Procedure for the Reporting and Follow up of Serious Adverse Incidents, November 2016 at www.hscboard.hscni.net [27]

[27] HSCB Loc. Cit Section 4

3.0 Stage 2 Identifying and tracing service users at risk

One of the most important stages of the Lookback Review Process is the accurate identification and tracing of the service user cohort who have been identified as being affected by the triggering event. The HSC organisation is responsible for the identification and tracing of the affected service users must allocate appropriate resources to ensure that this is undertaken.

In the context of the Lookback Review process, this Stage involves the review of care/ processes against explicit standards and criteria to identify those who may not have received the required standard of care or where the procedure used did not adhere to explicit standards and criteria. [28]

3.1 Role of the Steering Group –Terms of Reference and Action Planning

The Steering Group should continue to ensure the management of immediate safety issues and care for those harmed or potentially harmed by the triggering event.

The Steering Group is responsible for ensuring the identification and tracing of the cohort of service users to be included in the service user lookback and recall phases of the Lookback Review Process. The Steering Group will need a clear definition of which service users should be recalled/ offered further tests/assessments, what they should be recalled for, how test/assessment outcomes will be categorised and how each category will be managed/followed-up (Sections 3.2 – 3.4 and Appendix 3).

The Steering Group should review their Terms of Reference and Group membership at this stage and consider if additional membership from the service area/support services and from service users advocacy services are required for either the Steering Group or the Operational Group/ Lookback Review Management Team if applicable (see Section 2.3). The extent and complexity of the Lookback Review Process will determine the resources and responses required.

The Steering Group should also review the Lookback Review Action plan (Section 2.5). As required, expert advice or linkages may be also made with resources such as relevant Professional Bodies and Faculties (e.g. Royal Colleges) to assist with this stage of the Lookback Review.

[28] HSE. *Op.Cit*. Section 7.7 Page 17

The Steering Group should also consider the service user recall methodology for the next stage and further develop the Communication Plan (including the formation of Helplines/Information Lines and use of the organisation's web page to provide general information and Frequently Asked Questions and responses Section 4.4).

The Steering Group will need to meet on a regular basis to ensure that they receive situation reports (SITREPS) and provide a co-ordinated approach to the oversight of the Process. SITREPS should also be shared with internal stakeholders (Executive Team/Senior Management Team and Board) and external stakeholders i.e. HSCB, PHA and DoH.

3.2 Establish the Service User Database

The HSC organisation will need to develop a service user database to collate the details of the service users that have been identified for inclusion in the service review/ audit stage of the Process. It is important to consider the output from the service user notification database at the outset. The list of service users will be needed to:

- Generate letters to service users;
- Check if service users at risk have made contact;
- Keep track of who requires further review/testing;
- Record who has had results;
- At the end of the Lookback Review Process to generate information on numbers of service users identified, further assessed and their outcomes.

The database needs to be updated, by administrative staff, on a regular, and at some stages at least on a daily basis. This will ensure the information held is the most up to date and reliable.

The database may already exist on one of the organisations Information Technology (IT) systems. In some circumstances (for example service users who have not been reviewed for a period of time), it may be necessary to check the service user details with the General Register Office for NI to identify if any of these service users have

since deceased.[29] Information Technology staff are essential members of the sub team to assist in accessing existing databases/establishing databases. Specific data variables, will be determined by the nature of the triggering event and the audit methodology to be applied. If a database of service user details does not already exist then a suggested core dataset for service users at risk has been outlined in Appendix 2.

The Steering Group should give special consideration in the Lookback Review Action Plan as to whether or not the cases of deceased persons meet the inclusion criteria, how their records should be handled and how best to communicate with their relatives.[30]

3.3 Establish the Process for the Identification of Affected Service Users[31]

The Steering Group should establish and record clear processes for the identification of the service users/ staff to be included in the Recall Stage. This will include the development/ agreement of the:

- Audit criteria (criteria as to what will be considered within acceptable practice limits, minor or major discrepancy, the clinical significance of these discrepancies, and actions to be taken in each category, guided by national and international best practice, faculty requirements etc.);
- Scope of Audit (including timeframes and definition of records to be reviewed);
- Audit Methodology;
- Audit Tool;
- Instructions to ensure consistent recording of audit results;
- Instructions for analysis of audit data;
- Procedures for ensuring the validity and reliability of the audit to ensure that all auditors interpret and apply audit criteria in the same way;
- Process for the submission of audit outcomes to the Steering Group.

The HSC organisation should take account of extant guidance in relation to maintaining service user confidentiality.[32] [33] [34] The audit of service user's healthcare

[29] General Register Office for Northern Ireland @ www.gov.uk.
[30] HSE. *Op.Cit.* Section 7.7.4, page 18.
[31] Ibid. Section 7.7.3 Page 17

records should be undertaken by the healthcare team who would ordinarily have the right to access the service user's healthcare records as part of the delivery of health and social care. However, if the audit team is extended to include healthcare personnel who would not have a right to access the service user's healthcare records, and consent has not been provided by the service user for these personnel to access their records, then these records must be sufficiently anonymised, such that an individual is not identifiable to those undertaking the audit.[35]

3.4 Undertaking the Audit

The Steering Group will commission the audit of the healthcare records of the affected service users as identified in Stage 1 (risk assessment). The audit methodology and tools will have been defined by the Steering Group (see Section 3.3).

The audit will involve clinical staff with the necessary skill and knowledge of the specialty involved. However, depending on the nature, extent and complexity of the Lookback Review the HSC organisation may need to commission relevant experts to undertake the audit or service review.

Again, depending on the nature of the Lookback Review the team may initially be required to screen the service users' notes/x- rays/test results etc. to establish if they are in the affected cohort. A system for the initial identification of the service users including flow charts, service review proformas and service user notification letters are contained in Appendix 3. These are examples only and are provided as reference material and should be adapted by the HSC organisation for the specific health and social care trigger event on a case by case basis.

Following initial screening and identification of service users affected, further assessment may be required.

The service user database will be used to document the service users/ staff who are included and excluded following each stage of the Lookback Review Process (see

[32] EU Data Protection Regulation (GDPR) 25 May 2018 @ https://eugdpr.org
[33] Data Protection Act 2018 @ www.legislation.gov.uk .
[34] DoH 'Code of Practice for protecting the confidentiality of service user information' 31 January 2012 @ www.health,n-i.gov.uk
[35] HSE. *Op.cit*. Section 7.7.3.

Section 3.2 above). In general, it will be used to track persons affected and to record actions, interventions and outcomes.

Upon completion of the audit, the service review team will provide the Steering Group with the results of the audit which will inform the Steering Group of the persons affected to be included in the Recall Stage.

4.0 Stage 3 Service User Recall

4.1 Planning the Recall

Following completion of Stage 2, the Steering Group will move to the third stage, the Service User Recall Stage. The Steering Group and Operational Group should ensure that their Terms of Reference include the following; purpose of Recall, scope, method and timeframe.

The Steering Group will also establish the Recall Team(s) which will consist of experts in the subject area/ discipline which is the covered by the Lookback Review Process.

The Steering Group must agree with the Recall Team(s) a realistic work-plan with timelines that reflect the urgency and complexity of the Lookback Review Process.

The Steering Group will have to consider the following which will form the basis of the Operation Group/Lookback Review Management Team work-plan:

- Identify venue for the conduct of the Recall stage;
- Secure administrative support;
- Establish an appointment system including DNA management;
- Secure clinical and other specialist support e.g. laboratory/x-ray etc.;
- Arrange transportation of samples and results;
- Manage arrangements for assisting service users affected to attend the Recall Stage (for example car parking, site maps, signage/ 'meet and greet' arrangements, public transport, taxis, meals);
- Agree a system for recording of results;
- Ensure that counselling and welfare services are available to service users and to staff;
- Agree the communication and service user support arrangements (see Section 4.3);
- Consider the arrangements for overtime/out-of- hours working for staff.

Ideally, a liaison person/team should be appointed to oversee the seamless conduct of each attendance a service user has as part of the Recall stage, whether they are clinic appointments or repeat tests/x-rays etc. Responsibilities would include; providing a point of contact, follow-up of DNAs , quality assurance of the Process (correct letter to correct person) and checking that the service user affected are referred into the 'system' for subsequent follow-up.[36]

Depending on the extent, nature and complexity of the Process, the Steering Group will have to meet on (at least) a daily basis to ensure they receive SITREPS and continue to have an accurate oversight of the Lookback Review at this Stage (see Section 3.1).

4.2 Service User Communication and Support

One of the most important areas of managing any Lookback Review Process is the communication with all the affected service users. When communicating it is equally important to be able to say who is not affected. The timing of any communication is critical and every effort should be made to notify the entire group simultaneously. The method of doing this will be dictated by the numbers of service users involved (see Section 4.3). Service user notification must be co-ordinated with public announcements made by the organisation. In an ideal situation service users should be contacted before a media announcement is made. However, this is not always possible given the nature/scale of some Lookback Review Processes or if there is a breach in confidentiality at an earlier stage. Where applicable, the Steering Group should identify any service user representative bodies/third sector and brief them.

The Steering Group should agree key messages to ensure consistent and accurate information to provide confidence in the process. The Steering Group should consider the person(s) best suited to communicating bad news with affected service users, their families and/or carers. A spokesperson, should be identified to act as the organisation's spokesperson and be available for interview by the media etc. Media training should be provided on a case to case basis (see also Section 4.6).

The following should be included in the service user communication and support plan:

[36] *Ibid.* Section 7.8.2 Page 22.

- access to professional interpreters as required;
- a designated point of contact for service users, their families and/or carers;
- regular and ongoing information updates provided to service users and families and/or carers;
- affected service users offered a written apology by the health service organisation;
- establishment of a Helpline/Information Line/website to ask questions and to obtain information (see Section 4.5 and Appendix 4 for practical guidance);
- affected service users who need additional consultation have these appointments expedited to allay any anxieties or concern that they may have.

Communication and support of families should include:

- identifying immediate and ongoing management needs of service users, their families and/or carer;
- ensuring that service users understand the processes for ongoing management and have written advice/fact sheets concerning this;
- ensuring that relevant fact sheets containing information on the lookback review are published on the health service inter/intranet website;
- ensuring adequate resources are in place to provide the level of service required;
- provide counselling and welfare services;
- initial communication should be direct, either face-to-face or via telephone, where the service user must be given the opportunity to ask questions.

4.3 Service User Notification by Letter

Depending on the extent of the Lookback Review Process notification may be by a letter sent to the service users affected by the issue. As above, the timing of service user notification must be carefully choreographed with any public announcement made by the organisation. If the Process has affected small numbers of service users organisations may wish to consider alternative forms of direct communication

e.g. telephone calls in first instance which should be supplemented by a follow-up letter containing the pertinent information. A sample of letters has been provided in Appendix 3 for reference/guidance.

The service user letter should be signed by the Chief Executive or a Director of the HSC organisation. Service user letters should be sent by first class post in an envelope marked “Private and Confidential -To be opened by addressee only” and “If undelivered return to...(*the relevant Trust*)...”

Letters to the service user should include the following if appropriate:

- Unique service user identifier number;
- Service user information leaflet/ fact sheet;
- The website/freephone helpline number(s) and hours of opening;
- Location map with details of public transport routes;
- Free access to parking facilities;
- Arrangements for reimbursement of travelling expenses.

It can be helpful to include a reply slip with a pre-paid envelope to confirm that service users have received the letter. Alternatively, the organisation may consider using a recorded delivery service or hand delivering the letters if number are manageable.

Depending on the individual Lookback Review Process the HSC organisation may need to identify any service users under 16 and/or other vulnerable groups to write to their parent/guardian/ representative.

The Steering Group should plan for how service users who do not respond to an invitation and/or ‘lost to follow-up should be managed. The Steering Group should ensure that ‘every reasonable effort’ is made to contact all service users at risk for example by telephone or through General Practitioners. It is accepted that service users may have moved out of the region or abroad.

4.4 Public Announcement of the Recall Stage

The Steering Group will determine the timing of the Public Announcement of the Recall Stage of the Lookback Review Process. Communications management throughout the Lookback Review Process should be guided by the principles of

'Being Open'[37] balanced with the need to provide reassurance and avoid unnecessary concern.

Recall Stage will be announced to the public by the relevant HSC organisation lead Director in line with the Communication Plan (Section 4.2 and 4.6). As stated in Section 4.3, it is vital that the Steering Group strive to ensure that the Lookback Review Process is not publicly announced until all of the persons affected have been notified and a clear public message can be given regarding the extent of the cohort and those that are not affected. This is not always possible, as breaches of confidentiality may occur and therefore the Communication Plan should be prepared for this eventuality at all times.

When it is determined that communication with the public is required it should not be announced until all of the service users affected have been notified. As above it is recognised that this is not always possible. Key principles of public announcements include:

- Being open with information as it arises from the Lookback Review Process;
- Ongoing liaison with the media throughout the Lookback Review Process;
- Preliminary notification being made public where a situation requires additional time for the discovery of accurate information to be provided to service users and the wider public.

It essential that the findings in relation to the Lookback Review Process should not be released into the public domain until the Process is complete, all the findings are known and all affected service users are informed of the implications of the findings for them.[38]

4.5 Setting up a Service User Helpline/ Information Line

Once it has been agreed that the Lookback Review process is to be publicly announced HSC organisations need to have in place a system to deal with potentially large numbers of enquiries from service users, their families and the general public. It is recommended that site-specific helplines are considered for persons affected and a more general information line for the wider public.

[37] DoH 'Saying sorry – when things go wrong'. January 2020.
[38] HSE *Op Cit* Page 20

Consideration should also be given to providing information on the Trust's website for example Frequently Asked Questions (FAQs) and responses. Planning at this stage is vital to ensure that public confidence in the service is not further eroded. Guidance on setting up a service user helpline/information line are contained in Appendix 4.

4.6 Communication with the Media

Adverse incidents, especially those involving a service user lookback generate intense media attention. Regardless of the nature or intensity of media inquiries, information given to them should never exceed that which has been shared with the service users affected.[39]

The Steering Group should consider developing a 'media pack' (see below). The Head of Communications/Communications Manager should take a lead on developing this strategy. Depending on the extent, nature and complexity of the Lookback Review Process the Head of Communications/Communications Manager will liaise with the DoH Communications branch to seek advice on the communication strategy for the media and general public.

As part of the Communications Plan for dealing with the media, the Steering Group should:

- nominate a spokesperson for public and media communications;
- minimise the delay in response to the public and the media
- develop a media pack which should contain;
    - key messages
    - frequently asked questions (FAQs) and answers
    - draft media statements for each phase of the review process.

Media statements in relation to the issue, should be accurate and not add to the anxiety of the service users and their families/carers. Media statements should not be released prior to notification of the Lookback Review Process (see Sections 4.3

[39] *Ibid.* Section 7.11.2 Page 26

and 4.4). In the circumstances where a media statement is released it should state that a Lookback Review Process is being carried out, and immediately limit the area of concern to time period, region and service area within which the Process is being conducted. It should detail the numbers of persons affected being included in the recall stage of the process and the expected timeframe for the completion of the recall stage, if known.[40]

The media statement should note that all service users affected have been contacted (and method of contact) and that a Helpline/Information line/website has been established, giving the opening time(s) of the line and the contact details. The FAQs can be provided to the media as well as any additional briefing information such as an information leaflet.

