEDICAL OFFICER GROUP**Chief Medical Officer**

Dr Michael McBride

Personal Information redacted by the USI

Deputy Chief Medical Officers

Dr Naresh Chada

Personal Information redacted by the USI

Dr Lourda Geoghegan

Personal Information redacted by the USI

Population Health Director

Liz Redmond

Personal Information redacted by the USI

Chief Dental Officer

Simon Reid

Personal Information redacted by the USI

Chief Pharmaceutical Officer

Cathy Harrison

Personal Information redacted by the USI

Senior Medical Officer

Dr Carol Beattie

Personal Information redacted by the USI

CHIEF NURSING OFFICER**Chief Nursing Officer**

Charlotte McArdle

Personal Information redacted by the USI

Deputy Chief Nursing Officer

Heather Finlay

Personal Information redacted by the USI

☒ Initial call made to (DoH) on DATE

Follow-up Pro-forma for Early Alert Communication:

Details of Person making Notification:

Name Organisation
Position Telephone

Criteria under which event is being notified (mark as appropriate)

1. Urgent regional action
2. Contacting patients/clients about possible harm
3. Press release about harm
4. Regional media interest
5. Police involvement in investigation
6. **Events involving children/young people in care or receiving after care support**
7. Suspension of staff or breach of statutory duty

Brief summary of event being communicated: * **If this relates to a child please specify DOB, legal status, placement detail**
If there have been previous events reported of a similar nature please state dates and reference number. In the event of the death or serious injury to a child - Looked After or on CPR - Please confirm report has been forwarded to Chair of the Safeguarding Board for Northern Ireland (SBN).

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Appropriate contact within the organisation should further detail be required:

Name of appropriate contact:

Contact details:

Email address (work or home)

Mobile (work or home) Telephone (work or home)

Forward pro-forma to the Department at: Personal Information redacted by the USI and the HSC Board at:

Personal Information redacted by the USI

FOR COMPLETION BY DoH:

Early Alert Communication received by: Office:

Forwarded for consideration and appropriate action to: Date:

Detail of follow-up action (if applicable)

**From the Chief Medical Officer
Dr Michael McBride**



Department of
**Health, Social Services
and Public Safety**
www.dhsspsni.gov.uk

BY EMAIL

Chief Executives, HSC Trusts
Chief Executive, HSC Board
Chief Executive, Public Health Agency
Chief Executive, NIBTS
Chief Executive, Business Services Organisation

Castle Buildings
Stormont
BELFAST
BT4 3SQ
Tel: 028 9052 0563
Fax: 028 9052 0574
Email: Personal Information redacted by the USI
Your Ref:
Our Ref: DH1/12/83057
Date: 6 October 2014

Dear Colleagues

HSC (SQSD) 7/2014 – PROPER USE OF THE EARLY ALERT SYSTEM - REMINDER

Recent events have highlighted the importance of ensuring proper adherence to the requirements of the Early Alert System. The system is designed to ensure that the Department receives prompt and timely details of events which fulfil criteria which are set out in TAB A by way of reminder. Some of these events (but not all) may become serious adverse incidents and may be notified separately to the HSCB. This does not negate the need for them to be reports as Early Alerts.

Trusts were originally advised of the system on 28 May 2010, when Circular HSC (SQSD) 10/2010] was issued. It can be accessed at: http://www.dhsspsni.gov.uk/hsc_sqsd_10-10.PDF. However, there would seem to be a number of issues around the proper use of the system and speed of reporting. On some occasions events have not been reported at all or not reported immediately and, on a number of occasions, HSC bodies have not followed up their initial telephone notification of an Early Alert to the Department by forwarding a completed pro-forma (attached at Annex A of the 2010 circular) providing further details of the incident to Personal Information redacted by the USI within 24 hours of the initial telephone notification.

You are reminded that it is not sufficient to share details via a telephone conversation with a senior official. If an event fulfils the Early Alert criteria, you must notify the Department formally using the proforma as part of the Early Alert system within 24 hours.

The Early Alert System preserves the governance arrangements which are associated with reporting incidents. It ensures that consideration is given as to who should have sight of the detail of event/issues thus providing Department staff and their colleagues with the opportunity to brief Minister or to contribute to that briefing where they are not the lead official.

The importance of the Early Alert System was also emphasised in November 2013 at the public hearings of the Inquiry into Hyponatraemia-Related Deaths. Several witnesses gave evidence of the time when the system was not in place and those arrangements have already been heavily criticised. The Early Alert System was designed to improve upon that situation.

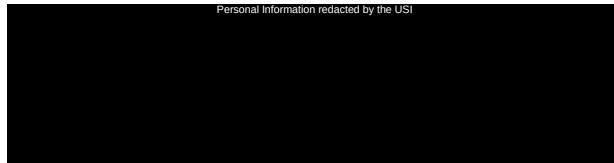
I remind you that it is the responsibility of the reporting HSC organisation to ensure that someone of Director level or higher level reports to a senior member of staff in the Department (Permanent Secretary, Deputy Secretary, Chief Professional Officer, or Assistant Secretary) and that in ALL cases the initial contact is followed up in the written pro forma within 24 hours.

You are asked to:

- Note the purpose, criteria and operational arrangements outlined within the Early Alert System
- Communicate this letter and the originating circular [HSC (SQSD 10/2010)] to all relevant staff within your organisation.
- Ensure full compliance with the guidance.

Thank you for your assistance in this matter.

Yours sincerely



DR MICHAEL MCBRIDE

cc Catherine Daly
Sean Holland
Julie Thompson
Charlotte McArdle
Mark Timoney
Simon Reid
Ronan Henry
Hazel Whinning
Brian Godfrey
Fergal Bradley
Conrad Kirkwood

Initial call made to (DHSSPS) on (DATE)

Follow-up Proforma for Early Alert Communication:

Details of Person making Notification:

Name Organisation
 Position Telephone

Criteria (from para 1.3) under which event is being notified (tick as appropriate)

1. **urgent regional action**
2. **contacting patients/clients about possible harm**
3. **press release about harm**
4. **regional media interest**
5. **police involvement in investigation**
6. **events involving children**
7. **suspension of staff or breach of statutory duty**

Brief summary of event being communicated: ** If this relates to a child please specify DOB, legal status, placement address if in RCC. If there have been previous events reported of a similar nature please state dates and reference number. In the event of the death or serious injury to a child - Looked After or on CPR - please confirm report has been forwarded to Chair of Regional CPC.*

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Appropriate contact within the organisation should further detail be required:

Name of appropriate contact

Contact details: Telephone (work or home)

Mobile (work or home)

Email address (work or home)

Forward proforma to the Department at: Personal Information redacted by the USI and the HSC Board at:

Personal Information redacted by the USI

FOR COMPLETION BY DHSSPS:

Early Alert Communication received by: Office:

Forwarded for consideration and appropriate action to: Date:

Detail of follow-up action (if applicable)

Jim Livingstone
Director of Safety, Quality and Standards



Department of

**Health, Social Services
and Public Safety**

www.dhsspsni.gov.uk

AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poustie, Resydënter Heisin
an Fowk Siccar**

POLICY CIRCULAR

Subject:

Early Alert system

For action by:

- Chief Executives, HSC Trusts
- Chief Executive, HSC Board
- Chief Executive, Public Health Agency
- Chief Executive, NIBTS
- Chief Executive, Business Services Organisation
- General Medical, Community Pharmacy
- General Dental & Ophthalmic Practices

For Information to:

- Chief Executive, Patient and Client Council
- Director of Public Health, PHA
- Director of Performance Management and Service Improvement, HSC Board
- Directors of Social Care and Children in HSC Board and HSC Trusts
- Directors of Nursing and AHP in PHA and HSC Trusts
- Director of Integrated Care in HSC Board
- Medical Directors in HSC Trusts
- Chair, Regional Area Child Protection Committee
- Chair, Regional Adult Protection Forum
- Chief Executive, Regulation & Quality Improvement Authority
- CSCG/Risk management leads
- Unscheduled care improvement managers

Summary of Contents:

The Circular provides guidance on the operation of an Early Alert System, designed to ensure that the Department is made aware in a timely fashion of significant events occurring within HSC organisations.

Enquiries:

Any enquiries about the content of this Circular should be addressed initially to:

Safety & Quality Unit
DHSSPS
Room D1
Castle Buildings
Stormont
BELFAST
BT4 3SQ

Tel: [Redacted]

E-mail: [Redacted]

Circular Reference: HSC (SQSD) 10/2010

Date of Issue: 28 May 2010

Related documents

HSC (SQSD) 22/2009: Phase 1 - Learning from Adverse Incidents and Near Misses reported by HSC organisations and FPS

HSC (SQSD) 08/2010: Phase 2 – Learning from Adverse Incidents and Near Misses reported by HSC organisations and FPS

Superseded documents

Status of Contents:

Action

Implementation:

From 1 June 2010

Additional copies:

Available to download from

<http://www.dhsspsni.gov.uk/index/phealth/sqs/sqsd-guidance.htm>

Dear Colleague

ESTABLISHMENT OF AN EARLY ALERT SYSTEM

In March 2009, I wrote to you about the initial steps being taken to phase out the reporting of Serious Adverse Incidents (SAIs) to the Department, and the implementation of the Regional Adverse Incident and Learning (RAIL) system (Circular HSC (SQSD) 22/2009).

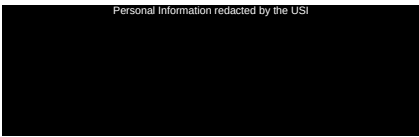
Circular HSC (SQSD) 08/2010, which issued on 30 April 2010, advised of the transfer of responsibility for managing SAIs from the Department to the HSC Board and Public Health Agency with effect from 1st May 2010, and the revised reporting arrangements which will be in place until the new RAIL system is fully implemented.

The purpose of this circular is to provide specific guidance on the arrangements which should be followed with effect from 1st June to ensure that the Department (and thus the Minister) receive prompt and timely details of events (these may include potential serious adverse incidents), which may require urgent attention or possible action by the Department.

You are asked to ensure that this circular is communicated to relevant staff within your organisation.

Yours sincerely

Personal Information redacted by the USI



Dr Jim Livingstone
Director Safety, Quality and Standards Directorate

Introduction of an Early Alert System

Purpose of the Early Alert System

- 1.1 The Early Alert System will provide a channel which will enable Chief Executives and their senior staff (Director level or higher) in Health and Social Care (HSC) organisations to notify the Department in a prompt and timely way of events or incidents which have occurred in the services provided or commissioned by their organisations, and which may require immediate attention by Minister, Chief Professional Officers or policy leads, and/or require urgent regional action by the Department.

It is important to note that this reporting system is intended to complement, not replace, existing channels of communication, both formal and informal.

- 1.2 While it is likely that some of the notifications reported as Early Alerts will also require to be managed as adverse incidents by HSC organisations, **many adverse incidents will NOT need to be reported through this channel.**

Criteria for using the Early Alert System

- 1.3 The established communications protocol between the Department and HSC organisations emphasises the principles of 'no surprises', and an integrated approach to communications. Accordingly, HSC organisations should notify the Department promptly (within 48 hours of the event in question) of any event which has occurred within the services provided or commissioned by their organisation, or relating to Family Practitioner Services, and which meets one or more of the following criteria:

- 1. Urgent regional action may be required by the Department, for example, where a risk has been identified which could potentially impact on the wider HSC service or systems;**
- 2. The HSC organisation is going to contact a number of patients or clients about harm or possible harm that has occurred as a result of the care they received. Typically, this does not include contacting an individual patient or client unless one of the other criteria is also met;**
- 3. The HSC organisation is going to issue a press release about harm or potential harm to patients or clients. This may relate to an individual patient or client;**
- 4. The media have inquired about the event;**
- 5. The PSNI is involved in the investigation of a death or serious harm that has occurred in the HSC service, where there are concerns that a HSC service or practice issue (whether by omission or commission) may have contributed to or caused the death of a patient or client. This does not include any deaths routinely referred to the Coroner, unless:**
 - i. there has been an event which has caused harm to a patient or client and which has given rise to a Coroner's investigation; or**
 - ii. evidence comes to light during the Coroner's investigation or inquest which suggests possible harm was caused to a patient or client as a result of the treatment or care they received, or**
 - iii. the Coroner's inquest is likely to attract media interest.**

6. The following should always be notified:

- i. the death of, or significant harm to, a child, and abuse or neglect are known or suspected to be a factor;**
- ii. the death of, or significant harm to, a Looked After Child or a child on the Child Protection Register;**
- iii. allegations that a child accommodated in a children's home has committed a serious offence; and**
- iv. any serious complaint about a children's home or persons working there.**

7. There has been an immediate suspension of staff due to harm to patient/client or a serious breach of statutory duties has occurred.

- 1.4 Family Practitioner Services should notify the HSC Board about events within the services they provide that meet one or more of these criteria. The HSC Board will then notify the Department.

Operational Arrangements

- 1.5 It is the responsibility of the reporting HSC organisation to ensure that a senior person from the organisation (at Director level or higher) communicates with a senior member of staff in the Department (i.e. the Permanent Secretary, Deputy Secretary, Chief Professional Officer, or Assistant Secretary) regarding the event, and also an equivalent senior executive in the HSC Board, and the Public Health Agency, as appropriate, and any other relevant bodies.
- 1.6 It is the responsibility of the reporting Family Practitioner Service practice to ensure that a senior person from the practice speaks in person to the Director of Integrated Care (or deputy) in the HSC Board regarding the event.
- 1.7 The next steps will be agreed during the call and appropriate follow-up action taken by the relevant parties. In all cases, however, the reporting organisation must arrange for the content of the initial contact to be recorded on the pro forma attached at **Annex A**, and forwarded, within 24 hours of notification of the event, to the Department at Personal Information redacted by the USI and the HSC Board at Personal Information redacted by the USI

ANNEX A

Initial call made to (DHSSPS) on (DATE)

Follow-up Proforma for Early Alert Communication:

Details of Person making Notification:

Name Organisation
 Position Telephone

Criteria (from para 1.3) under which event is being notified (tick as appropriate)

1. *urgent regional action*
2. *contacting patients/clients about possible harm*
3. *press release about harm*
4. *regional media interest*
5. *police involvement in investigation*
6. *events involving children*
7. *suspension of staff or breach of statutory duty*

Brief summary of event being communicated: ** If this relates to a child please specify DOB, legal status, placement address if in RCC. If there have been previous events reported of a similar nature please state dates and reference number. In the event of the death or serious injury to a child - Looked After or on CPR - please confirm report has been forwarded to Chair of Regional CPC.*

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.....

Appropriate contact within the organisation should further detail be required:

Name of appropriate contact

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Forward proforma to the Department at: Personal Information redacted by the USI and the HSC Board at:

Personal Information redacted by the USI

FOR COMPLETION BY DHSSPS:

Early Alert Communication received by: Office:

Forwarded for consideration and appropriate action to: Date:

Detail of follow-up action (if applicable)



Southern Health
and Social Care Trust
Quality Care - for you, with you

Northern Ireland Regional Point of Care Testing Policy

Lead Policy Author & Job Title:	Chair, Northern Ireland Pathology Network Point of Care Testing Specialty Forum
Directorate responsible for document:	Acute
Issue Date:	07 April 2022
Review Date:	07 April 2024



Working together



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Policy Checklist

Policy name:	Northern Ireland Regional Point of Care Testing Policy
Lead Policy Author & Job Title:	Chair, Northern Ireland Pathology Network Point of Care Testing Specialty Forum
Director responsible for Policy:	Melanie McClements
Directorate responsible for Policy:	Acute
Equality Screened by:	Dr Derek McKillop
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This document has been signed off by representatives from the 5 HSC Trusts, and approved by the Pathology Network Board (20.04.2021).

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Introduction

Point of Care Testing¹ (POCT) refers to testing that is performed near or at the site of a patient (as opposed to central laboratory testing) with the result leading to possible change in the clinical management of the patient. POCT most commonly involves testing in body fluids such as blood or urine but may include other modalities such as transcutaneous measurements or the analysis of exhaled air. The types of analytical equipment employed may range from single use visual inspection testing strips, hand held strip readers to desktop analysers. POCT is generally (but not always) performed by clinical rather than laboratory staff. POCT is widely used to support the clinical management of patients.

Although POCT may bring benefits in patient care, POCT may also introduce risks that derive from the inherent characteristics of the device, operator error and in result interpretation. The use of POCT as an alternative to central laboratory testing should be considered as a clinical governance issue and therefore be subject to examination of clinical effectiveness. Before deciding whether to implement a particular point-of-care test it is essential to establish a clinical need, including an assessment as to whether reconfiguration of a central laboratory service would be a more effective option. Consideration of clinical need should be evidence based where possible and clearly identify benefits and risks of introducing a point of care test.

This document has been developed by the NI Regional POCT Specialty Forum in accordance with the Trusts Key Principles for Policy Development.

Purpose and Aims

The purpose of the Policy is to ensure that POCT is effectively managed in the HSC Trust so as to maximize the clinical benefit of POCT in patient care and to limit the risks to patients and staff associated with its use. Risk to the patient can be managed by a well-designed, fully implemented quality management system that facilitates:

- Evaluation of new or alternative POCT instruments and systems;
- Evaluation and approval of end-user proposals and protocols;
- Purchase, installation and maintenance of equipment;
- Maintenance of consumable supplies and reagents;
- Training, certification and recertification of POCT system operators; and
- Quality control and quality assurance.

Objectives of Policy

This policy will ensure that POCT systems in all HSC Organisations are managed in accordance with national/international best practice guidelines and accreditation standards, in particular ISO15189:2012 (Medical Laboratories – Requirements for quality and competence)² and ISO 22870:2016 (Point of Care Testing [POCT] – Requirements for quality and competence).³

Policy Statement

The Trust is committed to the following governance procedures for POCT:

1. The POCT service should be Clinically and Professionally led by a senior member of laboratory staff (Consultant Pathologist or Consultant Clinical Scientist). The POCT Professional Lead shall plan and develop the processes needed for POCT in line with the requirements of ISO 15189; 2012 and ISO 22870:2016. These will include quality objectives and requirements for POCT; establishment of processes and documents and provision of resources specific to POCT; verification, validation and monitoring of activities specific to POCT; maintenance of records to provide evidence that POCT processes and procedures meet requirements.
2. The POCT Professional Lead may delegate selected duties and/or responsibilities to qualified personnel. The POCT Professional Lead shall maintain the ultimate responsibility for the overall operation and administration of the POCT service, within the scope defined by the POCT Multidisciplinary committee.
3. The HSC Trust will aspire to have compliance with relevant ISO Standards [ISO 15189; 2012 and ISO 22870:2016] assessed by an external body such as United Kingdom Accreditation Service (UKAS) or other competent body.
4. The POCT Professional Lead shall have a documented reporting line to the governing body of the HSC Trust which will have responsibility for ensuring that appropriate measures are in place to monitor the accuracy and quality of POCT conducted within the organization.
5. The POCT Professional Lead shall establish, document, implement and maintain a quality management system for POCT and continually improve its effectiveness.
6. The POCT quality management system shall include a quality policy, quality manual and quality objectives,
7. The POCT Quality Manual shall outline the procedures for the audit of all aspects of POCT activity including the identification and control of non-conformities and determine corrective and preventive actions to eliminate the cause of potential non-conformities.
8. The HSC Trust will establish a multidisciplinary professional grouping which will be responsible to the governing body for defining the scope of POCT to be made available, taking into consideration the clinical need for POCT, its financial implications, technical feasibility and the ability of the organization to fulfil the need. To obtain approval from the POCT group, a New or Replacement Point of Care Testing Proposal Form (available on Sharepoint in the POCT/Medical Devices section) should be submitted to the multidisciplinary professional group.
9. The POCT Professional Lead will establish a multidisciplinary POCT management group to advise on the provision of POCT. The POCT management group will ensure responsibilities and authorities for POCT are defined and communicated within the HSC Trust. The management group will

consider all proposals to introduce a new POC test. The management group will assist in the selection and evaluation of POCT devices.

10. The POCT Professional Lead shall implement a periodic [ideally annual] management review of the functioning of the POCT service.
11. No POC tests should be procured or introduced into clinical care without the approval of the POCT Professional Lead.
12. All requests for the introduction of POCT equipment / tests must be submitted to the POCT Professional Lead for consideration [in conjunction with the multi-disciplinary POCT management group] with details outlining the clinical need and assessment of outcomes including costs. The POCT Professional Lead in conjunction with the POCT management group will consider the appropriateness of any request, the reliability and robustness of the equipment available, the interfacing requirements, the risk-benefit and cost-benefit analyses, quality assessment and compliance with other HSC Trust's policies including infection control^{4,5} and COSHH.⁶ Where necessary, advice should be sought from Finance, Infection Prevention and Control and other teams. POCT devices which have been approved must be procured in line with the HSC Trust standard procurement procedures.
13. The use of POCT should not be considered where a laboratory can provide the relevant test result in a timely manner that meets the requirements of clinical efficiency and effectiveness.
14. POCT equipment and tests which have not been approved by the POCT Professional Lead must not be used.
15. Technical Requirements of the POCT service: The POCT Professional Lead shall define the technical requirements for POCT in line with ISO 15189: 2012 and ISO 22870:16 and will include:
 - Personnel including staff to deliver and manage the POCT service, evaluate POCT devices / tests, training and competency assessment;
 - Accommodation and environmental conditions;
 - Equipment including selection criteria for the procurement of equipment, material and reagents;
 - Pre-examination procedures including sample identification and traceability;
 - Examination procedures including standard operating procedures for each test;
 - Assuring the quality of pre-examination procedures including quality control, external quality assurance procedures;
 - Post-examination procedures including sample handling and disposal;
 - The reporting of results and incorporation of the result into the patient's medical record (in a manner which distinguishes the result from those of the central laboratory), the identity of the person performing the test.
16. All POCT tests/devices procured by the HSC Trust shall:
 - Be evaluated and procured in collaboration with the POCT Professional Lead;

- Align, where possible and practical, with the laboratory-based methods in current use in the HSC Trust;
 - Where possible have IT connectivity of appropriate specification to allow central management of POCT devices and documentation of results and transmission of results to the patient Electronic Care Record;
 - Be used in accordance with manufacturer's or supplier's instructions;
 - Be subject to regular maintenance as specified by the supplying manufacturer; and
 - Only be used for the purpose for which it has been evaluated and approved.
17. All POCT must be enrolled in an External Quality Assurance scheme (if available) or, if this is impractical, arrangements for parallel testing with the local laboratory should be considered. Internal Quality Control must be performed according to the test / instrument specific Standard Operating Procedure (SOP).
 18. Where possible and practical, electronic devices rather than devices requiring a subjective visual read by the user should be used. (It is recommended that where such visual read devices are in use, the results are checked by at least two trained members of staff).
 19. Where possible, IT Connectivity should be made available and resourced to appropriate specification to allow central management of POCT devices and documentation of results in accordance with robust quality management.
 20. Device specific Standard Operating Procedures (SOP) must be developed, implemented and made available to all POCT users. SOPs will include pre-examination procedures, examination procedures and post examination procedures. The SOP will outline relevant internal and external quality control procedures.
 21. Only staff that have been trained and assessed as competent can use POCT equipment. Training in the use of POCT devices will only be delivered by staff who have been approved to do so by the POCT Professional Lead. Where possible, POCT equipment will be passcode-protected and only accessible to certified users. Sharing of passcode in breach of this policy may result in disciplinary action.
 22. Retraining and recertification intervals will be established by the POCT Professional Lead.
 23. All patient and quality control testing results must be recorded. The procedure for this shall be outlined in the relevant SOP. Patient results must be recorded in such detail as to allow unequivocal patient identification, the result, date and time of analysis, and the name of the person performing the test. This record must be in addition to records made in the patient notes and, where available, should be electronic. Such records should be retained in accordance with guidelines issued by the RCPATH.⁷

24. All reagent/cartridge/consumable lot numbers must be recorded to facilitate patient tracking in the event of product recall. Storage conditions must be adhered to. These procedures shall be outlined in the relevant SOP.
25. All adverse events relating to POCT must be reported according to the HSC Trust's Incident Reporting Procedures policy and drawn to the attention of the POCT Professional Lead [by the relevant ward manager] as soon as possible. There should be a low threshold for reporting suspected incidents – IF IN DOUBT – REPORT. The POCT Professional Lead has the authority to withdraw or suspend a POCT service in the event of a safety-related or performance issue or lack of clinical or cost effectiveness. The POCT Professional Lead shall be responsible for ensuring that any relevant learning opportunities are shared in a timely manner with the NI POCT Specialty Forum members and where necessary reported to NIAIC (MHRA).
26. The POCT Professional Lead has the authority to suspend the certification of a POCT operator in the event of failure of the operator to adhere to required operating procedures.
27. See Appendix 1 for governance points specific to SHSCT.

Scope of Policy

This policy applies to all HSC Trust staff undertaking or having responsibility for POCT and to all Departments and Services in which POCT is undertaken. This policy refers exclusively to POCT undertaken in a hospital or community using equipment procured by the HSC Trust and undertaken by HSC Trust staff. Patient self-testing falls outside the scope of this policy.

The following staff should observe this policy and follow its procedures:

- Any member of staff who performs POCT;
- Any member of staff with managerial responsibility for POCT within his/her clinical service; and
- Any member of staff wishing to introduce POCT into a clinical service.

Responsibilities

The Trust Executive and Senior Management Teams are responsible for ensuring the appropriate staffing, accommodation, and resources required to provide POCT within the Trust.

The POCT Committee and the Professional Lead are responsible for oversight and governance of the POCT within the Trust.

The POCT Team is responsible for the day-to-day management of POCT within the Trust

All staff members who use POCT within the remit of their employment must adhere to the governance procedures within this policy. Failure to do so may result in disciplinary procedures.

Legislative Compliance, Relevant Policies, Procedures, and Guidance

This Policy ensures compliance with the following legislation, policies, and guidance:

1. British Standard EN ISO 15189:2012 (Medical Laboratories - Requirements for quality and competence). The British Standards Institution 2012
2. British Standard ISO 22870:2016 (Point-of-Care Testing [POCT] – Requirements for quality and competence). The British Standards Institution 2012
3. Department of Health Advisory Committee on Dangerous Pathogens (2003) Infection at work controlling the risk.
4. Health Services Advisory Committee (2003) Safe working and the prevention of infection in clinical laboratories and similar facilities.
5. Health and Safety Executive, Control of Substances Hazardous to Health (COSHH) 2002
6. Royal College of Pathologists and Institute of Biomedical Science. The Retention and Storage of Pathological Records and Archives (2009).
7. MHRA. Management and use of IVD point of care test devices, V1.2 (2021)

Equality and Human Rights Considerations

This policy has been screened for equality implications as required by Section 75 and Schedule 9 of the Northern Ireland Act 1998.

Equality Commission guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity so that greatest resources can be devoted to these. Using the Equality Commission's screening criteria, no significant equality implications have been identified. The policy will therefore not be subject to an equality impact assessment.

Similarly, this policy has been considered under the terms of the Human Rights Act 1998, and was deemed compatible with the European Convention Rights contained in the Act.

See Appendix 2 for further information.

References

1. Price CP, St John A Hicks JM. Point of care testing Washington DC: AACC Press, 2nd edition 2004
2. British Standard EN ISO 15189:2012 (Medical Laboratories - Requirements for quality and competence). The British Standards Institution 2012; BSI Standards Ltd 2012
3. British Standard ISO 22870:2016 (Point-of-Care Testing [POCT] – Requirements for quality and competence). The British Standards Institution 2012; BSI Standards Ltd 2012
4. Department of Health Advisory Committee on Dangerous Pathogens (2003) Infection at work controlling the risk. Department of Health, London
5. Health Services Advisory Committee (2003) Safe working and the prevention of infection in clinical laboratories and similar facilities. Health and Safety Executive, HSE Books, Sudbury.

6. Health and Safety Executive, Control of Substances Hazardous to Health (COSHH) 2002
7. Royal College of Pathologists and Institute of Biomedical Science. The Retention and Storage of Pathological Records and Archives, 4th edition (2009).
8. MHRA. Management and use of IVD point of care test devices, V1.2 (2021)

Appendix 1: Appendix to the NI Regional POCT Policy (Southern Trust)

The NI Regional POCT Policy contains some minor differences when it comes to the governance processes that are currently in place in the SHSCT for POCT. To that end, the SHSCT POCT Committee felt it appropriate to have an Appendix to the Policy until any necessary changes can be adopted to bring the SHSCT into line with the overarching NI Regional POCT Policy.

All current deviations from the NI POCT Policy are outlined below.

Point 9 NI POCT Policy: The POCT Management Group in SHSCT (the layer of management below the POCT Committee) is not multidisciplinary. It consists of staff in Biochemistry who are members of the Trust POCT team. Advice is sought from Staff in other disciplines, such as microbiology and haematology, when appropriate.

Point 11 and 12 NI POCT Policy: The SHSCT POCT Committee approves/rejects applications for new POCT devices or tests being introduced into the Trust. All applications for such devices or methods (compiled in consultation with the POCT team) are submitted to the SHSCT POCT Committee via the POCT Committee Chair.

Point 14 NI POCT Policy: POC tests and equipment not approved by the Trust POCT Committee and POCT Team must not be used.

Point 16 NI POCT Policy: All POC tests/devices procured by the Trust must be evaluated and procured in collaboration with the POCT Team (of which the Professional Lead is a member).