All media statements and briefing notes should be ratified by the Steering Group.

4.7 Staff Communication and Support

While the public will need to be reassured that every effort is being made to conduct a full and thorough review, it is essential that the involved healthcare workers are protected and supported during this time. They need to be kept fully informed at all times during the exercise. Support from a peer and counselling should be offered by the employer. This is particularly important during the early stages of the lookback review process when there will be intense media interest. One point of contact, such as the Director of Human Resources should be identified to lead on this aspect throughout the process. In the case of an individual(s) being managed under the HSC organisation's capability/performance management/disciplinary procedures then the relevant HR policies should apply. These parallel processes are not included in the scope of this guidance (see Section 1.3).[41]

A communication and support plan should be devised for staff. This should include communication and support for:

- All staff who are managing the lookback process;
- All staff working in the area of concern;
- All other staff that may be affected.

[40] *Ibid*. Page 27.
[41] DoH Policy for Implementing a Lookback Review Process Section 4.

5.0 Stage 4 Closing, Evaluating and Reporting on the Lookback Review Process

A Lookback Review Process Guideline Checklist has been included in Appendix 5. The Checklist is a memory aid only and must be used in conjunction with the guidelines.[42]

The Steering Group are responsible for formally closing the Lookback Review Process when all service users affected have been reviewed and the care of service users requiring further treatment and care management have been transferred to the appropriate service and all the service users have been written to with the outcome of the review.

At the end of any Look Back process it is the responsibility of the Lead Director/Chair of the Steering Group to evaluate the management of the Lookback Review to assess the efficiency and effectiveness of the process and to identify any lessons learned from the process. Key measures should be assessed and strategies for further improvement should be implemented and reported to the Chief Executive as required.

The findings should be included in a Look Back Review Report. The content will be unique to each Lookback Review Process. The report should be shared with all relevant internal and external stakeholders. This report should be used to form the basis of the Serious Adverse Incident Report (Section 2.10) to facilitate the dissemination of learning across the HSC as a whole.

For the purposes of a report on a Lookback Review Process the report should contain the following information:

- Introduction including:
  - Details of Terms of Reference(s) (include Terms of Reference(s) in the
  - Appendices section of the report)
  - Composition and roles of the Safety Incident Management Team
  - Composition and roles of the Audit Team
  - Composition and roles of the Recall Team
- Methodology applied to the Look-back Review Process including:

[42] HSE. *Ibid*. Appendix 8.

- Methodology applied to preliminary review/Risk Assessment
- Clear audit methodology for the Audit Stage including:
  - Audit Criteria
  - Scope of Audit
  - Audit Methodology
  - Audit Tool
- Procedures for ensuring the validity and reliability of the Audit stage to ensure that all auditors interpret and apply audit criteria in the same way.
- Recall Stage methodology
- Communications Plan
- Information and Help Line Plan
- Plans for follow up for persons affected following both the Audit and Recall Stage

- Results/ Findings of Stage 1 Preliminary Findings/Risk Assessment;
- Results/ Findings of Stage 2 service review/ audit;
- Results/ Findings of the Recall stage;
- Actions taken to date to address findings;
- Learning and further recommended actions to address findings.

Peer review publication of issues relating to the Lookback Review Process, for instance; the development of an audit tool, logistics and communication with service users/families and staff may be of benefit and should be encouraged.[43]

[43] HSE. *Op. Cit*. Section 7.10.

Glossary

Term	Definition
Adverse Incident	Any event or circumstance that could have or did lead to harm, loss or damage to people, property, environment or reputation.
Audit	In the context of the lookback review process, audit involves the review of care/processes against explicit standards and criteria to identity those who may not have received the required standard of care or where the procedure used did not adhere to explicit standards and criteria.
Clinical Review	A re-examination of a medical and or clinical process/es which has delivered results that were not to the expected quality standard.
Cohort	A group of people who share a common characteristic or experience within a defined period (e.g., are currently living, are exposed to a drug or vaccine or pollutant, or undergo a certain medical procedure) i.e. a sub-group selected by a predetermined criteria.
Contributory factor	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.
Database	The ability to record information for retrieval at a later date. In this instance it may be on paper if the numbers involved are small. If the numbers are large, ITC equipment and competent administration staff may be required.
Harm	1 **Harm to a person**: Any physical or psychological injury or damage to the health of a person, including both temporary and permanent damage.

	2 **Harm to a thing**: Damage to a thing may include damage to facilities or systems; for example environmental, financial data protection breach, etc.
Hazard	A circumstance, agent or action with the potential to cause harm.
Lookback Review	A re-examination of a process(es) which has delivered results that were not to the expected quality standards.
Proforma	A page on which data is recorded. The page has predefined prompts and questions which require completing.
Quality Assurance	A check performed and recorded that a certain function has been completed. Negative outcomes must be reported and actioned.
Recall	An act or instance of officially recalling someone or something. In the context of the Lookback Review Process, the recall will involve the examination of the service user and/ or the review all relevant records in line with the Terms of Reference and will identify any deviations from required standards of care. Appropriate corrective actions will be identified as appropriate.
Risk	The chance of something happening that will impact on objectives.
Risk Assessment	A careful examination of what could cause harm to people, to enable precautions to be taken to prevent injury or ill-health.
Serious Adverse Incident	In the context of a Lookback Review Process an SAI is any event or circumstance that meet the specific criteria laid out within the HSCB Procedure for the Reporting and Follow up of SAIs 2016 at www.hscboard.hscni.net.

Service Review Team/expert advisory group	A specially selected group of individuals, competent in the required field of expertise, to perform the Lookback Review Process
Service User	Members of the public who use, or potentially use, health and social care services as patients, carers, parents and guardians. This also includes organisations and communities that represent the interests of people who use health and social care services.
Triggering Event	The initial concern(s) or adverse incident which lead to the HSC organisation considering the initiation of the Lookback Review Process.

Appendices

Template for Risk Assessment

Appendix 1

Information about the event or concern that has given rise to the need to consider a lookback review process (include information in relation to any actual harm that has been caused as a result of this issue)**:**

Information about the potential extent of the issue (include information about the number of people, number of HSC organisations that might be adversely affected by the issue)**:**

Information about the potential outcomes of the issue (include information about the potential consequences of the issue e.g. missed diagnosis / missed return appointments / harm from contaminated equipment):

Information about the risk level of the issue (include information about the severity of harm that might occur in the people adversely affected by the issue). Use the Regional Risk Matrix (Section 2.7) to evaluate the risk.

Please tick one:

Additional Details:

Extreme	
High	
Medium	
Low	

Information about the potential cohort of service users affected (number, gender, age range):

Details of Immediate Action Required

Recommendations to Steering Group regarding Stage 2 Lookback Review (include recommendations for the Terms of Reference for the Lookback Review including recommended inclusion and exclusion criteria; and for scoping audit(s) of service users that might fall within the inclusion criteria):

Details of personnel who undertook the Risk Assessment:

Name	Title

Date of Risk Assessment :

Establishing the Service User Database – Core Dataset Appendix 2

The data below is a minimum dataset, it is however subject to change depending on the individual situation. Ideally the use of an existing HSC organisation database(s) is preferred.

- Unique identifier number;
- Surname;
- Forename;
- Title;
- Date of birth;
- Sex;
- Address line one (House name, number and road name);
- Address line two (Town);
- Address line three (County);
- Postcode.

- GP name;
- GP address line one;
- GP address line two;
- GP address line three;
- Postcode.

- Named consultant;
- Date of appointment/procedure1;
- Date of appointment/procedure 2;
- Date of appointment/procedure 3;
- Procedure one description;
- Procedure two description;
- Procedure three description.

- Reviewer 1 description;
- Reviewer 2 description;
- Data entered by – identification;
- Data updated 1 by – identification;

- Data updated 2 by – identification;
- Data updated 3 – identification.

Appendix 3

Initial Identification of Service Users involved in the Service Review/ Audit Stage

See Flow Chart - Process for advising that all service users who may have been affected (Appendix 3.1 Section 1)

See Flow Chart - Process for advising all service users known to be the affected cohort (Appendix 3.1 Section 2)

The retrieval of notes/x-rays/test results must be co-ordinated with the support from Medical Records staff.

A Service Review Proforma (Appendix 3.2) is attached to each set of notes.

The service user database needs to be updated after completion of this Proforma.

A quality assurance check is provided by Administration which is essential to ensure that the correct letter is sent to the correct service user.

The Service Review Proforma should be transferred from the front of the notes and filed into the service users' records.

Conducting Further Assessment (Notes/X-rays/Test Results etc.)

A Notes/X-ray/Test Results Review Proforma (Appendix 3.3) is attached to the front of each set of service user notes.

The service review team will undertake a further detailed audit of the notes to review the outcomes of previous assessment/scans/tests.

The service review team will then decide if previous outcomes/diagnosis were accurate.

The Proforma will be completed by the Service Review Team.

- A green or red sticker is placed on the pro forma. The **green** sticker identifies a positive outcome and that no further follow up is required - Letter D is sent to service user.

- A **red** sticker identifies a negative outcome that requires a further assessment – Letter E is sent to service user.

The service user database needs to be updated after completion of this pro forma.

A quality assurance check is provided by Administration which is essential to ensure that the correct letter is sent to the correct service user.

The Notes Review Pro forma should be removed from the front of the notes and filed into the healthcare record.

Conducting Further Assessment (Clinical)

A Clinical Review Pro Forma (Appendix 3.4) is attached to the front of each set of healthcare record.

The service review team will undertake a clinical examination/test/scan etc. as appropriate to determine a positive or negative outcome. One must bear in mind that timescales for test/scan results may differ depending on individual situations.

The pro forma is then completed by the Service Review Team. A **green** or **red** sticker is placed on the pro forma.

- The **green** sticker identifies a positive outcome and that no further follow up is required - Letter F is sent to service user.

- A **red** sticker identifies a negative outcome that requires further treatment which should be managed within normal clinical arrangements – Letter G is sent to service user.

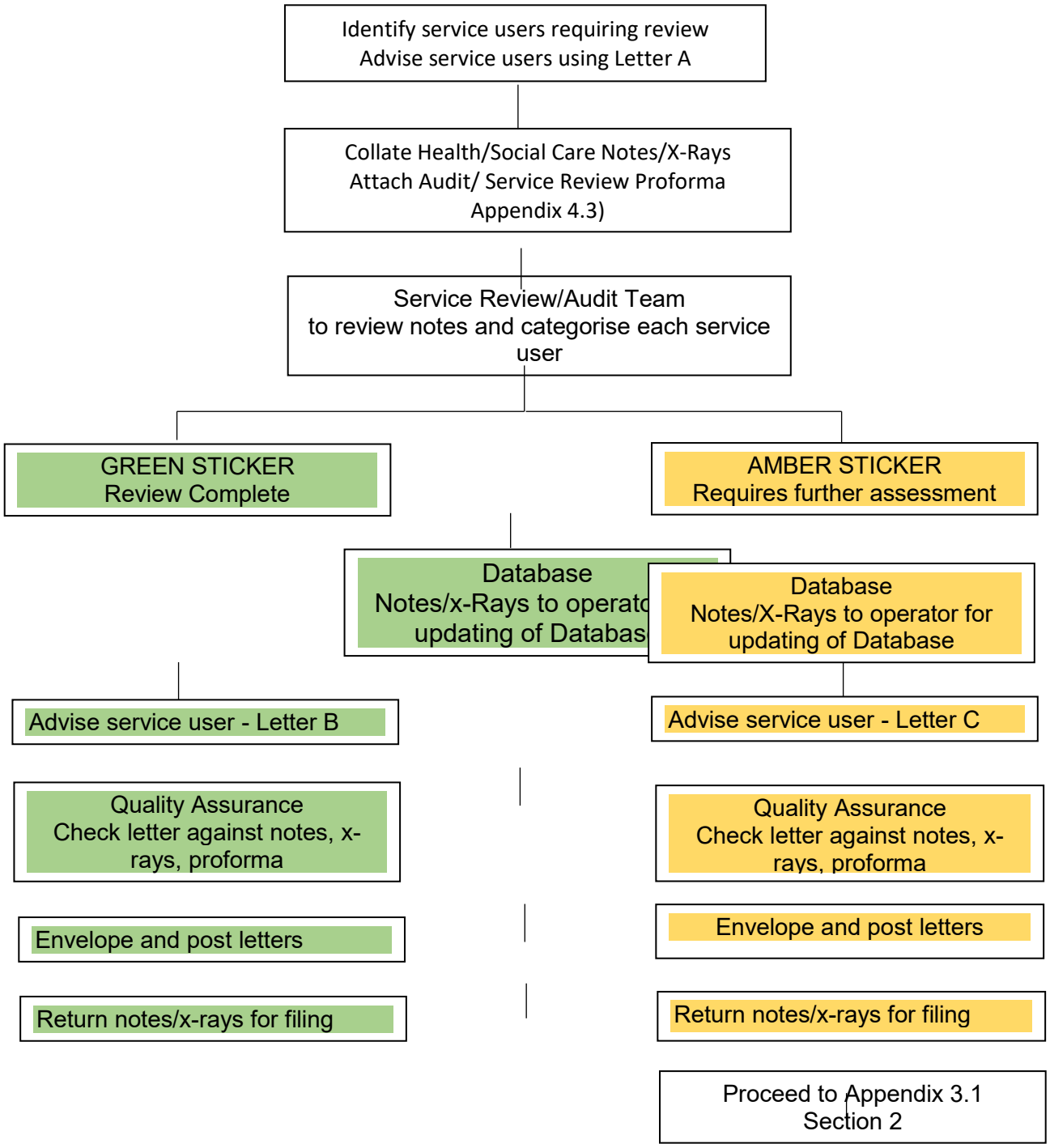
The service user database needs to be updated after completion of this proforma.

A quality assurance check is provided by Administration which is essential to ensure that the correct letter is sent to the correct service user.

The Clinical Review Pro Forma should be transferred from the front of the notes.