Point 25 NI POCT Policy: All adverse incidents relating to POCT are initially drawn to the attention of the POCT team, who will quickly investigate the issue and report any findings to the Professional Lead.

Point 26 NI POCT Policy: Using established criteria, all members of the POCT team have the authority to suspend the certification of a POCT operator.

Appendix 2: Equality & Human Rights Considerations – full version



Equality POCT.docx



Quality Care - for you, with you

Interim Risk Management Strategy 2019 -2022

Risk Management Strategy	
Author	Trudy Reid Interim Assistant Director of Clinical and Social Care Governance
Date of Issue	September 2019
Date of Approval by Governance Committee	5 th September 2019
Date of Review	September 2022

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Foreword

The Southern Health & Social Care Trust (the Trust) seeks to deliver high quality care in all aspects of its services to patients/service users, staff, visitors, and the local communities. Risks occur daily in most activities undertaken within the Trust. Failure to manage these risks can result in injury or loss to patients/service users, staff or visitors, claims against the Trust and resources lost from patient care. It is therefore vital to implement a strategy to effectively manage risks, which will result in better quality of care.

The strategy is based on best practice, statutory requirements, national guidance and complies with the following:

- BSI ISO 31000:2018 – Risk Management Guidelines
- HM Treasury's 'Management of Risk – Principles and Concepts (the 'Orange Book')
- Assurance Frameworks –HM Treasury-December 2012
- DoH guidance document - An Assurance Framework : a Practical Guide for Boards of DHSSPS Arm's Length Bodies 2009
- Institute of Risk Management
- Audit and Risk Assurance Committee Handbook (NI) 2018
- Good Governance Institute –Risk Appetite Matrix
- This document complies with a number of Departmental circulars including
 - Circular HSS (PPM) 4/2005 – Risk Management
 - Circular HSS (PPM) 5/2003 (updated 2016/17) - Governance in the HPSS – Risk Management

This strategy will assist the Trust understand what might prevent achievement of Trust objectives (the risk). It also assists in responding to our risks. This means trying to reduce the chance of each risk happening, or reducing the consequences if it does occur. It is not about totally eliminating risk, as this is not possible within a health and social care environment. Therefore we must then decide which risks are urgent and more likely to occur, and the importance of their consequences.

The Trust and HSCB works in a constantly changing environment, with circumstances evolving both within and outside the Trust. This strategy reflects current best practice across the National Health Service (NHS) and Health & Social Care (HSC) and the guidance's in Departmental circulars and related areas such as risk management, controls assurance and clinical and social care governance.

The Trust is fully committed to the effective management of risks in all areas. This strategy provides the tools to make our risk management systems robust and systematic. Please use it to help you understand and appreciate why your job is so important in the management of risk.

This document should be read in conjunction with other Trust Risk management documents which include:

- Health & Safety Risk Assessment Guidance

- Control of Substances Hazardous to Health: Guidance Note on Risk Assessment
- Display Screen Equipment (DSE) Guidance
- LOLER & Manual Handling Policy
- Guidance on the Risk Assessment process for New and/or Expectant Mothers at Work
- Guidance for Risk Assessment of Young Persons at Work
- Guidance on Shared Work Premises
- Incident Management Strategy
- Health and Safety Policy and Whistleblowing Policy also highlight the responsibility on each employee to report any relevant issues
- Trust Business Continuity Management Plans

Section 1 – Context

Optimising and improving Patient and Service User quality and safety are core aims of the Southern Trust. Sound Clinical and Social Care Governance and Risk Management and Assurance processes are essential in realising these aims. The Clinical and Social Care Governance Strategy and its measures are dealt with in a separate publication. These strategies are to be read in conjunction with the Southern Trust Patient and Service User Strategy.

Risk Management Policy Statement

It is the policy of the Trust that a proactive approach to risk management is taken in order to:

- Bring about the desired continual improvements in the care/services the Trust provides;
- Ensure the Trust does its reasonable best to ensure the safety of staff and clients and the security of Trust premises for those that visit, live or work in them;
- Improve the way the Trust conducts its business;
- Enhance the services, reputation and efficient management of resources of the Trust
- Comply with the statutory and public duties placed upon the Trust.
- To ensure that there is a consistent approach to the assessment and recording of risk across the organisation

Trust Vision and Key Objectives

The Risk Management Strategy has been developed in line with the Trust vision and key objectives.

Vision and Purpose

The Trust's vision is to deliver safe, high quality care, that is co-produced and co-designed in partnership with service users and staff who deliver our serves



Our vision and values guide all that we do and will do in the future. Alongside this we want to be very clear about what we want to achieve. The Trust's priorities are set out in our six key objectives:

The Corporate Objectives are:-



Aims and Objectives

The aims and objectives of the Risk Management Strategy underpin the vision and corporate objectives of the Trust and are outlined below.

The aim of the Trust Risk Management Strategy is to:

- Cultivate and foster an 'open and fair' culture in order to encourage openness, honesty, reporting and facilitate learning for all staff
- Ensure a systematic approach to the identification, assessment and analysis of risk, and the allocation of resources to eliminate, reduce and control risk.
- Mitigate risks and/or manage those risks which are deemed as acceptable.

The objectives of the Risk Management Strategy which underpin the above aims are to:

- Manage risks to the quality of services provided and the safety of service users, clients, visitors, staff and contractors
- Manage risks associated with the corporate functions of Human Resources, Finance and Informatics
- Manage risks associated with service continuity
- Manage risks associated with the reputation, community expectation and equity of services of the Trust
- Minimise damage and financial losses that arise from avoidable, unplanned events

Section 2 - Definitions of Risk and Risk Management

This section of the Strategy provides a definition of risk and risk management. It also establishes the Trust's risk management strategy statement and associated objectives.

Definition of Risk

Risk is the chance, great or small, that damage or an adverse outcome of some kind will occur as a result of a particular hazard. It is the threat that an event or some action will adversely affect the Southern Trust's ability to successfully execute its strategies and achieve its objectives. Risk also includes failing to exploit opportunities and maintain organisational resilience.

Based on the ISO 31000: 2018 the following definition of risk is used regionally:-

Risk is the "effect of uncertainty on objectives".

Risk is also often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.

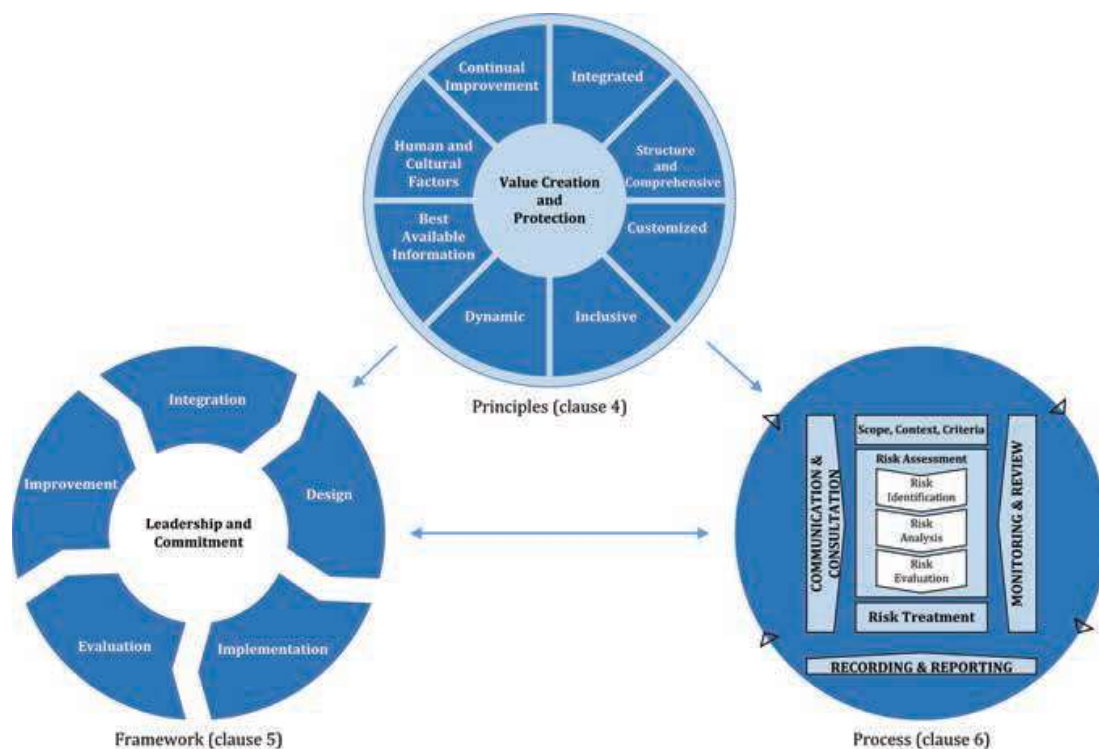
Section 3 - Principles of Risk Management

Managing Risk (Aligned with ISO 31000)

Managing risk is part of good governance and is fundamental to how an organisation is managed at all levels. Managing risk is part of all activities associated with an organisation and includes interaction with stakeholders; consideration of the external and internal context of the organisation, including behaviour and cultural factors.

ISO 31000: 2018 has three components for managing risk. These relate to (i) the identification of core **principles of risk management** with the intention that these will be addressed by (ii) the development of a **risk management framework**. In turn, the framework assists in managing risk through the (iii) **risk management processes** as outlined in the ISO 31000 standard. These are illustrated in diagrammatic format at Figure 1 below.

Figure 1 – Principles, Framework and Processes for Risk Management¹



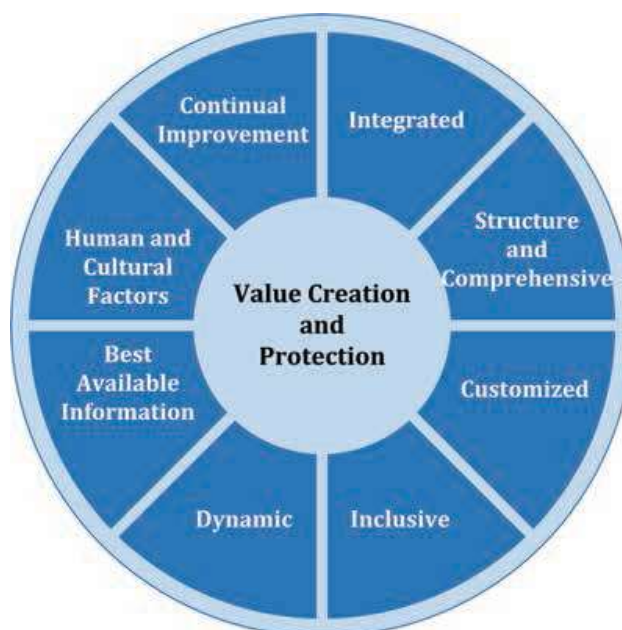
Principles of Risk Management

To be fully effective any risk management process must satisfy a minimum set of principles or characteristics. ISO 31000 includes a section (Clause 4) on these principles and these are shown in diagrammatic format in Figure 2 below. The

¹ Source – BSI ISO 31000:2018 – Risk Management Guidelines

principles are the foundation for managing risk and should be considered when establishing the organisation's risk management framework and processes and will help the organisation manage the effects of uncertainty on its objectives.

Figure 2 - Principles of Risk Management²



The principles are further explained in a short narrative format below:-

Component	Description
Integrated	Risk management should be integrated within all organisational activities.
Structured and comprehensive	A structured and comprehensive approach to risk management contributes to assurances in the Governance Statement.
Customised	The risk management framework and process should be customised and proportionate to the organisation's external and internal context related to its objectives.
Inclusive	Appropriate and timely involvement of stakeholders needs to be considered. This will better inform the organisation's risk management system.
Dynamic	Risks can emerge, change or disappear as an organisation's external and internal context changes. The risk management system needs to respond to these changes in a timely manner.
Best available information	Information should be timely, clear and available to relevant stakeholders.
Human and cultural factors	Human and cultural factors significantly influence all aspects of risk management.
Continual improvement	Risk management is continually improved through learning and experience and will feed into the organisation's quality improvement framework/systems.

² Source – BSI ISO 31000:2018 – Risk Management Guidelines

Section 4 - Risk Management Framework

Figure 3 below illustrates the elements of the second component - Risk Management Framework that is proposed to be adopted. Whilst each item is self-explanatory a short narrative about each is listed below.

Figure 3 – Components of a Risk Management Framework³



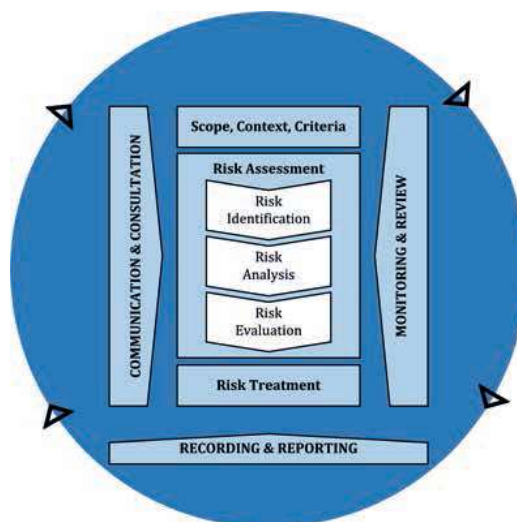
Component	Description
Leadership and Commitment	Management needs to ensure that risk management is integrated into all organisational activities and demonstrate leadership and commitment by implementing all components of the framework. This in turn will help align risk management with its objectives, strategy and culture.
Integration	Integrating risk management relies on an understanding of organisational structures and context. Risk is managed in every part of the organisation's structure. Everyone in an organisation has responsibility for managing risk.
Design	The organisation should examine and understand its external and internal context when designing its risk management framework.
Implementation	Successful implementation of the framework requires the awareness of all staff within the organisation.
Evaluation	The organisation should periodically measure its risk management framework against its purpose, implementation plans, risk management key performance indicators and expected behaviour. This will ensure it remains fit for purpose.
Improvement	The organisation should continually review, monitor and update its risk management framework to ensure it is fit for purpose.

³ Source – BSI ISO 31000:2018 – Risk Management Guidelines

Section 5 - Risk Management Process

The third component – Risk Management Process is outlined in diagrammatic format in Figure 4 below with short descriptors of each item.

Figure 4 – Risk Management Process⁴



Communication and consultation

Communication and consultation with appropriate external and internal stakeholders should take place within and throughout all steps of the risk management process.

Scope, context and criteria

Scope, context and criteria involve defining the scope of the process, and understanding the external and internal context.

Risk Assessment

Component	Description
Risk identification	Risk identification should be a formal, structured process that considers sources of risk, areas of impact, and potential events and their causes and consequences.

⁴ Source – BSI ISO 31000:2018 – Risk Management Guidelines

Risk Analysis	Risks should be analysed by considering the consequences/severity of the risk and the likelihood/frequency that those consequences may occur. The risk criteria contained within the regionally agreed Risk Rating Matrix and Impact Assessment Table will provide a guide for analysis.
Risk Evaluation	Risk evaluation involves making a decision about the level of risk and the priority for attention through the application of the criteria developed when the context was established. This stage of the risk assessment process determines whether the risks are acceptable or unacceptable. Acceptable risks are those as outlined in the organisation's Risk Management Strategy i.e. its risk appetite.

Risk Treatment

The purpose of risk treatment is to select and implement options for addressing risk. Risk treatment involves an iterative process of:

- Formulating and selecting risk treatment options;
- Planning and implementing risk treatment;
- Assessing the effectiveness of that treatment;
- Deciding whether the remaining risk is acceptable;
- If not acceptable, take further treatment/action.

Monitoring and Review

Monitoring and review should take place in all stages of the process. Monitoring and review includes planning, gathering and analysing information, recording results and providing feedback. The results of monitoring and review should be incorporated throughout the organisation's performance management, measurement and reporting activities.

Recording and Reporting

The risk management process and its outcomes should be documented and reported through appropriate mechanisms

Risk Registers

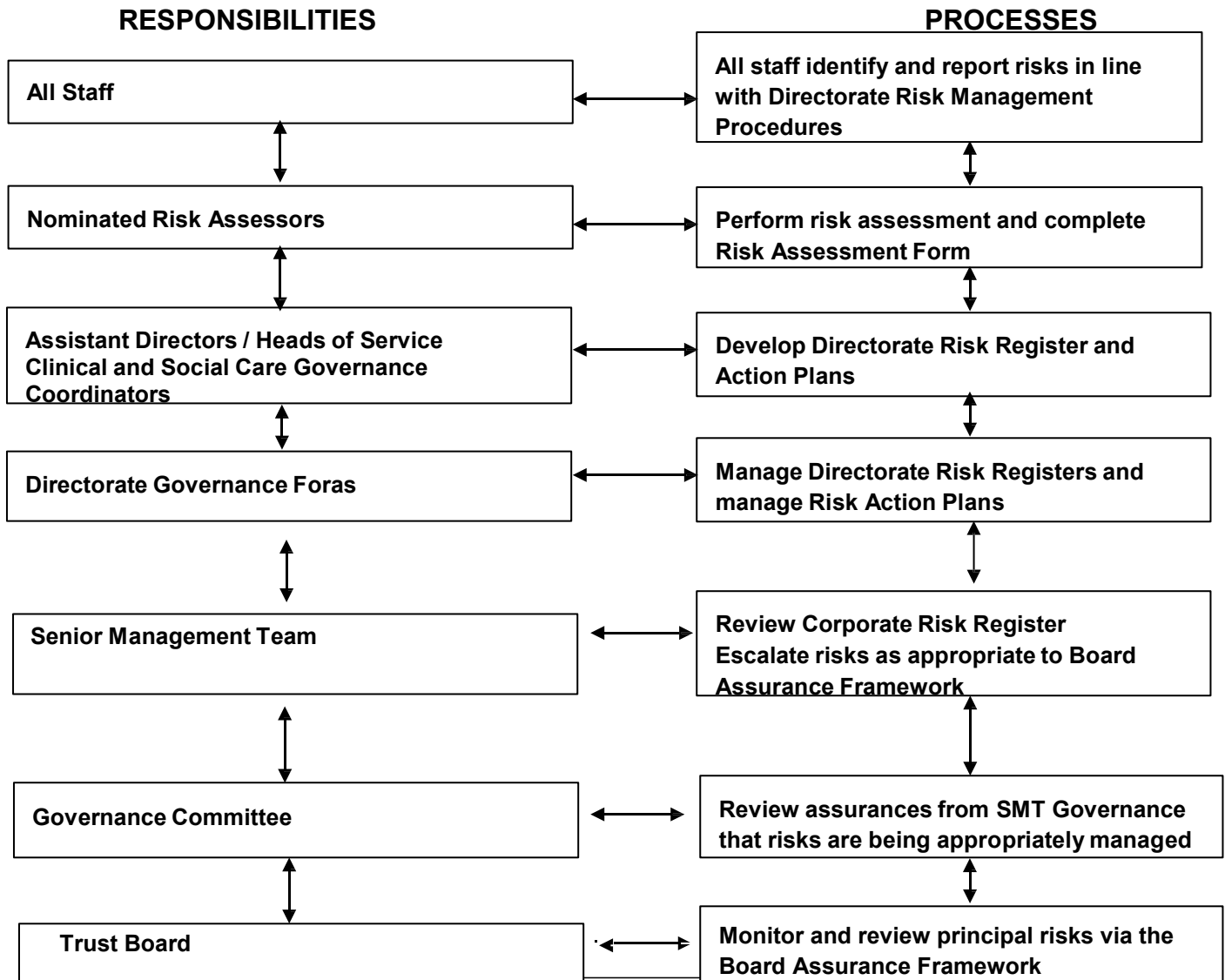
In order to develop and be aware of its risk profile and to identify the key areas for investment in risk reduction/management, the Trust has developed a framework for risk registers. This comprises both Corporate and Directorate risks. The Risk Registers will enable the Trust to identify the totality of its risk and quantify those that are deemed as acceptable or present significant risks that may affect the objectives of the Trust.

A Risk Register is a log of significant risks (clinical, non-clinical, financial etc.) that threaten the Trust's success in achieving its aims and objectives. It is populated through the various risk assessments undertaken within the organisation, together with external reviews and reports. This enables risk to be quantified and ranked to inform the Trust Board and aid decision-making and resource allocation processes.

Section 6 - Governance Arrangements in place to manage risk in the Trust

The specific governance arrangements relating to the Risk Management Strategy are described in the sub-sections which follow. A summary of the responsibilities and processes associated with risk management in the Trust is illustrated in Figure 5.

Figure 5 - Governance Arrangements in place to manage risk in the Trust



Trust Board

Within the context of this Strategy the Trust Board has a specific role in reviewing principal risks and significant gaps in control and assurance via the Board Assurance Framework, and ensuring that where gaps have been identified, corrective actions are taken.

The Trust Board is responsible for ensuring that the organisation consistently follows the principles of good governance applicable to HSC organisations. This includes reviewing the effectiveness of internal controls - financial, organisational, clinical and social care governance and risk management. In the context of this Strategy the Trust Board will:

- Demonstrate its commitment to risk management through the endorsement of the Risk Management Strategy
- Ensure, through the Chief Executive, that the responsibilities and structure for risk management outlined in this document are fully introduced
- Oversee risk assurance processes
- Consider strategic and corporate level risks, including agreeing the related risk control measures and monitoring implementation of same
- Ensure that the Trust has robust and effective arrangements in place for clinical and social care governance and risk management
- Ensure that high standards of corporate governance and personal behaviour are maintained in the conduct of the business of the whole organisation

Governance Committee

The remit of the Governance Committee is to ensure that:

- There are effectively and regularly reviewed structures in place to support the effective implementation and development of integrated governance across the Trust
- Risk management is a planned and systematic approach to identifying, evaluating and responding to risks and providing assurance that responses are effective
- Principal risks and significant gaps in controls and assurances are considered by the Trust Board
- Timely reports are made to the Trust Board, including recommendations and remedial action taken or proposed, if there is an internal failing in systems or services
- There is sufficient independent and objective assurance as to the robustness of key processes across all areas of governance.

Both the Governance and Audit Committees separately review the adequacy of all governance and risk management and control related disclosure statements (the Governance Statement).

Within the context of this Strategy the Governance Committee will receive assurances from the Trust Senior Management Team (SMT) that risks are being effectively managed.

Senior Management Team (SMT)

It is the remit of the Senior Management Team to:

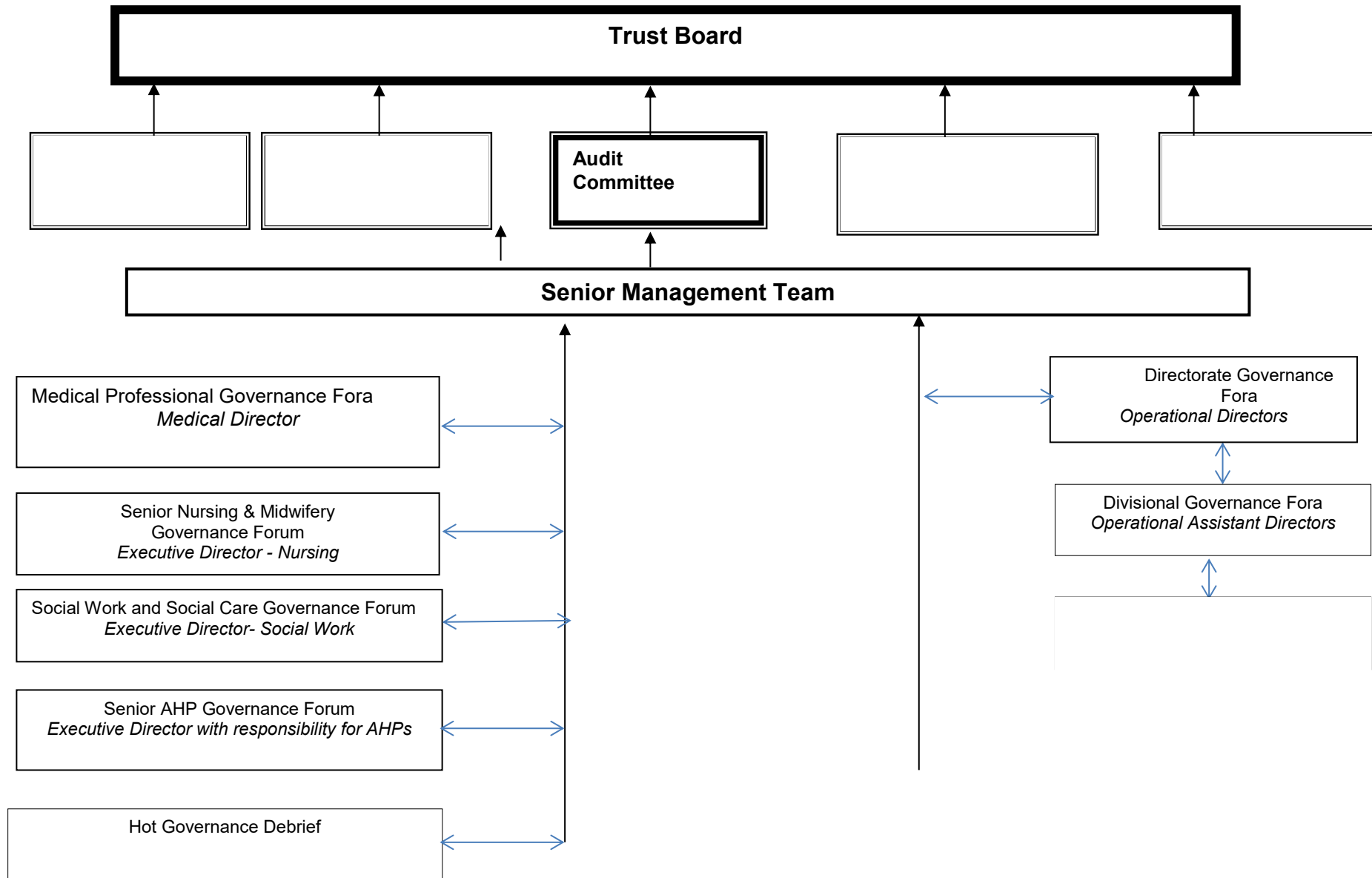
- Ensure that the Trust has an effective Corporate Risk Register
- Review the Corporate Risk Register and ensure that risks are escalated to the Board Assurance Framework as appropriate
- Receive completed investigation reports of serious adverse events
- Receive completed reports of findings of Root Cause and Systems Analysis
- Implement and keep under review the Integrated Governance Framework
- Receive assurance of the
 - adequacy of systems for quality assurance,
 - managing risk / risk management strategies/ interventions
 - control of the environment
- Receive assurance regarding the implementation of activities associated with action plans for the
 - Controls Assurance programme,
 - HPSS Quality Standards
 - RQIA Recommendations etc.
- Accept and review reports and strategy documents pertaining to risk management and governance for endorsement by the Governance Committee
- Assess the adequacy of the Governance Sub Committees to provide accountability and assurance that governance arrangements are effective

The SMT is constituted from the following membership:

- Chief Executive (Chair)
- Executive Medical Director
- Interim Executive Director of Nursing , Midwifery and AHPs
- Executive Director of Social Work / Director of Children
- Director of Human Resources and Organisational Development
- Executive Director of Finance, Procurement and Estate
- Director of Performance and Reform
- Director of Mental Health & Disability
- Director of Acute Services
- Director of Older People & Primary Care
- Director of Children & Young People/Executive Director of Social Work

Other senior staff members will be required to attend meetings as the SMT considers necessary.

High Level Governance Structure



Operational Directorate Governance Foras

Operational Directorate Governance Foras are responsible for reviewing and managing Directorate Risk Registers. Directorates will be supported in this function by the Clinical and Social Care Governance (CSCG) Co-coordinators and Governance Officers aligned to each of the directorates. Directorate Governance Foras meet monthly and are reflective of all speciality interests/service areas across Directorates/Divisions.

Membership of Directorate Governance Foras should be drawn from (though not limited to) Associate Medical Directors, Clinical Directors, Assistant Directors, Heads of Service and the Clinical and Social Care Governance (CSCG) Coordinators and Governance Officers aligned to the Directorates of Acute, Children & Young People, Older People & Primary Care and Mental Health & Disability, as appropriate.

Within the context of this strategy, the Directorate Governance Foras manage the processes associated with developing, assessing and evaluating risk and developing Risk Registers within the Directorates as outlined in Section 3 of this Risk Management Strategy.

The Directorate Governance Foras through the appropriate Director present those risks which cannot be managed at Directorate level and/or may require consideration in respect of addition to the Corporate Risk Register to the Senior Management Team.

The processes associated with developing, assessing and evaluating risk and developing Risk Registers is documented in Section 4 of this Risk Management Strategy.

Section 7 - Roles and Responsibilities

Chief Executive

The Chief Executive is the Accounting Officer of the Trust and has overall responsibility for the effective and efficient management of the Trust and for the quality of health and social care provided. This responsibility encompasses the financial arrangements within the Trust and for the statutory duty of quality, as well as the governance, risk management and controls assurance arrangements. Whilst this overall responsibility is maintained, responsibilities for some aspects of governance have been delegated to executive directors as outlined below

Medical Director

The Medical Director is the Executive Director with delegated responsibility for risk management and clinical and social care governance.

This role encompasses:

- The effective co-ordination of clinical and social care risk and governance – specifically this relates to the functional areas of patient/service user safety, patient/service user liaison, litigation, effectiveness and evaluation, risk management and multi-disciplinary research.
- The provision of risk management support to Trust Directors via the clinical and social care governance structures of the medical directorate.
- Clinical and social care governance support for clinicians, nursing staff, social workers and allied health professionals.
- Regional/national initiatives related to clinical and social care governance are addressed and brought to the attention of appropriate staff.
- Regular clinical and social care governance reports/information are brought to the Governance committee (in line with the Governance reporting framework) and the Trust Board.

The Executive Medical Director is supported by the **Assistant Director for Clinical and Social Care Governance and the Medical Directorate** who are responsible for the development of systems and processes for clinical and social care governance and risk management. This includes the development of the strategic approach to patient client safety initiatives, patient service user liaison (this includes management of complaints and users' views), litigation, effectiveness and evaluation (this includes standards, guidelines and audit) and risk management.

Executive Directors of Nursing & AHP and Social Work

The Executive Directors of Nursing & AHP and Social Work with accountability for professional governance are responsible for ensuring effective risk management and

governance arrangements are in place across the Trust in respect of their professional group. The Directors will be supported by professional governance leads in ensuring that professional standards of care and practice are maintained

Directors

Whilst the Chief Executive has overall responsibility for Risk Management, Trust Directors are required to ensure that the Risk Management processes outlined in this Strategy are applied and working effectively in their own relevant areas. With the support of Assistant Director of Clinical and Social Care Governance and the Clinical and Social Care Governance Coordinators' aligned to Directorates, Trust Directors are required to:

- Ensure local Risk Management procedures are established for their area of responsibility based on the Trust-wide strategy including Risk Assessment, adverse incident reporting and Risk Registers
- Ensure that risk identification, reduction and management is a standing agenda item at team meetings
- Ensure there is a system for monitoring the application of risk management within the Directorates and that risks are actioned in accordance with the risk grading action guidance
- Provide reports that contribute to the Trust-wide monitoring and auditing of risk
- Ensure staff attend relevant mandatory and local training programmes and training in risk management
- Ensure there is a system in place to facilitate feedback to staff on risk management issues and the outcome of adverse incident reporting
- Ensure the specific responsibilities of managers and staff in relation to risk management and controls assurance are identified within the job descriptions of posts and that objectives are reflected in the individual performance review/staff appraisal process

Managers

Managers at all levels in the Trust must encourage, support and facilitate staff in the application of good risk management practice and ensure staff are provided with the education and training to allow them to do so.

Managers must be fully conversant with the Trust's approach to risk management and where applicable Controls Assurance and the Quality Standards for Health and Social Care. Managers will be supported in this role by the Clinical and Social Care Governance Co-ordinators and Governance Officers aligned to their directorates.

All Staff

All staff of the Trust are responsible for providing each patient/service user with the highest possible quality of care/services and for taking all appropriate action to promote patient and staff safety by minimising risk where possible.

Issues of concern should be highlighted through existing professional and or line management lines of accountability and expect timely feedback on what has been done to address their concerns. Where individual staff continue to have specific concerns of risks which may impact on the delivery of safe and effective care, they have a duty to highlight them through the Trust's Whistle Blowing Policy and to expect timely feedback on what has happened as a result.

All members of staff should:

- Demonstrate and awareness of risk/patient safety and its consequences at all times
- Consider the risks to patient/staff safety involved in what they do and minimise those risks where possible to an agreed acceptable level
- Practice in accordance with their professional Codes of Conduct
- Comply with the Risk Management Strategy and associated procedures for example The Incident Management Procedure
- Notify line managers of any hazard or risk identified in their area of work which cannot be managed and requires attention
- Participate in the Trusts Risk Management training and education programmes
- Accept personal and collective responsibility for maintaining a safe working environment

Clinical and Social Care Governance Co-ordinators'

The Key role of the CSCG Co-ordinator is to, on behalf of the Director, ensure that there are processes in place to support the implementation of this strategy and they must challenge and support the Directorate in the regular review of:

- Directorate/department Risk Registers
- Support the Assistant Directors and Heads of Service Directorate in preparation of actions plans to manage and minimise risk
- To monitor the progress of action plans and escalate barriers to progress to the appropriate directorate and Governance Fora
- Support and assist the Directorates in reviewing adverse incident trends
- Co-ordinate investigations into serious adverse incidents, medium to extreme incidents
- Support and monitor the Directorates in implementing recommendations arising from investigations on behalf of the Director
- Ensure that there are systems and processes in place to provide feedback to staff reporting risks and adverse incidents
- Report through the Assistant Director for Clinical and Social Care Governance to the Medical Director and Senior Management Team using weekly Governance Debrief using an agreed proforma.

Board Assurance Manager

On the delegated authority of the Chair (the Chief Executive) of SMT, the Board Assurance Manager is responsible for maintaining the Corporate Risk Register and Board Assurance Framework and supporting the Governance Committee and Trust Board in ensuring the provision of regular risk reporting and monitoring information and assurances.

Internal Audit

The internal audit function is responsible for providing independent advice and assurance to the Trust Board that risk management systems are in place, fit for purpose and meeting Trust objectives of improving Patient Quality Care and Safety.

Patients, Service Users and the Public

The Trust welcomes the value of risk reporting from patients and or members of the public, and assumes a positive approach to the complaints or comments from which potential risks are identified. The Trust is an open and learning organisation and will ensure that learning from the investigation of complaints, compliments and comments is shared to improve patient/service user quality care and safety.

External Providers, Contractors and Agency Staff

It is essential that External Providers, Contractors and agency staff are advised of their responsibilities to work safely within the Trust and acknowledge that the management of risk is an individual as well as a collective responsibility.

They should be informed of the reporting mechanisms in the local area they are working in for reporting any hazards, risks and incidents whether they impact upon the contractor, agency staff, patient, client, staff or visitor. All Service Level Agreements and Contracts will include a section on Risk Management.

Section 8 – SHSCT Trust Risk Management Procedure

The Trust's Risk Management Model is based on the ISO 31000 Standard as adopted by all regional HSC Trusts.

Establish the Scope, Context and Criteria

The following risk impact assessment criteria have been derived from the risk management objectives and will be used for the assessment of risks as part of the impact grading in the Trust's Risk Grading Matrix:

- Risks to people (impact physical/psychological on the Health/Safety/Welfare of any person affected: e.g. Patient/Service User, Staff, Visitor, Contractor)
- Risks to quality and professional standards/guidelines (Meeting quality/professional standards/statutory functions/responsibilities and Audit Inspections)
- Risks to reputation (Adverse publicity, enquiries from public representatives/media Legal/Statutory requirements)
- Risks to Finance, Information and Assets (Protect assets of the organisation and avoid loss)
- Risks to resources (Service and business interruption, problems with service provision, including staffing (number and competence), premises and equipment)
- Risks to the environment (air, land, water, waste management)

Risk Identification/Safety Management

There are several aspects to risk identification, all of which need to be present in an effective risk management system. Risks should be assessed anytime when there is the potential for unexplored and unidentified issues diverting the organizational resources from its objectives and goals. The risk management process should be applied to business planning at all levels and risk management issues should be communicated to key stakeholders where necessary.

Adverse incident reporting, legal claims, complaints, and user views, internal and external e.g. RQIA audit reports provide robust data but by definition are retrospective. Internal and external assessment are less quantifiable than adverse incident information but are critical in identifying key risks which have the potential to impact on the Trust.

The key elements for risk identification are detailed below:-

External Scrutiny and Inspection	Occurrences	Internal Assessments
Prospective	Retrospective	Prospective
Internal Audit Reports	Adverse Incident Reporting	Controls Assurance – Self Assessments
External Audit Reports	User Views	Performance reporting
Accreditation Bodies Report	Complaints	Specialist Committees e.g. Infection Control Health & Safety etc.
RQIA reports	Locally resolved expressions of dissatisfaction	Risk Assessments (including H&S; business/project planning e.g. new activities, services; referrals)
Reports from Professional Bodies	Legal Claims	Management of relationship risk – i.e., service partners/key suppliers taking into account the behaviour and risk priorities of those partners
Health and Safety Executive Reports/Visits	Patient and Client Satisfaction Measures	Networking – use of media reports and information from other Trusts
Environmental Health Reports	Employee Satisfaction Measures	Other self-assessment tools - Health and Social Care Quality Standards Audit Commission.
Independent Reviews	Measures of psychological safety	
Coroner's Reports	Sickness and Absence Records	
Contract management meeting reports from external providers	Staff Turnover	
Contract management meeting reports from external contractors	Levels of Agency Utilisation	
All internal C&SCG data e.g. safety thermometer, waiting time report etc.	Medical Device and Equipment Alerts	
NCEPOD enquiries/reports	Introduction of new Standards and Guidelines	
	Outcome of Audit	

Directorates are required to develop appropriate systems and mechanisms to support the identification of risk. Some potential mechanisms are:

- Data review – review of adverse incidents, complaints, lessons learned from investigations, user views, claims data, and patient safety data.
- Workplace Risk Assessment – review of current risk assessments to identify trends and recurrent risks across the organisation e.g. staff shortages, psychological safety, engagement
- External Review(s) – examine review reports to identify risks identified by the external review team e.g. coroners investigations, RQIA, Internal Audit, Standards & Guidelines, College & Professional Body Reports, National and Confidential Enquiries.
- Contract management meeting reports from external providers & contractors

Using the above identification methods risks should be identified and recorded in Risk Registers.

A risk assessment form (Appendix 1) should be applied to this risk assessment process.

Risk Analysis and Evaluation

For each risk identified an assessment will be made of the **likelihood** of the risk occurring and the consequence or **impact** if this were to happen. The assessment will be made taking into account the effectiveness of controls that are already in place to mitigate the risk.

Once identified, risks will be analysed and actioned following the steps below:

i) Step 1 - Determining Risk Likelihood

In assessing **likelihood** it is important to consider the nature of the risk being assessed. On the one hand, risk may be scored in relation to **probability of future occurrence**. However, in using **likelihood scores** reactively, for example, when reviewing adverse incidents a more appropriate perspective might be 'How likely is this to occur again? / How frequently has this occurred?'

Figure 4 should be used to assign a descriptor for this perceived risk. This should be determined by **either** frequency or **likelihood**.

Risk Likelihood Scoring Table			
Likelihood Scoring Descriptors	Score	Frequency (How often might it/does it happen?)	Time framed Descriptions of Frequency
Almost certain	5	Will undoubtedly happen/recur on a frequent basis	Expected to occur at least daily
Likely	4	Will probably happen/recur, but it is not a persisting issue/circumstances	Expected to occur at least weekly
Possible	3	Might happen or recur occasionally	Expected to occur at least monthly
Unlikely	2	Do not expect it to happen/recur but it may do so	Expected to occur at least annually
Rare	1	This will probably never happen/recur	Not expected to occur for years

ii) Step 2 – Determining the Risk Impact/Consequence

The risk impact/consequence table at Figure 5 (known as the 5x5 matrix) provides guidance on applying the impact criteria. In determining the risk impact/consequence the following question should be asked:

If harm occurred, what are the likely consequences to the Trust achieving its objectives?

All risks should be assessed **across each** of the 5 consequence / impact categories. The highest value attained against any one of the categories will be the impact / consequence grade will be used to indicate the level of risk.

HSC Regional Impact Table – with effect from April 2013 (updated June 2016 & August 2018)

DOMAIN	IMPACT (CONSEQUENCE) LEVELS [can be used for both actual and potential]				
	INSIGNIFICANT (1)	MINOR (2)	MODERATE (3)	MAJOR (4)	CATASTROPHIC (5)
PEOPLE (Impact on the Health/Safety/Welfare of any person affected: e.g. Patient/Service User, Staff, Visitor, Contractor)	Near miss, no injury or harm.	- Short-term injury/minor harm requiring first aid/medical treatment. - Any patient safety incident that required extra observation or minor treatment e.g. first aid - Non-permanent harm lasting less than one month - Admission to hospital for observation or extended stay (1-4 days duration) - Emotional distress (recovery expected within days or weeks).	- Semi-permanent harm/disability (physical/emotional injuries/trauma) (Recovery expected within one year). - Admission/readmission to hospital or extended length of hospital stay/care provision (5-14 days). - Any patient safety incident that resulted in a moderate increase in treatment e.g. surgery required	- Long-term permanent harm/disability (physical/emotional injuries/trauma). - Increase in length of hospital stay/care provision by >14 days.	- Permanent harm/disability (physical/emotional trauma) to more than one person. - Incident leading to death.
QUALITY & PROFESSIONAL STANDARDS/ GUIDELINES (Meeting quality/ professional standards/ statutory functions/ responsibilities and Audit Inspections)	- Minor non-compliance with internal standards, professional standards, policy or protocol. - Audit / Inspection – small number of recommendations which focus on minor quality improvements issues.	- Single failure to meet internal professional standard or follow protocol. - Audit/Inspection – recommendations can be addressed by low level management action.	- Repeated failure to meet internal professional standards or follow protocols. - Audit / Inspection – challenging recommendations that can be addressed by action plan.	- Repeated failure to meet regional/ national standards. - Repeated failure to meet professional standards or failure to meet statutory functions/ responsibilities. - Audit / Inspection – Critical Report.	- Gross failure to meet external/national standards. - Gross failure to meet professional standards or statutory functions/ responsibilities. - Audit / Inspection – Severely Critical Report.
REPUTATION (Adverse publicity, enquiries from public representatives/media Legal/Statutory Requirements)	- Local public/political concern. - Local press < 1day coverage. - Informal contact / Potential intervention by Enforcing Authority (e.g. HSE/NIFRS).	- Local public/political concern. - Extended local press < 7 day coverage with minor effect on public confidence. - Advisory letter from enforcing authority/increased inspection by regulatory authority.	- Regional public/political concern. - Regional/National press < 3 days coverage. Significant effect on public confidence. - Improvement notice/failure to comply notice.	- MLA concern (Questions in Assembly). - Regional / National Media interest >3 days < 7days. Public confidence in the organisation undermined. - Criminal Prosecution. - Prohibition Notice. - Executive Officer dismissed. - External Investigation or Independent Review (e.g. Ombudsman). - Major Public Enquiry.	- Full Public Enquiry/Critical PAC Hearing. - Regional and National adverse media publicity > 7 days. - Criminal prosecution – Corporate Manslaughter Act. - Executive Officer fined or imprisoned. - Judicial Review/Public Enquiry.
FINANCE, INFORMATION & ASSETS (Protect assets of the organisation and avoid loss)	- Commissioning costs (£) <1m. - Loss of assets due to damage to premises/property. - Loss – £1K to £10K. - Minor loss of non-personal information.	- Commissioning costs (£) 1m – 2m. - Loss of assets due to minor damage to premises/ property. - Loss – £10K to £100K. - Loss of information. - Impact to service immediately containable, medium financial loss	- Commissioning costs (£) 2m – 5m. - Loss of assets due to moderate damage to premises/ property. - Loss – £100K to £250K. - Loss of or unauthorised access to sensitive / business critical information - Impact on service contained with assistance, high financial loss	- Commissioning costs (£) 5m – 10m. - Loss of assets due to major damage to premises/property. - Loss – £250K to £2m. - Loss of or corruption of sensitive / business critical information. - Loss of ability to provide services, major financial loss	- Commissioning costs (£) > 10m. - Loss of assets due to severe organisation wide damage to property/premises. - Loss – > £2m. - Permanent loss of or corruption of sensitive/business critical information. - Collapse of service, huge financial loss
RESOURCES (Service and Business interruption, problems with service provision, including staffing (number and competence), premises and equipment)	- Loss/ interruption < 8 hour resulting in insignificant damage or loss/impact on service. - No impact on public health social care. - Insignificant unmet need. - Minimal disruption to routine activities of staff and organisation.	- Loss/interruption or access to systems denied 8 – 24 hours resulting in minor damage or loss/ impact on service. - Short term impact on public health social care. - Minor unmet need. - Minor impact on staff, service delivery and organisation, rapidly absorbed.	- Loss/ interruption 1-7 days resulting in moderate damage or loss/impact on service. - Moderate impact on public health and social care. - Moderate unmet need. - Moderate impact on staff, service delivery and organisation absorbed with significant level of intervention. - Access to systems denied and incident expected to last more than 1 day.	- Loss/ interruption 8-31 days resulting in major damage or loss/impact on service. - Major impact on public health and social care. - Major unmet need. - Major impact on staff, service delivery and organisation - absorbed with some formal intervention with other organisations.	- Loss/ interruption >31 days resulting in catastrophic damage or loss/impact on service. - Catastrophic impact on public health and social care. - Catastrophic unmet need. - Catastrophic impact on staff, service delivery and organisation - absorbed with significant formal intervention with other organisations.
ENVIRONMENTAL (Air, Land, Water, Waste management)	Nuisance release.	On site release contained by organisation.	- Moderate on site release contained by organisation. - Moderate off site release contained by organisation.	Major release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc.).	Toxic release affecting off-site with detrimental effect requiring outside assistance.

iii) Step 3 – Determining the Risk Rating

Following the identification of the level of likelihood and impact/consequence of the identified risk, a risk rating will be calculated using the matrix in Figure 6. This rating will prioritise and inform the further management of the risk identified.

Figure 6

Likelihood Scoring Descriptors	Impact (Consequence) Levels				
	Insignificant(1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Almost Certain (5)	Medium	Medium	High	Extreme	Extreme
Likely (4)	Low	Medium	Medium	High	Extreme
Possible (3)	Low	Low	Medium	High	Extreme
Unlikely (2)	Low	Low	Medium	High	High
Rare (1)	Low	Low	Medium	High	High

An example of a risk rating using the risk matrix is:

Likelihood x Consequence (Potential Impact) = Risk Rating e.g. Possible x Moderate = Yellow (9)

iv) Step 4 - Risk Action Planning

As part of the process, those carrying out the risk assessment exercise should also develop proposals for management of the risks identified. This should be documented in the risk action plan. All options should be considered including accepting a higher level of risk if doing so increases the quality of life for a patient/client. It is unlikely that proposals to completely eliminate all risks impacting on the organisation will always be feasible. Proposals should strike a balance between improving the risk situation, the level of resource input required and a realistic timescale in which to bring the risk faced to an acceptable level.

All action plans should clearly set out the action required to manage the identified risk. The Trust recognises it is not always possible to eliminate or reduce risks to the lowest level of rating and that some risks will have to be accepted at a high level. The process for acceptance of these risks is outlined in the Risk Acceptance Framework, Section 5.

In developing risk action plans consideration should be given where: -

- There are no control measures at all;
 - Current control measures are ineffective; or
 - Additional control measures are required to the existing effective controls in place.
1. An individual with explicit responsibility must be identified for ensuring the action is taken.
 2. The name of this person together with a target date for completion of the action must be recorded against the proposed action in the plan.
 3. A planned date for the first review of the risk assessment, to assess progress initially, should be agreed and recorded in the action plan.
 4. This date should be determined by the initial risk rating.

A **predicted** risk rating once all control measures are implemented should be determined.

If there are anticipated resource implications associated with the action plan, details and costs should be recorded.

The relevant Trust manager should sign off each action plan and ensure the risk is managed according to the process outlined in the Risk Acceptance Framework.

The management of the risk must then be reviewed on an ongoing basis to:

- Monitor whether the risk profile is changing; and
- Gain assurance that the risk action plan is effective and to identify when further action is necessary.

Details of subsequent reviews should be recorded in the action plan, including the date of the review, a summary of the current position and a re-assessment of the risk rating. The risk rating may change as actions are completed and this should be recorded.

Section 9: Risk Acceptance Framework

The Trust recognises that it is impossible, and not always desirable, to eliminate all risks especially in the delivery of care to patients/clients. A mark of good risk management is the innovative and imaginative use of resources in finding ways to avoid or reduce risks whenever possible.

Fine and balanced judgments will be necessary regarding the health and welfare of individuals especially within a person centred approach to patient/client care. It is sometimes the case that a higher level of risk may be accepted to facilitate a new and innovative service, which increases the quality of life for patients/clients.

The risk management process should identify the hazard and apply appropriate risk assessment and management action plans. Regardless of the level of risk assessed, all risk assessments must be recorded in the risk register, monitored and reviewed when necessary, determined by the risk rating, to ensure desirable outcomes.

Despite thorough risk assessment and management action plans, things can still go wrong and it is therefore essential that there are controls in place to deal with this situation.

It is crucial that Business Continuity Plans/local emergency plans are in place for the management of situations in which control failure leads to material realisation of risk.

Definition of Risk Appetite and Tolerance

Definition of Risk Appetite

According to ISO 31000, a risk appetite definition is “the amount and type of risk that an organization is prepared to pursue, retain or take.”

Tolerance Is related to risk appetite. It is the level of variation the organisation is willing to accept around *specific* objectives. (Institute of Risk Management)

Risk Appetite General Statement

The Trust must take risks in order to achieve its aims and deliver beneficial outcomes to stakeholders. Risks will be taken in a considered and controlled manner. Exposure to risks will be kept to a level deemed acceptable by the Board

The risk appetite of the Trust is the decision on the appropriate exposure to risk it will accept in order to deliver its strategy over a given time frame. In practice, risk appetite should address several dimensions:

- The nature of the risks to be assumed;
- The amount of risk to be taken;
- The desired balance of risk versus reward;

The overarching areas of:

- Risk to patients / service users

- Organisational risk
- Reputational risk
- Opportunistic risk
- Financial risk

Risks throughout the organisation should be managed within the Trust's risk appetite, or where this is exceeded, action taken to reduce the risk."

Appetite Level	Described as
None	Avoid the avoidance of risk and uncertainty is a Key Organisational objective
Low	Minimal the preference for ultra-safe delivery options that have a low degree of inherent risk and only for limited reward potential
Moderate	Cautious the preference for safe delivery options that have a low degree of inherent risk and may only have limited potential for reward
High	Open and be willing to consider all potential delivery options and choose while also providing an acceptable level or reward (and VfM)
Significant	Seek and to be eager to be innovative and to choose options offering potentially higher business rewards (despite greater inherent risk). Also described as Mature being confident in setting high levels of risk appetite because controls, forward scanning and responsiveness systems are robust.

The Trust recognises that its long term sustainability depends upon the delivery of its strategic objectives and its relationships with its patients, the public and strategic partners. As such, the Trust will not accept risks that materially impact on patient safety. However, the Trust has a greater appetite to take considered risks in terms of their impact on organisational issues. The Trust's greatest appetite to pursue innovation and challenge current working practices in terms of taking opportunities where positive gains can be anticipated, within the constraints of the regulatory environment.

Risk Acceptance Framework Categorisations

The Risk Acceptance Framework for the Southern Trust applies a 'traffic light' system with regard to the categorisation of risks against the scale of very low, low, moderate and high. The categorisation of risk against these scales determines if a risk is acceptable or not, and the level and urgency of intervention required. The Risk Acceptance categorisation process should be applied as a guide. Individual managers are encouraged to consider the acceptance of risk on an individual case by case basis. This judgement should be used to inform the level and urgency of action required. The 'traffic light' system applied to the Risk Acceptance Framework is as follows:

Green Risks (Low)

Identified risks which fall in the green area are deemed as low (acceptable) risks and may require no immediate action, but must be monitored regularly to assess if and when action is required. These risks must be entered onto the local Risk Register.

Yellow Risks (Medium)

Identified risks which fall in the yellow area are deemed medium risk to the Trust but require action to reduce the risk. Responsibility for taking action would normally remain at a local level within the appropriate Directorates / Service Areas and be entered on the Team / Service Risk Register.

Where these risks cannot be managed locally they should be forwarded to the appropriate Directorate Governance Fora for consideration for further local action, resourcing or acceptance by the Directorate Governance Fora for the Directorate Risk Register.

These risks must be entered on the local risk register and where appropriate the Directorate Risk Register for information and monitoring purposes.

Amber Risks (High)

Identified risks which fall in the amber area are deemed high risk to the Trust and require prompt action to reduce the risk to an acceptable level. When risks cannot be reduced locally they should be submitted to the Directorate Governance Fora for consideration and recommended action, i.e. further local action, resourcing or acceptance.

Where these risks cannot be managed within the Directorate they should be referred to the Senior Management Team for consideration and/or addition to the Corporate Risk Register.

These risks must be entered on the local risk register and where appropriate the Directorate Risk Register.

Red Risks (Extreme)

Identified risks which fall in the red area are deemed extreme risk to the Trust and must be reported to the appropriate Director and Chief Executive. Immediate action is required to reduce the level of risks to an acceptable level. The appropriate Director will ensure the implementation of a time monitored action plan with regular reports to the Chief Executive and Governance Committee.

SMT will be the gate keepers of the Corporate Risk Register and will use the following criteria to inform their decision making in escalating risks to the Corporate Risk Register.

- The risk represents an issue that has the potential to hinder achievement of one or more of the corporate objectives
- The risk cannot be addressed at directorate level
- It requires further control measures to reduce or eliminate the risk
- It is likely to require considerable input of resources to resolve the risk (finance, people, time, etc)

These risks will be entered onto the Directorate, and if appropriate the Corporate Risk

Register(s) for monitoring by the SMT.

Where the identified risks have the potential to threaten the achievement of the Trust's corporate objectives, they will be escalated by the SMT to the Board Assurance Framework.

Any definition of risk must be pragmatic and time dependent as the passage of time will reduce the tolerance of risk once deemed acceptable. In an attempt to help prioritise all risks the following definitions should be applied as a guide to the management of risks by the Trust:

Definition of Acceptable Risk

As a guide the Trust considers green (low and medium) risks to be acceptable (as defined by the risk rating matrix, Figure 6).

This definition is to be used as a guide only and managers are encouraged to take action on green and yellow (low and very low) risks identified particularly when these risks can be easily eliminated or reduced.

Definition of Unacceptable Risk

The Trust considers all amber (high) and red (extreme) risks to be unacceptable (as defined by the risk rating matrix, Figure 6). Managers are expected to take immediate action on amber (high) and red (extreme) risks identified and document action taken.

Definition of Significant Risk

Those red (extreme) risks, which have been identified as potentially threatening the achievement of the Trust's objectives or represent significant gaps in controls / assurances, are escalated by the SMT Governance to the Board Assurance Framework.

In addition to these guidance notes, Directors, Directorates, Service Areas etc. should consider notifying the Governance Committee and Trust Board of frequently occurring lower graded risks via SMT.

The Corporate Risk Register will be reviewed monthly by the SMT. Trust Board review the Board Assurance Framework bi-annually in conjunction with a high level summary of the Corporate Risk Register.

The Corporate Risk Register is also shared with the Department of Health mid-year and year end as part of the accountability process.

Where the resolution of a risk includes funding implications that cannot be contained within the available budgets, a business case should be developed as part of the Trust's business planning process.

Risk Treatment / Action Planning

A risk action plan should be developed to document the management actions and controls to be adopted. The plans should involve:

- Formulating and selecting risk treatment options;
- Planning and implementing risk treatment;
- Assessing the effectiveness of that treatment;
- Deciding whether the remaining risk is acceptable;
- If not acceptable, take further treatment/action.

It is the responsibility of the Clinical and Social Care Governance Coordinators for the Directors of Acute, Children and Young People, Older People and Primary Care and Mental Health and Disability in conjunction with relevant Directors/Senior Managers/Heads of Service to develop and maintain risk action plans for Directorate/Departmental risk registers.

On the delegated authority of the Chair (the Chief Executive) of SMT Governance, the Board Secretary, is responsible for maintaining risk action plans for the Corporate Risk Register.

Risk action plans should be developed using the proforma (and maintained in a suitable electronic format) incorporating the following information:

- Risk ID Number
- The action to be taken and the risks such actions address.
- Identified individual(s) responsible for implementing the plan.
- Budgetary allocation (where appropriate)
- Timetable for implementation
- Details of mechanism and frequency or review of action plan

Risk Registers

Each Directorate maintains a risk register. Each Directorate has a forum in which these Risk Registers are monitored. Each Directorate Risk Register is owned by the Director for that Directorate. It is the responsibility of Clinical and Social Care Governance Coordinators for the Acute, Children and Young People, Older People and Primary Care and Mental Health and Disability Directorates to maintain Directorate level risk registers in conjunction with relevant Directors/Senior Managers/Heads of Service.

Risks identified at a corporate level will be recorded on the Corporate Risk Register which is managed by the Senior Management Team. It is reviewed by SMT review on a monthly basis and reported to the Governance Committee who review it on a quarterly basis providing challenge and advice. Based on the knowledge of risks identified, Directors will determine the level of assurance that should be available to them with regard to those risks.

With regard to both Directorate/Departmental and Corporate Risk Registers risks will be

entered in accordance with the risk rating and action guidance. Risk registers should be developed using the proforma attached in Appendix 1.

- Risk ID Number
- Source
- Risk title and description (including location and local details)
- Potential for harm
- Summary of current control measures
- Initial risk rating
- Action plan
- Nominated person responsible for each action
- Review date
- Monitoring arrangements
- Lead individual

Board Assurance Framework

The Board Assurance Framework is the tool used by the Board to identify high level risks to the delivery of the Trust's corporate objectives and provide assurances for the control and management of those risks. The Board Assurance Framework works 'top down' from the Trust's corporate objectives determining proactively, the high level risks and what controls and assurance processes are in place. As part of the process, the Trust Board is committed to discussing and making the connections between the corporate objectives, the high level risks that could affect achievement of those objectives and the range and effectiveness of existing assurance reporting. The Trust Board own the Board Assurance Framework and review it on a six-monthly basis.