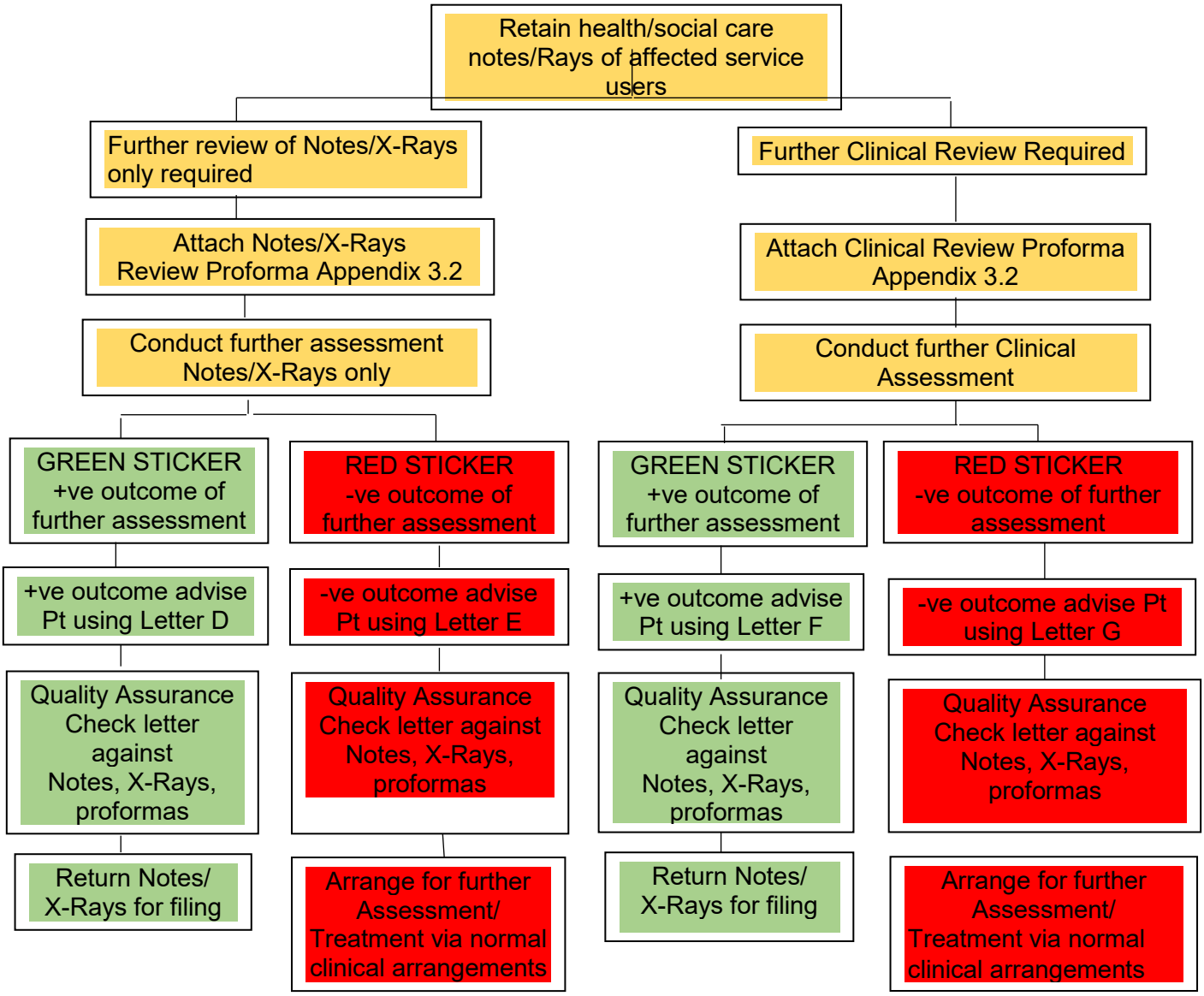
- If it has a **green** sticker attached: file into service user notes.
- If it has a **red** sticker attached: return service user notes and pro forma to admin support for processing within normal clinical arrangements.

Appendix 3.1 (Section 1) Advising service users who may be in the affected service user cohort



Appendix 3.1 (Section 2)

Process for Advising Service users known to be in the affected cohort.



Appendix 3.2 Service Review Proforma

SERVICE USER DETAILS (ATTACH LABEL)

CASENOTES REVIEWED ☐

X-RAYS REVIEWED ☐

OTHER MEDICAL DIAGNOSTIC/DATA REVIEWED ☐

(Give details)

DATE OF APPOINTMENT/SCAN/EXAMINATION REVIEWED ☐

REVIEWER 1 REVIEWER 2

Signature & date

Signature & date

GREEN STICKER – REVIEW COMPLETE

AMBER STICKER – FURTHER FOLLOW UP REQUIRED

DATABASE UPDATED ☐ **(Signature & date)**

ADMIN QA CHECK ☐ **(Signature & date)**

LETTER SENT ☐ **(Signature & date)**

Appendix 3.3 NOTES/X RAY REVIEW PROFORMA

SERVICE USER DETAILS (ATTACH LABEL)

INF
OR
MAT
ION

ADDITIONAL

CASENOTES REVIEWED ☐

X-RAYS/SCANS REVIEWED ☐

OTHER MEDICAL DIAGNOSTIC/DATA REVIEWED ☐

ADDITIONAL TESTS/SCANS/X-RAYS REQUIRED ☐

CLINICAL REVIEW REQUIRED ☐

REVIEWER 1 REVIEWER 2

Signature & date

Signature & date

GREEN STICKER – REVIEW COMPLETED

RED STICKER – FURTHER FOLLOW UP REQUIRED

DATABASE UPDATED ☐ **(Signature & date)**

ADMIN QA CHECK ☐ **(Signature & date)**

LETTER SENT ☐ **(Signature & date)**

Appendix 3.4 CLINICAL REVIEW PROFORMA

DETAILS (ATTACH LABEL)

	OUTCOME	
	+VE	**-VE**
CLINICAL EXAMINATION	☐	☐
TEST	☐	☐
SCAN/X-RAY	☐	☐
BIOPSY	☐	☐

OTHER MEDICAL DIAGNOSTIC/DATA REVIEWED
(Give details)

	YES	**NO**
FURTHER FOLLOW REQUIRED: PROCESS INTO NORMAL CLINICAL ARRANGEMENTS	☐	☐

CONSULTANTS SIGNATURE: _____DATE:_____

GREEN STICKER – REVIEW COMPLETED

AMBER STICKER – FOLLOW UP REQUIRED
PROCESS INTO NORMAL CLINICAL ARRANGEMENTS

RED STICKER - FOLLOW UP REQUIRED
REQUIRED URGENT REFERRAL

DATABASE UPDATED ☐ (Signature & date) _____

ADMIN QA CHECK ☐ (Signature & date) _____

LETTER SENT ☐ (Signature & date) _____

Appendix 3.5 DRAFT LETTERS

Although there will be one "master" letter, you will need to generate several variants from it for different circumstances e.g. when the service user is a child.

The following are provided for suggested content only.

LETTER A: Advising of a Lookback Review Process

LETTER B: No further follow up required

LETTER C (version 1): Further follow up is required – Notes only

LETTER C (version 2): Further follow up is required – Clinical

LETTER D: Positive outcome of further assessment – Notes only

LETTER E: Negative outcome of further assessment –Notes only

LETTER F: Positive outcome of further assessment – Clinical

LETTER G: Negative outcome of further assessment – Clinical

LETTER H: Letter to General Practitioner to advise them that the service user(s) are being included in the Recall Phase of Lookback Review Process

LETTER A: Advising of a service review/lookback review process

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear < Title>

<***Title of Lookback Review Process***>

It has come to the attention of <*HSC organisation*> that < *a healthcare worker/system*> has <brief outline of the incident>.

We have decided as a precautionary measure to review each of the cases with which this <*healthcare worker/system*> has been involved since <*date range*>.

Your case will be included in this review, which will be a substantial process <*involving…..*>. We have initiated a Service Review Process and will endeavour to deal with this as timely as possible.

I wanted to inform you directly about this rather than letting you hear it through another source and I believe it is important that you are kept fully informed of the review process. We will write to you immediately after your case has been reviewed to advise you whether or not it will be necessary for you to have <*a follow up appointment/test*>.

If in the interim you have any queries, a special telephone helpline has been set up on <*freephone/Tel:xxxxxxxx*> so that you can discuss any concerns. It is staffed from <*date and time to date and time*>. This line is completely confidential and operated by professional staff who are trained to answer your questions.

Although there are a large number of call handlers, there will be times of peak activity and there may be occasions where you may not get through. In this event I would ask you to please call again at another time.

<*Enclosed is a factsheet with more detailed information, which you may find helpful*>.

Please have your letter when you call the helpline, as you will be asked to quote the unique reference number from the top of the page.

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER B: No further follow up required

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

<Title of Lookback Review Process>

We had previously written to advise you that <*HSC Organisation*> had decided, as a precautionary measure, to review your individual case.

Your case was reviewed <*by xx / using the protocol*> and I am pleased to inform you that your <*case notes/assessment/test*> has now been reviewed and that **no further follow up is required.**

I fully appreciate that this has been a worrying time for you and I apologise for any upset this may have caused. However, I am sure you will understand that, although the risk <*of missed diagnosis/contracting xx*> was thought to be very low, we had an obligation to remove any uncertainty.

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER C (version 1): Further follow up is required – Notes only

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

<Title of Lookback Review Process>

We had previously written to advise you that <HSC Organisation> had decided, as a precautionary measure, to review your individual case.

Your case was reviewed <*by xx/using the protocol*> and the <*clinician/consultant*> has advised that **further follow up is required.** I must emphasise that this does not necessarily mean that <*illness/infection*> has been detected but that more investigation is required to reach a definite diagnosis.

I fully appreciate that this has been a worrying time for you and I deeply regret that your previous <*assessment/test/treatment*> has been found to be inadequate.

We have made special arrangements for <*name and grade of person*> to <*review notes/assessment*> and we will contact you again as soon as this is complete.

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER C (version 2): Further follow up is required – Clinical

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

<***Title of Lookback Review Process***>

We had previously written to advise you that <*HSC Organisation*> had decided, as a precautionary measure, to review your individual case.

Your case was reviewed <*by xx/using the protocol*> and the <clinician/consultant> has advised that **further follow up is required.** I must emphasise that this does not necessarily mean that <*illness/infection*> has been detected but that more investigation is required to reach a definite diagnosis.

I fully appreciate that this has been a worrying time for you and I deeply regret that your previous <*assessment/test/treatment*> has been found to be inadequate.

We have made special arrangements for you to be seen in <*where*> on <*date & time of appointment*>.

Our service review team will be available at this appointment to discuss the clinical aspects of your case. I have enclosed directions to <*xxxxxxx*> and information on parking arrangements.

If you are unable to attend this appointment please contact <*Tel xxxxxx*> to allow us to reorganise this for you.

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER D: Positive outcome of further assessment – Notes only

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

<***Title of Lookback Review Process***>

Further to our letter dated <*date*> regarding the need for further assessment of your individual case.

I am pleased to advise you that your case has been reviewed by <*name and grade of person*> and we would wish to reassure you that <*he/she*> is satisfied with the quality of your original <*assessment/investigation/test*>.

We would however wish to offer you the opportunity to be reviewed by <*whomever*> at a forthcoming clinic. This will give us the opportunity to examine you and to help reassure you of the outcome of the Service Review Process we have undertaken.

If you wish us to arrange an appointment please contact <*Tel xxxxx*> quoting the unique reference number at the top of this letter.

Once again I would take this opportunity to apologise for the distress and anxiety caused by conducting this review. However, I am sure you will understand that, although the risk <*of missed diagnosis/contracting xx*> was thought to be very low, we had an obligation to remove any uncertainty.

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER E: Negative outcome of further assessment – Notes only

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

<***Title of Lookback Review Process***>

Further to our letter dated <*date*> regarding the need for further assessment of your individual case.

Your case has been reviewed by <*name and grade of person*> and we are sorry to advise you that <*he/she*> has confirmed that the quality of your original <*assessment/investigation/test*> was unsatisfactory.

As a result of this we have arranged for you to be seen by <*whomever*> at <*where*> on <*date and time*>. This will give us the opportunity to examine you and to assess what further treatment you may require.

If the appointment above is unsuitable, please contact <*Tel xxxxx*> quoting the unique reference number at the top of this letter, so that we may reorganise it for you.

I would take this opportunity to apologise for the distress and anxiety caused by this letter, I have enclosed a fact sheet which may help answer any further queries you may have ahead of your appointment.

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER F: Positive outcome of further assessment – Clinical

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

<***Title of Lookback Review Process***>

Thank you for attending <*special clinic*> on <*date*> for follow up assessment.

Your results have been reviewed by <*name and grade of person*> and we are pleased to advise you that <*he/she*> has confirmed that your <*investigation/test*> result was **NEGATIVE**. This indicates that you have not been exposed to <*infection/illness*>.

We would however wish to offer you the opportunity to be reviewed by <*whomever*> at a forthcoming clinic. This will give us the opportunity to examine you and to help reassure you of the outcome of the Service Review Process we have undertaken.

If you wish us to arrange an appointment please contact <*Tel xxxxx*> quoting the unique reference number at the top of this letter.

Once again I would take this opportunity to apologise for the distress and anxiety caused by conducting this review. However, I am sure you will understand that, although the risk <*of missed diagnosis/contracting xx*> was thought to be very low, we had an obligation to remove any uncertainty.

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER G: Negative outcome of further assessment – Clinical

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

<***Title of Lookback Review Process***>

Thank you for attending <*special clinic*> on <*date*> for follow up assessment.

Your results have been reviewed by <*name and grade of person*> and we are sorry to advise you that <*he/she*> has confirmed that your <*investigation/test*> result was **POSITIVE**. This indicates that you have been exposed to <*infection/illness*>.

As a result of this we have arranged for you to be seen by <*whomever*> at <*where*> on <*date and time*>. This will give us the opportunity to examine you and to assess what further treatment you may require.

If the appointment above is unsuitable, please contact <*Tel xxxxx*> quoting the unique reference number at the top of this letter, so that we may reorganise it for you.

I would take this opportunity to apologise for the distress and anxiety caused by this letter, I have enclosed a fact sheet which may help answer any further queries you may have ahead of your appointment.

Yours faithfully

(Chief Executive/Director of HSC Trust)

Letter H: Letter to General Practitioner (informing them of the inclusion of their patient(s) in the Recall Phase of the Lookback Review Process)

Service user name & address

Dear <*Doctor Name*>

<Title of Lookback Review Process>

<*Service Name*> recently reviewed <*Procedure*> undertaken at the hospital in <*Date(s)/Year(s*)>. This review was part of a quality assurance process as we were not satisfied with the quality of a number of <*Procedure(s)*> carried out. As a precautionary measure our medical advisors have recommended that a number of service users who attended for <*Procedure*> are offered a <*Specialty*> outpatients appointment.

Our records show that your patient <*Name*> previously attended <*name of location*> for <*name of procedure*>. We have written to your patient to advise them that their file was reviewed as part of this process and to offer them an outpatient appointment.

If you have any queries about this letter, please contact <*Name person and contact details*>.

Yours Faithfully

(Chief Executive/Director of HSC Organisation)

Appendix 4 Setting up a Service User Helpline or Information Line

Once it has been agreed that the Lookback Review process is to be publicly announced HSC organisations need to have in place a system to deal with potentially large numbers of calls from service users, their families and the general public. It is recommended that site specific helplines are considered for persons affected and a more general information line for the wider public.

The following points should be considered by the Steering Group:

- An individual, such as a senior manager should be identified to coordinate and implement the Telephone Help Line;
- A meeting needs to be convened with a small number of individuals, with the necessary knowledge of the speciality, to establish the necessary systems to support the helpline/information line. It may be that Lead and Specialist Nurses are ideally placed to assist at this crucial stage of planning;
- Information Technology staff are essential members of this team to assist in establishing databases and the necessary technology. A senior member of staff from the Telephone Exchange is invaluable at this stage in planning.