Risk Monitoring and Review

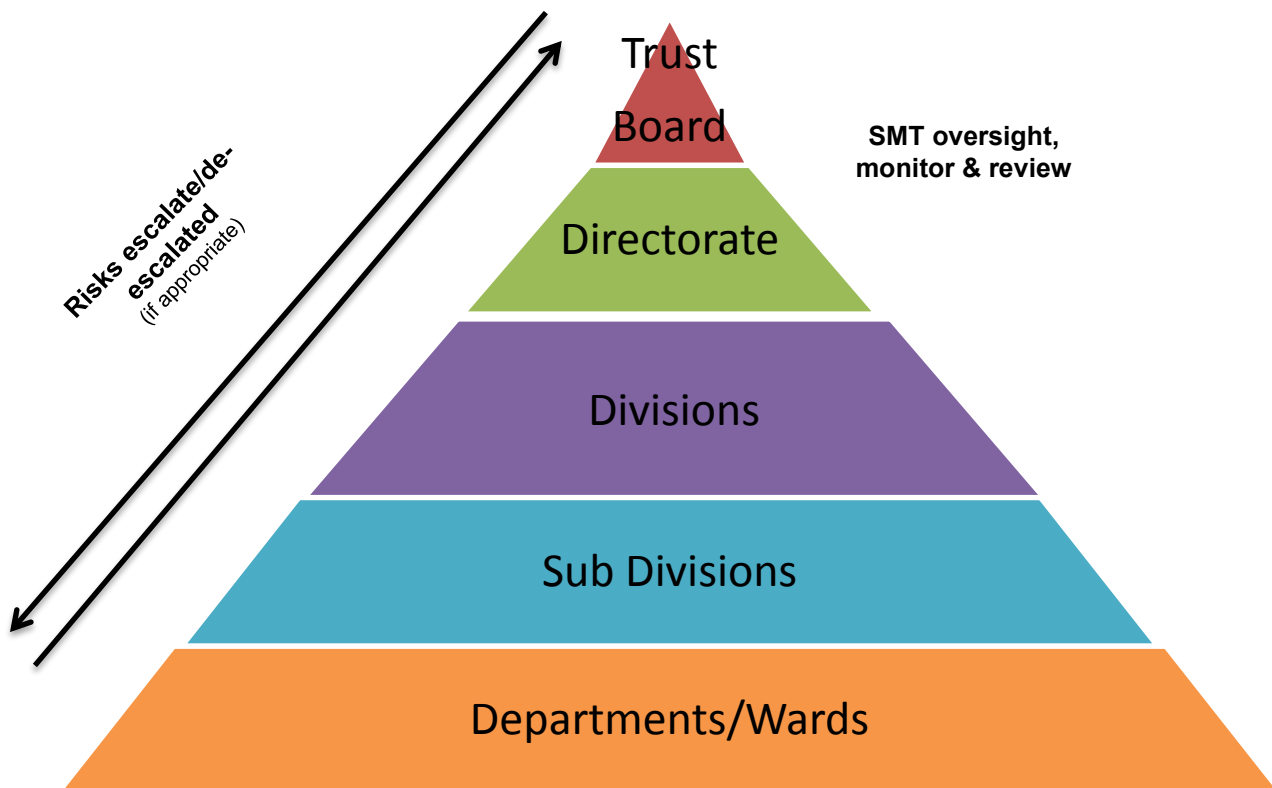
Monitoring and review should take place in all stages of the process. Monitoring and review includes planning, gathering and analysing information, recording results and providing feedback. The results of monitoring and review should be incorporated throughout the organisation's performance management, measurement and reporting activities.

Risk Escalation and De-Escalation

The grade of each risk not only determines who is responsible for managing the risk but also where it should be escalated to – Division, Directorate or Trust level. The timescale in which risks are escalated varies or assurance on the management of a risk varies according to the significance of the risk. This may be through routine monitoring systems or fast tracked. Senior Managers and Directors use judgement to determine the timescale for escalation, influenced by the impact the issue has on the delivery of safe, high quality care or organisational reputation.

It is the responsibility of the Chair of each group or committee to escalated risks, to ensure each escalated risk is reconsidered in the context of other risks already included in the Risk Register at that level. Each Risk Register should be reviewed to identify and understand themes in risks on the register, how this impacts on each other and the Trust and whether this identifies new risks or affects the grade of existing risks.

When actions to reduce a risk have been completed and the risk score is lowered to a level that no longer requires inclusion on a risk register, the risk can be de-escalated.



Assurance and Escalation Pyramid

Risk Owners

Each risk that is identified in a risk register will have a risk owner who will:-

- Ensure adequate and effective controls are implemented
- Review and update individual records regularly

Risk Recording and Reporting

The risk management process and its outcomes should be documented and reported through appropriate mechanisms

Risk Strategy Education and Training

The Trust is committed to the education and training of all staff which ensures the welfare and health and safety of patients, clients and the public.

Risk management training will be assessed and delivered by the Directorate Governance Teams based on organisational/staff needs. Directorates are required to maintain risk management training records, monitor attendance of staff at training, and report on risk management training to SMT Governance as required. Trust induction programmes will include standardised risk management training.

Appendix 1 – Trust Risk Assessment Form for Risk Register

SOUTHERN HEALTH & SOCIAL CARE TRUST		
RISK ASSESSMENT FORM		Risk ID No
Directorate:	Facility/Department/Team:	Date:
Where is this being carried out? (e.g. Trust premises/home of client/staff/ private nursing home etc)		Objective(s) i.e. Corporate, Legislative requirements etc.
Risk Title: (Threat to achievement of objective) Description of Risk: (Describe the risk being assessed identifying who is at risk e.g. patient/staff/other care provider) Outline the potential for harm: (Consider injury to client, staff, litigation, etc.)		

Summary of current control measures: (Consider equipment, staffing, environment, policy/procedure, training, documentation, information - this list is not exhaustive).

Are these controls: (a) Effective or (b) Require Further Action (if [b], complete Action Plan)

Please list control measures considered but discounted and why (where appropriate):

Assessment of Risk	Likelihood e.g. Likely	Consequence/ Impact e.g. Moderate	Risk Rating L and C = RR e.g. Likely and Moderate = YELLOW	
ACTION PLAN OF FURTHER CONTROL MEASURES REQUIRED (risk treatment):				
Action/Treatment	Action Lead	Start Date	Target Date	Progress/Review Date
Date of first review (to be determined by risk rating)				
Predicted Risk Assessment once all control measures are implemented	Likelihood e.g. Likely	Consequence/ Impact e.g. Moderate	Risk Rating L and C =RR e.g. Likely and Moderate = YELLOW	

Openness and honesty when things go wrong: the professional duty of candour

The professional duty of candour

Every health and care professional must be open and honest with patients and people in their care when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress.¹ This means that health and care professionals must:

- tell the person (or, where appropriate, their advocate, carer or family) when something has gone wrong
- apologise to the person (or, where appropriate, their advocate, carer or family)
- offer an appropriate remedy or support to put matters right (if possible)
- explain fully to the person (or, where appropriate, their advocate, carer or family) the short and long term effects of what has happened.

Health and care professionals must also be open and honest with their colleagues, employers and relevant organisations, and take part in reviews and investigations when requested. They must also be open and honest with their regulators, raising concerns where appropriate. They must support and encourage each other to be open and honest, and not stop someone from raising concerns.

About this guidance

- 1 When we refer to 'patients' in this guidance, we also mean people who are in your care.
- 2 All health and care professionals have a duty of candour – a professional responsibility to be honest with patients when things go wrong. This is described in The professional duty of candour, which introduces this guidance.
- 3 As a doctor, nurse, midwife or nursing associate, you must be open and honest with patients, colleagues and your employers.
- 4 This guidance gives more information about how to follow the principles set out in *Good medical practice*² and *The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates*.³ Appendix 1 sets out relevant extracts from General Medical Council (GMC) and Nursing and Midwifery Council (NMC) standards and guidance. The GMC's guidance applies to all doctors registered with it, the NMC's standards and guidance apply to all nurses, midwives and nursing associates registered with it.

5 This guidance is divided into two parts.

- a Your duty to be open and honest with patients in your care, or those close to them, if something goes wrong. This includes advice on apologising (paragraphs 7–22).
- b Your duty to be open and honest with your organisation, and to encourage a learning culture by reporting adverse incidents that lead to harm, as well as near misses (paragraphs 23–29).

6 This guidance is for individuals. We recognise that care is normally provided by multidisciplinary teams, and we don't expect every team member to take responsibility for reporting adverse incidents and speaking to patients if things go wrong. However, we do expect you to make sure that someone in the team has taken on responsibility for each of these tasks, and we expect you to support them as needed.

Being open and honest with patients in your care, and those close to them, when things go wrong

Discuss risks before beginning treatment or providing care

- 7 Patients must be fully informed^{4,5} about their care. When discussing care options with patients, you must discuss the risks as well as the benefits of the options.
- 8 You or an appropriate person⁶ must give the patient clear, accurate information about the risks of the proposed treatment or care, and the risks of any reasonable alternative options, and check that the patient understands. You should discuss risks⁷ that occur often, those that are serious even if very unlikely, and those that the patient is likely to think are important.⁸

In what circumstances do I need to apologise to the patient?

- 9 This guidance is not intended for circumstances where a patient's condition gets worse due to the natural progression of their illness. It applies when something goes wrong with a patient's care, and they suffer harm or distress as a result. This guidance also applies in situations where a patient may yet suffer harm or distress as a result of something going wrong with their care.
- 10 When you realise that something has gone wrong, and after doing what you can to put matters right, you or someone from the healthcare team must speak to the patient.⁹ The most appropriate team member will usually be the lead or accountable clinician.¹⁰ If this is not you, then you must follow the guidance in paragraph 6.

When should I speak to the patient or those close to them, and what do I need to say?

- 11 You should speak to the patient as soon as possible after you realise something has gone wrong with their care. When you speak to them, there should be someone available to support them (for example a friend, relative or professional colleague). You do not have to wait until the outcome of an investigation to speak to the patient, but you should be clear about what has and has not yet been established.
- 12 You should share all you know and believe to be true about what went wrong and why, and what the consequences are likely to be. You should explain if anything is still uncertain and you must respond honestly to any questions.¹¹ You should apologise to the patient (see paragraphs 14–20).

What if people don't want to know the details?

- 13** Patients will normally want to know more about what has gone wrong. But you should give them the option not to be given every detail. If the patient does not want more information, you should try to find out why. If after discussion, they don't change their mind, you should respect their wishes as far as possible,¹² having explained the potential consequences. You must record the fact that the patient does not want this information and make it clear to them that they can change their mind and have more information at any time.

Saying sorry

- 14** Patients expect to be told three things as part of an apology:

- a** what happened
- b** what can be done to deal with any harm caused
- c** what will be done to prevent someone else being harmed.

- 15** Apologising to a patient does not mean that you are admitting legal liability¹³ for what has happened. This is set out in legislation in parts of the UK¹⁴ and NHS Resolution also advises that saying sorry is the right thing to do.¹⁵ In addition, a fitness to practise panel may view an apology as evidence of insight.^{16, 17}

- 16** When apologising to patients and explaining what has happened, we do not expect you to take personal responsibility for something going wrong that was not your fault (such as system errors or a colleague's mistake). But the patient has the right to receive an apology from the most appropriate team member (see paragraph 10), regardless of who or what may be responsible for what has happened.

- 17** We do not want to encourage a formulaic approach to apologising since an apology has value only if it is genuine. However, when apologising to a patient, you should consider each of the following points.

- a** You must give patients the information they want or need to know in a way that they can understand.¹⁸
- b** You should speak to patients in a place and at a time when they are best able to understand and retain information.
- c** You should give information that the patient may find distressing in a considerate way, respecting their right to privacy and dignity.
- d** Patients are likely to find it more meaningful if you offer a personalised apology – for example 'I am sorry...' – rather than a general expression of regret about the incident on the organisation's behalf. This doesn't mean that we expect you to take personal responsibility for system failures or other people's mistakes (see paragraph 16).
- e** You should make sure the patient knows who to contact in the healthcare team to ask any further questions or raise concerns. You should also give patients information about independent advocacy, counselling or other support services¹⁹ that can give them practical advice and emotional support.
- f** You should record the details of your apology in the patient's clinical record.^{20, 21} A verbal apology may need to be followed up by a written apology, depending on the patient's wishes and on your workplace policy.²²

Speaking to those close to the patient

- 18** If something has gone wrong that causes a patient's death or such severe harm that the patient is unlikely to regain consciousness or capacity, you must be open and honest with those close to the patient.^{3, 23} Take time to convey the information in a compassionate way, giving them the opportunity to ask questions at the time and afterwards.²⁴
- 19** You must show respect for, and respond sensitively to, the wishes and needs of bereaved people. You must take into account what you know of the patient's wishes about what should happen after their death, including their views about sharing information. You should be prepared to offer support and assistance to bereaved people – for example by explaining where they can get information about, and help with, administrative and practical tasks following a death; or by involving other members of the team, such as chaplaincy or bereavement care staff.^{25, 26}
- 20** You should make sure, as far as possible, that those close to the patient have been offered appropriate support, and that they have a specific point of contact in case they have concerns or questions at a later date.

Being open and honest with patients about near misses

- 21** A 'near miss' is an adverse incident that had the potential to result in harm but did not do so.²⁷ You must use your professional judgement when considering whether to tell patients about near misses. Sometimes there will be information that the patient needs to know or would want to know, and telling the patient about the near miss may even help their recovery. In these cases, you should talk to the patient about the near miss, following the guidance in paragraphs 11–17.
- 22** Sometimes failing to be open with a patient about a near miss could damage their trust and confidence in you and the healthcare team. However, in some circumstances, patients may not need to know about an adverse incident that has not caused (and will not cause) them harm, and to speak to them about it may distress or confuse them unnecessarily. If you are not sure whether to talk to a patient about a near miss, seek advice from your healthcare team or a senior colleague.

Encouraging a learning culture by reporting errors

- 23** When something goes wrong with patient care, it is crucial that it is reported at an early stage so that lessons can be learnt quickly and patients can be protected from harm in the future.
- 24** All health and care organisations have a duty to support their staff to report adverse incidents. Health and care organisations should have a policy for reporting adverse incidents and near misses, and you must follow your organisation's policy.²⁸

- 25** A number of reporting systems and schemes exist around the UK for reporting adverse incidents and near misses.
- a** Patient safety incidents in England and Wales are reported to the National Reporting and Learning System, or its replacement, the Learn from patient safety events (LFPSE) service.^{29, 30}
 - b** You must use the UK-wide Yellow Card scheme³¹ to inform the Medicines and Healthcare products Regulatory Agency (MHRA) about:
 - i. serious suspected adverse reactions to a medicine
 - ii. any suspected adverse reactions to products marked with a Black Triangle symbol (▼).³²
 - c** Adverse incidents involving medical devices, including those caused by human error, that put, or have the potential to put, the safety of patients, health and care professionals or others at risk must be reported to the medical device safety lead in your organisation (if there is one) and the relevant national body:
 - i. in England and Wales - MHRA reporting adverse incidents
 - ii. in Northern Ireland - Northern Ireland Adverse Incident Centre
 - iii. in Scotland - Health Facilities Scotland online incident reporting.
 - d** Healthcare Improvement Scotland has a national framework,³³ which aims to support health and social care services in Scotland effectively manage adverse events.
 - e** The Health and Social Care Board has published a procedure for the reporting and follow-up of serious adverse incidents in Northern Ireland.³⁴
 - f** In England, general practitioners and other primary medical services must submit all notifications³⁵ directly to the Care Quality Commission (CQC).
- 26** In addition to contributing to these systems, you should comply with any system for reporting adverse incidents that put patient safety at risk within your organisation. If your organisation does not have such a system in place, you should speak to your manager and – if necessary – raise a concern in line with our guidance.^{36, 37}
- 27** Your organisation has a duty to support you to report adverse incidents and near misses routinely. If you do not feel supported to report, and in particular if you are discouraged or prevented from reporting, you should raise a concern in line with our guidance.^{36, 37}
- 28** You must not try to prevent colleagues or former colleagues from raising concerns about patient safety.³⁸ If you are in a management role, you must make sure that individuals who raise concerns are protected from unfair criticism or action, including any detriment or dismissal.
- 29** You must take part in regular reviews and audits^{39, 40} of the standards and performance of any team you work in, taking steps to resolve any problems. You should also discuss adverse incidents and near misses at your appraisal.^{41, 42}

Additional duties for doctors, nurses and midwives with management responsibilities and for senior or high-profile clinicians

- 30** Senior clinicians have a responsibility to set an example and encourage openness and honesty in reporting adverse incidents and near misses. Clinical leaders should actively foster a culture of learning and improvement.^{43, 44}
- 31** If you have a management role or responsibility, you must make sure that systems are in place to give early warning of any failure, or potential failure, in the clinical performance of individuals or teams. These should include systems for conducting audits and considering patient feedback. You must make sure that any concerns about the performance of an individual or team are investigated and, if appropriate, addressed quickly and effectively.
- 32** If you are managing or leading a team, you should make sure that systems, including auditing and benchmarking, are in place to monitor, review and improve the quality of the team's work.
- a** You must work with others to collect and share information on patient experience and outcomes.
 - b** You should make sure that teams you manage are appropriately trained in patient safety and supported to openly report adverse incidents.
 - c** You should make sure that systems or processes are in place so that:
 - i.** lessons are learnt from analysing adverse incidents and near misses
 - ii.** lessons are shared with the healthcare team

- iii.** concrete action follows on from learning
- iv.** practice is changed where needed.

The organisational duty of candour

- 33** All health and care organisations have a duty to support staff to be open and honest with patients if something goes wrong with their care. Each of the four UK governments has considered ways to implement the organisational duty of candour, with some writing it into law (see appendix 2).

Appendix 1: Extracts from GMC and NMC standards and guidance that are referenced in this document

From *Good medical practice*

- 23** To help keep patients safe you must:
- a** contribute to confidential inquiries
 - b** contribute to adverse event recognition
 - c** report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk
 - d** report suspected adverse drug reactions
 - e** respond to requests from organisations monitoring public health.

When providing information for these purposes you should still respect patients' confidentiality.

- 24** You must promote and encourage a culture that allows all staff to raise concerns openly and safely.

55 You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:

- a** put matters right (if that is possible)
- b** offer an apology
- c** explain fully and promptly what has happened and the likely short-term and long-term effects.

From Raising and acting on concerns about patient safety

13 Wherever possible, you should first raise your concern with your manager or an appropriate officer of the organisation you have a contract with or which employs you – such as the consultant in charge of the team, the clinical or medical director or a practice partner. If your concern is about a partner, it may be appropriate to raise it outside the practice – for example, with the medical director or clinical governance lead responsible for your organisation. If you are a doctor in training, it may be appropriate to raise your concerns with a named person in the deanery – for example, the postgraduate dean or director of postgraduate general practice education.

Doctors with extra responsibilities

- 21** If you are responsible for clinical governance or have wider management responsibilities in your organisation, you have a duty to help people report their concerns and to enable people to act on concerns that are raised with them.
- 22** If you have a management role or responsibility, you must make sure that:
- a** there are systems and policies in place to allow concerns to be raised and for incidents, concerns and complaints to be investigated promptly and fully

- b** you do not try to prevent employees or former employees raising concerns about patient safety – for example, you must not propose or condone contracts or agreements that seek to restrict or remove the contractor's freedom to disclose information relevant to their concerns
- c** clinical staff understand their duty to be open and honest about incidents or complaints with both patients and managers
- d** all other staff are encouraged to raise concerns they may have about the safety of patients, including any risks that may be posed by colleagues or teams
- e** staff who raise a concern are protected from unfair criticism or action, including any detriment or dismissal.

Also see the raising concerns decision making tool on the GMC website.

From Leadership and management for all doctors

24 Early identification of problems or issues with the performance of individuals, teams or services is essential to help protect patients.

All doctors

- 25** You must take part in regular reviews and audits of the standards and performance of any team you work in, taking steps to resolve any problems.
- 26** You should be familiar with, and use, the clinical governance and risk management structures and processes within the organisations you work for or to which you are contracted. You must also follow the procedure where you work for reporting adverse incidents and near misses. This is because routinely identifying adverse incidents or near misses at an early stage, can allow issues to be tackled, problems to be put right and lessons to be learnt.

- 27** You must follow the guidance in *Good medical practice* and *Raising and acting on concerns about patient safety* when you have reason to believe that systems, policies, procedures or colleagues are, or may be, placing patients at risk of harm.

Doctors with extra responsibilities

- 28** If you have a management role or responsibility, you must make sure that systems are in place to give early warning of any failure, or potential failure, in the clinical performance of individuals or teams. These should include systems for conducting audits and considering patient feedback. You must make sure that any such failure is dealt with quickly and effectively.
- 29** If you are managing or leading a team, you should make sure that systems, including auditing and benchmarking, are in place to monitor, review and improve the quality of the team's work. You must work with others to collect and share information on patient experience and outcomes. You must make sure that teams you manage are appropriately supported and developed and are clear about their objectives.

From *Decision making and consent*

- 87** We use the term 'overall benefit' to describe the ethical basis on which decisions are made about treatment and care for adult patients who lack capacity to decide for themselves. This involves weighing up the risks of harm and potential benefits for the individual patient of each of the available options, including the option of taking no action. The concept of overall benefit is consistent with the legal requirements to consider whether treatment 'benefits' a patient (Scotland), or is in the patient's 'best interests' (England, Wales and Northern Ireland).

- 88** If you are the treating doctor, before concluding that it is your responsibility to decide which option(s) would be of overall benefit to a patient who lacks capacity, you should take reasonable steps to find out:

- a** whether there's evidence of the patient's previously expressed values and preferences that may be legally binding, such as an advance statement or decision
- b** whether someone else has the legal authority to make the decision on the patient's behalf or has been appointed to represent them.

- 89** If there is no evidence of a legally binding advance refusal of treatment, and no one has legal authority to make this decision for them, then you are responsible for deciding what would be of overall benefit to your patient.

In doing this you must:

- a** consult with those close to the patient and other members of the healthcare team, take account of their views about what the patient would want, and aim to reach agreement with them
- b** consider which option aligns most closely with the patient's needs, preferences, values and priorities
- c** consider which option would be the least restrictive of the patient's future options.

- 90** If a proposed option for treatment or care will restrict a patient's right to personal freedom, you must consider whether you need legal authorisation to proceed with it in the circumstances.

- 91** You should allow enough time, if possible, for discussions with those who have an interest in the patient's welfare, and you should aim to reach agreement about how to proceed.

From *Treatment and care towards the end of life: good practice in decision making*

84 Death and bereavement affect different people in different ways, and an individual's response will be influenced by factors such as their beliefs, culture, religion and values. You must show respect for and respond sensitively to the wishes and needs of the bereaved, taking into account what you know of the patient's wishes about what should happen after their death, including their views about sharing information. You should be prepared to offer support and assistance to the bereaved, for example, by explaining where they can get information about, and help with, the administrative practicalities following a death; or by involving other members of the team, such as nursing, chaplaincy or bereavement care staff.

From *The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates*

Preserve safety

You make sure that patient and public safety is not affected. You work within the limits of your competence, exercising your professional 'duty of candour' and raising concerns immediately whenever you come across situations that put patients or public safety at risk. You take necessary action to deal with any concerns where appropriate.

14 Be open and candid with all service users about all aspects of care and treatment, including when any mistakes or harm have taken place

To achieve this, you must:

14.1 act immediately to put right the situation if someone has suffered actual harm for any reason or an incident has happened which had the potential for harm

14.2 explain fully and promptly what has happened, including the likely effects, and apologise to the person affected and, where appropriate, their advocate, family or carers

14.3 document all these events formally and take further action (escalate) if appropriate so they can be dealt with quickly.

16 Act without delay if you believe that there is a risk to patient safety or public protection

To achieve this, you must:

16.1 raise and, if necessary, escalate any concerns you may have about patient or public safety, or the level of care people are receiving in your workplace or any other health and care setting and use the channels available to you in line with our guidance and your local working practices

16.2 raise your concerns immediately if you are being asked to practise beyond your role, experience and training

16.3 tell someone in authority at the first reasonable opportunity if you experience problems that may prevent you working within the Code or other national standards, taking prompt action to tackle the causes of concern if you can

16.4 acknowledge and act on all concerns raised to you, investigating, escalating or dealing with those concerns where it is appropriate for you to do so

16.5 not obstruct, intimidate, victimise or in any way hinder a colleague, member of staff, person you care for or member of the public who wants to raise a concern

16.6 protect anyone you have management responsibility for from any harm, detriment, victimisation or unwarranted treatment after a concern is raised.

For more information, please see Raising concerns: Guidance for nurses and midwives

From Future Nurse: Standards of proficiency for registered nurses (NMC, 2018)

- 1.3** understand and apply the principles of courage transparency and the professional duty of candour, recognising and reporting any situations, behaviours or errors that could result in poor care outcomes.

From Standards of proficiency for midwives (NMC, 2019)

- 1.19** understand and apply the principles of courage, integrity, transparency, and the professional duty of candour, recognising and reporting any situations, behaviours, or errors that could result in sub-standard care, dysfunctional attitudes and behaviour, ineffective team working, or adverse outcomes.

From Standards of proficiency for registered nursing associates (NMC, 2018)

- 1.3** understand the importance of courage and transparency and apply the Duty of Candour, recognising and reporting any situations, behaviours or errors that could result in poor care outcomes.

Appendix 2: The statutory duty of candour for care organisations across the UK**England**

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 sets out a duty of candour. It requires all health and social care providers registered with the Care Quality Commission (CQC) to be open and transparent with people using services, and their families, in relation to their treatment and care. The regulation also sets out specific actions that providers must take when a 'notifiable safety incident' occurs. This includes informing people about the incident, providing reasonable support and providing truthful information and a timely apology. The CQC can prosecute for a breach of parts 20(2)a and 20(3) of this regulation.

The organisational duty of candour does not apply to individuals, but organisations providing health and care are expected to implement the duty throughout their organisation by making sure that staff understand the duty and are appropriately trained. The CQC provides guidance⁴⁵ for providers on meeting the duty of candour.

Northern Ireland

In April 2021 the Department of Health (Northern Ireland) launched a consultation on Duty of Candour Policy proposals and a 'Being Open Framework'.

The consultation outlined three policy proposals relating to a statutory duty of candour:

- A Statutory Individual Duty of Candour (IDC) with criminal sanctions, and a Statutory Organisational Duty with criminal sanctions;
- A Statutory IDC without criminal sanctions. Individuals would be sanctioned by their employer, regulator, and professional body, and a Statutory Organisational Duty with criminal sanctions; and

- A Statutory IDC without criminal sanctions, and separate criminal sanctions for withholding, destroying, or providing false or misleading information, and a Statutory Organisational Duty with criminal sanctions.

The consultation followed recommendations for a statutory duty of candour made by the Inquiry into Hyponatraemia-Related Deaths, which reported in January 2018. This examined the circumstances relating to the deaths of five children in Northern Ireland hospitals.

Scotland

The Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and The Duty of Candour Procedure (Scotland) Regulations 2018 set out an organisational duty of candour on health, care and social work services in Scotland. The duty came into effect on 1 April 2018. The overall purpose of the duty is to ensure that organisations are open, honest and supportive when there is an unexpected or unintended incident resulting in harm or death, as defined by the Act.

Organisations are required to follow a duty of candour procedure which includes notifying the person affected, apologising and offering a meeting to give an account of what happened.

The duty also requires the organisation to review each incident and consider the support available to those affected (this includes both those who deliver and receive care and support services).

Organisations are also required to publish an annual report on when the duty has been applied. This includes the number of incidents, how the organisation has implemented the duty and what learning and improvements have been put in place.

Alongside the legal requirements set by the Act, the Scottish Government has also published guidance⁴⁶ on the implementation of duty of candour for all organisations that provide health services, care services or social work services in Scotland.

Wales

The *National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011* place a number of duties on responsible bodies providing NHS care. This includes a duty to be open when harm may have occurred:

'where a concern is notified by a member of the staff of the responsible body, the responsible body must, where its initial investigation determines that there has been moderate or severe harm or death, advise the patient to whom the concern relates, or his or her representative, of the notification of the concern and involve the patient, or his or her representative, in the investigation of the concern'.

The Welsh Government's *Health and Care Standards Framework*, includes a standard called 'listening and learning from feedback'. In meeting this standard, the framework advises that 'health services are open and honest with people when something goes wrong with their care and treatment'. The standards provide a framework for how services are organised, managed and delivered on a day-to-day basis.

On 1 June 2020, The Health and Social Care (Quality and Engagement) (Wales) Act became law. It is expected to come into force in spring 2023.

The Act will establish an organisational duty of candour on providers of NHS services, requiring them to be open and honest with patients and service users when things go wrong.

The legislation places a duty of candour on providers of NHS services (NHS bodies and primary care). The duty requires NHS providers to follow a process – to be set out in Regulations – when a service user suffers an adverse outcome which has or could result in unexpected or unintended harm that is more than minimal and the provision of health care was or may have been a factor.

The Act also requires NHS providers to report annually about when the duty has come into effect.

The Welsh Government intends to issue statutory guidance in relation to the duty of candour to support its implementation. In a Written Statement on 24 March 2021, the Welsh Government also stated its intentions to:

- review the Health and Care Standards (see above); and
- place a duty of candour on independent healthcare providers.

Endnotes

- 1 General Chiropractic Council, General Dental Council, General Medical Council, General Optical Council, General Osteopathic Council, General Pharmaceutical Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland (2014) Joint statement from the Chief Executives of statutory regulators of healthcare professionals (accessed 17 January 2022). Please note that, in this section of the GMC-NMC guidance, some stylistic changes have been made to the text of the original 2014 joint statement.
- 2 General Medical Council (2013) *Good medical practice* (accessed 17 January 2022), paragraphs 24 and 55
- 3 Nursing and Midwifery Council (2018) www.nmc.org.uk/standards/code/ *The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates* (accessed 17 January 2022), section 14
- 4 General Medical Council (2020) www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent *Decision making and consent*
- 5 Nursing and Midwifery Council (2018) www.nmc.org.uk/standards/code/ *The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates* (accessed 17 January 2022), section 4.2
- 6 General Medical Council (2020) *Decision making and consent*, www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent#paragraph-42 paragraphs 42-45

- 7 General Medical Council (2020) *Decision making and consent*, paragraphs 12, 17-24, 27-30, 66-67 and 58f.
- 8 The Supreme Court (2015) www.supremecourt.uk/cases/uksc-2013-0136.html *Judgment: Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)* (accessed 17 January 2022), paragraphs 86–91
- 9 If the patient has died, or is unlikely to regain consciousness or capacity, 'patient' in <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong/being-open-and-honest-with-patients-in-your-care-and-those-close-to-them-when-things-go-wrong#paragraphs-9> paragraphs 10–17 should be read as 'those close to the patient'.
- 10 General Medical Council (2014) *Guidance for doctors acting as responsible consultants or clinicians* (accessed 17 January 2022)
- 11 General Medical Council (2013) *Good medical practice* (accessed 17 January 2022), <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong/being-open-and-honest-with-patients-in-your-care-and-those-close-to-them-when-things-go-wrong> paragraph 11
- 12 If the patient needs to give their consent to a proposed investigation or treatment, then you need to give them enough information to make an informed decision.
- 13 'Legal liability' here refers to a clinical negligence claim. NHS Resolution 'will never refuse cover on a claim because an apology has been given'.
- 14 www.legislation.gov.uk/ukpga/2006/29/contents *Compensation Act 2006 (England and Wales)* (accessed 17 January 2022), section 2
- 15 *NHS Resolution Saying Sorry* (accessed 17 January 2022)
- 16 General Medical Council Sanctions guidance for members of medical practitioners tribunals and for the General Medical Council's decision makers
- 17 Nursing and Midwifery Council (2018) *Factors to consider before deciding on sanctions* (accessed 17 January 2022)
- 18 General Medical Council (2020) *Decision making and consent*, <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent#paragraph-27> paragraphs 27–29
- 19 For example, you could direct them to Action against Medical Accidents (AvMA), which works across the UK, or to their local Healthwatch group in England, the Patient and Client Council in Northern Ireland, the Patient Advice and Support Service in Scotland or the Community Health Council in Wales. See <https://prodsitecore.gmc-uk.org/concerns/information-for-patients> Patients' help on the GMC website or www.nmc.org.uk/concerns-nurses-midwives/concerns-complaints-and-referrals/ Support for patients, families and the public on the NMC website for further information.
- 20 General Medical Council (2013) *Good medical practice* (accessed 17 January 2022), <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong/being-open-and-honest-with-patients-in-your-care-and-those-close-to-them-when-things-go-wrong> paragraph 21

- 21 Nursing and Midwifery Council (2018) www.nmc.org.uk/standards/code/ *The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates* (accessed 17 January 2022), section 14.3
- 22 <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong/appendix-2-the-statutory-duty-of-candour-for-care-organisations-across-the-uk> see appendix 2 for detail of the statutory duty of candour for organisations providing health and care.
- 23 General Medical Council (2013) *Good medical practice* (accessed 17 January 2022), <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/domain-3---communication-partnership-and-teamwork#paragraph-33> paragraphs 33, <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/domain-4---maintaining-trust#paragraph-65> 65, <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/domain-4---maintaining-trust#paragraph-68> 68
- 24 If a patient has previously asked you not to share personal information about their condition or treatment with those close to them, you should respect their wishes. While doing so, you must do your best to be considerate, sensitive and responsive to those close to the patient, giving them as much information as you can.
- 25 The following provide information on where people can find help and support following a bereavement:

England: <https://www.gov.uk/after-a-death/bereavement-help-and-support?step-by-step-nav=4f1fe77d-f43b-4581-baf9-e2600e2a2b7a>

Northern Ireland: <https://www.nidirect.gov.uk/articles/who-tell-about-death>

Scotland: <https://www.mygov.scot/bereavement-support>

Wales: <https://www.citizensadvice.org.uk/wales/family/death-and-wills/what-to-do-after-a-death/>
- 26 General Medical Council (2010) *Treatment and care towards the end of life: good practice in decision making* (accessed 17 January 2022), <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/treatment-and-care-towards-the-end-of-life> paragraph 84
- 27 This does not include adverse incidents that may result in harm but have not yet done so – the patient must be told about these events and they must be reported in line with this guidance.
- 28 General Medical Council (2013) *Good medical practice* (accessed 17 January 2022), <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/domain-2---safety-and-quality#paragraph-23> paragraph 23
- 29 <https://www.england.nhs.uk/patient-safety/report-patient-safety-incident/> NHS England Report a patient safety incident (accessed 17 January 2022)
- 30 The LFPSE service was launched in July 2021 and will eventually replace the NRLS. During the transition period professionals will need to identify which system their organisation is using to report incidents. Further information on the LFPSE service is available on NHS England and Improvement's website.
- 31 The MHRA provides guidance for healthcare professionals, patients and the public on reporting adverse incidents with medicines and medical devices to the Yellow Card scheme.

- 32 New medicines and vaccines that are under additional monitoring may be marked with an inverted black triangle symbol (▼). The symbol appears in the British National Formulary (BNF), summaries of product characteristics, patient information leaflets and elsewhere.
- 33 Healthcare Improvement Scotland (2019) *Learning from adverse events through reporting and review: A national framework for Scotland* (accessed 17 January 2022)
- 34 Health and Social Care Board (Northern Ireland) *Procedure for the Reporting and Follow up of Serious Adverse Incidents* (accessed 17 January 2022)
- 35 Registered providers in England are required to notify the CQC about certain incidents. For guidance see CQC's information for providers on Notifications.
- 36 General Medical Council (2012) <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/raising-and-acting-on-concerns> *Raising and acting on concerns about patient safety* (accessed 17 January 2022)
- 37 Nursing and Midwifery Council (2018) www.nmc.org.uk/standards/guidance/raising-concerns-guidance-for-nurses-and-midwives *Raising concerns: guidance for nurses, midwives and nursing associates* (accessed 17 January 2022)
- 38 A fitness to practise panel is likely to consider a more serious sanction if there is evidence of a failure to raise a concern, or of an attempt to cover up.
- 39 Nursing and Midwifery Council (2018) www.nmc.org.uk/standards/code/ *The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates* (accessed 17 January 2022), section 23
- 40 General Medical Council (2013) *Good medical practice* (accessed 17 January 2022), <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/domain-2----safety-and-quality#paragraph-22> paragraphs 22 - 23
- 41 General Medical Council (2012) <https://prodsitecore.gmc-uk.org/registration-and-licensing/managing-your-registration/revalidation/guidance-on-supporting-information-for-appraisal-and-revalidation> *Supporting information for appraisal and revalidation* (accessed 17 January 2022), p8
- 42 The Nursing and Midwifery Council provides guidance on revalidation.
- 43 Nursing and Midwifery Council (2018) <https://www.nmc.org.uk/code> *The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates* (accessed 17 January 2022), sections 16.6 and 25.2
- 44 General Medical Council (2012) <https://prodsitecore.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/leadership-and-management-for-all-doctors> *Leadership and management for all doctors* (accessed 17 January 2022)
- 45 Care Quality Commission (2021) *The duty of candour: guidance for providers* (accessed 17 January 2022)
- 46 Scottish Government (2018) *Organisational duty of candour: guidance* (accessed 17 January 2022)

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Information Governance Policy

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1. INTRODUCTION

Information is a vital asset, both in terms of the clinical management of patients and the efficient management of services and resources. It plays a key part in corporate governance, service planning and performance management.

It is therefore of paramount importance to ensure that information is efficiently managed and that appropriate policies, procedures and management accountability provide a robust governance framework for information management.

1.1 PURPOSE

The purpose of this document is to provide guidance to all Health & Social Care (HSC) Trust staff on Information Governance compliance. Information Governance sets out the protocol for handling information in a confidential and secure manner to appropriate ethical and quality standards within the HSC.

The aim of this document is:

- To maximise the value of the Trust assets by ensuring that data is:
 - held securely and confidentially;
 - obtained fairly and lawfully;
 - recorded accurately and reliably;
 - used effectively and ethically; and
 - shared and disclosed appropriately and lawfully.

2. SCOPE OF POLICY

This policy applies to all individuals, whether employed or contracted to work for the Southern Health and Social Care Trust (the Trust) including:

- bank/agency/temporary;
- volunteer;
- student;
- secondees; and
- contractors (including Consultants and Field Experts (working in or on behalf of the Trust))

Reference to “information governance” in this document shall also mean reference to the following areas:

- Access to information (Freedom of Information Act 2000 and Subject Access Requests and Environmental Information Regulations);
- Data Protection Act 2018;
- Information Security assurance;
- Data Quality assurance;
- Secondary Use Assurance;

- Records Management compliance; and
- Confidentiality and the common law Duty of Confidentiality.

This policy applies to all processing activities on information held in any format and type such as (but is not limited to):

- patient/client/service user information;
- staff and personnel information;
- organisation, business and operational information;
- research, audit and reporting information.

All staff, whether employed or contracted, should be aware of their individual responsibilities for the maintenance of confidentiality, data protection, information security management and data quality (as set out in the contract of employment). Failure to maintain confidentiality may lead to disciplinary action, up to and including dismissal. Staff should also be aware of the [Code of Practice on Protecting the Confidentiality of Service User Information published by the Department of Health \(NI\)](#)

3.0 ROLES AND RESPONSIBILITIES

3.1 THE TRUST

The Trust Board is responsible for ensuring that the information governance function is appropriately managed in a manner which complies with relevant legislation and standards and that an Information Governance Framework is in place. The Trust undertakes the role of the Data Controller.

3.2 THE CHIEF EXECUTIVE

The Chief Executive as the Accountable Officer has overall accountability and responsibility for Information Governance in the Trust and is required to provide assurance through the Statement of Internal Control that all risks, including those relating to information, are effectively managed and mitigated.

3.3 PERSONAL DATA GUARDIAN

The Medical Director and the Director of Children's and Young People Services have been appointed as the Trust Personal Data Guardians (PDGs). The PDG:

- ensures that the Trust satisfies the highest practical standards for handling personal identifiable information;
- actively supports work to facilitate and enable information sharing, and advises on options for lawful and ethical processing of information as required;
- has a strategic role, which involves representing and championing information governance requirements and issues at Trust or management team level and,

where appropriate, at a range of levels within the organisation's overall governance framework.

3.4 THE SENIOR INFORMATION RISK OWNER

The Director of Performance and Reform is the Senior Information Risk Owner (SIRO). The SIRO has overall responsibility for managing information risk across the Trust and is the owner of the Information Asset Register. The SIRO is a member of the Senior Management Team and the Trust Board and provides written advice to the Accounting Officer on the content of the Statement of Internal Control in regard to information risk. See **Appendix B - Key Responsibilities of the Senior Information Risk Owner (SIRO)** for list of key responsibilities.

The SIRO is responsible to the Trust Board for ensuring that all Information risks are recorded and mitigated where applicable. The SIRO is responsible for ensuring that all record management issues (including electronic media) are managed in accordance with the Trust's Information Governance and Records Management Policies.

3.5 INFORMATION GOVERNANCE LEAD

The Assistant Director of Informatics leads on the Information Governance Programme and provides assurance to the SIRO.

3.6 HEAD OF INFORMATION GOVERNANCE & DATA PROTECTION OFFICER (DPO)

The Head of Information Governance & DPO is responsible for ensuring compliance on a day to day basis:

- to review and update Information Governance policy in line with local and national requirements;
- ensure that line managers are aware of the requirements of Information Governance and associated policies;
- monitor and report on compliance with Freedom of Information Act and Data Protection Act 2018;
- assess risk and advise on information incidents and data breaches to ensure consistent reporting to regulatory bodies;
- achieve compliance with the Information Management Controls Assurance Standard (IM CAS); and
- provide advice and guidance on Information Governance issues with targeted training as appropriate.

3.7 IT CYBER SECURITY MANAGER

The IT Cyber Security Manager is responsible for IT security within the Trust by

- providing advice on the design and implementation of IT security aspects of IT solutions;

- providing technical leadership on all aspects of the Trust's ICT security infrastructure ensuring Best Practice standards are adhered to;
- investigating ICT security breaches and incidents and where necessary reporting Network Security Systems breaches to the Competent Authority and;
- ensuring ICT security services operational documentation is up-to-date.

3.8 INFORMATION ASSET OWNER

Information Asset Owners (IAOs) are directly accountable to the SIRO and must provide assurance that information risk is being managed effectively in respect of the information assets that they 'own'.

The IAO role is to understand and assess risks to the information assets they 'own' and to provide assurance to the SIRO (via Head of Information Governance) on the security and use of those assets. They will ensure that all threats, vulnerabilities and impacts are properly assessed and included in their Directorate Risk Register and where necessary that these are escalated to the Corporate Risk Register by the Director.

See **Appendix C - Key Responsibilities of the IAO** - for a list of key responsibilities for Information Asset Owners.

3.9 ALL STAFF

It is the responsibility of each employee to adhere to this policy and all supporting Information Governance policies, procedures and guidance.

All staff members are required to undertake mandatory information governance e-learning modules. Information governance training is required to be undertaken on a three yearly basis.

All staff must ensure that they use the Trust's Information Technology systems appropriately, and adhere to the acceptable use of Information, Communication, Technology (ICT) Policy.

3.10 INFORMATION GOVERNANCE FORUM

The Information Governance Forum has responsibility for overseeing the implementation of the Information Governance Strategy, Information Governance Framework, and the Information Governance Policy. The Forum is also responsible for the annual Information Management Assurance Checklist (IMAC) assessment and oversees and monitors the implementation of the IMAC Action Plan.

4.0 KEY POLICY STATEMENT

4.1 DEFINITIONS

Information Governance is the framework of law and best practice that regulates the manner in which information (including information relating to and identifying individuals) is managed, i.e. obtained, handled, used and disclosed.

4.2 POLICY STATEMENT

The Trust's Information Governance Policy sets out a framework of Policies and Procedures, Standards and Guidance to cover all aspects of Information Governance which are aligned to the Trust's Information Governance Framework and the Regional Information Management Assurance Checklist. The Trust's performance is mandated by the Information Management Assurance Checklist Guidance (IMAC), is reported annually to the Department of Health (DoH) and forms a part of the Trust's assurance processes.

4.3 LEGISLATIVE COMPLIANCE, RELEVANT POLICIES, PROCEDURES AND GUIDANCE

Information Governance provides a consistent way for employees to deal with the many different information handling requirements.

The Trust, as the "legal person" and Data Controller for the purposes of the Data Protection Act 2018 will ensure that all personal data it holds is controlled and managed in accordance with the principles of the Data Protection Act 2018, the UK General Data Protection Regulations, European Convention of Human Rights (Article 8), Human Rights Act 1998 and common law Duty of Confidentiality. This is set out in the Trust's Data Protection Policy and Records Management Policy.

4.4 PRIVACY IMPACT ASSESSMENTS

For new service implementation or service change, the Project lead must liaise with the Head of Information Governance regarding the completion of a Data Protection Impact Assessment (DPIA). This assessment will consider privacy aspects and mitigate against any potential risk to personal/personal sensitive information.

4.5 INFORMATION GOVERNANCE DATA INCIDENTS

Head of Information Governance must be notified immediately of all information security incidents involving the unauthorised disclosure of personal identifiable data/information for consideration of any necessary actions.

A key function of the Information Governance Forum is to monitor and review untoward occurrences and incidents relating to Information Governance and to ensure that effective remedial and preventative action is taken.

Information incident reporting is in line with the Trust's overall incident reporting processes.

5.0 IMPLEMENTATION & MONITORING OF THIS POLICY

The implementation of this Policy is evidenced and monitored through the agenda of the Information Governance Committee. The Information Governance Committee agenda and the Information Management Controls Assurance Standard action plan (IM CAS) encompass the objectives of this policy and Data Protection Act principles.

5.1 DISSEMINATION

This policy will be disseminated via the Policy Scrutiny Committee in line with Trust procedure. It is the responsibility of all Managers to ensure that staff have access to this policy.

5.2 RESOURCES TRAINING AND EDUCATION

All staff should receive basic information governance training appropriate to their role through either face to face training or an eLearning package on the Trust's eLearning platform.

Information Governance Training is incorporated into the Trust's Mandatory Training programme. It is a **mandatory** requirement for all staff in the Trust, without exception to undertake Data Protection training which is appropriate to their role. This includes staff on temporary contracts, secondments, agency staff, students and volunteers.

Different levels of training will be delivered:

- All staff to receive Information Governance awareness training as part of their corporate induction programme.
- Departmental induction must ensure that staff are made fully aware of all Information Governance policies and procedure.
- Practitioner level training e.g. SIRO (Senior Information Risk Owner), Personal Data Guardian, Information Asset Owners and Information Governance Team.

6.0 REVIEW AND MONITORING

This Policy will be reviewed in line with the Trust's Information Governance Strategy Incorporating Framework and monitoring process to ensure compliance with

legislation and the requirements of the Information Management Controls Assurance Standard.

7.0 EVIDENCE BASE

- DHSSPS Information Management Controls Assurance Standard (2013);
- Southern Health & Social Care Trust Information Governance Strategy Incorporating Framework 2014/2015 – 2016/2017;
- IT Security Policy
- Records Management Policy
- Data Protection Act Policy
- Data Quality Policy

8.0 CONSULTATION PROCESS

The consultation process will be in line with the Trust's procedure for consultation on the introduction of new/revision of existing Trust policy.

9.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out.

The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact. ☒

10.0 ALTERNATIVE FORMATS

This document can be made available on request in alternative formats, e.g. plain English, Braille, disc, audiocassette and in other languages to meet the needs of those who are not fluent in English.

APPENDICES

Appendix A – Information Risk/Roles and Responsibilities

Appendix B – Key Responsibilities of the SIRO

Appendix C – Key Responsibilities of the IAO

Appendix A - Information Risk/Roles and Responsibilities

Accountable Officer
Chief Executive

- *Receive advice*
- *Statement of Internal Control*
- *Receive SIRO Annual Report*
- *Receive Regular reporting*

SIRO
**Director of Performance
and Reform**

- *Own Risk Policy/Review*
- *Own Risk Assessment Process*
- *Information Risk Action Plan*
- *Advise on Information Risk Issues*
- *Receive risk reviews*
- *Provide regular advice/assurance*
- *Undertake training.*

IAO

IAO

IAO

- *Authorise Information Asset Transfers*
- *Provide/receive regular advice*
- *Create/maintain own IA register*
- *Conduct biannual review of owned assets*
- *Provide annual written Risk Assessment to SIRO via HOS IG*
- *Authorise requests for access*
- *Undertake Training*

Appendix B - Key Responsibilities of the Senior Information Risk Owner (SIRO)

- To oversee the development of an Information Risk Policy, and a Strategy for implementing the policy within the existing Information Governance Strategy Incorporating Framework.
- To take ownership of the risk assessment process for information risk, including review of the annual information risk assessment to support and inform the Statement of Internal Control.
- To review and agree an action plan in respect of identified information risks via the Information Governance Forum.
- To ensure that the Trust's approach to information risk is effective in terms of resource, commitment and execution and that this is communicated to all staff.
- To provide a focal point for the resolution and/or discussion of information risk issues.
- To ensure the Board is adequately briefed on information risk issues.
- To advise the Chief Executive and the Trust Board on information risk management strategies and provide periodic reports and briefings on the Information Governance annual programme of work.

Appendix C - Key Responsibilities of the Information Asset Owners (IAO)

- To understand and address risks to the information assets they 'own' and provide assurance to the SIRO on the security and use of these assets (understands the Trust's plans to achieve and monitor the right Information Governance culture across the Trust.
- IAO's will take appropriate actions to:
 - Know what information they hold,
 - Know who has access to the information and why,
 - Ensure the confidentiality, integrity, and availability of all information that their system creates, receives, maintains, or transmits and protect against any reasonably anticipated threats or hazards to the security or integrity of such information.
 - Ensure that information assets are considered within the Directorate Risk Register assessment process on a quarterly basis
 - provide assurance to the SIRO on an annual basis in respect of security of information assets
 - Approve and oversee the disposal of information of the asset when no longer needed in line with ICT Procedure and or/the Trust Retention & Disposal Schedule.

Wamsley, Chris

From: Cardwell, David
Sent: 21 October 2022 14:12
To: Wamsley, Chris
Subject: FW: RE DATix and Complaints

From: Carroll, Kay [Personal Information redacted by the USI]
Sent: 24 May 2022 00:42
To: Cardwell, David [Personal Information redacted by the USI]; Farrell, Roisin
[Personal Information redacted by the USI] Connolly, Carly [Personal Information redacted by the USI]; Wamsley, Chris
[Personal Information redacted by the USI]
Subject: RE DATix and Complaints

Dear all

Could someone please send through Datix and Complaints for Cardiology across both sites March and April
Sorry need for Governance meeting on Thursday am

Thanks
Kay

Kay Carroll
Head Of Service [Personal Information redacted by the USI]

SOUTHERN HEALTH & SOCIAL CARE TRUST		
RISK ASSESSMENT FORM		Risk ID No
Directorate:	Facility/Department/Team:	Date:
Where is this being carried out? (e.g. Trust premises/home of client/staff/ private nursing home etc)		Objective(s) i.e. Corporate, Legislative requirements etc.:
Risk Title: (Threat to achievement of objective)		
Outline the potential for harm: <i>(Consider injury to client, staff, litigation, etc)</i>		
Description of Risk: <i>(Describe the risk being assessed identifying who is at risk e.g. patient/staff/other care provider)</i>		

Summary of current control measures: (Consider equipment, staffing, environment, policy/procedure, training, documentation, information - this list is not exhaustive).

Are these controls: (a) Effective or (b) Require Further Action (if [b], complete Action Plan)

Please list control measures considered but discounted and why (where appropriate):

Initial Assessment of Risk	Likelihood e.g. Likely	Consequence/ Impact e.g. Moderate	Risk Rating VLow(Green), Low(Yellow), Moderate (Amber) or High(Red)	
ACTION PLAN OF FURTHER CONTROL MEASURES REQUIRED (risk treatment):				
Action/Treatment	Action Lead	Start Date	Target Date	Progress/Review Date
Date of first review (to be determined by risk rating)				
Predicted Risk Assessment once all control measures are implemented. (Residual Risk rating)	Likelihood e.g. Likely	Consequence/ Impact e.g. Moderate	Risk Rating VLow(Green), Low(Yellow), Moderate (Amber) or High(Red)	

ANTICIPATED RESOURCE IMPLICATIONS (details and cost)				£
None				
Funding identified?	Yes	No	N/A	Source of funding

Action	Date	By Whom (PRINT & SIGN)
To be managed by Facility/Department Team Manager/Leader		
Referred to Divisional Risk Register		
Referred to Directorate Risk Register		
Shared with another Team/Directorate Risk Committee for information/consideration		
Referred to Trust Risk Management Forum		
Referred to Corporate Risk Register		
Referred to Board Assurance Framework		

Risk Assessor(s)		
Name (PRINT & SIGN)	Designation	Date
Manager		
Name (PRINT & SIGN)	Designation	Date

MONITORING			
Summary of current position			
Current Risk Rating	Likelihood e.g. Likely	Consequence/ Impact e.g. Moderate	Risk Rating VLow(Green), Low(Yellow), Moderate (Amber) or High(Red)
Name (PRINT & SIGN)	Designation		Date of Review

Summary of current position

<u>Current</u> Risk Rating	Likelihood	Consequence / Impact	Risk Rating VLow(Green), Low(Yellow), Moderate (Amber) or High(Red)
Name (PRINT & SIGN)	Designation		Date of Review

Summary of current position

<u>Current</u> Risk Rating	Likelihood	Consequence/ Impact	Risk Rating VLow(Green), Low(Yellow), Moderate (Amber) or High(Red)
Name (PRINT & SIGN)	Designation		Date of Review

LIKELIHOOD	CONSEQUENCE (POTENTIAL IMPACT)				
	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
(5) Almost Certain (will undoubtedly recur, a persistent issue) 1:10					
(4) Likely (will probably recur, not a persistent issue) 1:100					
(3) Possible (may recur occasionally) 1:1,000					
(2) Unlikely (do not expect it to happen again) 1:10,000					
(1) Rare (can't believe it will ever happen again) 1:100,000					

Green Risks (VLow)

Identified risks which fall in the green area are deemed as acceptable risks and require no immediate action, but must be monitored regularly. These risks must be entered onto the local Risk Register. A full risk assessment form does not need to be completed for such risks.

Yellow Risks (Low)

Identified risks which fall in the yellow area are deemed Low risk to the Trust and require action to reduce risk to an acceptable level. Responsibility for taking action would normally remain at a local level within the appropriate Directorates / Programmes / Service Areas and be entered on the Team / Service Risk Register. Where these risks cannot be managed locally they should be forwarded to the appropriate Divisional Governance Forum for consideration for further local action, resourcing, acceptance on to the Divisional Risk Register. Low risks must be entered on the local risk register and where appropriate the Divisional Risk Register for information and monitoring purposes. A full risk assessment form does not need to be completed for such risks.

Amber Risks (Moderate)

Identified risks which fall in the amber area are deemed Moderate risk to the Trust and require prompt action to reduce the risk to an acceptable level. When risks cannot be reduced locally they should be submitted to the Divisional Governance Forum for consideration for recommended action, i.e. further local action, resourcing or acceptance. Where these risks cannot be managed within the Division/ they should be referred to the Directorate Risk Register for consideration and/or addition to the Corporate Risk Register. These risks must be entered on the local risk register and where appropriate the Divisional/Directorate Risk Register. A full risk assessment form needs to be completed for such risks.

Red Risks (High)

Identified risks which fall in the red area are deemed High risk to the Trust and must be reported to the appropriate Director and Chief Executive. Immediate action is required to reduce the level of risks to an acceptable level. The appropriate Director will ensure the implementation of a time monitored action plan with regular reports to the Chief Executive and Governance Committee. These risks will be entered on to the Divisional/Directorate, and if appropriate the Corporate Risk Register(s) for monitoring by the SMT Governance Steering Group. Where the identified risks represent significant gaps in controls/assurances they will be escalated by the SMT Governance Steering Group to the Board Assurance Framework. A full risk assessment form needs to be completed for such risks.

Figure 7 – Risk Impact/Consequence Table (5x5 Matrix)

CATEGORY

WIT-66076

Draft 0.1

CONSEQUENCE / IMPACT

	PEOPLE (Any person affected by an Incident: Patient/Client, Staff, User, Visitor or Contractor)	RESOURCES (Premises, money, equipment, Business interruption, problems with service provision)	ENVIRONMENT (Air, Land, Water, Waste management)	REPUTATION (Adverse publicity, Complaints, Legal/Statutory Requirements, Litigation)	QUALITY AND PROFESSIONAL STANDARDS (including Government priorities, targets and organisational objectives)
CATASTROPHIC	Incident that leads to one or more deaths	Severe organisation wide damage / loss of services / unmet need	Toxic release affecting off-site area with detrimental effect requiring outside assistance	National adverse publicity. DHSSPS executive investigation following an incident or complaint. Criminal prosecution.	Gross failure to meet external standards, priorities.
MAJOR	Permanent physical / emotional injuries / trauma / harm.	Major damage, loss of property / service / unmet need.	Release affecting minimal off-site area requiring outside assistance (fire brigade, radiation, protection service etc)	Local adverse publicity. External investigation or Independent Review into an incident / complaint. Criminal prosecution / prohibition notice.	Repeated failure to meet external standards.
MODERATE	Semi permanent physical / emotional injuries / trauma / harm (recovery expected within 1 year). Includes RIDDOR reportable incidents.	Moderate damage, loss of property / service / unmet need.	On site release contained by organisation.	Damage to public relations. Internal investigation (high level), into an incident / complaint. Civil action.	Repeated failure to meet internal standards or follow protocols.
MINOR	Short-term injury / harm. Emotional distress. (Recovery expected within days / weeks.)	Minor damage, loss of property / service / unmet need.	On site release contained by organisation.	Minimal risk to organisation. Local level internal investigation into an incident / complaint. Legal challenge.	Single failure to meet internal standards or follow protocol.
INSIGNIFICANT	No injury / harm or no intervention required	No damage or loss, no impact on service. Insignificant unmet need.	Nuisance release.	Minimal risk to organisation, Informal complaint	Minor non compliance.