Identification of Venue for Helpline/Information Line

- Ideally the Helpline should not be isolated from the main hub of the organisation. Staff need to be able to access others to seek advice while the Helpline is operational. However, it does need to allow confidential conversations to take place and requires a dedicated space.
- Cabling to allow sufficient telephones is required. Once the media report on the issue is in the public domain then there is likely to be an influx of calls.
- Free phone telephone numbers need to be agreed with Telephone Exchange staff or relevant department.
- It is advisable to have a failsafe system to capture additional calls if the telephone lines become blocked with calls. This may involve agreeing with the Telephone Exchange staff to take details from those callers who are unable to get through quickly and ensure one of the Helpline staff return the call within an acceptable timeframe.

- Once the number of Helpline stations are agreed, personal computers are required for each to facilitate easy access to service user information. IT staff will assist in accessing the necessary cabling and hardware.

Briefing Paper for Helpline Staff

- It is important that those manning the Helpline should be trained and briefed. They should be provided with training and background information on the circumstances surrounding the Look Back exercise.
- Files should be prepared and updated daily with the initial press release and briefing notes on the subject (see Key Messages below).

Production of Algorithms

- Staff manning the Helpline will find it useful to have simple algorithms which assist in giving accurate information to callers. It may be that the caller has no reason to be alarmed when they are informed they are not within the affected group of service users.

Production of Key Messages

- Helpline staff need to be confident in the messages they are giving to callers. To assist this “key messages” should be agreed with the clinical teams and these are read to callers in response to specific questions. Helpline staff must not deviate from these messages.
- Some anxious callers will ring on many occasions and it is vital that if they speak to different Helpline staff they are being given a consistent message.
- Key messages will change as the review progresses. These then require to be updated in the individual files for Helpline staff.

Production of Proforma

- As each call is received it is important to maintain a record. A proforma should be designed to capture the relevant information. It should not be so detailed that the caller feels annoyed, however there needs to be sufficient to ascertain if follow up action is required.
- If the Helpline staff believe that follow up is required then a system needs to be agreed to segregate proformas, perhaps by identifying follow up calls with

a red dot. By the following day these need to have been actively followed up, probably by clinical staff in the speciality being reviewed.

- For completeness and post Look Back audit purposes a database of Helpline calls might be helpful.

Production of Rotas

- The Helpline opening times need to be agreed at the outset so that rotas can be produced. However as stated earlier the extent to which the matter is covered in the media will largely dictate when the calls might be made and some flexibility might be required. There is a strong correlation between media reports and number of calls made.
- In the early stages it will be essential to have staff with good communication skills. Staff will need to be released very quickly from their "normal" duties to assist with this work. There may need to be back filling of these posts to release these staff to assist.
- While staff should not be asked to work more than 6 hours at any one time on the Helpline, it is recognised that in the first few days resources may be stretched. On occasion some normal hospital business may need to be suspended temporarily. Overtime and out-of-hours arrangements should be considered and agreed through the Human Resources Department prior to the commencement of the Helpline.
- Ideally if new staff are coming onto the rota there should always be one member of staff who is familiar with the system and can advise others and co-ordinate overall. As far as possible the help lines should be staffed by experienced people with an understanding of the governance and duty of care responsibilities. Briefing on this area is helpful to understand the corporate responsibility.

Staff Briefing

- Briefing of staff, particularly in the early stages of the exercise is vital. A leader needs to be identified to take this role. This would normally be an Executive Director.

- Staff need to feel they are being listened to during the exercise. If they believe that the system could be improved they should have that opportunity to discuss their views at a daily staff briefing session.
- Catering arrangements should be in place for staff who assist in this work. Regular coffee breaks should be accommodated.

Appendix 5 Lookback Review Process Guideline – Process Checklist Template

	Look-back Review Process The purpose of the check-list is to act as an aide memoir to managers and staff to assist them to ensure compliance with the HSE Look-back Review Process Guidelines. The check-list must always be used in conjunction with the Lookback Review Process Guidelines. References to the relevant sections of the Guideline have been included in the check-list.	You should refer to the relevant Guideline Section(s) for guidance on each stage of the process.	Tick as appropriate		
1	Stage 1: Scoping the extent, nature and complexity of the Lookback Review	Section	Yes	No	N/A
1.1	Chief Executive notified that a Lookback Review Process may be required	**2.1**			
1.2	Chief Executive or nominated Director has established a Steering Group and Terms of Reference were agreed	**2.2 – 2.4**			
1.3	The Risk Assessment was commissioned by the Steering Group	**2.7**			
1.4	Using the information obtained from the Risk Assessment, the Steering Group made a decision to progress to the Service Review/ Audit and Recall stages of the Lookback Review Process	**2.7 – 2.8**			
1.5	The Chair of the Steering Group has notified the relevant bodies (DoH, HSCB, PHA) of the decision to progress with the Lookback Review Process	**2.9 – 2.10**			
2	Stage 2: Identifying and Tracing Service Users at Risk	Section	Yes	No	N/A
2.1	The Steering Group agreed the Scope and the Terms of Reference of the Service Review/ Audit and Recall stages of the Lookback Review Process	**3.1**			
2.2	The Steering Group developed a Lookback Review Action/Work Plan to inform the Audit and Recall Stages of the Lookback Review Process	**3 .1 – 3.2**			
2.3	A database was established to collate and track the information gathered by the Lookback Review Process	**3.2 – 3.3**			
2.4	The Service Review/ Audit was undertaken by nominated team or experts commissioned by the Steering Group	**3.4**			
2.5	The Service Review/Audit identified persons affected to be included in the Recall stage	**3.4**			
2.6	The Helpline/ Information Line was established by the Steering Group	**4.2 , 4.5 & Appendix 4**			

3	Stage 3: Recall Stage	Section	Yes	No	N/A
3.1	The Recall stage was announced by the relevant Director	4.3 – 4.4			
3.2	The Recall stage was announced after persons affected had been informed of their inclusion in the Recall stage of the Lookback Review Process	4.4			
3.3	The Recall Team(s) implemented the Recall stage as per the Steering Group Action Plan	4.1			
3.4	The Recall Team identified actions to be taken to address any deviations from required standards of care	4.1			
3.5	The Recall Team implemented actions and/ or communicated required actions to the Steering Group	4.1			
3.6	The Steering Group undertook an evaluation of the Lookback Review Process and developed an anonymised report with recommendations and learning	5			
3.7	The Chair of the Steering Group submitted the anonymised report to Chief Executive and relevant external bodies	5			

Policy for Implementing a Lookback Review Process

Final draft

Contents

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This policy should be read in conjunction with the Regional Guidance for Implementing a Lookback Review Process.

This policy, and the accompanying Regional Guidance, replaces HSS (SQSD) 18/2007 issued by the Office of the Chief Medical Officer on 8 March 2007.

Lookback Review Policy

1.0 Introduction

A Lookback Review Process is implemented as a matter of urgency where a number of people have potentially been exposed to a specific hazard, in order to identify if any of those exposed have been harmed and to identify the necessary steps to ameliorate the harm as well as to prevent further potential occurrences of harm.[1]

A Lookback Review is a process consisting of four stages;

- immediate action including a preliminary investigation and risk assessment to establish the extent, nature and complexity of the issue(s),
- the identification of the service user cohort to identify those potentially affected,
- the recall of affected service users and finally
- closing and evaluating the Lookback Review Process and the provision of a report including any recommendations for improvement.

The decision that a Lookback Review is required, often occurs after a service user, staff member or third party such as a supplier has reported concerns about the death or harm to a service user, or the potential for death or harm, the performance or health of healthcare staff, the systems and processes applied, or the equipment used.

The triggers for consideration of a Lookback Review may include, but are not limited to the following:

- Equipment found to be faulty or contaminated and there is the potential that people may have been placed at risk of harm;
- Concern about missed, delayed or incorrect diagnoses related to diagnostic services such as screening, radiology or pathology services;
- Concerns about incorrect procedures being followed or evidence of non-compliance with extant guidance;
- Concerns raised regarding the competence of practitioner(s) or outdated practices;

[1] Health Service Executive (HSE) 'Guideline for the Implementation of a Look-back Review Process in the HSE', HSE National Incident Management and Learning Team, 2015. Section 1 page 4.

- A service review or audit of practice shows that the results delivered by either a service or an individual were not in line with best practice standards and there is a concern that there was potential harm caused to a cohort of service users as a result;
- Identification of a staff member who carries a transmissible infection such as Hepatitis B and who has been involved in exposure-prone procedures which have placed service user at risk; or as
- A result of the findings from a preceding Serious Adverse Incident review, or thematic review by the Regulation Quality and Improvement Authority.

This Policy, should be read in conjunction with the 'Regional Guidance for the Implementation of a Lookback Review Process' which documents the steps, including the service user and staff support and communication plans that are to be undertaken by Health and Social Care (HSC) organisations when a Lookback Review Process is initiated. HSC organisations should develop their own local policies and procedures, consistent with this Regional Policy and related Guidance, to address any potential Lookback Review Processes.

As the triggers for considering a Lookback Review process may also constitute a Serious Adverse Incident (SAI) and/or an Early Alert, the Policy should also be read in conjunction with the Health and Social Care Board (HSCB) SAI Regional Guidance [2] and Department of Health (DoH) Early Alert Guidance.[3]

The circumstances may also require the HSC organisation to notify other statutory bodies such as the Coroners Service for Northern Ireland, the Police Service for Northern Ireland and/or the Health and Safety Executive for Northern Ireland. In that regard, all existing statutory or mandatory reporting obligations, will continue to operate in tandem with this Regional Policy.

2.0 Purpose

The purpose of this policy and regional guidance is to ensure a consistent, coordinated and timely approach for the notification and management of potentially/affected service users carried out in line with the principles of openness

[2] HSCB 'Procedure for the Reporting and Follow up of Serious Adverse Incident'. November 2016.
[3] DoH 'Early Alert System' Reference HSC (SQSD) 5/19.

and candour, [4] [5] [6] whilst taking account of the requirements of service user confidentiality and Data Protection. [7] [8]

3.0 Objectives

The objectives of this policy are to:

1. Assist HSC organisations adopt a risk-based approach and ensure the timely management of appropriate and relevant care for affected groups of service users.

2. Establish a standard approach to notification of service users, families/carers, healthcare managers and the public of adverse incidents involving potential injury, loss or other harm to groups of service users.

3. Ensure that communication with, and support for, all affected and potentially affected service users, their families and/or carers and also staff occurs as soon as reasonably practicable, and in as open a manner as possible.

4. Ensure that the HSC organisation adopts appropriate support mechanisms for the health and well-being of staff involved.

5. Ensure that communication with the Department of Health (DoH), the Health and Social Care Board (HSCB) and the Public Health Agency (PHA) and the public occurs in a consistent and timely manner.

6. Ensure that HSC organisations' services have established and consistent processes in place when a Lookback Review is undertaken, that also maintain the business continuity of existing services and public confidence;[9]

7. Ensure that HSC organisations appropriately reflect upon the issues which prompted the Review and any learning from the outcomes of a Lookback Review within their systems of governance.

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[4] In his Inquiry into Hyponatraemia Related Deaths (IHRD), Judge O'Hara made recommendations concerning openness and candour. This included a recommendation for the legal duty of candour for HSC organisations and staff, as well as support and protections to enable staff to fulfil that duty. Work is underway to introduce the necessary legislation and policies to implement these recommendations.
[5] DoH 'Being Open – Saying sorry when things go wrong'. January 2020.
[6] National Patient Safety Agency (NPSA) 'Being open – communicating patient safety incidents with patients and their carers'. September 2005. Archived on 18 February 2009 at webarchive.nationalarchives.gov.uk.
[7] European Union (EU) 'General Data Protection Regulations (GDPR)'. 25 May 2018 at https://eugdpr.org.
[8] Data Protection Act 2018 at www.legislation.gov.uk
[9] South Australia Health ' Lookback Review Policy Directive', Safety & Quality, System Performance & Service Delivery, July 2016. Section 1 page 4.

4.0 Scope

This policy and related guidance applies to all HSC organisations. The purpose of the policy and guidance is to provide a person-centred risk-based approach to the management of a Lookback Review and support to any service users and their families/carers who may have been exposed to harm, and to identify the necessary steps to ameliorate that harm. The scope of the policy and related guidance also includes providing information and support to those not directly exposed to the harm in question i.e. concerned members of the public.

Whilst the outcomes of a Lookback Review may inform other processes e.g. Serious Adverse Incident reviews or a Coroner's Inquest, this is not the primary purpose of a Lookback Review Process.

Section 1 identifies some typical examples of the concerns which may lead to a Lookback Review Process being initiated. Where those concerns relate to the health, capacity or performance of practitioner(s) this may trigger a parallel process of investigation and/or performance management. This lies outside the scope of this guidance.

5.0 Roles and Responsibilities

5.1 The Chief Executive is responsible for:

- Commissioning the Lookback Review Process and establishing a Steering Group to oversee the implementation of the Lookback Review in line with extant policy, procedure and guidelines. This will usually be delegated to an Executive Director/Service Director who will act as Chair of the Steering Group (see below);
- Ensuring that effective Lookback Review Processes are implemented, when required, in line with extant policies, procedures and guidelines and that adequate resources are allocated to facilitate effective Lookback Review Processes;
- Reporting the rationale for the implementation of a Lookback Review Process to the DoH, HSCB and PHA as appropriate and as per extant guidance; [10] [11]

[10] DoH. (SQSD) 5/19. *Op.cit.*
[11] HSCB. November 2016. *Op.cit.*

- Ensuring that the Lookback Review process is conducted with openness and transparency; and
- Providing service users, families and/or carers with a meaningful apology, where appropriate;
- Communicating the findings of the Lookback Review Process to the HSC organisation's Board and to the DoH, HSCB and PHA as appropriate and as per extant guidance. [12] [13]

5.2 The Oversight Group/Steering Group is responsible for:

- Overseeing the service review/ risk assessment process to identify the scope of the issue and inform the decision to progress to the service review/audit and recall stages of the Lookback Review Process as required;
- Deciding on the requirement for progression to Stage 2 Identifying and Tracing the Service User's at risk and Stage 3 Service User Recall;
- Communicating the need for the service review/audit and recall stages of the Lookback Review Process through the organisation's governance structures/Assurance Framework to the Board of Directors and external stakeholders (including DoH);[14]
- Developing the Scope and Terms of Reference for each element of the Lookback Review Process;
- Overseeing operational management of all aspects of the Lookback Review Process;
- Developing a Lookback Review Action/ Work Plan which outlines the methodologies to be implemented in relation to the Audit and the Recall stages of the Lookback Review Process;
- Ensuring that arrangements are in place to capture and report information on the outcome of the Lookback Review Process;
- Ensuring that the impact on 'business as usual' for all service users is assessed and reported on;
- Ensuring that service managers implement contingency plans for service continuity where necessary, including providing for additional health care demands which may arise as a consequence of the Lookback Review

[12] DoH. *Op.cit.*
[13] HSCB *Op.cit*
[14] DoH. HSCB*. Loc. Cit.*

Process, this should include service users not included in the 'at risk' cohort who also may be affected by the impact on services as a result of the Lookback Review Process;

- Ensuring that arrangements are in place to provide support to both service users and staff e.g. counselling and welfare services;
- Ensuring that service managers allocate the necessary resources to implement the Lookback Review Process and to meet associated demands;
- Ensuring communication at the appropriate time and implementation of recommended actions arising from the Lookback Review Process.