Appendix 2

Governance & Patient Safety meeting
Agenda / Record of meeting

M&M team		Date		Time	
Venue					

Estimated time

1. Welcome, Attendance, Apologies Received by Chair
 Note:
2. Review of last G&PS meeting - Outstanding Issues
 Note:
 Action(s):
3. Mortality & Morbidity Review – RM&MRs on NIECR.
 a. Verification of last meeting report
 Note:
4. Safety Graphs
 a. Crash Call Review
 b. Safety Improvement graphs: e.g. HCAs, Falls, VTE review, avoidable pressure ulcers
 Note:
 Action(s):
5. Local incident themes : Ward, Unit issues
 Note:
 Action(s):
6. Pharmacy issues, incidents and medicine/safety alerts
 a. *Insert list of documents discussed*
 Note:
 Action(s):
7. Shared learning from Complaints / SAs / other M&M meeting / any other source.
 a. *Insert list of documents discussed*
 Note:
 Action(s):
8. Shared learning from Litigation / Coroner Cases/PM reports
 a. *Insert list of documents discussed*
 Note:
 Action(s):
9. Safety Alerts and Circulars– NICE, NCEPOD, DHSS, HSC (SGSD), HSCB, PHA, BHSCT.
 a. *Insert list of documents discussed*
 Note:
 Action(s):
10. Local Audit reports (Specialty Specific)
 a. *Insert list of documents discussed*
 Note:
 Action(s):

11. Consultant Outcome data - NCEPOD / National / Specialty

Note:
Action(s):

12. A.O.B.

Note:
Action(s):

13. Date of Next Meeting

Clinical & Social Care Governance Officer
Band 5

Acute Services



Working together



Excellence



Openness & Honesty



Compassion



Quality Care - for you, with you

JOB DESCRIPTION

JOB TITLE	Clinical & Social Care Governance Officer
BAND	Band 5
DIRECTORATE	Acute
INITIAL LOCATION	Craigavon Area Hospital
REPORTS TO	Acute Clinical and Social Governance Coordinator
ACCOUNTABLE TO	Director of Acute Services

JOB SUMMARY

The post holder will play a key role in supporting the Acute Directorate Clinical and Social Care Governance (CSCG) Coordinator to provide a high quality clinical and social care service to the Directorate.

This post holder will assist the CSCG Coordinator and Acute Assistant Directors in the areas of clinical quality, patient safety and risk management with their division.

This role will include the development and management of CSCG processes to facilitate patient/client safety initiatives, audit, complaints, SAI, inspection action plans completion, ensure all learning is shared, incident and risk management.

The post holder will be required to liaise with numerous departments, staff / patients / clients / relatives in order to fulfil CSCG functions.

The role will incorporate the production and analysis of reports from the CSCG information systems for sharing with various internal/external audiences.



KEY DUTIES / RESPONSIBILITIES

- ***Audit, Effectiveness and Research.***

1. Work collaboratively with Assistant Director's operational team to improve the assurance of services provided and assist in implementation of quality improvement initiatives.
2. Undertake a variety of activities related to clinical audit including data collection, data retrieval, use of data collection tools, data input, data analysis, reporting of findings
3. Follow up of audits to ensure appropriate actions plans and recommendations are developed and implemented in consultation with appropriate senior manager/clinician.
4. Support, advise and work with staff to develop quality audits
5. Contribute to the preparation of data for discussion and review by clinical and senior management teams.

- ***Incident and Risk Management***

1. Work collaboratively with the Acute Governance Managers and operational teams to improve the control of incident reporting, investigations and trends within their division.
2. Monitor of incidents to ensure that those within the threshold for Serious Adverse Incident Screening are referred for review.
3. Assist in the correlation of information to facilitate a streamlined screening process of all incidents which reach the threshold.
4. Monitor incidents within the division to ensure timely completion and ongoing compliance with regionally agreed incident review timeframes.
5. Monitor incident themes within the division to assist with proactively addressing risks.
6. At request from Assistant Directors or CSCG Coordinator will assist in the development of timelines for complex incidents.

- ***Action Plan Facilitation and Project work.***

1. Work collectively with Complaints Officers and Acute Governance Managers to ensure a timely development of action plans following complaint responses and Serious Adverse Incident Investigations.
2. Assist operational teams in facilitating action plans to address recommendations from complaints, external reviews and Serious Adverse Incidents to improve quality, safety and service user experience with Southern Trust services.
3. Monitor and ensure timely completion of action plans in line with Health and Social Care Board.



4. Ensure that all Serious Adverse Incident action plans are reviewed operationally on an annual basis to ensure ongoing compliance with the recommendations.
5. Support operational teams through completion of specific project work generated from daily operational practices to improve performance and provide assurance.

- ***Distribution Learning***

1. To work collaboratively with operational teams to facilitate a timely review of incidents, complaints, etc. to develop early learning to be shared and implemented into practice to improve quality and safety.
2. Work with operational team to develop an effective process to ensure learning is shared effectively throughout the division.
3. Liaison with Complaints office and Governance managers to provide assurance surrounding effective sharing of learning. To all relevant professional groups/teams from Serious Adverse Incidents,

- ***General***

1. The post holder will have excellent communication and empathetic skills having appreciation for the sensitive and complex processes with CSCG.
2. The post holder will provide significant support to the Directorate Governance Coordinator in challenging clinical/operational teams to ensure that identified areas requiring improvement in relation to patient/client safety in CSCG are addressed.
3. Monitor the use of CSCG information system, liaising with the systems manager, corporate office to ensure standardisation, high quality information and data accuracy.

RAISING CONCERNS - RESPONSIBILITIES

1. The post holder will promote and support effective team working, fostering a culture of openness and transparency.
2. The post holder will ensure that they take all concerns raised with them seriously and act in accordance with the Trust's 'Your Right to Raise a Concern (Whistleblowing)' policy and their professional code of conduct, where applicable.

PERSONAL AND PUBLIC INVOLVEMENT RESPONSIBILITIES (PPI)

Promote and support the implementation of the Trust's PPI Strategy and ensure all staff are aware of their responsibilities as appropriate to their job role.



GENERAL REQUIREMENTS

The post holder will be required to:

1. Ensure the Trust's policy on equality of opportunity is promoted through his/her own actions and those of any staff for whom he/she has responsibility.
2. Co-operate fully with the implementation of the Trust's Health and Safety arrangements, reporting any accidents/incidents/equipment defects to his/her manager, and maintaining a clean, uncluttered and safe environment for patients/clients, members of the public and staff.
3. Adhere at all times to all Trust policies/codes of conduct, including for example:
 - Smoke Free policy
 - IT Security Policy and Code of Conduct
 - standards of attendance, appearance and behaviour
4. Contribute to ensuring the highest standards of environmental cleanliness within your designated area of work.
5. Co-operate fully with regard to Trust policies and procedures relating to infection prevention and control.
6. All employees of the Trust are legally responsible for all records held, created or used as part of their business within the Trust including patients/clients, corporate and administrative records whether paper-based or electronic and also including emails. All such records are public records and are accessible to the general public, with limited exceptions, under the Freedom of Information Act 2000 the Environmental Information Regulations 2004, the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. Employees are required to be conversant with the [org name] policy and procedures on records management and to seek advice if in doubt.
7. Take responsibility for his/her own ongoing learning and development, in order to maximise his/her potential and continue to meet the demands of the post.
8. Represent the Trust's commitment to providing the highest possible standard of service to patients/clients and members of the public, by treating all those with whom he/she comes into contact in the course of work, in a pleasant, courteous and respectful manner.



This Job Description will be subject to review in the light of changing circumstances and is not intended to be rigid and inflexible but should be regarded as providing guidelines within which the individual works. Other duties of a similar nature and appropriate to the grade may be assigned from time to time.

It is a standard condition that all Trust staff may be required to serve at any location within the Trust's area, as needs of the service demand.





Quality Care - for you, with you

PERSONNEL SPECIFICATION

JOB TITLE AND BAND Clinical & Social Care Governance Officer
Band 5

DEPARTMENT / DIRECTORATE Acute Governance
Acute Services

SALARY

HOURS 37.5

Ref No: <to be inserted by HR>

<Month & Year>

Notes to applicants:

1. You must clearly demonstrate on your application form under each question, how you meet the required criteria as failure to do so may result in you not being shortlisted. You should clearly demonstrate this for both the essential and desirable criteria.
2. Shortlisting will be carried out on the basis of the essential criteria set out in Section 1 below, using the information provided by you on your application form. Please note the Trust reserves the right to use any desirable criteria outlined in Section 3 at shortlisting. You must clearly demonstrate on your application form how you meet the desirable criteria.
3. Proof of qualifications and/or professional registration will be required if an offer of employment is made – if you are unable to provide this, the offer may be withdrawn.

ESSENTIAL CRITERIA

SECTION 1: The following are **ESSENTIAL** criteria which will initially be measured at shortlisting stage although may also be further explored during the interview/selection stage. You should therefore make it clear on your application form whether or not you meet these criteria. Failure to do so may result in you not being shortlisted. The stage in

Factor		Method of Assessment
Experience	1) Demonstrate experience of working proactively with effective planning, organisation and prioritisation skills in order to meet demands and deadlines. 2) Demonstrate experience of working with effectively with multiple teams/services to obtain improved outcomes.	Shortlisting by Application Form



	3) Demonstrate experience of investigating, extracting learning, developing and delivering on recommendations to improve safety/quality within a governance process. 4) Demonstrate experience and proficiency in the use of Microsoft office products including Word, Excel, and PowerPoint.	
Qualifications/ Registration	1) Relevant degree or recognised professional qualification or equivalent/higher qualification AND 1 years' experience in a clerical/ administrative/ clinical role at Band 4 level or above. OR HNC/HND or equivalent/higher qualification in a relevant field AND 2 years' experience in a clerical/ administrative/ clinical role to include at least 1 year at band 4 level or above. OR 5 years' experience in a clerical/ administrative/ clinical role at Band 4 level.	Shortlisting by Application Form
Other	Hold a current full driving licence which is valid for use in the UK and have access to a car on appointment. <i>This criteria will be waived in the case of applicants whose disability prohibits driving but who have access to a form of transport approved by the Trust which will permit them to carry out the duties of the post.</i>	Shortlisting by Application Form
SECTION 2: The following are ESSENTIAL criteria which will be measured during the interview/ selection stage:		
Skills / Abilities	1) Ability to collate, analyse and present information. 2) Effective Communications skills to meet the needs of the post in full, including the ability to empathise, listen and de-escalate emotional situations.	Interview



	3) Effective planning and organisational skills with an ability to prioritise own workload. 4) Ability to work using own initiative as well as part of a team. 5) Ability to identify solutions to problems and implement them effectively. 6) Ability to work to tight timescales whilst meeting targets	
Knowledge	Ability to demonstrate a basic understanding of the SHSCT Complaints Policy/Process, the Serious Adverse Incident (SAI) process, audit and Root Cause and System analysis models.	Interview

DESIRABLE CRITERIA

criteria to ensure files are manageable. You should therefore make it clear on your application

Factor		Method of Assessment
Experience	1) Experience of participating in or providing support to patient/client/staff safety projects/initiatives Experience of working in a Clinical and Social Care Governance or Professional Governance Role.	Shortlisting by Application Form

As part of the Recruitment & Selection process it may be necessary for the Trust to carry out an Enhanced Disclosure Check through Access NI before any appointment to this post can be confirmed.

Successful applicants may be required to attend for a Health Assessment

THE TRUST IS AN EQUAL OPPORTUNITIES EMPLOYER





HSC Value	What does this mean?	What does this look like in practice? - Behaviours
W Working Together	We work together for the best outcome for people we care for and support. We work across Health and Social Care and with other external organisations and agencies, recognising that leadership is the responsibility of all.	• I work with others and value everyone's contribution • I treat people with respect and dignity • I work as part of a team looking for opportunities to support and help people in both my own and other teams • I actively engage people on issues that affect them • I look for feedback and examples of good practice, aiming to improve where possible
Compassion	We are sensitive, caring, respectful and understanding towards those we care for and support and our colleagues. We listen carefully to others to better understand and take action to help them and ourselves.	• I am sensitive to the different needs and feelings of others and treat people with kindness • I learn from others by listening carefully to them • I look after my own health and well-being so that I can care for and support others
Excellence	We commit to being the best we can be in our work, aiming to improve and develop services to achieve positive changes. We deliver safe, high-quality, compassionate care and support.	• I put the people I care for and support at the centre of all I do to make a difference • I take responsibility for my decisions and actions • I commit to best practice and sharing learning, while continually learning and developing • I try to improve by asking 'could we do this better?'
Openness & Honesty	We are open and honest with each other and act with integrity and candour.	• I am open and honest in order to develop trusting relationships • I ask someone for help when needed • I speak up if I have concerns • I challenge inappropriate or unacceptable behaviour and practice

All staff are expected to display the HSC Values at all times



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#teamSHSCT
#bettertogether

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Southern Health
and Social Care Trust
Quality Care - for you, with you

‘YOUR RIGHT TO RAISE A CONCERN’ (WHISTLEBLOWING)

SOUTHERN HSC TRUST POLICY ON RAISING CONCERNS

Lead Policy Author & Job Title:	Regional HSC Policy
Directorate responsible for document:	HR & Organisational Development
Issue Date:	01 April 2018
Review Date:	01 April 2021

Policy Checklist

Policy name:	'Your Right to Raise a Concern' (Whistleblowing)
Lead Policy Author & Job Title:	Head of Employee Relations
Director responsible for Policy:	Vivienne Toal
Directorate responsible for Policy:	HR & Organisational Development
Equality Screened by:	Lynda Gordon, Head of Equality, Sarah Moore, HR Manager and Lesley Dowey, HR Advisor on 03/01/2018
Trade Union consultation?	Yes ☒ No ☐
Policy Implementation Plan included?	Yes ☐ No ☒
Date approved by Policy Scrutiny Committee:	
Date approved by SMT:	
Policy circulated to:	Directors, Assistant Directors, Heads of Service for onward distribution to line managers/staff, Global email, Staff Newsletter
Policy uploaded to:	SharePoint and Trust Intranet

Version Control

Version:	Version 1_0		
Supersedes:	N/A		
Version History			
Version	Notes on revisions/modifications and who document was circulated or presented to	Date	Lead Policy Author
N/A	N/A	N/A	N/A

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1. Introduction

All of us at one time or another may have concerns about what is happening at work. The Southern Health & Social Care Trust (the Trust) wants you to feel able to raise your concerns about any issue troubling you with your managers at any time. It expects its managers to listen to those concerns, take them seriously and take action to resolve the concern, either through providing information which gives assurance or taking action to resolve the concern. However, when the concern feels serious because it is about a possible danger, professional misconduct or financial malpractice that might affect patients, colleagues, or the Trust itself, it can be difficult to know what to do.

The Trust recognises that many issues are raised by staff and addressed immediately by line managers – this is very much encouraged. This policy and procedure is aimed at those issues and concerns which are **not resolved, require help to get resolved or are about serious underlying concerns.**

Whistleblowing refers to staff reporting suspected wrongdoing at work, for example, concerns about patient safety, health and safety at work, environmental damage or a criminal offence, such as, fraud.

You may be worried about raising such issues and may think it best to keep it to yourself, perhaps feeling it is none of your business or that it is only a suspicion. You may also feel that raising the matter would be disloyal to colleagues, to managers or to the organisation. It may also be the case that you have said something but found that you have spoken to the wrong person or raised the issue in the wrong way and are not sure what to do next.

Remember that if you are a healthcare professional you may have a professional duty to report a concern. **If in doubt, please raise it.**

2. Aims and Objectives

The Trust is committed to running the organisation in the best way possible. The aim of the policy is to promote a culture of openness, transparency and dialogue which at the same time:

- reassures you that it is safe and acceptable to speak up;
- upholds patient confidentiality;
- contributes towards improving services provided by the Trust;
- assists in the prevention of fraud and mismanagement;
- demonstrates to all staff and the public that the Trust is ensuring its affairs are carried out ethically, honestly and to high standards;
- provides an effective and confidential process by which you can raise genuine concerns so that patients, clients and the public can be safeguarded.

The Trust's roles and responsibilities in the implementation of this policy are set out at **Appendix A**.

3. Scope

The Trust recognises that existing policies and procedures which deal with conduct and behaviour at work (Disciplinary Procedure, Grievance Procedure, Maintaining High Professional Standards Framework, Conflict, Bullying & Harassment Policy, Complaints Procedure and the Accident/Incident Reporting Procedure) may not always be appropriate to extremely sensitive issues which may need to be handled in a different way.

This policy provides a procedure for all staff of the Trust, including permanent, temporary and bank staff, staff in training working within the Trust, independent contractors engaged to provide services, volunteers and agency staff who have concerns where the interests of others or of the organisation itself are at risk. **If in doubt - raise it!**

Examples may include:

- malpractice or ill treatment of a patient or client by a member of staff;

- where a potential criminal offence has been committed, is being committed or is likely to be committed;
- suspected fraud;
- breach of Standing Financial Instructions;
- disregard for legislation, particularly in relation to Health and Safety at Work;
- the environment has been, or is likely to be, damaged;
- a miscarriage of justice has occurred, is occurring, or is likely to occur;
- showing undue favour over a contractual matter or to a job applicant;
- research misconduct; or
- information on any of the above has been, is being, or is likely to be concealed.

If you feel that something is of concern, and that it is something which you think the Trust should know about or look into, you should use this procedure. If, however, you wish to make a complaint about your employment or how you have been treated, you should follow the Trust's Grievance procedure, Harassment at Work procedure or Working Well Together procedure which can be obtained from your manager. This policy complements professional and ethical rules, guidelines and codes of conduct and freedom of speech. It is not intended to replace professional codes and mechanisms which allow questions about professional competence to be raised. (However such issues can be raised under this process if no other more appropriate avenue is apparent).

4. Suspected Fraud

If your concern is about possible fraud or bribery the Trust has a number of avenues available to report your concern. These are included in more detail in the Trust's Anti-Fraud Policy & Fraud Response Plan and Anti-Bribery Policy and are summarised below.

Suspensions of fraud or bribery should initially be raised with the appropriate line manager but where you do not feel this is not appropriate the following officers may be contacted:

- Director of Finance, Procurement & Estates
Ms Helen O'Neill
- Fraud Liaison Officer (FLO)
Mrs Fiona Jones

Employees can also contact the regional HSC fraud reporting hotline on **0800 096 33 96** or report their suspicions online to www.reportthehealthfraud.hscni.net. These avenues are managed by Counter Fraud and Probity Services (CFPS) on behalf of the HSC and reports can be made on a confidential basis.

The Trust's Fraud Response Plan will be instigated immediately on receipt of any reports of a suspicion of fraud or bribery.

The prevention, detection and reporting of fraud and bribery and other forms of corruption are the responsibility of all those working for the Trust or under its control. The Trust expects all staff and third parties to perform their duties impartially, honestly, and with the highest integrity.

5. Our Commitment to You

5.1 Your safety

The Trust Board and Senior Management Team, the Chief Executive, managers and the trade unions/professional organisations are committed to this policy. If you raise a genuine concern under this policy, you will not be at risk of losing your job or suffering any detriment (such as a reprisal or victimisation). The Trust will not tolerate the harassment or victimisation of anyone who raises a genuine concern.

The Trust expects you to raise concerns about malpractices. If any action is taken that deters anyone from raising a genuine concern or victimises them, this will be viewed as a disciplinary matter.

Provided you are acting in good faith, it does not matter if you are mistaken or if there is an innocent explanation for your concerns, you will be protected under the

law. However, it is not uncommon for some staff to maliciously raise a matter they know to be untrue. In cases where staff maliciously raise a matter they know to be untrue, protection under the law cannot be guaranteed and the Trust reserves the right to take disciplinary action if appropriate.

5.2 Confidentiality

With these assurances, the Trust hopes that you will raise concerns openly. However, we recognise that there may be circumstances when you would prefer to speak to someone in confidence first. If this is the case, you should say so at the outset to a member of staff in Human Resources.

The Trust is committed to maintaining confidentiality for everyone involved in a concern. This includes the person raising the concern and the person(s) whom the concern is about. Confidentiality will be maintained throughout the process and after the issue has been resolved.

If you ask for your identity not to be disclosed, we will not do so without your consent unless required by law. You should however understand that there may be times when we will be unable to resolve a concern without revealing your identity, for example, where personal evidence is essential. In such cases, we will discuss with you whether and how the matter can best proceed.

5.3. Anonymity

Remember that if you do not disclose your identity, it will be much more difficult for us to look into the matter. It will also not be possible to protect your position or give you feedback. So, while we will consider anonymous reports in the exact same manner as those which are not anonymised, these arrangements are not best suited to deal with concerns raised anonymously.

If you are unsure about raising a concern you can get independent advice from Protect (see contact details under Independent Advice).

6. Raising a concern

If you are unsure about raising a concern, you can get independent advice at any stage from your trade union/professional organisation, or from one of the organisations listed in Section 7. You should also remember that you do not need to have firm evidence before raising a concern. However, you should explain as fully as possible the information or circumstances that gave rise to the concern.

6.1 Who should I raise a concern with?

Option 1: In many circumstances the easiest way to get your concern resolved will be to raise it with your line manager (or lead clinician or tutor). But where you do not think it is appropriate to do this, you can use any of the other options set out below.

Option 2: If raising it with your line manager (or lead clinician or tutor) does not resolve matters, or you do not feel able to raise it with them, please raise the matter with another senior person you can trust. This might be another manager / professional lead or a Senior HR representative and again you may wish to involve a Trade Union representative or colleague.

The Deputy Director of HR Services, Mrs Siobhan Hynds is the designated HR representative for Raising Concerns

If exceptionally, the concern is about the Chief Executive, then it should be made (in the first instance) to the Chair, who will decide on how the investigation will proceed.

Option 3: If you still remain concerned after this, you can contact:

- Mrs Vivienne Toal - Director of Human Resources & Organisational Development who is the lead director for Raising Concerns
- Dr Maria O'Kane - Executive Medical Director
- Mrs Heather Trouton – Interim Executive Director of Nursing, Midwifery & AHPs
- Mr Paul Morgan – Executive Director of Social Work
- Mrs Helen O'Neill – Executive Director of Finance, Procurement & Estates

- Mr John Wilkinson – Lead Non-Executive Director for Raising Concerns on Trust Board – contactable through the Office of the Chair, Trust HQ.

All these people are required to receive training in dealing with concerns and will give you information about where you can go for more support.

Option 4: If for any reason you do not feel comfortable raising your concern internally, you can raise concerns with external bodies (see paragraph 7 below).

6.2 Independent advice

If you are unsure whether to use this policy, or if you require confidential advice at any stage, you may contact your trade union/professional organisation.

Advice is also available through the independent charity, Protect (formerly Public Concern at Work (PCaW)) on 020 3117 2520.

6.3 How should I raise my concern?

You can raise your concerns with any of the people listed above, in person, by phone or in writing. A dedicated email address is also available: raising.concerns@southerntrust.hscni.net.

Whichever route you choose, please be ready to explain as fully as you can the information and circumstances that gave rise to your concerns.

If in writing or email, you should set out the background and history of the concerns, giving where possible:

- names,
- dates,
- places, and
- the reasons why you are particularly concerned about the situation.

If you do not feel able to put the concern in writing, you can of course raise your concern via telephone or in person. A statement can be taken of your concern which can be recorded for you to verify and sign.

6.4 Supporting you

It is recognised that raising concerns can be difficult and stressful. Advice and support is available from the Deputy Director of HR Services or a nominated deputy throughout any investigation process. The Deputy Director of HR Services will not undertake an investigation role in the whistleblowing case but will provide support throughout the process, ensuring that feedback is provided at appropriate stages of the investigation. The Trust also provides independent support services to all employees through its Employee Assistance Programme - Inspire; this service is free to all employees and is available 24/7. Contact details are: 0808 800 0002.

The Trust will take steps to minimise any difficulties which you may experience as a result of raising a concern. For example if you are required to give evidence at disciplinary proceedings, the Deputy Director of HR Services will arrange for you to receive advice and support throughout the process. If you are dissatisfied with the resolution of the concern you have raised or you consider you have suffered a detriment for having raised a concern, this should be raised initially with the Deputy Director of HR Services.

7. Raising a concern externally

The Trust hopes this policy reassures you of its commitment to have concerns raised under it taken seriously and fully investigated, and to protect an individual who brings such concerns to light.

Whilst there may be occasions where individuals will wish to report their concerns to external agencies or the PSNI, the Trust would hope that the robust implementation of this policy will reassure staff that they can raise such concerns internally in the first instance.

However, the Trust recognises that there may be circumstances where you can raise a concern with an outside body including those listed below:

- Department of Health;
- A prescribed person, such as:

- General Chiropractic Council, General Dental Council, General Medical Council, General Osteopathic Council, Health & Care Professional Council, Northern Ireland Social Care Council, Nursing and Midwifery Council, Pharmaceutical Society Northern Ireland, General Optical Council
- The Regulation and Quality Improvement Authority;
- The Health and Safety Executive;
- Serious Fraud Office,
- Her Majesty's Revenue and Customs,
- Comptroller and Auditor General;
- Information Commissioner
- Northern Ireland Commissioner for Children and Young People
- Northern Ireland Human Rights Commission

Disclosure to these organisations/persons will be protected provided you honestly and reasonably believe the information and associated allegations are substantially true.

We would wish you to raise a matter with the external agencies listed above than not at all. Protect (formerly PCaW) or your Trade Union representative will be able to advise you on such an option and on the circumstances in which you may be able to contact an outside body safely.

8. The Media

You may consider going to the media in respect of concerns if you have done all you can by raising them with the Trust or an external body and you feel they have not been properly addressed. Your professional regulatory body, if applicable, will be able to provide guidance / advice in this situation. You should carefully consider any information you choose to put into the public domain to ensure that patient/client confidentiality is maintained at all times. The Trust reserves the right to take disciplinary action if patient/client confidentiality is breached.

Communications with the media are coordinated by the Communications Department on behalf of the Trust. Any member of staff approached by the media should direct the media to our Communications Department in the first instance.

9. Conclusion

While we cannot guarantee that we will respond to all matters in the way that you might wish, we will strive to handle the matter fairly, impartially and properly. By using these whistleblowing arrangements you will help us to achieve this.

Please note, this document has been developed to meet best practice and comply with the Public Interest Disclosure (NI) Order 1998 (the Order) which provides employment protection for whistleblowing.

The Order gives significant statutory protection to staff who disclose information reasonably in the public interest. To be protected under the law an employee must act with an honest and reasonable belief that a malpractice has occurred, is occurring or is likely to occur. Disclosures may be made to certain prescribed persons or bodies external to the Trust listed in the Order. The Order does not normally protect employees making rash disclosures for example to the media, when the subject could have been raised internally.

10. Equality, Human Rights & DDA

The Southern Health & Social Care Trust confirm this policy has been drawn up and reviewed in the light of Section 75 of the Northern Ireland Act (1998) which requires the Trust to have due regard to the need to promote equality of opportunity.

This policy has been screened for equality implications as required by Section 75 and Schedule 9 of the Northern Ireland Act 1998. Equality Commission guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity so that greatest resources can be devoted to these.

Using the Equality Commission's screening criteria, no significant equality implications have been identified. The policy will therefore not be subject to an

equality impact assessment.

Similarly, this policy has been considered under the terms of the Human Rights Act 1998, and was deemed compatible with the European Convention Rights contained in the Act.

11. Alternative Formats

This document can be made available on request on disc, larger font, Braille, audio-cassette and in other minority languages to meet the needs of those who are not fluent in English.

12. Sources of advice in relation to this document

The Director of Human Resources & Organisational Development should be contacted with regard to any queries on the content of this policy.

APPENDIX A

Roles and Responsibilities

The Trust Board and Senior Management Team of the Southern Health & Social Care Trust

- To listen to our staff, learn lessons and strive to improve patient care;
- To ensure that this policy enables genuine issues that are raised to be dealt with effectively
- To promote a culture of openness and honesty and ensure that issues are dealt with responsibly and taken seriously
- To ensure that employees who raise any issues are not penalised for doing so unless other circumstances come to light which require this, e.g. where a member of staff knowingly raises an issue regarding another member of staff which they know to be untrue.
- To share learning, as appropriate, via the Trust's lessons learned arrangements

Lead Non-Executive Director (NED)

- To provide assurance to Trust Board that there are robust arrangements in place in relation to raising and handling concerns
- To have responsibility for oversight of the culture of raising concerns within the Trust.

Director of Human Resources & Organisational Development

- To take responsibility for ensuring the implementation of the whistleblowing arrangements
- To ensure that any safety issue about which a concern has been raised is dealt with properly and promptly and escalated appropriately through appropriate management levels / professional lines
- To ensure that all awareness and training requirements arising from this policy are delivered
- To establish a network of advocates, to support the implementation of this policy

All Directors & Managers

- To ensure staff are familiar with and have access to the Raising Concerns Policy and Procedure
- To recognise that raising a concern can be a difficult experience for some staff and to treat the matter in a sensitive and confidential manner
- To respond quickly to concerns and take all concerns seriously and in confidence, wherever possible
- To seek immediate advice from HR on the handling of any concern raised, and other professionals within the Southern Health & Social Care Trust where appropriate
- To ensure that staff are supported following the raising of a concern so as not to suffer detriment
- To foster an environment in which their teams are engaged in the delivery of high quality and safe services and feel secure to raise concerns as a matter of good practice
- To create an open and safe atmosphere (in team meetings, appraisals etc.) where staff feel their views, regarding the effective and safe delivery of care and services to our service users, will be welcomed and be seen as an opportunity to learn and to consider how services can be improved
- To ensure feedback/ learning at individual, team and organisational level on concerns and how they were resolved.

Deputy Director of HR Services

- To ensure Medical Director, Director of Nursing & AHPs, or Director of Social Work is informed, if the concern raised deems this to be appropriate in order to ensure the safety of patients and clients.
- To oversee any investigation undertaken and provide support to the individual raising the concern throughout the process, ensuring that feedback is provided at appropriate stages of the investigation.
- To intervene if there are any indications that the person who raised a concern is suffering any recriminations.
- To work with Directors and Managers to address the culture and tackle the obstacles to raising concerns.

All Members of Staff

- To recognise that it is your duty to draw to the Trust's attention any matter of concern
- To adhere to the procedures set out in this policy
- To maintain the duty of confidentiality to patients and the Trust and consequently, where any disclosure of confidential information is to be justified, you should first, where appropriate, seek specialist advice for example from a representative of a regulating organisation such as the Nursing & Midwifery Council or the General Medical / Dental Council.

Role of Trade Unions and other Organisations

- All staff have the right to consult and seek guidance and support from their Professional Organisations, Trade Union or from statutory bodies such as the Nursing & Midwifery Council, the General Medical Council, Health & Care Professions Council and the Northern Ireland Social Care Council.

APPENDIX B**SOUTHERN HSC TRUST PROCEDURE FOR RESPONDING TO CONCERNS****HOW WE WILL DEAL WITH THE CONCERN****Stage 1**

- 1) Any manager / Director to whom a concern is raised must arrange to meet with the employee to discuss the detail of the concern **without delay**.
- 2) The manager / Director should be clear on the range of other Trust policies and procedures in the event that the concern raised might be more appropriately dealt with under another policy / procedure e.g. Grievance Procedure, Working Well Together Procedure, Maintaining High Professional Standards (Medical & Dental staff).
- 3) The manager / Director should establish the background and history of the concerns, including names, dates, places, where possible, along with any other relevant information. The manager should also explore the reason why the employee is particularly concerned about the matter. The manager should document a summary of the discussion.
- 4) The manager should explain that they will need to seek advice from their Assistant Director / Director, providing there are no specific objections raised by the employee regarding protection of their confidentiality in this regard. If there are concerns expressed as to who should be made aware, then the manager / Director should seek advice immediately from the Director of HR or Deputy Director of HR Services.
- 5) ALL whistleblowing concerns must be notified by the Assistant Director / Director to the HR Director's office for logging and decision on best course of action to address the concern.
- 6) If the concern is raised with the Director of HR, s/he will refer the concern to the Deputy Director of HR Services to arrange to meet with the employee to discuss the detail of the concern.

It may be necessary with anonymous allegations to consider whether it is possible, based on limited information provided in the complaint, to take any further action. Where it is decided that further action cannot be justified, the reasons for this decision should be documented and retained by the HR Director's Office.

Stage 2

Once the issue(s) of concern has been established, the approach to independently investigating the concern will be discussed and agreed by an Oversight Group, chaired by the Director of HR and an Executive Director, depending on the nature of the concern. The Director of HR will advise the relevant operational Director that a concern has been raised and the nature of it. The Director of HR will withhold the identity of the individual raising the concern, if requested.

A record should be made of the decisions and/or agreed actions which should be signed and dated. Agreed Terms of Reference for any investigation should be established.

The Director of HR will ensure that the Deputy Director of HR Services is aware of the concern (if not previously aware) to ensure any necessary support can be provided to the employee raising the concern.

Stage 3

Within a prompt and reasonable timescale of the concern being received, the Deputy Director of HR Services must meet with the employee to:

- Acknowledge that the concern has been received
- Discuss if confidentiality is to be / can be maintained throughout investigation, and ensure this is documented using the ***Record of Discussion Regarding Confidentiality***
- Discuss how the matter will be dealt with and by whom
- Outline the support available
- Provide an estimate as to how long it will take to provide a final response.

A summary of the discussions will be followed up in writing.

Stage 4

A proportionate investigation – using someone suitably independent (usually from a different part of the organisation), will be undertaken and conclusion reached within a reasonable timescale. The investigation will be objective and evidence-based, and a report of the findings will be produced.

Stage 5

The Oversight Group will consider the report and determine any action required, based on the findings, including any lessons to be learned to prevent problems recurring.

Stage 6

The HR Director will ensure that feedback to the individual raising the concern is provided.

If You Remain Dissatisfied

If you are unhappy with the response you receive when you use this procedure, remember you can go to the other levels and bodies detailed in the Trust's Policy. While we cannot guarantee that we will always respond to all matters in the manner you might wish, we will do our best to handle the matter fairly and properly.

RECORD OF DISCUSSION REGARDING CONFIDENTIALITY

Name of individual raising concern

SUMMARY OF DISCUSSION REGARDING CONFIDENTIALITY

Please record a summary of the discussion with the individual raising a concern regarding maintaining their confidentiality under the Trust's Raising Concerns (Whistleblowing) Policy

CONSENT TO REVEAL IDENTITY

Does the individual wish to their identity to remain confidential during any whistleblowing investigation?

YES / NO

Who has the individual given consent for their name to be revealed to as part of the whistleblowing investigation?

Is the individual aware that should further action be required following a whistleblowing investigation in the form of disciplinary action for example, that their identity may have to be revealed following discussion with them and that they may have to provide a witness statement?

YES / NO

INFORMATION STORAGE

Summary of discussion regarding how information will be held and investigation undertaken to ensure identity is protected.

Signed by individual raising concern(s):

Date:

Signed by Trust representative :

Date:



Quality Care - for you, with you

HOW STAFF CAN RAISE CONCERNS

As staff in the Southern Trust, we all have a responsibility to protect our service users, staff, the public and the Trust. If you have a concern as a member of staff about any aspect of the quality and safety of our services, another member of staff, or about any of the functions of the Trust, those concerns can be raised internally in one of the following ways:

1: You are encouraged to raise any concerns in the first instance with your line manager, either in writing or orally. You may involve a trade union representative or colleague to assist and advise you.

2. You can also raise concerns through your trade union representatives, who regularly meet with senior management.

3: If, for any reason, you feel unable to raise the concern with your line manager or through your trade union representative, then please raise it with another manager you can trust, an HR Advisor or a member of staff from the Trust's Employee Engagement Relations Team. Once again you may involve a trade union representative or colleague to assist and advise you.

4: If you believe the concern to be so serious it cannot be discussed with any of the above please contact:

- ❖ The Trust Chief Executive @ Personal Information redacted by the USI
- ❖ The Trust Chairman/ Non Executive Director @ Personal Information redacted by the USI
- ❖ The Director of HR & OD @ Personal Information redacted by the USI

5: If you believe that you have exhausted all the above options or feel that none of these ways are appropriate given the nature of your concern and you

are acting in good faith with evidence to support your concern you can also contact:

- ❖ Relevant Professional Organisation or Regulatory Organisation (eg Nursing & Midwifery Council, GMC, NI Social Care Council, HPC)
- ❖ Statutory bodies such as the Mental Health Commission and RQIA
- ❖ Department of Health, Social Services and Public Safety
- ❖ The Health & Safety Executive of Northern Ireland

Before raising a concern – you must have a reasonable belief in what you claim and it will help the Trust to better and more quickly investigate your concerns.

Some staff choose to raise their concerns anonymously but if you don't give us your name or sufficient information to allow your concern to be investigated, it makes it very difficult to investigate the matter, to resolve the issue and we cannot provide you with information as to what steps we have taken.

For more information please see the Trust's Whistleblowing Policy by clicking [here](#).

Raising concerns

Guidance for nurses,
midwives and
nursing associates

We're the independent regulator for nurses, midwives and nursing associates. We hold a register of all the 690,000 nurses and midwives who can practise in the UK, and nursing associates who can practise in England.

Better and safer care for people is at the heart of what we do, supporting the healthcare professionals on our register to deliver the highest standards of care.

We make sure nurses, midwives and nursing associates have the skills they need to care for people safely, with integrity, expertise, respect and compassion, from the moment they step into their first job.

Learning does not stop the day nurses, midwives and nursing associates qualify. To promote safety and public trust, we require professionals to demonstrate throughout their career that they are committed to learning and developing to keep their skills up to date and improve as practitioners.

We want to encourage openness and learning among healthcare professionals to improve care and keep the public safe. On the occasions when something goes wrong and people are at risk, we can step in to investigate and take action, giving patients and families a voice as we do so.

Last updated January 2019

Introduction

This document provides guidance for nurses, midwives and nursing associates on raising concerns (which includes 'whistleblowing'). It explains the processes you should follow when raising a concern, provides information about the legislation in this area, and tells you where you can get confidential support and advice.

As a nurse, midwife or nursing associate, you have a professional duty to put the interests of the people in your care first and to act to protect them if you consider they may be at risk. Where we use the term **in your care** throughout this document, it is used to indicate all of those people you come across or know about because of your work as a nurse, midwife or nursing associate, not just those people you deliver specific care for or have direct clinical or managerial responsibility for.

This guidance supports and should be read together with **The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates (the Code)**. No matter what sort of healthcare environment or geographical area you work in, it's important that you know how to raise concerns appropriately. This guidance can't cover every single situation that you may face, but it sets out the broad principles that will help you to think through the issues and take appropriate action in the public interest.

You should use this guidance with whistleblowing policies issued by your employer and with local clinical governance and risk management procedures, which will provide information on reporting incidents early or near misses. You should also make sure that you understand and follow your local authority's safeguarding policies.

Safeguarding the health and wellbeing of those in your care means these people should not be exposed to abuse or neglect. Abuse or neglect and the different circumstances in which they take place can take many forms. A list of actions that may constitute neglect or abuse and should give rise to concern includes the following (taken from Chapter 14, **Care and Support Statutory Guidance** (2014) issued by the Department of Health under the Care Act 2014).

- Physical abuse
- Domestic violence
- Sexual abuse
- Psychological abuse
- Financial or material abuse
- Modern slavery
- Discriminatory abuse
- Organisational abuse
- Neglect and acts of omission
- Self-neglect.

Immediate concerns about abuse or neglect should be dealt with under local safeguarding procedures first. For more information about this, please see your local safeguarding policies and the further reading section.

This guidance is for all nurses, midwives, nursing associates and pre-registration nursing and midwifery students, no matter where you might work. The principles supporting this guidance also apply to all healthcare professionals, so this guidance may be helpful to other staff within the workplace. However, if you are self-employed or working as a volunteer, we recommend that you get more advice before raising any concerns you might have (see the section 'Where can I get help or advice?').

We recognise that it is not always easy to report concerns. You may not know how to, or you may worry that you are being disloyal, or fear reprisals from your employer's reaction. It may also be particularly difficult for those of you who work and live in remote and small communities. However, the health and wellbeing of the people in your care must always be your main concern. Raising your concern early can prevent minor issues becoming serious ones, and so protect the public from harm and improve standards of care.

If you aren't sure how this guidance applies to your situation, or if you want some confidential advice before you raise your concern, or at any stage during the process, we recommend that you get advice from your professional body, trade union or the independent whistleblowing charity **Protect** (formerly Public Concern at Work). Protect provides confidential advice to employees who witness wrongdoing or malpractice in the workplace and who aren't sure whether or how to raise their concern.

Professional bodies and trade unions can play a vital role in offering local support and guidance to staff who have concerns about any part of their work, including fears about patient or client care. They can also raise matters formally with your organisation on your behalf and can access other forums within your organisation. Raising a concern can often seem isolating and intimidating – having this support can help you to meet your professional standards with more confidence.

Your role in raising concerns

- 1 As a nurse, midwife or nursing associate, you have a professional duty to report any concerns from your workplace which put the safety of the people in your care or the public at risk.
- 2 The Code (section 16) states the following.
 - 2.1 Act without delay if you believe that there is a risk to patient safety or public protection.
 - 2.2 To achieve this you must:
 - 2.3 Raise and, if necessary, escalate (take further action on) any concerns you may have about patient or public safety, or the level of care people are receiving at your workplace or any other healthcare setting and use the channels available to you in line with our guidance and your local working practices.
 - 2.4 Raise your concerns immediately if you are being asked to practise beyond your role, experience and training.
 - 2.5 Tell someone in authority at the first reasonable opportunity if you experience problems that may prevent you working within the Code or other national standards, taking prompt action to tackle the causes of concern if you can.
 - 2.6 Acknowledge and act on all concerns raised to you, investigating, escalating or dealing with those concerns where it is appropriate for you to do so.
 - 2.8 Not obstruct, intimidate, victimise or in any way hinder a colleague, member of staff, person you care for or member of the public who wants to raise a concern.
 - 2.9 Protect anyone you have management responsibility for from any harm, detriment, victimisation or unwarranted treatment after a concern is raised.
- 3 Speaking up on behalf of people in your care and clients is an everyday part of your role. Just as raising genuine concerns represents good practice, 'doing nothing' and failing to report concerns is unacceptable. We recognise that nurses, midwives and nursing associates who raise a genuine concern and act with the best of intentions and in line with the principles laid down in this guidance are meeting their professional responsibilities and keeping to the Code.
- 4 Failure to report concerns may bring your fitness to practise into question and put your registration at risk. If you experience any negative reactions within your workplace after raising a concern appropriately, you should contact your professional body or trade union for support and advice.
- 5 In line with the Code, we expect the professionals on our register to work with others to protect the health and wellbeing of those in their care. As a result, this guidance applies to a wide range of situations, not just where a concern relates to the practice of individual nurses, midwives and nursing associates. Examples may include the following.
 - 5.1 Danger or risk to health and safety, such as where health and safety rules or guidelines have been broken.
 - 5.2 Issues to do with staff conduct, such as unprofessional attitudes or behaviour, including concerns related to equality and diversity.
 - 5.3 Issues to do with delivering care involving nurses, midwives, nursing associates or other staff members.
 - 5.4 Issues to do with care in general, such as concerns over resources, products, people, staffing or the organisation as a whole.
 - 5.5 Issues to do with the health of a colleague, which may affect their ability to practise safely.

- 5.6 Misuse or unavailability of clinical equipment, including lack of adequate training.
- 5.7 Financial malpractice, including criminal acts and fraud.
- 6 You don't need to have all the facts to prove your concern but you must have a reasonable belief that wrongdoing is either happening now, took place in the past, or is likely to happen in the future.
- 7 If you witness or suspect there is a risk to the safety of people in your care and you consider that there is an immediate risk of harm, you should report your concerns straight away to the appropriate person or authority.

Nursing and midwifery students

- 8 The principles in this guidance apply to student nurses, midwives and nursing associates in the same way that they apply to registered nurses, midwives and nursing associates. To uphold these principles, you should act as set out below in the following situations.
 - 8.1 Inform your mentor, tutor or lecturer immediately if you believe that you, a colleague or anyone else may be putting someone at risk of harm.
 - 8.2 Seek help immediately from an appropriately qualified professional if someone you are providing care for has suffered harm for any reason.
 - 8.3 Seek help from your mentor, tutor or lecturer if people indicate that they are unhappy about their care or treatment.
- 9 We recognise that it might not be easy for you to raise a concern; you may not be sure what to do or the process may

seem quite daunting. If you want some advice at any stage, we recommend that you talk to your university tutor or lecturer, your mentor or another registered nurse, midwife or nursing associate in your practice area. You can also speak to your professional body, trade union or Protect, who can offer you valuable confidential advice and support.

The difference between raising a concern and making a complaint

- 10 If you are raising a concern, you are worried generally about an issue, wrongdoing or risk which affects others. You are acting as a witness to what you have observed, or to risks that have been reported to you, and are taking steps to draw attention to a situation which could negatively affect those in your care, staff or the organisation.
- 11 However, if you are making a complaint to your employer, you are complaining about how you personally have been treated at work (such as conditions of employment). In these circumstances, you should follow your employer's complaints or grievance procedure.

Respecting an individual's right to confidentiality

- 12 The Code states that people in your care have the right to confidentiality and the right to expect that you only use the information they have given to you for the purpose for which it was given. You should only discuss information with someone outside of the healthcare team if the person in your care has agreed you can. In very exceptional circumstances, you can pass on information without their permission if you believe someone may be at risk of harm and you are acting in their best interests.
- 13 These decisions are complex and you must assess each case individually. Before reporting a concern which might reveal someone's identity, you should get advice. You can find more information in **Confidentiality: NHS Code of Practice** (2003) and its **supplementary code of practice on public interest disclosures** (2010). Both of these are available on the Department of Health, gov.uk and NHS Digital websites. The principles of both these publications can be applied equally to the independent and voluntary sectors in healthcare. Equivalent guidance is also available in **Scotland, Wales and Northern Ireland**.

Can I be guaranteed confidentiality when raising a concern?

- 14 We recommend that you give your name when raising a concern. This makes it easier for your concern to be investigated and is the best way for you to be protected under the law. However, we recognise that there may be circumstances when you would like to keep your identity confidential. In this case, you should say so at the start.
- 15 You should understand that there may be practical or legal limits to this confidentiality where the concern can't be

dealt with without revealing your identity, or that others may guess who has raised the concern. If you raise your concern anonymously, it will be much more difficult for the matter to be investigated, which in turn, affects public safety.

How do I raise a concern?

- 16 Normally you will be able to raise your concern directly with the person concerned or your line manager and, in many instances, the matter will be easily dealt with. However, there may be times when this approach fails and you need to raise your concern through a more formal process. We outline the various stages of this process below. They are based on the tiered approach reflected in the Public Interest Disclosure Act 1998 (PIDA) (see the section 'What legislation is in place to protect me?').
- 17 Where possible, you should follow your employer's policy on raising concerns or whistleblowing. This should provide advice on how to raise your concern and give details of a designated person who has responsibility for dealing with concerns in your organisation. Sometimes, if you are worried about how or whether to raise your concern or if you can't find the policy, it can help to discuss things informally with a senior, impartial member of staff. They should ideally be an NMC registered nurse or midwife, such as one of the following.
 - 17.1 Clinical supervisor.
 - 17.2 Lead nurse, lead midwife or other professional or clinical lead.
 - 17.3 University tutor or lecturer (if a student).
 - 17.4 Mentor or practice placement manager (if a student).

Stage 1: Raising your concern with your line manager

- 17.5 Health and safety team (when the concern is about health and safety).
- 17.6 Risk, quality assurance or clinical governance team (when the issue is quality or risk).
- 18 Your concerns may not be limited to the care of a particular person, but about the overall standards of care or practice in an area. In these cases, you may find it helpful to speak to a clinical or professional lead (who may be a consultant, or specialist nurse or midwife) as they will be concerned with professional standards and quality of care, and so will be interested in knowing if things aren't as they should be.
- 19 A 'lead professional' has organisational responsibility for the quality of nursing or midwifery practice, and so will often investigate and work to settle concerns raised about practice and risk in these areas. They also might be able to help you better understand the standards or practice you are concerned about and offer the support you might need to raise your concerns.
- 20 It's also valuable to get advice on how to raise a concern from a representative of your professional body, trade union or Protect. They have a wealth of expertise, and can provide independent and confidential support during this process.

21 Immediate concerns

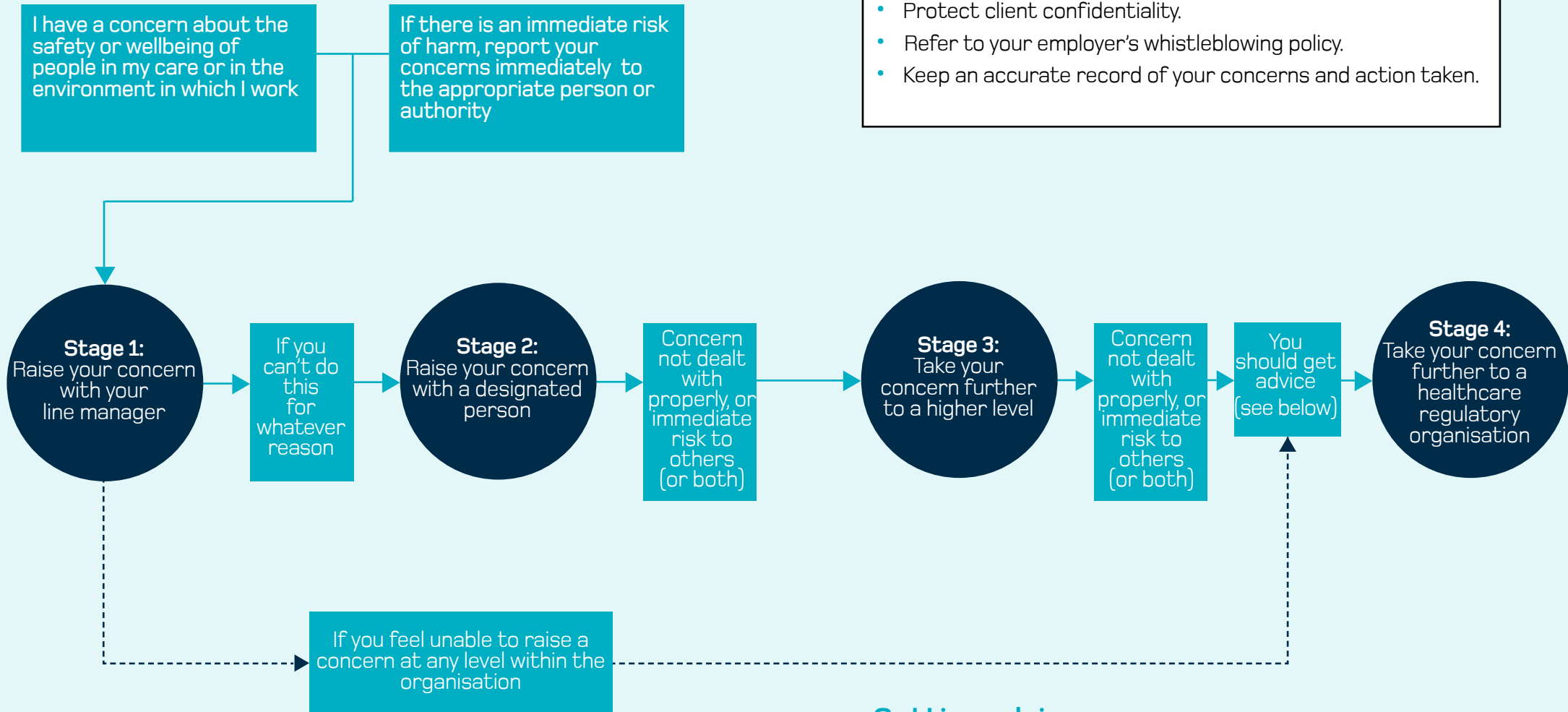
If you witness or suspect that there is a risk of immediate harm to a person in your care, you should report your concerns to the appropriate person or authority immediately. You must act straight away to protect their safety.

- 22 Normally, you will be expected to raise your concern internally first, such as with your line manager. You can do this verbally or in writing. Be clear, honest and objective about the reasons for your concern.
- 23 You should keep a clear written record of your concern and any steps that you have taken to deal with the matter including who you raised the concern with and on what date, and an outline of your concern.
- 24 While you should also keep a record of any written or verbal communication that you send or receive from your employer, be aware of the need to protect confidentiality. For example, if you need to refer to an incident with a particular patient or client, record details of the event and take appropriate steps to maintain confidentiality.

Stage 2: Raising your concern with a designated person

- 25 If for any reason you feel unable to raise your concern with your line manager, you should raise your concern with the designated person in your organisation. You should be able to find out who this is by looking at your employer's raising concerns or whistleblowing policy. The designated person will normally be someone who has been given special responsibility and training in dealing with employees' concerns. If you want your identity to remain confidential, you should say so at this stage.

Stages in raising concerns



Key points

- Take immediate action.
- Protect client confidentiality.
- Refer to your employer's whistleblowing policy.
- Keep an accurate record of your concerns and action taken.

Getting advice

If you aren't sure about whether or how to raise a concern at any stage, you should get advice.

You can get independent, confidential advice from your professional body, trade union or Protect. Students can also speak to their university tutor or mentor.

Stage 3: Taking your concern to a higher level

- 26 If you have raised a concern with your line manager or with the designated person within your organisation, but feel they haven't dealt with it properly, you should raise your concern with someone more senior within your organisation. For example, in the NHS you could take your concern to your department manager, head of midwifery, director of nursing or chief executive. You may also choose to do this from the start if, for whatever reason, you feel unable to raise your concern with the internal staff mentioned in stages 1 and 2.

Stage 4: Taking your concern to a regulatory organisation or a helpline

- 27 If you have raised your concern internally but feel it hasn't been dealt with properly, or if you feel unable to raise your concern at any level in your organisation, you may want to get help from outside your place of work. For example, if you are a clinical leader, you may choose to do this if you feel your concerns haven't been dealt with adequately within your organisation.
- 28 So that your concern can be investigated and for your own protection under current legislation, you should use a recognised organisation that is responsible for investigating the issue. This could be a regulator of health or social care services, if your concern is about a health or care setting. If it is about individual professionals, then it could be a regulator of health or social care professionals.

- 29 For example, if you are working in England you may choose to raise your concerns directly with the Care Quality Commission (CQC), using the helpline they have set up to help staff raise concerns about the health or social care provider they work for. All information is treated in confidence and you don't have to give your name. The CQC provides detailed guidance for workers and service providers on their website, www.cqc.org.uk/contact-us.
- 30 If you work in England, you can raise your concerns through the NHS Whistleblowing Helpline. People working in the NHS and social care sector can use this helpline to report concerns about malpractice, wrongdoing, fraud or any other issues that could undermine public confidence and threaten patient safety. The service also provides advice and guidance for those who don't know what to do about their concerns, and can be used by employees, employers and professional or trade bodies through a free telephone hotline service, email or online forms. You can get more information on the Whistleblowing Helpline at www.wbhelpline.org.uk.
- 31 Before reporting your concerns to any regulatory organisation or hotline, we recommend that you get advice. This will help you to receive appropriate support and guidance in these difficult circumstances. We also suggest you tell your employer what action you are taking.

Raising your concern with the NMC

- 32 We have a page on our website dedicated to whistleblowing, www.nmc.org.uk/whistleblowing.
- 33 If you wish to raise a concern with us directly, please use our dedicated email address, whistleblowing@nmc-uk.org, or phone us on 020 7637 7181 for advice.

Raising your concern externally

- 34 You should only consider this if you have tried all of the above procedures and your concern hasn't been dealt with properly. Raising your concern externally (for example to the media or an MP) without clear evidence of first raising the concern internally or with a regulatory organisation, would only be considered appropriate and give you protection under PIDA in the most extreme circumstances and if it could clearly be shown that you were acting in the public interest. For more details of PIDA, see the section 'What legislation is in place to protect me?'.
- 35 If you are thinking of raising your concern externally, you should always get advice from your professional body, trade union or Protect.

The role of clinical leaders

- 36 We recognise the important role that clinical leaders play in raising concerns, particularly those who are nurses and midwives. Promoting an open work environment in which staff are accountable and encouraged to raise concerns about the safety of people in their care will help identify and prevent more problems, and will protect the public.
- 37 If you are a clinical leader or hold a position where others may bring their concerns to you, you should do the following.
 - 37.1 Make sure appropriate systems for raising concerns are in place and that all staff can access them. Consider whether staff can gain access confidentially to your organisation's whistleblowing or raising concerns policy.
 - 37.2 Make sure staff can see all concerns are taken seriously, even if they are later seen to be unfounded.

- 37.3 Tell the employee who raised the concern how you propose to handle it in line with your employer's policies, and give a timeframe in which you will get back to them, both verbally and in writing.
- 37.4 Investigate concerns promptly and include a full and objective assessment.
- 37.5 Keep the employee who raised the concern up to date with what's happening. This will give them and others confidence in the system.
- 37.6 Take action to deal with the concern and, record and monitor this action.
- 37.7 Make sure staff who raise concerns are protected from unjustified criticism or actions.
- 37.8 Have processes in place to support employees raising concerns. This support may need to be offered confidentially from outside the organisation.
- 37.9 If harm has already been caused to a person in your care, explain fully and promptly what has happened and the likely outcomes. This duty is clearly supported by the Code.
- 38 We recognise that those in leadership positions, or managers of nurses, midwives and nursing associates, aren't always in a position to deal with the concerns raised to them, or may themselves feel that senior managers haven't done enough to sort out the matter. Clinical leaders can get support and advice at all levels from professional bodies, trade unions or Protect. Also, guidance for employers on putting whistleblowing arrangements in place, *Speak up for a healthy NHS* (NHS, 2010), has been produced by the Social Partnership Forum.

The role of employers

- 39 Employers have a key role to play in the whistleblowing process. In particular, NHS Employers supports NHS organisations to encourage openness at work so all staff can feel free to raise concerns in a reasonable and responsible way, without fear of being victimised.
- 40 NHS Employers is an organisation which provides guidance for employers in England. It helps them to put in place and develop policies and procedures that are targeted at helping NHS staff to report concerns about patient safety, or other issues, appropriately. It works closely with the national Whistleblowing Helpline which was launched in December 2011 to provide free, independent advice and support to NHS staff. It was later extended to cover all staff and employers working in the wider social care sector.
- 41 NHS Employers recognises the importance of understanding and being aware of the legislation to protect those who raise concerns. A whole section of its website provides guidance and resources to help employers to establish and develop systems which encourage early intervention. This also allows staff to feel confident enough to raise concerns and for all members of staff to recognise this as good professional practice.
- 42 The website directs employers to guidance, legislation, communication tools and frequently asked questions. It also provides guidance and further support for staff when they are considering whether to raise a concern.
- 43 For more information, please see the Whistleblowing: Raising concerns at work section on the NHS Employers' website, **www.nhsemployers.org/your-workforce/retain-and-improve/raising-concerns-at-work-and-whistleblowing**.