5.3 The Operational Group/Lookback Review Management Team are responsible for:

- Supporting the Steering Group in the implementation of the Steering Group Lookback Review Action/Work plan (see above);
- Putting in place arrangements to capture and report information on the progress of the Lookback Review Process;
- Implementing contingency plans for service continuity including implementing plans for referral pathways, rapid access clinics, diagnostic or pathology services;
- Providing support to both service users and staff e.g. counselling and welfare services;
- Providing the operational arrangements to support the communication plan, at the appropriate time with the implementation of actions arising from the Steering Group's Action plan to meet Stage 2 and Stage 3 of the Lookback Review Process.

5.4 The HSC Organisation Board of Directors is responsible for:

- Ensuring appropriate oversight of the Lookback Review and that this is reflected within the organisation's system of governance e.g. risk register;
- Satisfying itself that the Lookback Review Process is being undertaken in line with extant policy;

- Satisfying itself that the Lookback Review Process has been appropriately resourced in terms of funding, people with relevant expertise, access to expert advice and support, IT and any other infrastructure required;
- Satisfying itself that the impact of the Lookback review process on 'Business as Usual' is assessed, monitored and reported on with mitigating measures in place where possible;
- Satisfy itself that required actions identified by the Lookback Review Process are implemented;
- Providing challenge, management advice/guidance and support to the Lookback Review Commissioning Director and the Lookback Review Steering Group as required.

5.5 The Public Health Agency is responsible for;

- Providing advice/guidance and support to the Lookback Review Steering Group as required;
- Dissemination of information and notification to the wider health services of the adverse incident or concern as required;
- Assisting the HSC organisation with the Lookback Review Process Action Plan and Communication Plan as required.

5.6 The Health and Social Care Board is responsible for;

- Providing advice/guidance and support to the Lookback Review Steering Group as required;
- Dissemination of information and notification to the wider health services of the adverse incident or concern as required;
- Assisting the HSC organisation with the Lookback Review Process Action Plan and Communication Plan as required;
- Monitoring compliance with the HSCB 'Procedure for the Reporting and Follow-up of Serious Adverse Incidents';
- Assisting with the dissemination of learning from the Lookback Review Process.

5.7 The Department of Health is responsible for;

- Ensuring that the HSC reporting organisation complies with the Policy Directive;
- Providing advice and information to the Minister.
- Assisting the HSC organisation with the development and management of communication strategies to the wider health service.

6.0 Legislative and Regional Guidelines

- Health and Safety at Work (NI) Order 1978;
- Management of Health & Safety at Work Regulations (Northern Ireland) 2000;
- Freedom of Information Act 2000;
- EU Data Protection Regulation (GDPR) 25 May 2018;
- Data Protection Act 2018;
- Department of Health 'Code of Practice for protecting the confidentiality of service user information' 31 January 2012;
- HSCB Procedure for the Reporting and Follow-up of Serious Adverse Incidents 2016;
- Department of Health Early Alert System HSC (SQSD) 5/19;
- Department of Health 'Being Open – Saying sorry when things go wrong'. January 2020.

Belfast Health and Social Care Trust

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JOB DESCRIPTION

POST: Service Manager Public Inquiry and Trust Liaison

LOCATION: Muckamore Abbey Hospital AND Royal Victoria Hospital with travel between Trust sites required

BAND: 8B

REPORTS TO: Interim Director, Learning Disability Services

RESPONSIBLE TO: Chief Executive

Job Summary / Main Purpose

In the first instance, the post holder will be responsible through the Director for Learning Disability Services, and working closely with the Co-Director Risk and Governance, for ensuring that the Trust meets the legal requirements of the Inquiries Act 2005 in respect of the Muckamore Abbey Hospital Public Inquiry. The post holder will also act as the Trust's Liaison Officer for the Inquiry Panel, the Directorate of Legal Services and other external stakeholders, for example, the Department of Health.

This is a permanent post and as such it is recognised that while the focus will in the first phase be on the Muckamore Abbey Hospital Public Inquiry, there will be future requirements for such a role following the completion of this particular Inquiry.

Main Duties / Responsibilities

For each of the following, the postholder will;

- Provide administrative support to the Public Inquiry Oversight Steering Group and any Task and Finish Groups which may arise. This will include the organisation of agendas, the co-ordination of papers and reports and completion of accurate and concise minutes to record key issues and decision-making.
- Be responsible for preparation of briefing notes to the Oversight Steering Group, the Executive Team and Trust Board, and the preparation of other ad hoc briefings as required.
- Oversee the collation, cataloguing, storage and maintenance of evidence anticipated to be required for the Public Inquiry, and evidence subsequently submitted to the Inquiry.
- Ensure that there is a safe, secure and retrievable system for storage of evidence anticipated to be required for the Inquiry, and for storage of evidence that is subsequently submitted to the Inquiry.
- Be responsible for briefing and supporting staff who are required to participate in the Inquiry and for providing guidance on best practice throughout the Inquiry process.
- Respond to any queries of the Inquiry Panel and the Director of Legal Services and to ensure the timely provision of witness evidence, and other evidence, as stipulated by the Inquiry Panel.

- Be responsible for developing and maintaining governance processes associated with implementation of agreed recommendations, actions and learning from the findings of the Public Inquiry.

Setting Direction and Service Delivery

- Provide effective leadership in the co-ordination of the Trust's response to the Muckamore Abbey Hospital Public Inquiry ensuring that the Trust meets its statutory duties.
- Oversee the co-ordination, collation and provision of evidence, including witness evidence, as required by the Inquiry Panel and/or Directorate of Legal Services, in line with Trust Policy and Regional Guidance on the Provision of Witness Statements.
- Ensure that there is a safe, secure and retrievable system for storage of evidence anticipated to be required for the Inquiry, and for storage of evidence that is subsequently submitted to the Inquiry.
- Ensure that there are systems and processes in place to optimise the timeliness and responsiveness to the Inquiry Panel requests.
- Provide timely information to employees in the requesting of reports and statements required by the Inquiry Panel.
- Ensure that the relevant line manager is aware that a member of staff is being asked to attend the Inquiry.
- Ensure that staff who are required to participate in the Public Inquiry receive adequate support throughout the entire Inquiry process, keeping the team informed of developments in the case and dates and times of any consultations. This will include supporting the relevant directorate management team to guide them through the process and ensure their preparedness to enable them to support staff.
- Escalate any concerns in relation to potential delays in the provision of information to the Inquiry Panel through the Trust's assurance/accountability framework to the Executive Team.
- Provide administrative support to the Public Inquiry Oversight Steering Group and any Task and Finish Groups which may arise. This will include the organisation of agendas, the co-ordination of papers and reports and completion of accurate and concise minutes to record key issues and decision-making.
- Be responsible for preparation of briefing notes to the Oversight Steering Group, the Executive Team and Trust Board, and the preparation of other ad hoc briefings as required.

Corporate Management

- Contribute to the Trust's overall corporate governance processes to ensure its compliance with public sector values and codes of conduct, operations and accountability.

Collaborative Working and Communication

- Establish collaborative relationships and networks with internal and external stakeholders.
- Engage with stakeholders across the organisation including the Risk and Governance Team and the Medical Directors Office to ensure the provision of accurate and timely information to the Inquiry Panel.
- Work collaboratively with external stakeholders including the Directorate of Legal Services and the PSNI.
- Responsible for developing and maintaining sound internal and external communications systems.

- Represent the Trust, as appropriate, on external groups and/or representations Director where appropriate and as required in respect of the Trust's approach to the Public Inquiry.

Financial and Resource Management

- Responsible for the management of any financial allocation/budget associated with the Trust's preparation and involvement in the Public Inquiry, in conjunction with financial management colleagues.

People Management and Development

- Be responsible for the line management of the Assurance Co-ordinator.
- Promote the corporate values and culture of the organisation through the development and implementation of relevant policies and procedures, and appropriate personal behaviour.
- Be responsible for ensuring that the Health and Social Care Records service complies with employment law and is consistent in their application of the Trust's policies.
- Be responsible for ensuring that staff are appraised at least annually and Knowledge and Skills framework is in place.
- Be responsible for his/her own performance and take action to address identified personal development areas.
- Manage recruitment processes, to ensure staff are recruited in a timely and professional manner and vacancies are filled appropriately.

General Responsibilities

Employees of the Trust are required to promote and support the mission and vision of the service for which they are responsible and:

- At all times provide a caring service and to treat those with whom they come into contact in a courteous and respectful manner.
- Demonstrate their commitment by their regular attendance and the efficient completion of all tasks allocated to them.
- Comply with the Trust's Smoke Free Policy.
- Carry out their duties and responsibilities in compliance with the Health and Safety Policies and Statutory Regulations.
- Adhere to Equality and Good Relations duties throughout the course of their employment.
- Ensure the ongoing confidence of the public in-service provision.
- Maintain high standards of personal accountability.
- Comply with the HPSS Code of Conduct.
- The post holder will promote and support effective team working, fostering a culture of openness and transparency. The post holder will ensure that they take all concerns raised with them seriously and act in accordance with Belfast Trust's Whistleblowing Policy and their professional code of conduct, where applicable.
- The post holder will, in the event of a concern being raised with them, ensure it is managed correctly under the Belfast Trust's Whistleblowing Policy, and ensure that feedback/learning is communicated at individual, team and organisational level regarding the concerns raised, and how they were resolved.

Information Governance

All employees of Belfast Health & Social Care Trust are legally responsible for all records held, created or used as part of their business within the Belfast Health and

Social Care Trust, including patient/client, corporate and administrative records whether paper based or electronic and also including e-mails. All such records are public records and are accessible to the general public, with limited exceptions, under the Freedom of Information Act 2000, the Environment Regulations 2004, the General Data Protection Regulation (GDPR) and the Data Protection Act 2018. Employees are required to be conversant and to comply with the Belfast Health and Social Care Trust policies on Information Governance including for example the ICT Security Policy, Data Protection Policy and Records Management Policy and to seek advice if in doubt.

For further information on how we use your personal data within HR, please refer to the Privacy Notice available on the HUB or Your HR

Environmental Cleaning Strategy

The Trusts Environmental Cleaning Strategy recognises the key principle that "Cleanliness matters is everyone's responsibility, not just the cleaners" Whilst there are staff employed who are responsible for cleaning services, all Trust staff have a responsibility to ensure a clean, comfortable, safe environment for patients, clients, residents, visitors, staff and members of the general public.

Infection Prevention and Control

The Belfast Trust is committed to reducing Healthcare associated infections (HCAIs) and all staff have a part to play in making this happen. Staff must comply with all policies in relation to Infection Prevention and Control and with ongoing reduction strategies. Standard Infection Prevention and Control Precautions must be used at all times to ensure the safety of patients and staff.
This includes:-

- Cleaning hands either with soap and water or a hand sanitiser at the appropriate times (WHO '5 moments');
- Using the correct '7 step' hand hygiene technique;
- Being 'bare below the elbows' when in a clinical environment;
- Following Trust policies and the Regional Infection Control Manual (found on intranet);
- Wearing the correct Personal Protective Equipment (PPE);
- Ensuring correct handling and disposal of waste (including sharps) and laundry;
- Ensuring all medical devices (equipment) are decontaminated appropriately i.e. cleaned, disinfected and/or sterilised;
- Ensuring compliance with High Impact Interventions.

Personal Public Involvement

Staff members are expected to involve patients, clients, carers and the wider community were relevant, in developing, planning and delivering our services in a meaningful and effective way, as part of the Trust's ongoing commitment to Personal Public Involvement (PPI).

Please use the link below to access the PPI standards leaflet for further information.

http://www.publichealth.hscni.net/sites/default/files/PPI_leaflet.pdf

Clause: ***This job description is not meant to be definitive and may be amended to meet the changing needs of the Belfast Health and Social Care Trust.***

Belfast Health and Social Care Trust

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PERSONNEL SPECIFICATION

JOB TITLE / BAND: Service Manager, Public Inquiry and Trust Liaison / Band 8B

DEPT / DIRECTORATE: Muckamore Abbey Hospital AND Royal Victoria Hospital with travel between Trust sites required / Adult Social & Primary Care

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 below, using the information provided by you on your application form. Please note the Trust reserves the right to use any desirable criteria outlined below 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

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 the process when the criteria will be measured is stated below.

Factor	Criteria	Method of Assessment
Experience Qualifications Registration	• Have a university degree or relevant professional qualification at graduate or diploma level **AND** worked for at least 2 years in a *senior management role in a complex organisation **OR** Have worked for at least 3 years in a *senior management role in a major complex organisation. ***Note *senior management role will be considered to be at Band 8A or equivalent or above.***	Shortlisting by Application Form
Other (e.g. Driving etc.)	• Full UK Driving Licence and access to a car. *'Where disability prohibits driving, this criteria will be waived if the applicant is able to organise suitable alternative arrangements.'*	Shortlisting by Application Form

Knowledge **Skills** **Abilities**	• Delivered against challenging performance management programmes for a minimum of 2 years meeting a full range of key targets and making significant improvements. • Have worked with a diverse range of stakeholders, both internal and external to the organisation, to achieve successful outcomes for a minimum of 2 years. • Successfully demonstrate high level people management, leadership and organisational skills for a minimum of 2 years. • Have good communication skills (written, oral, presentational and interpersonal) with the ability to communicate effectively with all levels of staff within the Trust, and outside the organisation. • Have the ability to collate and critically analyse statistical and qualitative information and the ability to make and take decisions after analysis of options and implications. • Ability to multi-task and continue to function to a high standard when under pressure. • Determination, drive to succeed, perseverance, and resilience. • IT literacy -proficient in MS Word, Excel, PowerPoint, etc.	Shortlisting by Application Form **And / Or** Interview

DESIRABLE CRITERIA

Desirable criteria will **ONLY** be used where it is necessary to introduce additional job related criteria to ensure files are manageable. You should therefore make it clear on your application form how you meet these. Failure to do so may result in you not being shortlisted.

Factor	Criteria	Method of Assessment
Experience **Qualifications** **Registration**	• Experience of working with legal services and/or working on legal processes.	Shortlisting by Application Form

NOTE:

Where educational/professional qualifications form part of the criteria you will be required, if shortlisted for interview, to produce original certificates *and* one photocopy of same issued by the appropriate authority. Only those certificates relevant to the shortlisting criteria should be produced. If educational certificates are not available an original letter *and* photocopy of same detailing examination results from your school or college will be accepted as an alternative.

If successful you will be required to produce documentary evidence that you are legally entitled to live and work in the United Kingdom. This documentation can be a P45, Payslip, National Insurance Card or a Birth Certificate confirming birth in the United Kingdom or the Republic of Ireland. *Failure to produce evidence will result in a non-appointment*.

Where a post involves working in regulated activity with vulnerable groups, post holders will be required to register with the Independent Safeguarding Authority.

Healthcare Leadership Competencies

Candidates who are shortlisted for interview will need to demonstrate at interview that they have the required competencies to be effective in this demanding leadership role.

The competencies concerned are set out in the NHS Healthcare Leadership Model, details of which can be found at:

http://www.leadershipacademy.nhs.uk/resources/healthcare-leadership-model.