- 44 Employers can also refer to our publication *Advice and information for employers of nurses, midwives and nursing associates* (NMC, 2012), **www.nmc-uk.org/Publications/Information-for-employers**.

What legislation is in place to protect me?

- 45 The Public Interest Disclosure Act (1998) (PIDA) was introduced to protect people who raise genuine concerns about wrongdoing or malpractice in the workplace, when they do so in good faith, are acting in the public interest and are victimised or dismissed (or both) for doing so. The act has a tiered approach to disclosures (whistleblowing) which gives workers protection for raising a concern internally.
- 46 Section 17 of the Enterprise and Regulatory Reform Act 2013 makes it clear that whistleblowing must be 'in the public interest' if the Act is to offer protection.
- 47 Also, there is protection for disclosures to all health and social care regulatory bodies as set out in the Public Interest Disclosure (Prescribed Persons) Order 2014. Disclosures to the NMC under these provisions may be made on:
 - "Matters relating to:
 - (a) the registration or regulation of a member of a profession regulated by the Council; and
 - (b) any activities not covered by (a) in relation to which the Council exercises its functions."
- 48 From 6 April 2015 whistleblower protection was extended to students on an NMC-approved training course if they make a 'qualifying disclosure' to us. This is under the Protected Disclosures (Extension of Meaning of Worker) Order 2015.

49 From 6 June 2014 under Schedule 1 of the Public Interest Disclosure (Prescribed Persons) (Amendment) Order (Northern Ireland) 2014, employees in Northern Ireland will be protected from their employer if they make a 'protected disclosure' to a designated body. As we are listed as a designated body in Northern Ireland, employees there are protected from action by their employer if they disclose to us:

"Matters relating to:

(a) the registration and fitness to practise of a member of a profession regulated by the Council; and

(b) any activities not covered by (a) in relation to which the Council has functions."

50 In exceptional circumstances, wider disclosures (for example to an MP or the media) may also be protected. However, before following these routes, we strongly recommend that you get advice.

51 You can find more information about relevant legislation at **www.protect-advice.org.uk/law-policy**.

Where can I get help or advice?

Trade unions

Royal College of Nursing (RCN)
0345 772 6100
www.rcn.org.uk

Royal College of Midwives (RCM)
0300 303 0444
www.rcm.org.uk

UNISON
0800 084 7847
www.unison.org.uk

CPHVA/Unite
020 7611 2500
www.unitetheunion.org

Independent organisations

Protect
020 3117 2520
www.protect-advice.org.uk

Whistleblowing Helpline (England only)
08000 724 725
www.wbhelpline.org.uk

Medical Defence Union
0800 716 646
www.the-mdu.com

Medical and Dental Defence Union of Scotland
0333 043 4444
www.mddus.com

Regulatory organisations

Regulators of healthcare professionals

The Nursing and Midwifery Council

020 7637 7181

www.nmc.org.uk

whistleblowing@nmc-uk.org

General Medical Council

Regulator for medical doctors throughout the UK in all healthcare sectors

0161 923 6602

www.gmc-uk.org

Health and Care Professions Council

Regulator for the allied health professions and social workers in England

0300 500 6184

www.hpc-uk.org

Regulators of health and social care services

These organisations regulate healthcare systems and work settings.

England

Care Quality Commission

03000 616 161

www.cqc.org.uk

Ofsted

Regulator of education, early years and children's social care

0300 123 1231

www.ofsted.gov.uk

Department of Health (England)

020 7210 4850

www.dh.gov.uk

Professional Standards Authority for Health and Social Care

020 7389 8030

www.professionalstandards.org.uk

NHS Improvement

0300 123 2257

www.improvement.nhs.uk

Wales

Care and Social Services Inspectorate Wales

Responsible for social services and care homes.

0300 7900 126

www.cssiw.org.uk

Health Inspectorate Wales

Responsible for all NHS-funded care (including independent hospitals).

0300 062 8163

www.hiw.org.uk

Department for Health and Social Services (Wales)

English 0845 010 3300

Welsh 0845 010 4400

www.wales.gov.uk

Scotland

Care Inspectorate

0345 600 9527

www.careinspectorate.com

Healthcare Improvement Scotland

Edinburgh 0131 623 4300

Glasgow 0141 225 6999

www.healthcareimprovementscotland.org

The Scottish Government
0300 244 4000
www.gov.scot/health

Northern Ireland

Regulation and Quality Improvement Authority Northern Ireland
028 9051 7500
www.rqia.org.uk

Department of Health (Northern Ireland)
028 9052 0500
www.health-ni.gov.uk

Crown dependencies

Jersey

States of Jersey, Health and Social Services Department
01534 442 000
www.gov.je

Guernsey

States of Guernsey, Health and Social Services Department
01481 725 241
www.gov.gg

Isle of Man

Isle of Man Government, Department of Health and Social Care
01624 642 608
www.gov.im

Further reading

You should read this guidance together with the following.

NMC publications

- The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates (2018).
- Advice and information for employers of nurses, midwives and nursing associates (2014, updated 2016).

External publications

- Being open: communicating patient safety incidents with patients, their families and carers (2009) National Patient Safety Organisation.
- Confidentiality: NHS Code of Practice (2003) and supplementary code of practice on public interest disclosures (2010) Department of Health.
- NHS Constitution (2015) Department of Health.
- Care and support statutory guidance (2014, updated 2017) issued by the Department of Health under the Care Act 2014.
- Safeguarding adults: a national framework of standards for good practice and outcomes in adult protection work (2005) Association of Directors of Social Services (Northern Ireland, Wales and England).
- Speak up for a healthy NHS (2010) Department of Health, the Social Partnership Forum and Public Concern at Work.
- Bridging the Gap Summary Report (2013) Whistleblowing Helpline.
- Freedom to speak up: raising concerns policy for the NHS (2016) NHS Improvement.
- Raising concerns: a guide for RCN members (2015) Royal College of Nurses.



23 Portland Place, London W1B 1PZ
T +44 20 7637 7181

www.nmc.org.uk

The nursing and midwifery regulator for England,
Wales, Scotland and Northern Ireland

Registered charity in England and Wales (1091434) and in Scotland (SC038362)

The Code

Professional standards of practice
and behaviour for nurses, midwives
and nursing associates

prioritise people



practise effectively



preserve safety



**promote professionalism
and trust**



About us

The Nursing and Midwifery Council exists to protect the public. We do this by making sure that only those who meet our requirements are allowed to practise as a nurse or midwife in the UK, or a nursing associate in England. We take action if concerns are raised about whether a nurse, midwife or nursing associate is fit to practise.

It is against the law to claim to be, or to practise as, a nurse or midwife in the UK, or as a nursing associate in England, if you are not on the relevant part of our register.

It is also a criminal offence for anyone who, with intent to deceive, causes or permits someone else to falsely represent them as being on the register, or makes a false representation about them being on the NMC register.

Publication date: 29 January 2015 **Effective from:** 31 March 2015
Updated to reflect the regulation of nursing associates: 10 October 2018

A note on this version of the Code

All regulators review their Codes from time to time to make sure they continue to reflect public expectations. This new version of the Code is substantially similar to the 2015 version, but it has been updated to reflect our new responsibilities for the regulation of nursing associates. In joining the register, nursing associates will uphold the Code.

The current versions of our Code, standards and guidance can always be found on our website. Those on our register should make sure they are using the most up to date version of the Code.

For more information about the Code, please visit:
www.nmc.org.uk/code

Introduction

The Code contains the professional standards that registered nurses, midwives and nursing associates¹ must uphold. Nurses, midwives and nursing associates must act in line with the Code, whether they are providing direct care to individuals, groups or communities or bringing their professional knowledge to bear on nursing² and midwifery practice in other roles, such as leadership, education, or research. The values and principles set out in the Code can be applied in a range of different practice settings, but they are not negotiable or discretionary.

Our role is to set the standards in the Code, but these are not just our standards. They are the standards that patients and members of the public tell us they expect from health professionals. They are the standards shown every day by those on our register.

When joining our register, and then renewing their registration, nurses, midwives and nursing associates commit to upholding these standards. This commitment to professional standards is fundamental to being part of a profession. We can take action if those on our register fail to uphold the Code. In serious cases, this can include removing them from the register.

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- 1** Anyone practising as a registered nurse or midwife in the UK, or a nursing associate in England, has to be registered with us. The nursing associate role is being used only in England.
 - 2** We have used the word ‘nursing’ in this document to apply to the work of nurses and nursing associates. Nursing associates are a distinct profession with their own part of our register, but they are part of the nursing team.

The Code sets out common standards of conduct and behaviour for those on our register. This provides a clear, consistent and positive message to patients, service users and colleagues about what they can expect of those who provide nursing or midwifery care.

The professions we regulate have different knowledge and skills, set out in three distinct standards of proficiency. They can work in diverse contexts and have different levels of autonomy and responsibility. However, all of the professions we regulate exercise professional judgement and are accountable for their work.

Nurses, midwives and nursing associates uphold the Code within the limits of their competence. This means, for example, that while a nurse and nursing associate will play different roles in an aspect of care, they will both uphold the standards in the Code within the contribution they make to overall care. The professional commitment to work within one's competence is a key underpinning principle of the Code (see section 13) which, given the significance of its impact on public protection, should be upheld at all times.

In addition, nurses, midwives and nursing associates are expected to work within the limits of their competence, which may extend beyond the standards they demonstrated in order to join the register.

The Code should be useful for everyone who cares about good nursing and midwifery.

- Patients and service users, and those who care for them, can use it to provide feedback to nurses, midwives and nursing associates about the care they receive.
- Those on our register can use it to promote safe and effective practice in their place of work.
- Employer organisations should support their staff in upholding the standards in their professional Code as part of providing the quality and safety expected by service users and regulators.
- Educators can use the Code to help students understand what it means to be a registered professional and how keeping to the Code helps to achieve that.

For the many committed and expert practitioners on our register, this Code should be seen as a way of reinforcing professionalism. Through revalidation, nurses, midwives and nursing associates provide evidence of their continued ability to practise safely and effectively. The Code is central to the revalidation process as a focus for professional reflection. This gives the Code significance in the professional life of those on our register, and raises its status and importance for employers.

The Code contains a series of statements that taken together signify what good practice by nurses, midwives and nursing associates looks like. It puts the interests of patients and service users first, is safe and effective, and promotes trust through professionalism.

Prioritise people

You put the interests of people using or needing nursing or midwifery services first. You make their care and safety your main concern and make sure that their dignity is preserved and their needs are recognised, assessed and responded to. You make sure that those receiving care are treated with respect, that their rights are upheld and that any discriminatory attitudes and behaviours towards those receiving care are challenged.

1 Treat people as individuals and uphold their dignity

To achieve this, you must:

- 1.1** treat people with kindness, respect and compassion
- 1.2** make sure you deliver the fundamentals of care effectively
- 1.3** avoid making assumptions and recognise diversity and individual choice
- 1.4** make sure that any treatment, assistance or care for which you are responsible is delivered without undue delay
- 1.5** respect and uphold people's human rights

The fundamentals of care include, but are not limited to, nutrition, hydration, bladder and bowel care, physical handling and making sure that those receiving care are kept in clean and hygienic conditions. It includes making sure that those receiving care have adequate access to nutrition and hydration, and making sure that you provide help to those who are not able to feed themselves or drink fluid unaided.

2 Listen to people and respond to their preferences and concerns

To achieve this, you must:

- 2.1** work in partnership with people to make sure you deliver care effectively
- 2.2** recognise and respect the contribution that people can make to their own health and wellbeing
- 2.3** encourage and empower people to share in decisions about their treatment and care
- 2.4** respect the level to which people receiving care want to be involved in decisions about their own health, wellbeing and care
- 2.5** respect, support and document a person's right to accept or refuse care and treatment
- 2.6** recognise when people are anxious or in distress and respond compassionately and politely

3 Make sure that people's physical, social and psychological needs are assessed and responded to

To achieve this, you must:

- 3.1** pay special attention to promoting wellbeing, preventing ill health and meeting the changing health and care needs of people during all life stages
- 3.2** recognise and respond compassionately to the needs of those who are in the last few days and hours of life

- 3.3** act in partnership with those receiving care, helping them to access relevant health and social care, information and support when they need it
- 3.4** act as an advocate for the vulnerable, challenging poor practice and discriminatory attitudes and behaviour relating to their care

4 Act in the best interests of people at all times

To achieve this, you must:

- 4.1** balance the need to act in the best interests of people at all times with the requirement to respect a person's right to accept or refuse treatment
- 4.2** make sure that you get properly informed consent and document it before carrying out any action
- 4.3** keep to all relevant laws about mental capacity that apply in the country in which you are practising, and make sure that the rights and best interests of those who lack capacity are still at the centre of the decision-making process
- 4.4** tell colleagues, your manager and the person receiving care if you have a conscientious objection to a particular procedure and arrange for a suitably qualified colleague to take over responsibility for that person's care

You can only make a 'conscientious objection' in limited circumstances. For more information, please visit our website at **www.nmc.org.uk/standards**

5 Respect people's right to privacy and confidentiality

As a nurse, midwife or nursing associate, you owe a duty of confidentiality to all those who are receiving care. This includes making sure that they are informed about their care and that information about them is shared appropriately.

To achieve this, you must:

- 5.1** respect a person's right to privacy in all aspects of their care
- 5.2** make sure that people are informed about how and why information is used and shared by those who will be providing care
- 5.3** respect that a person's right to privacy and confidentiality continues after they have died
- 5.4** share necessary information with other health and care professionals and agencies only when the interests of patient safety and public protection override the need for confidentiality
- 5.5** share with people, their families and their carers, as far as the law allows, the information they want or need to know about their health, care and ongoing treatment sensitively and in a way they can understand

Practise effectively

You assess need and deliver or advise on treatment, or give help (including preventative or rehabilitative care) without too much delay, to the best of your abilities, on the basis of best available evidence. You communicate effectively, keeping clear and accurate records and sharing skills, knowledge and experience where appropriate. You reflect and act on any feedback you receive to improve your practice.

6 Always practise in line with the best available evidence

To achieve this, you must:

- 6.1** make sure that any information or advice given is evidence-based including information relating to using any health and care products or services
- 6.2** maintain the knowledge and skills you need for safe and effective practice

7 Communicate clearly

To achieve this, you must:

- 7.1** use terms that people in your care, colleagues and the public can understand
- 7.2** take reasonable steps to meet people's language and communication needs, providing, wherever possible, assistance to those who need help to communicate their own or other people's needs
- 7.3** use a range of verbal and non-verbal communication methods, and consider cultural sensitivities, to better understand and respond to people's personal and health needs

- 7.4** check people's understanding from time to time to keep misunderstanding or mistakes to a minimum
- 7.5** be able to communicate clearly and effectively in English

8 Work co-operatively

To achieve this, you must:

- 8.1** respect the skills, expertise and contributions of your colleagues, referring matters to them when appropriate
- 8.2** maintain effective communication with colleagues
- 8.3** keep colleagues informed when you are sharing the care of individuals with other health and care professionals and staff
- 8.4** work with colleagues to evaluate the quality of your work and that of the team
- 8.5** work with colleagues to preserve the safety of those receiving care
- 8.6** share information to identify and reduce risk
- 8.7** be supportive of colleagues who are encountering health or performance problems. However, this support must never compromise or be at the expense of patient or public safety

9 Share your skills, knowledge and experience for the benefit of people receiving care and your colleagues

To achieve this, you must:

- 9.1** provide honest, accurate and constructive feedback to colleagues
- 9.2** gather and reflect on feedback from a variety of sources, using it to improve your practice and performance
- 9.3** deal with differences of professional opinion with colleagues by discussion and informed debate, respecting their views and opinions and behaving in a professional way at all times
- 9.4** support students' and colleagues' learning to help them develop their professional competence and confidence

10 Keep clear and accurate records relevant to your practice

This applies to the records that are relevant to your scope of practice. It includes but is not limited to patient records.

To achieve this, you must:

- 10.1** complete records at the time or as soon as possible after an event, recording if the notes are written some time after the event
- 10.2** identify any risks or problems that have arisen and the steps taken to deal with them, so that colleagues who use the records have all the information they need
- 10.3** complete records accurately and without any falsification, taking immediate and appropriate action if you become aware that someone has not kept to these requirements
- 10.4** attribute any entries you make in any paper or electronic records to yourself, making sure they are clearly written, dated and timed, and do not include unnecessary abbreviations, jargon or speculation
- 10.5** take all steps to make sure that records are kept securely
- 10.6** collect, treat and store all data and research findings appropriately

11 Be accountable for your decisions to delegate tasks and duties to other people

To achieve this, you must:

- 11.1** only delegate tasks and duties that are within the other person's scope of competence, making sure that they fully understand your instructions
- 11.2** make sure that everyone you delegate tasks to is adequately supervised and supported so they can provide safe and compassionate care
- 11.3** confirm that the outcome of any task you have delegated to someone else meets the required standard

12 Have in place an indemnity arrangement which provides appropriate cover for any practice you take on as a nurse, midwife or nursing associate in the United Kingdom

To achieve this, you must:

- 12.1** make sure that you have an appropriate indemnity arrangement in place relevant to your scope of practice

For more information, please visit our website at **www.nmc.org.uk/indemnity**

Preserve safety

You make sure that patient and public safety is not affected. You work within the limits of your competence, exercising your professional 'duty of candour' and raising concerns immediately whenever you come across situations that put patients or public safety at risk. You take necessary action to deal with any concerns where appropriate.

13 Recognise and work within the limits of your competence

To achieve this, you must, as appropriate:

- 13.1** accurately identify, observe and assess signs of normal or worsening physical and mental health in the person receiving care
- 13.2** make a timely referral to another practitioner when any action, care or treatment is required
- 13.3** ask for help from a suitably qualified and experienced professional to carry out any action or procedure that is beyond the limits of your competence
- 13.4** take account of your own personal safety as well as the safety of people in your care
- 13.5** complete the necessary training before carrying out a new role

The professional duty of candour is about openness and honesty when things go wrong. "Every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress." Joint statement from the Chief Executives of statutory regulators of healthcare professionals.

14 Be open and candid with all service users about all aspects of care and treatment, including when any mistakes or harm have taken place

To achieve this, you must:

- 14.1** act immediately to put right the situation if someone has suffered actual harm for any reason or an incident has happened which had the potential for harm
- 14.2** explain fully and promptly what has happened, including the likely effects, and apologise to the person affected and, where appropriate, their advocate, family or carers
- 14.3** document all these events formally and take further action (escalate) if appropriate so they can be dealt with quickly

15 Always offer help if an emergency arises in your practice setting or anywhere else

To achieve this, you must:

- 15.1** only act in an emergency within the limits of your knowledge and competence
- 15.2** arrange, wherever possible, for emergency care to be accessed and provided promptly
- 15.3** take account of your own safety, the safety of others and the availability of other options for providing care

16 Act without delay if you believe that there is a risk to patient safety or public protection

To achieve this, you must:

- 16.1** raise and, if necessary, escalate any concerns you may have about patient or public safety, or the level of care people are receiving in your workplace or any other health and care setting and use the channels available to you in line with our guidance and your local working practices
- 16.2** raise your concerns immediately if you are being asked to practise beyond your role, experience and training
- 16.3** tell someone in authority at the first reasonable opportunity if you experience problems that may prevent you working within the Code or other national standards, taking prompt action to tackle the causes of concern if you can
- 16.4** acknowledge and act on all concerns raised to you, investigating, escalating or dealing with those concerns where it is appropriate for you to do so
- 16.5** not obstruct, intimidate, victimise or in any way hinder a colleague, member of staff, person you care for or member of the public who wants to raise a concern
- 16.6** protect anyone you have management responsibility for from any harm, detriment, victimisation or unwarranted treatment after a concern is raised

For more information, please visit our website at **www.nmc.org.uk/raisingconcerns**.

17 Raise concerns immediately if you believe a person is vulnerable or at risk and needs extra support and protection

To achieve this, you must:

- 17.1** take all reasonable steps to protect people who are vulnerable or at risk from harm, neglect or abuse
- 17.2** share information if you believe someone may be at risk of harm, in line with the laws relating to the disclosure of information
- 17.3** have knowledge of and keep to the relevant laws and policies about protecting and caring for vulnerable people

18 Advise on, prescribe, supply, dispense or administer medicines within the limits of your training and competence, the law, our guidance and other relevant policies, guidance and regulations

To achieve this, you must:

- 18.1** prescribe, advise on, or provide medicines or treatment, including repeat prescriptions (only if you are suitably qualified) if you have enough knowledge of that person's health and are satisfied that the medicines or treatment serve that person's health needs
- 18.2** keep to appropriate guidelines when giving advice on using controlled drugs and recording the prescribing, supply, dispensing or administration of controlled drugs

- 18.3** make sure that the care or treatment you advise on, prescribe, supply, dispense or administer for each person is compatible with any other care or treatment they are receiving, including (where possible) over-the-counter medicines
- 18.4** take all steps to keep medicines stored securely
- 18.5** wherever possible, avoid prescribing for yourself or for anyone with whom you have a close personal relationship

Prescribing is not within the scope of practice of everyone on our register. Nursing associates don't prescribe, but they may supply, dispense and administer medicines. Nurses and midwives who have successfully completed a further qualification in prescribing and recorded it on our register are the only people on our register that can prescribe.

For more information, please visit our website at **www.nmc.org.uk/standards**.

19 Be aware of, and reduce as far as possible, any potential for harm associated with your practice

To achieve this, you must:

- 19.1** take measures to reduce as far as possible, the likelihood of mistakes, near misses, harm and the effect of harm if it takes place
- 19.2** take account of current evidence, knowledge and developments in reducing mistakes and the effect of them and the impact of human factors and system failures (see the note below)
- 19.3** keep to and promote recommended practice in relation to controlling and preventing infection
- 19.4** take all reasonable personal precautions necessary to avoid any potential health risks to colleagues, people receiving care and the public

Human factors refer to environmental, organisational and job factors, and human and individual characteristics, which influence behaviour at work in a way which can affect health and safety – Health and Safety Executive. You can find more information at **www.hse.gov.uk**

Promote professionalism and trust

You uphold the reputation of your profession at all times. You should display a personal commitment to the standards of practice and behaviour set out in the Code. You should be a model of integrity and leadership for others to aspire to. This should lead to trust and confidence in the professions from patients, people receiving care, other health and care professionals and the public.

20 Uphold the reputation of your profession at all times

To achieve this, you must:

- 20.1** keep to and uphold the standards and values set out in the Code
- 20.2** act with honesty and integrity at all times, treating people fairly and without discrimination, bullying or harassment
- 20.3** be aware at all times of how your behaviour can affect and influence the behaviour of other people
- 20.4** keep to the laws of the country in which you are practising
- 20.5** treat people in a way that does not take advantage of their vulnerability or cause them upset or distress
- 20.6** stay objective and have clear professional boundaries at all times with people in your care (including those who have been in your care in the past), their families and carers

- 20.7** make sure you do not express your personal beliefs (including political, religious or moral beliefs) to people in an inappropriate way
- 20.8** act as a role model of professional behaviour for students and newly qualified nurses, midwives and nursing associates to aspire to
- 20.9** maintain the level of health you need to carry out your professional role
- 20.10** use all forms of spoken, written and digital communication (including social media and networking sites) responsibly, respecting the right to privacy of others at all times

For more guidance on using social media and networking sites, please visit our website at **www.nmc.org.uk/standards**

21 Uphold your position as a registered nurse, midwife or nursing associate

To achieve this, you must:

- 21.1** refuse all but the most trivial gifts, favours or hospitality as accepting them could be interpreted as an attempt to gain preferential treatment
- 21.2** never ask for or accept loans from anyone in your care or anyone close to them
- 21.3** act with honesty and integrity in any financial dealings you have with everyone you have a professional relationship with, including people in your care

- 21.4** make sure that any advertisements, publications or published material you produce or have produced for your professional services are accurate, responsible, ethical, do not mislead or exploit vulnerabilities and accurately reflect your relevant skills, experience and qualifications
- 21.5** never use your status as a registered professional to promote causes that are not related to health
- 21.6** cooperate with the media only when it is appropriate to do so, and then always protecting the confidentiality and dignity of people receiving treatment or care

22 Fulfil all registration requirements

To achieve this, you must:

- 22.1** keep to any reasonable requests so we can oversee the registration process
- 22.2** keep to our prescribed hours of practice and carry out continuing professional development activities
- 22.3** keep your knowledge and skills up to date, taking part in appropriate and regular learning and professional development activities that aim to maintain and develop your competence and improve your performance

For more information, please visit our website at **www.nmc.org.uk/standards**.

23 Cooperate with all investigations and audits

This includes investigations or audits either against you or relating to others, whether individuals or organisations. It also includes cooperating with requests to act as a witness in any hearing that forms part of an investigation, even after you have left the register.

To achieve this, you must:

- 23.1** cooperate with any audits of training records, registration records or other relevant audits that we may want to carry out to make sure you are still fit to practise
- 23.2** tell both us and any employers as soon as you can about any caution or charge against you, or if you have received a conditional discharge in relation to, or have been found guilty of, a criminal offence (other than a protected caution or conviction)
- 23.3** tell any employers you work for if you have had your practice restricted or had any other conditions imposed on you by us or any other relevant body
- 23.4** tell us and your employers at the first reasonable opportunity if you are or have been disciplined by any regulatory or licensing organisation, including those who operate outside of the professional health and care environment

When telling your employers, this includes telling (i) any person, body or organisation you are employed by, or intend to be employed by, as a nurse, midwife or nursing associate; and (ii) any person, body or organisation with whom you have an arrangement to provide services as a nurse, midwife or nursing associate.

- 23.5** give your NMC Pin when any reasonable request for it is made

For more information, please visit our website at **www.nmc.org.uk**.

24 Respond to any complaints made against you professionally

To achieve this, you must:

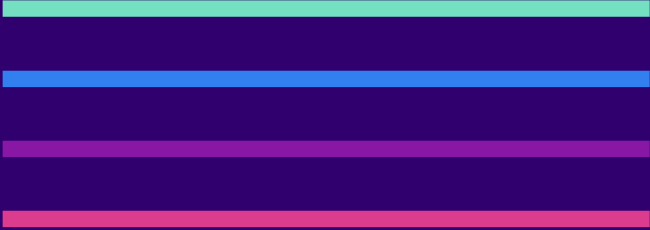
- 24.1** never allow someone's complaint to affect the care that is provided to them
- 24.2** use all complaints as a form of feedback and an opportunity for reflection and learning to improve practice

25 Provide leadership to make sure people's wellbeing is protected and to improve their experiences of the health and care system

To achieve this, you must:

- 25.1** identify priorities, manage time, staff and resources effectively and deal with risk to make sure that the quality of care or service you deliver is maintained and improved, putting the needs of those receiving care or services first
- 25.2** support any staff you may be responsible for to follow the Code at all times. They must have the knowledge, skills and competence for safe practice; and understand how to raise any concerns linked to any circumstances where the Code has, or could be, broken

Throughout their career, all our registrants will have opportunities to demonstrate leadership qualities, regardless of whether or not they occupy formal leadership positions.



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The nursing and midwifery regulator for England, Wales, Scotland and Northern Ireland
Registered charity in England and Wales (1091434) and in Scotland (SC038362)

Wamsley, Chris

From: Jameson, Hannah [Personal Information redacted by the USI]
Sent: 28 June 2021 06:58
To: Loughan, Patricia; Wamsley, Chris
Subject: Re: complaint

morning

this is my fault Patricia Chris was off when I received the complaint from the HCA

I was so disgusted so emailed Mary Averall who notified Chris on Friday and Bernie and Chris spoke to [Personal Information redacted by the USI] on Friday afternoon.

I will complete all forms today in regards to the two patients in question

[Personal Information redacted by the USI] wasn't working any more shifts from Thursday as he needed time away from the ward so was off all of July

thanks
Hannah

From: Loughan, Patricia
Sent: 27 June 2021 07:57:21
To: Jameson, Hannah; Wamsley, Chris
Subject: FW: complaint

Hi Both,

I am trying to understand why I have not been made aware of the attached considering the seriousness of the allegation's being made? And the obvious safeguarding issues surrounding the incidents highlighted?

Regards
Patricia

From: Wamsley, Chris
Sent: 25 June 2021 17:54
To: McVey, Anne
Cc: Averall, Mary; Loughan, Patricia
Subject: FW: complaint

Hi Anne

As per our telephone call I am sending through the complaint found by Mary this evening and a brief outline of events.

- Event discussed with [Personal Information redacted by the USI] and he has been sent home from duty
- Advised this will be processed through safeguarding due to the nature of the allegations made
- Mary has contacted his agency "direct medics" and advised of investigation and not to provide shifts in other areas.
- Hannah to complete APP1 forms for both patients on Monday as the first contact.
- Patients are deemed to be in a place of safety as the threat, [Personal Information redacted by the USI], has now been removed from their care.
- Bernie has been advised if the seriousness of events and importance or using the correct lines of escalation.
- I will meet with Hannah on Monday to discuss this also.

Many thanks

Chris

From: Overall, Mary
Sent: 25 June 2021 16:36
To: Wamsley, Chris
Subject: FW: complaint

From: Jameson, Hannah
Sent: 24 June 2021 13:46
To: Overall, Mary
Cc: McManus, Bernie
Subject: complaint

Hey

Please see attached letter of concern for Personal information redacted by the USI and regards to the next steps

any advice would be greatly appreciated

thanks

Hannah Jameson