Particular attention will be given to the following:

- Inspiring shared purpose
- Leading with care
- Evaluating information
- Connecting our service
- Sharing the vision
- Engaging the team
- Holding to account
- Developing capability
- Influencing for results

HSC Values

Whilst employees will be expected to portray all the values, particular attention is drawn to the following values for this role

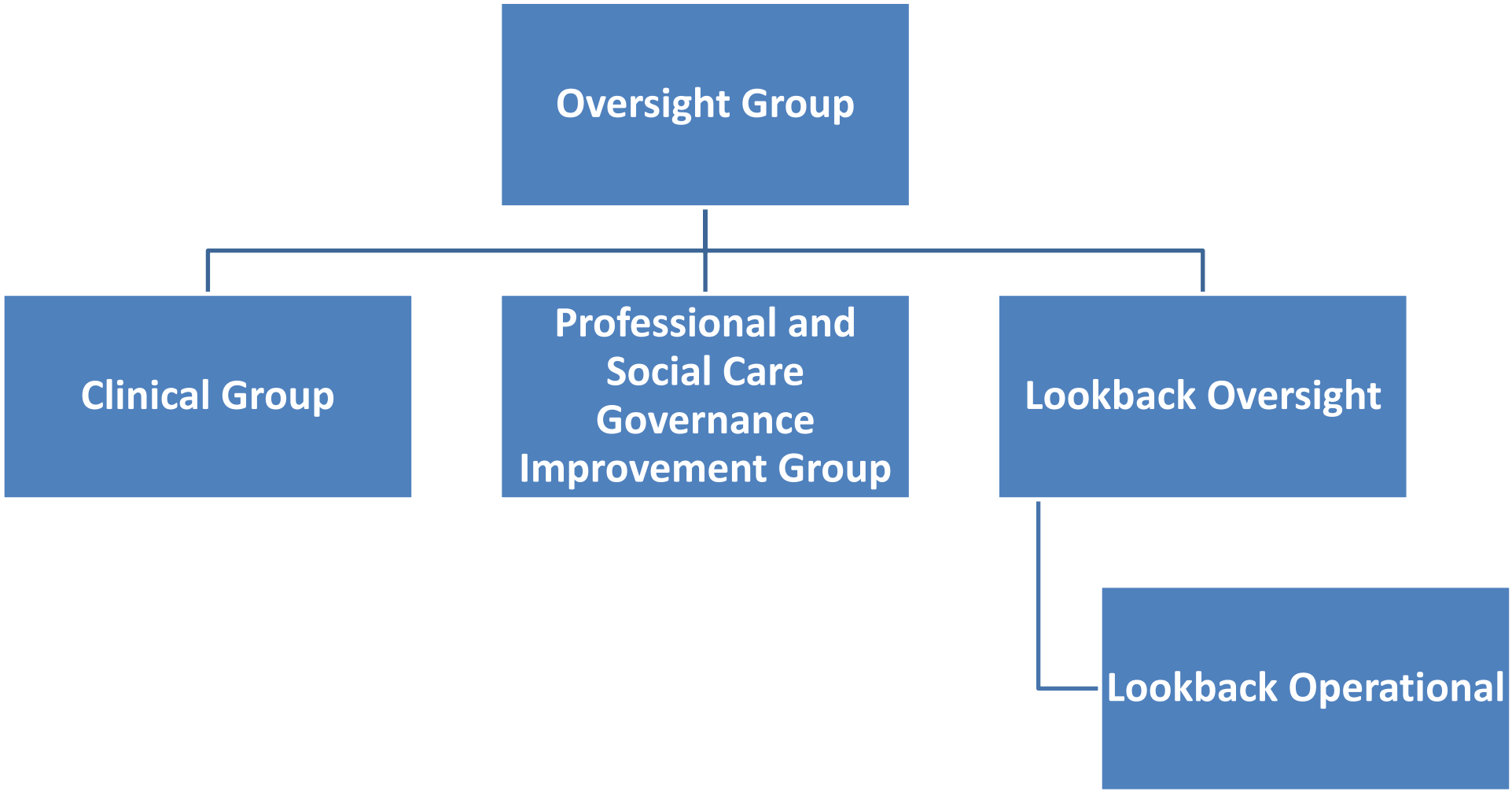
What does this mean?	What does this look like in practice?
 **Working together** We work together for the best outcome for people we care for and support. We work across Health and Social Care and with other external organisations and agencies, recognising that leadership is the responsibilty of all.	• 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.
 **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 to help when needed • I speak up if I have concerns • I challenge inappropriate or unacceptable behaviour and practice.
 **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 wellbeing so that I can care and support others.

Existing Urology Oversight Structure

Group Name	Roles	Membership	Frequency	ToR Agreed	Currently Established
Urology Oversight Group	?Public Inquiry Oversight Private Practice Audit IPT Oversight of Subject Matter Experts Royal College of Surgeons Update Engaging ISPs to undertake waiting list work Oversight of Patient Support Line Professional Governance - GMC Discussions - Litigation / DLS Update - Grievance Process - Administration Review Update Structured Clinical Record Review Family Liaison Role Corporate Comms Complaints Coronial Processes	Mark Haynes Maria O'Kane Martina Corrigan Stephen Wallace Melanie McClements Ronan Carroll Vivienne Toal Patricia Kingsnorth Siobhan Hynds Jane McKimm Damian Gormley	Fortnightly	No	Yes
Urology Clinical Group	Clinical specific issues	Mark Haynes Maria O'Kane Martina Corrigan Stephen Wallace Damian Gormley	Weekly (where possible)	No	Yes
Urology Professional and Social Care Governance Improvement Group	SAI Recommendation Implementation Quality Improvement	TBC	TBC	No	Commencing
Urology Lookback Steering Group	As per DoH Guidance	TBC	TBC	No	No
Urology Lookback Operational Group	As per DoH Guidance	TBC	TBC	No	No

Questions

- Will the urology oversight group be the overarching internal body?
- Will the public inquiry be facilitated via the urology oversight group?
- Requirement in the Lookback Guidance to nominate a lead director



Southern Health and Social Care Trust

Quality Care - for you, with you

2nd April 2021 Ref: ec/MOK

To All GP Practices

Dear Colleagues,

Re: Review of Southern Health and Social Care Trust Urology Service

I would like to provide you with an update further to my correspondence dated 24th November 2020 in relation to issues of concern which have been identified regarding the treatment and care provided by a Consultant Urologist at the Southern Health and Social Care Trust, who no longer works in health services. The Consultant Urologist was named by the Health Minister as Mr Aidan O'Brien.

As stated in my original correspondence the Trust conducted a scoping exercise regarding the NHS practice of Mr O'Brien during the period of 1st January 2019 to 30th June 2020. This scoping exercise has identified a number of patients who were under the care of the Consultant and require review to ensure that they have received appropriate treatment and care. The Trust is continuing the process of identifying and contacting these patients via letter. Should any of your patients be included in this group you will receive a copy of this correspondence.

As stated in my original correspondence we remain conscious that Mr O'Brien conducted a significant private practice from his home. Some of these patients will be known to the Trust. However an indeterminate proportion of this practice will exist outside of wider Health and Social Care services.

It has since been brought to our attention that there may be a cohort of private patients that have been transferred back to the care of general practice who may require ongoing

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Tel: Personal Information redacted by the USI Email: Personal Information redacted by the USI

monitoring or care by specialist urology services of which the Trust will not be aware. We would therefore be grateful for your assistance in identifying any previous private patients of Mr O'Brien's within your practice, who may require further ongoing urology care via referring these patients to the Trust.

If you consider it necessary, we can arrange for a Consultant Urologist to speak with you about specific patient concerns. Please contact **028 3756 0022** and we will arrange for a member of our team to call you back as soon as possible.

The Trust also has in place a patient advice telephone line **0800 4148520** which is available Monday to Friday from 10:00am to 3:00pm if patients wish to discuss concerns or questions they may have directly with the Trust urology team.

Once again, may I offer you my sincere apologies and assure you that we will do all that we can to ensure patients receive the best possible care. I am grateful for your cooperation and assistance.

Yours sincerely

Personal Information redacted by the USI

Dr Maria O'Kane
Medical Director

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ
Tel: Personal Information redacted by the USI Email: Personal Information redacted by the USI

Southern Health and Social Care Trust

Quality Care - for you, with you

2nd April 2021 Ref: MOK/ec

Dear Sir / Madam,

Re: Review of Care Provided by Mr Aidan O'Brien

My name is Dr Maria O'Kane and I am writing to you in my capacity as Medical Director of the Southern Health and Social Care Trust. In connection with its overarching responsibility for the provision of health services in Northern Ireland, the Department of Health has asked the Southern Health and Social Care Trust to provide support to patients seen privately by Mr Aidan O'Brien between the dates of 1st January 2019 and 30th August 2020. To facilitate our contact with you in relation to this review, Mr O'Brien has agreed to issue this letter to you on behalf of the Trust as he holds your contact details.

As you may be aware issues of concern have been identified in relation to the treatment and care provided by Mr Aidan O'Brien, a Consultant Urologist who, prior to his retirement, formerly worked in his NHS practice at the Southern Health and Social Care Trust. As a result of these concerns the Northern Ireland Minister for Health, Mr Robin Swann has ordered a Public Inquiry to investigate and review issues relating to this matter.

As of 15th December 2020 Mr O'Brien has been issued with an interim suspension order prohibiting him from practicing medicine by the Medical regulator, the General Medical Council.

Following on from this and as part of the Southern Health and Social Care Trust's responsibility to deliver safe services to our patients, we are reviewing the care provided by Mr O'Brien to his Trust patients. In addition to Mr O'Brien's Trust employment, we are also

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aware that he conducted an independent private practice from his home. We understand you were a patient who attended Mr O'Brien in a private capacity.

Although the concerns identified to date relate to the care provided in Mr O'Brien's practice while working for the Southern Health and Social Care Trust, we are keen to support patients who may have concerns regarding their care provided by Mr O'Brien in a private practice capacity.

We recognise that on receiving this letter, or indeed if you have heard of concerns in the media, you may be anxious regarding your care and treatment. We have established a dedicated patient advice telephone line where you can speak to a member of our urology service who will discuss any concerns you may have and, if appropriate, offer you an appointment with the Trust Urology team.

Urology Patient Advice Line Telephone Number: 0800 4148520
Available: Monday to Friday, 10:00am to 3:00pm

We understand that you may wish to discuss any potential concerns with your General Practitioner who can arrange onward referral to our Urology services if this is required.

Thank you for taking the time to read this correspondence, our Urology Advice line team remain ready to receive your call.

Yours sincerely

Personal Information redacted by the USI

Dr Maria O'Kane
Medical Director

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ
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Southern Health and Social Care Trust

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Strictly Confidential

Staffing Support Requirement for Serious Adverse Incident /Inquiry - Urology

3 December 2020

1.0 Introduction

There have been significant clinical concerns raised in relation to Consultant A which require immediate and coordinated actions to ensure patient safety is maintained. Comprehensive plans need to be put into place to undertake the following:

- Review of professional governance arrangements
- Liaison with professional bodies
- Review of patient safety and clinical governance arrangements
- Commencement of operational support activities including
  - Offering additional clinical activity
  - Provide complaints resolution
  - Media queries, Assembly Questions responses
  - Managing the volume of patients who require to be reviewed
  - Patient Support (Psychology / Telephone Support / Liaison)
  - Staff Support
  - Claim handling / medico-legal requests

This proposal identifies the staffing requirements and costs required to support the Serious Adverse Incident (SAI) Investigation/Inquiry for Urology in the Southern Trust.

This proposal will require revision as demands change over time.

2.0 Needs Assessment

A comprehensive review of patients who have been under the care of Consultant A will be required and this may likely number from high hundreds to thousands of patients.

Following discussions with the Head of Service the following clinics have initially been proposed and have been estimated in the first instance to continue for one year.

Clinics will commence in December 2020 and continue throughout 2021. A putative timetable has been included. We will require that consultants have access to records, have reviewed the contents and results and are familiar with each patient's care prior to face to face review where required. Each set of patient records will require 10-30 minutes to review depending on complexity. In addition, each of the patients reviewed will require 45 minute consultant urologist appointments to include time for administration/ dictation in addition to 15 mins preparation time on average. That is 8 patients require 8hrs Direct Clinical Contact (DCC) Programmed Activity (PA). 800 patients require 800 hours of Direct Clinical and so on. (Each consultant DCC PA is 4hrs).

The purpose of the clinical review is to ascertain if the:

1. diagnosis is secure
2. patient was appropriately investigated
3. Investigations, results and communications were requested in a timely fashion
4. Investigations, results and communications were responded to/ processed in a timely fashion
5. Patient was prescribed / is receiving appropriate treatment
6. Overall approach taken is reasonable
7. Patient has, is or likely to suffer harm as a result of the approach taken.

In addition, it will be expected that where there are concerns in relation to patient safety or inappropriate management that these will be identified and a treatment plan developed by the assessing consultant and shared with the urology team for ongoing oversight or with the patient's GP.

Table 2-1 Suggested timetable

Day	Clinic Session	Number of Patients
Monday	AM	8
Monday	PM	8
Tuesday	AM	8
Tuesday	PM	8
To be confirmed	AM	8
To be confirmed	PM	8
Total no of patients per week		48

3.0 Staffing Levels Identified

3.1 Information Line – First Point of Contact

An information line will be established for patients to contact the Trust to speak with a member of staff regarding any concerns they may have and will operate on Monday to Friday from 10am until 3pm. A call handler will receive the call and complete an agreed Proforma (appendix 1) with all of the patient's details and advise that a colleague will be in contact with them. The PAS handler will take the information received and collate any information included on PAS/ECR and this will be examined in detail by the Admin/Information Handler. The following staff have been identified as a requirement for this phase. It must be noted that the WTE is an estimate and will be adjusted dependent on the volume of calls received. Costs are included in Appendix 1.

Table 3-1 – Information Line Initial Staffing Requirements

Title	Band	WTE
Call Handlers	4	2
Admin Support for identifying notes/ looking up NIECR etc	4	2
Admin/Information Handler	5	1

3.2 Clinic Requirements

To date a clinical process audit has been carried out in relation to aspects of the Consultant's work over a period of 17 months.

In addition to this 236 urology oncology patients are being rapidly and comprehensively reviewed in the private sector. (Patients returned with management plan are included in Table 3.2/Table 3.4)

A further 26 urology oncology patients have been offered appointments or reviewed in relation to their current prescription of Bicalutamide.

Given the emerging patterns of concerns from these reviews and Multi-Disciplinary Meetings (MDMS) which have resulted in 9 patients' care meeting the standard for SAI based on this work to date, it is considered that a comprehensive clinical review of the other patients is required. The Royal College of Surgeons has advised that this includes 5 years of clinical activity in the first instance.

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The numbers and clinical prioritisation will be identified collectively by the Head of Service, Independent Consultant and the Clinical Nurse Specialist either face to face or via virtual clinics. The volume of patients is 2327 for 18 months in the first instance and the number of DCC PA has been identified as **. The staffing required to operate these clinics is detailed below. This work will be additionality and should not disrupt usual current urology services. It must be noted that again this is an estimate and will be dependent on the volume of patients involved. .

Clinic Requirements Staffing – 6 sessions as detailed in Section 2. Costs are included in Appendix 1.

Table 3-2 – Clinic Staffing Requirements

Title	Band	WTE
Outpatient Manager	7	0.7
Medical Secretarial Support	4	0.5
Booking clerk	3	0.7
Audio Typist	2	0.7
Medical Records	2	0.7
Nursing staff	5	0.7
Nurse Clinical Specialist	7	0.7
Health Care Assistant	3	0.7
Receptionist	2	0.7
Consultant		DCC
Pharmacist	8a	0.7
Psychology Band 8B and above		1 present per clinic
Domestic Support	2	0.7

3.3 Procedure Requirements

If the outcome of the patient review by the Independent consultant urologist is that the patient requires further investigation, this will be arranged through phlebotomy, radiology, day procedure, and pathology / cytology staff. The provision will be dictated by clinical demand. The following staffing levels have been identified as below for each 1 day sessions. Costs are included in Appendix 1.

Table 3-3 – Procedure Staffing Requirements

Title	Band	WTE
Secretary	4	
Reception	2	
Nurses	5	0.64

Title	Band	WTE
Health Care Assistant	3	0.22
Sterile Services	3	0.22
Consultant - locum		2 PAs
Anaesthetic cover		1 PA
Domestic Support	2	0.22

3.4 Multi-Disciplinary Weekly Meetings Requirements

In order to monitor and review the number of patients contacting the following multi-disciplinary team has been identified as a requirement. Costs are included in Appendix 1.

Table 3-4 -–Staffing Requirements for Multi-Disciplinary Meetings (weekly)

Title	Band	WTE
Cancer Tracker	4	0.4
Nurse Clinical Specialist	7	0.1
Consultant Urologist x 2		2 PAS
Consultant Oncologist		1 PA
Consultant Radiologist		1 PA
Consultant Pathologist		1 PA

3.5 Serious Adverse Incident Requirements

Work has commenced on 9 SAI's and the following staff have been identified as a requirement to support the SAI and the Head of Service to enable investigative work to take place and to enable current provision to continue. Costs are included in Appendix 1.

Table 3-5 -Additional staffing and Services required to support SAI

Title	Band	WTE
Head of Service (Acute) – SAI backfill	8b	1
Chair of Panel	N/A	sessional
Band 5 admin support	5	1
Governance Nurse/ Officer	7	2
Admin support to the panel	3	1
Psychology support	Inspire	sessional
Family Liaison SLA	7	1

3.6 Inquiry Requirements

Costs are included in Appendix 1.

Table 3-6 - Additional staffing and Services required to Support Inquiry

Title	**Band**	**WTE**
Head of Service Backfill	8b	1
Clinical Nurse Specialist	7	1
Admin Support for HOS	4	1
Admin Support to respond and collate requests for information for inquiry team	5	2
Health records staff to prepare notes for Inquiry Team	2	4
Urology Experts – WL Initiative Funding £138 per hour	Consultant	Sessional
Media queries, Assembly Questions responses	8a (uplift from Band 7's)	2
Admin Support for media queries/Assembly questions	4	1

3.7 Professional and Clinical Governance Requirements to Support the SAI/ Inquiry

Investigations involving senior medical staff are resource intensive due to the many concerns about patient safety, professional behaviours, demands on comprehensive information and communications with multiple agencies. In particular this case has highlighted the need for clinical and professional governance processes across clinical areas within the Trust, to develop these systems and to embed and learning from the SAIs and Inquiry. This work should be rigorous and robust and develop systems fit for the future.

This strand will have responsibility for undertaking activities to ensure embedding of learning, improvement and communication of Trust response to the Urology incidents. This includes providing assurance that improvement efforts are benchmarked outside the Trust from both a service development and national policy perspective and the acquired learning process and may include:

- Revision of Appraisal and Revalidation processes
- Quality Assurance of information processes in relation to Appraisal and Revalidation
- Development of systems and processes that marry professional and clinical governance
- Embedding and providing assurance regarding learning, improvement and communication
- Provide support on Trust communications regarding incident response
- Support triangulation of clinical and social care governance and professional governance information to improve assurance mechanisms
- Support the benchmarking of Trust service developments against regional and national perspectives
- Support liaison and communications with PHA / HSCB and Department of Health on matters relating to the urology incidents

- Support for corporate complaints department

Costs are included in Appendix 1.

Table 3-7 - Professional Governance, Learning and Assurance

Title	Band	WTE
AD Professional Governance, Learning and Assurance	8c	1
Project Lead	7	1
Administrative Support	4	1

Table 3-8 – Claims Management / Medico – Legal Requests (DLS 20%)

It is anticipated that the number of medico-legal requests for patient records and the number of legal claims will significantly increase as a result of the patient reviews and SAIs. This will require support for claims handling, responses to subject access requests and redaction of records.

Title	Band	WTE
Head of Litigation (uplift from band 7)	8a (uplift from band 7)	1
Specialist Claims Handler	7	1
Claims Administrative Support	4	1
Medico – Legal Admin Support	3	1
Service admin support – redaction	4	1
Support Health Professional for redaction – Clinical Nurse Specialist	7	1
2 x Solicitor Consultants (DLS)	sessional	

4.0 Identified Risks

Risk Identified	Mitigation Measure
• Recruitment of experienced staff –	• Complete recruitment documentation as soon as possible • Liaise with Human Resources
• Staff Backfill	• Complete recruitment

Risk Identified	Mitigation Measure
	documentation as soon as possible • Liaise with Human Resources
• Securing Funding	• Liaise with PHA and HSCB regarding additional funding required to support the SAI/Inquiry.
• Volume of calls received by the information line will exceed expectations leading to further complaints	• Monitoring of call volumes • Extending the operational hours to receive calls • Increasing the number of call handlers
• Number of clinics is insufficient to cope with the demand for review appointments	• Monitoring the number of review appointments required • Monitoring clinics and virtual clinics • Increasing the number of virtual clinics
• Current Service Provision will be impacted by the additional clinics being taken forward and Waiting Lists will continue to grow.	• Current provision continues • Utilise independent resources • Provide evening/weekend clinics
• Red flag appointments will not be seen within the required timeframe	• Monitor all current referrals and red flag appointments
• Reputation of Trust	• Provide a response within an agreed timeframe

5.0 Monitoring

Monitoring and reporting will continue throughout the investigation period and will be provided on a weekly basis. Meetings are scheduled on a weekly basis.

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JOB DESCRIPTION

POST: Service Manager Public Inquiry and Trust Liaison

LOCATION: Muckamore Abbey Hospital AND Royal Victoria Hospital with travel between Trust sites required

BAND: 8B

REPORTS TO: Interim Director, Learning Disability Services

RESPONSIBLE TO: Chief Executive

Job Summary / Main Purpose

In the first instance, the post holder will be responsible through the Director for Learning Disability Services, and working closely with the Co-Director Risk and Governance, for ensuring that the Trust meets the legal requirements of the Inquiries Act 2005 in respect of the Muckamore Abbey Hospital Public Inquiry. The post holder will also act as the Trust's Liaison Officer for the Inquiry Panel, the Directorate of Legal Services and other external stakeholders, for example, the Department of Health.

This is a permanent post and as such it is recognised that while the focus will in the first phase be on the Muckamore Abbey Hospital Public Inquiry, there will be future requirements for such a role following the completion of this particular Inquiry.

Main Duties / Responsibilities

For each of the following, the postholder will;

- Provide administrative support to the Public Inquiry Oversight Steering Group and any Task and Finish Groups which may arise. This will include the organisation of agendas, the co-ordination of papers and reports and completion of accurate and concise minutes to record key issues and decision-making.
- Be responsible for preparation of briefing notes to the Oversight Steering Group, the Executive Team and Trust Board, and the preparation of other ad hoc briefings as required.
- Oversee the collation, cataloguing, storage and maintenance of evidence anticipated to be required for the Public Inquiry, and evidence subsequently submitted to the Inquiry.
- Ensure that there is a safe, secure and retrievable system for storage of evidence anticipated to be required for the Inquiry, and for storage of evidence that is subsequently submitted to the Inquiry.
- Be responsible for briefing and supporting staff who are required to participate in the Inquiry and for providing guidance on best practice throughout the Inquiry process.
- Respond to any queries of the Inquiry Panel and the Director of Legal Services and to ensure the timely provision of witness evidence, and other evidence, as stipulated by the Inquiry Panel.

- Be responsible for developing and maintaining governance processes associated with implementation of agreed recommendations, actions and learning from the findings of the Public Inquiry.

Setting Direction and Service Delivery

- Provide effective leadership in the co-ordination of the Trust's response to the Muckamore Abbey Hospital Public Inquiry ensuring that the Trust meets its statutory duties.
- Oversee the co-ordination, collation and provision of evidence, including witness evidence, as required by the Inquiry Panel and/or Directorate of Legal Services, in line with Trust Policy and Regional Guidance on the Provision of Witness Statements.
- Ensure that there is a safe, secure and retrievable system for storage of evidence anticipated to be required for the Inquiry, and for storage of evidence that is subsequently submitted to the Inquiry.
- Ensure that there are systems and processes in place to optimise the timeliness and responsiveness to the Inquiry Panel requests.
- Provide timely information to employees in the requesting of reports and statements required by the Inquiry Panel.
- Ensure that the relevant line manager is aware that a member of staff is being asked to attend the Inquiry.
- Ensure that staff who are required to participate in the Public Inquiry receive adequate support throughout the entire Inquiry process, keeping the team informed of developments in the case and dates and times of any consultations. This will include supporting the relevant directorate management team to guide them through the process and ensure their preparedness to enable them to support staff.
- Escalate any concerns in relation to potential delays in the provision of information to the Inquiry Panel through the Trust's assurance/accountability framework to the Executive Team.
- Provide administrative support to the Public Inquiry Oversight Steering Group and any Task and Finish Groups which may arise. This will include the organisation of agendas, the co-ordination of papers and reports and completion of accurate and concise minutes to record key issues and decision-making.
- Be responsible for preparation of briefing notes to the Oversight Steering Group, the Executive Team and Trust Board, and the preparation of other ad hoc briefings as required.

Corporate Management

- Contribute to the Trust's overall corporate governance processes to ensure its compliance with public sector values and codes of conduct, operations and accountability.

Collaborative Working and Communication

- Establish collaborative relationships and networks with internal and external stakeholders.
- Engage with stakeholders across the organisation including the Risk and Governance Team and the Medical Directors Office to ensure the provision of accurate and timely information to the Inquiry Panel.
- Work collaboratively with external stakeholders including the Directorate of Legal Services and the PSNI.
- Responsible for developing and maintaining sound internal and external communications systems.

- Represent the Trust, as appropriate, on external groups and/or representations Director where appropriate and as required in respect of the Trust's approach to the Public Inquiry.

Financial and Resource Management

- Responsible for the management of any financial allocation/budget associated with the Trust's preparation and involvement in the Public Inquiry, in conjunction with financial management colleagues.

People Management and Development

- Be responsible for the line management of the Assurance Co-ordinator.
- Promote the corporate values and culture of the organisation through the development and implementation of relevant policies and procedures, and appropriate personal behaviour.
- Be responsible for ensuring that the Health and Social Care Records service complies with employment law and is consistent in their application of the Trust's policies.
- Be responsible for ensuring that staff are appraised at least annually and Knowledge and Skills framework is in place.
- Be responsible for his/her own performance and take action to address identified personal development areas.
- Manage recruitment processes, to ensure staff are recruited in a timely and professional manner and vacancies are filled appropriately.

General Responsibilities

Employees of the Trust are required to promote and support the mission and vision of the service for which they are responsible and:

- At all times provide a caring service and to treat those with whom they come into contact in a courteous and respectful manner.
- Demonstrate their commitment by their regular attendance and the efficient completion of all tasks allocated to them.
- Comply with the Trust's Smoke Free Policy.
- Carry out their duties and responsibilities in compliance with the Health and Safety Policies and Statutory Regulations.
- Adhere to Equality and Good Relations duties throughout the course of their employment.
- Ensure the ongoing confidence of the public in-service provision.
- Maintain high standards of personal accountability.
- Comply with the HPSS Code of Conduct.
- The post holder will promote and support effective team working, fostering a culture of openness and transparency. The post holder will ensure that they take all concerns raised with them seriously and act in accordance with Belfast Trust's Whistleblowing Policy and their professional code of conduct, where applicable.
- The post holder will, in the event of a concern being raised with them, ensure it is managed correctly under the Belfast Trust's Whistleblowing Policy, and ensure that feedback/learning is communicated at individual, team and organisational level regarding the concerns raised, and how they were resolved.

Information Governance

All employees of Belfast Health & Social Care Trust are legally responsible for all records held, created or used as part of their business within the Belfast Health and

Social Care Trust, including patient/client, corporate and administrative records whether paper based or electronic and also including e-mails. All such records are public records and are accessible to the general public, with limited exceptions, under the Freedom of Information Act 2000, the Environment Regulations 2004, the General Data Protection Regulation (GDPR) and the Data Protection Act 2018. Employees are required to be conversant and to comply with the Belfast Health and Social Care Trust policies on Information Governance including for example the ICT Security Policy, Data Protection Policy and Records Management Policy and to seek advice if in doubt.

For further information on how we use your personal data within HR, please refer to the Privacy Notice available on the HUB or Your HR

Environmental Cleaning Strategy

The Trusts Environmental Cleaning Strategy recognises the key principle that "Cleanliness matters is everyone's responsibility, not just the cleaners" Whilst there are staff employed who are responsible for cleaning services, all Trust staff have a responsibility to ensure a clean, comfortable, safe environment for patients, clients, residents, visitors, staff and members of the general public.

Infection Prevention and Control

The Belfast Trust is committed to reducing Healthcare associated infections (HCAIs) and all staff have a part to play in making this happen. Staff must comply with all policies in relation to Infection Prevention and Control and with ongoing reduction strategies. Standard Infection Prevention and Control Precautions must be used at all times to ensure the safety of patients and staff.
This includes:-

- Cleaning hands either with soap and water or a hand sanitiser at the appropriate times (WHO '5 moments');
- Using the correct '7 step' hand hygiene technique;
- Being 'bare below the elbows' when in a clinical environment;
- Following Trust policies and the Regional Infection Control Manual (found on intranet);
- Wearing the correct Personal Protective Equipment (PPE);
- Ensuring correct handling and disposal of waste (including sharps) and laundry;
- Ensuring all medical devices (equipment) are decontaminated appropriately i.e. cleaned, disinfected and/or sterilised;
- Ensuring compliance with High Impact Interventions.

Personal Public Involvement

Staff members are expected to involve patients, clients, carers and the wider community were relevant, in developing, planning and delivering our services in a meaningful and effective way, as part of the Trust's ongoing commitment to Personal Public Involvement (PPI).

Please use the link below to access the PPI standards leaflet for further information.

http://www.publichealth.hscni.net/sites/default/files/PPI_leaflet.pdf

Clause: ***This job description is not meant to be definitive and may be amended to meet the changing needs of the Belfast Health and Social Care Trust.***

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PERSONNEL SPECIFICATION

JOB TITLE / BAND: Service Manager, Public Inquiry and Trust Liaison / Band 8B

DEPT / DIRECTORATE: Muckamore Abbey Hospital AND Royal Victoria Hospital with travel between Trust sites required / Adult Social & Primary Care

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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 below, using the information provided by you on your application form. Please note the Trust reserves the right to use any desirable criteria outlined below 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

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 the process when the criteria will be measured is stated below.

Factor	Criteria	Method of Assessment
Experience Qualifications Registration	• Have a university degree or relevant professional qualification at graduate or diploma level **AND** worked for at least 2 years in a *senior management role in a complex organisation **OR** Have worked for at least 3 years in a *senior management role in a major complex organisation. ***Note *senior management role will be considered to be at Band 8A or equivalent or above.***	Shortlisting by Application Form
Other (e.g. Driving etc.)	• Full UK Driving Licence and access to a car. *'Where disability prohibits driving, this criteria will be waived if the applicant is able to organise suitable alternative arrangements.'*	Shortlisting by Application Form

Knowledge **Skills** **Abilities**	• Delivered against challenging performance management programmes for a minimum of 2 years meeting a full range of key targets and making significant improvements. • Have worked with a diverse range of stakeholders, both internal and external to the organisation, to achieve successful outcomes for a minimum of 2 years. • Successfully demonstrate high level people management, leadership and organisational skills for a minimum of 2 years. • Have good communication skills (written, oral, presentational and interpersonal) with the ability to communicate effectively with all levels of staff within the Trust, and outside the organisation. • Have the ability to collate and critically analyse statistical and qualitative information and the ability to make and take decisions after analysis of options and implications. • Ability to multi-task and continue to function to a high standard when under pressure. • Determination, drive to succeed, perseverance, and resilience. • IT literacy -proficient in MS Word, Excel, PowerPoint, etc.	Shortlisting by Application Form **And / Or** Interview

DESIRABLE CRITERIA

Desirable criteria will **ONLY** be used where it is necessary to introduce additional job related criteria to ensure files are manageable. You should therefore make it clear on your application form how you meet these. Failure to do so may result in you not being shortlisted.

Factor	Criteria	Method of Assessment
Experience **Qualifications** **Registration**	• Experience of working with legal services and/or working on legal processes.	Shortlisting by Application Form

NOTE:

Where educational/professional qualifications form part of the criteria you will be required, if shortlisted for interview, to produce original certificates *and* one photocopy of same issued by the appropriate authority. Only those certificates relevant to the shortlisting criteria should be produced. If educational certificates are not available an original letter *and* photocopy of same detailing examination results from your school or college will be accepted as an alternative.

If successful you will be required to produce documentary evidence that you are legally entitled to live and work in the United Kingdom. This documentation can be a P45, Payslip, National Insurance Card or a Birth Certificate confirming birth in the United Kingdom or the Republic of Ireland. *Failure to produce evidence will result in a non-appointment*.

Where a post involves working in regulated activity with vulnerable groups, post holders will be required to register with the Independent Safeguarding Authority.

Healthcare Leadership Competencies

Candidates who are shortlisted for interview will need to demonstrate at interview that they have the required competencies to be effective in this demanding leadership role.

The competencies concerned are set out in the NHS Healthcare Leadership Model, details of which can be found at:

http://www.leadershipacademy.nhs.uk/resources/healthcare-leadership-model.

Particular attention will be given to the following:

- Inspiring shared purpose
- Leading with care
- Evaluating information
- Connecting our service
- Sharing the vision
- Engaging the team
- Holding to account
- Developing capability
- Influencing for results

HSC Values

Whilst employees will be expected to portray all the values, particular attention is drawn to the following values for this role

What does this mean?	What does this look like in practice?
 **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 responsibilty 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.
 **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 to help when needed • I speak up if I have concerns • I challenge inappropriate or unacceptable behaviour and practice.
 **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 wellbeing so that I can care and support others.

Urology Oversight Group Minutes

Tuesday 1st December 2020, 4:00pm

Via Zoom

	Item	Actions
1	**In Attendance** Stephen Wallace — Melanie McClements Martina Corrigan — Dr Maria O'Kane Dr Damian Gormley — Ronan Carroll Siobhan Hynds Vivienne Toal Patricia Kingsnorth	
2	**Apologies** Jane McKimm Mr Mark Haynes	
3	**Ministerial Statement Update** Melanie updated that AOB solicitor has advised due to a family bereavement that no communications will be received for 10 days. A report was also issued to the DoH meeting updating on weekly Trust progress.	
	Management of Patient Reviews	
4	**Private Practice** Melanie advised that a letter had been issued to AOB requesting information however a response has not been received as per family bereavement notification.	
5	**Update on Radiology Review** Engagement with Subject Matter Experts to be progressed to support radiology review work	**Role description for SME to be developed**
6	**IPT for Review Process** Martina referred to the £200k for an additional consultant. Group discussed the potential for this to be diverted to Inquiry IPT.	**To be discussed at HSCB meeting**
7	**Additional Subject Matter Expertise / Royal College of Surgeons Engagement** Meeting took place with the RCS on 30th November to discuss potential engagement and invited review. Trust to outline terms of reference for consideration by HSCB / DoH then onward submission to RCS.	**Terms of reference to be developed**
	Bicalutamide Patient Review Engagement with Subject Matter Experts to be progressed to quality assure bicalutamide audit	**Role description for SME to be developed**
	Engagement of ISP to undertake waiting list work Group discussed Mr Keane's availability to undertake additional work beyond the oncology reviews.	**Martina / Mark to discuss with Mr Keane**
	Information Telephone Line Martina provided an update on this work, group discussed the need for additional clinical input to support this. Group discussed calls from MLAs that went through directly to CX office regarding urology incident. Group to speak to Jane McKimm to	**Standardised communication to be developed**

	agree a communication to MLA's to standardize methods of contact.	
	Professional Governance	
8	**GMC Discussions** Stephen advised that the final set of requested information is being issued to the GMC this week. A meeting with the new GMC ELA is being arranged for Dr O'Kane and Stephen.	**Stephen to issue information to the GMC**
9	**Administration Review Update** Martina and Anita meeting with Denise Lynd tomorrow, update to be provided next meeting	**Update for next meeting**
	Serious Adverse Incident Reviews	
12	**Process for Managing SAI's** Dr O'Kane referred to the model of Structured Judgement Reviews and its potential applicability in the absence of a formal SAI process while the Public Inquiry commences. Proposal to be discussed with the HSCB	**SJR model to be discussed with the HSCB**
13	**Initial Feedback from SAI Chair** Patricia advised that the chair had requested information regarding NIMDTA surveys / feedback. Patricia to go back and clarify the rationale / reason for information. Chair also proposed a meeting with AOB, group agreed the route would be via AOB solicitors, questions are to be set by Subject Matter Expert prior to engagement.	**Patricia to contact chair to discuss**
14	**Family Liaison Role** Post to be advertised for 6 months temporary via EOI process.	
	Communications	
17	**Media / Assembly Questions** Stephen referred the FAQ, asked the group to review prior to submission to the DoH	
	Any Other Business	
19	**Any Other Business** Vivienne asked for Grievance Appeal to be added to agenda.	
	Date of Next Meeting	
20	**Via Zoom – 8th December 2020**	

Southern Health and Social Care Trust

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Staffing Support Requirement for Serious Adverse Incident /Inquiry - Urology

3 December 2020

1.0 Introduction

There have been significant clinical concerns raised in relation to Consultant A which require immediate and coordinated actions to ensure patient safety is maintained. Comprehensive plans need to be put into place to undertake the following:

- Review of professional governance arrangements
- Liaison with professional bodies
- Review of patient safety and clinical governance arrangements
- Commencement of operational support activities including
  - Offering additional clinical activity
  - Provide complaints resolution
  - Media queries, Assembly Questions responses
  - Managing the volume of patients who require to be reviewed
  - Patient Support (Psychology / Telephone Support / Liaison)
  - Staff Support
  - Claim handling / medico-legal requests

This proposal identifies the staffing requirements and costs required to support the Serious Adverse Incident (SAI) Investigation/Inquiry for Urology in the Southern Trust.

This proposal will require revision as demands change over time.

2.0 Needs Assessment

A comprehensive review of patients who have been under the care of Consultant A will be required and this may likely number from high hundreds to thousands of patients.

Following discussions with the Head of Service the following clinics have initially been proposed and have been estimated in the first instance to continue for one year.

Clinics will commence in December 2020 and continue throughout 2021. A putative timetable has been included. We will require that consultants have access to records, have reviewed the contents and results and are familiar with each patient's care prior to face to face review where required. Each set of patient records will require 10-30 minutes to review depending on complexity. In addition, each of the patients reviewed will require 45 minute consultant urologist appointments to include time for administration/ dictation in addition to 15 mins preparation time on average. That is 8 patients require 8hrs Direct Clinical Contact (DCC) Programmed Activity (PA). 800 patients require 800 hours of Direct Clinical and so on. (Each consultant DCC PA is 4hrs).

The purpose of the clinical review is to ascertain if the:

1. diagnosis is secure
2. patient was appropriately investigated
3. Investigations, results and communications were requested in a timely fashion
4. Investigations, results and communications were responded to/ processed in a timely fashion
5. Patient was prescribed / is receiving appropriate treatment
6. Overall approach taken is reasonable
7. Patient has, is or likely to suffer harm as a result of the approach taken.

In addition, it will be expected that where there are concerns in relation to patient safety or inappropriate management that these will be identified and a treatment plan developed by the assessing consultant and shared with the urology team for ongoing oversight or with the patient's GP.

Table 2-1 Suggested timetable

Day	Clinic Session	Number of Patients
Monday	AM	8
Monday	PM	8
Tuesday	AM	8
Tuesday	PM	8
To be confirmed	AM	8
To be confirmed	PM	8
Total no of patients per week		48

3.0 Staffing Levels Identified

3.1 Information Line – First Point of Contact

An information line will be established for patients to contact the Trust to speak with a member of staff regarding any concerns they may have and will operate on Monday to Friday from 10am until 3pm. A call handler will receive the call and complete an agreed Proforma (appendix 1) with all of the patient's details and advise that a colleague will be in contact with them. The PAS handler will take the information received and collate any information included on PAS/ECR and this will be examined in detail by the Admin/Information Handler. The following staff have been identified as a requirement for this phase. It must be noted that the WTE is an estimate and will be adjusted dependent on the volume of calls received. Costs are included in Appendix 1.

Table 3-1 – Information Line Initial Staffing Requirements

Title	Band	WTE
Call Handlers	4	2
Admin Support for identifying notes/ looking up NIECR etc	4	2
Admin/Information Handler	5	1

3.2 Clinic Requirements

To date a clinical process audit has been carried out in relation to aspects of the Consultant's work over a period of 17 months.

In addition to this 236 urology oncology patients are being rapidly and comprehensively reviewed in the private sector. (Patients returned with management plan are included in Table 3.2/Table 3.4)

A further 26 urology oncology patients have been offered appointments or reviewed in relation to their current prescription of Bicalutamide.

Given the emerging patterns of concerns from these reviews and Multi-Disciplinary Meetings (MDMS) which have resulted in 9 patients' care meeting the standard for SAI based on this work to date, it is considered that a comprehensive clinical review of the other patients is required. The Royal College of Surgeons has advised that this includes 5 years of clinical activity in the first instance.

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The numbers and clinical prioritisation will be identified collectively by the Head of Service, Independent Consultant and the Clinical Nurse Specialist either face to face or via virtual clinics. The volume of patients is 2327 for 18 months in the first instance and the number of DCC PA has been identified as **. The staffing required to operate these clinics is detailed below. This work will be additionality and should not disrupt usual current urology services. It must be noted that again this is an estimate and will be dependent on the volume of patients involved. .

Clinic Requirements Staffing – 6 sessions as detailed in Section 2. Costs are included in Appendix 1.

Table 3-2 – Clinic Staffing Requirements

Title	Band	WTE
Outpatient Manager	7	0.7
Medical Secretarial Support	4	0.5
Booking clerk	3	0.7
Audio Typist	2	0.7
Medical Records	2	0.7
Nursing staff	5	0.7
Nurse Clinical Specialist	7	0.7
Health Care Assistant	3	0.7
Receptionist	2	0.7
Consultant		DCC
Pharmacist	8a	0.7
Psychology Band 8B and above		1 present per clinic
Domestic Support	2	0.7

3.3 Procedure Requirements

If the outcome of the patient review by the Independent consultant urologist is that the patient requires further investigation, this will be arranged through phlebotomy, radiology, day procedure, and pathology / cytology staff. The provision will be dictated by clinical demand. The following staffing levels have been identified as below for each 1 day sessions. Costs are included in Appendix 1.

Table 3-3 – Procedure Staffing Requirements

Title	Band	WTE
Secretary	4	
Reception	2	
Nurses	5	0.64

Title	Band	WTE
Health Care Assistant	3	0.22
Sterile Services	3	0.22
Consultant - locum		2 PAs
Anaesthetic cover		1 PA
Domestic Support	2	0.22

3.4 Multi-Disciplinary Weekly Meetings Requirements

In order to monitor and review the number of patients contacting the following multi-disciplinary team has been identified as a requirement. Costs are included in Appendix 1.

Table 3-4 -–Staffing Requirements for Multi-Disciplinary Meetings (weekly)

Title	Band	WTE
Cancer Tracker	4	0.4
Nurse Clinical Specialist	7	0.1
Consultant Urologist x 2		2 PAS
Consultant Oncologist		1 PA
Consultant Radiologist		1 PA
Consultant Pathologist		1 PA

3.5 Serious Adverse Incident Requirements

Work has commenced on 9 SAI's and the following staff have been identified as a requirement to support the SAI and the Head of Service to enable investigative work to take place and to enable current provision to continue. Costs are included in Appendix 1.

Table 3-5 -Additional staffing and Services required to support SAI

Title	Band	WTE
Head of Service (Acute) – SAI backfill	8b	1
Chair of Panel	N/A	sessional
Band 5 admin support	5	1
Governance Nurse/ Officer	7	2
Admin support to the panel	3	1
Psychology support	Inspire	sessional
Family Liaison SLA	7	1

3.6 Inquiry Requirements

Costs are included in Appendix 1.

Table 3-6 - Additional staffing and Services required to Support Inquiry

Title	**Band**	**WTE**
Head of Service Backfill	8b	1
Clinical Nurse Specialist	7	1
Admin Support for HOS	4	1
Admin Support to respond and collate requests for information for inquiry team	5	2
Health records staff to prepare notes for Inquiry Team	2	4
Urology Experts – WL Initiative Funding £138 per hour	Consultant	Sessional
Media queries, Assembly Questions responses	8a (uplift from Band 7's)	2
Admin Support for media queries/Assembly questions	4	1

3.7 Professional and Clinical Governance Requirements to Support the SAI/ Inquiry

Investigations involving senior medical staff are resource intensive due to the many concerns about patient safety, professional behaviours, demands on comprehensive information and communications with multiple agencies. In particular this case has highlighted the need for clinical and professional governance processes across clinical areas within the Trust, to develop these systems and to embed and learning from the SAIs and Inquiry. This work should be rigorous and robust and develop systems fit for the future.

This strand will have responsibility for undertaking activities to ensure embedding of learning, improvement and communication of Trust response to the Urology incidents. This includes providing assurance that improvement efforts are benchmarked outside the Trust from both a service development and national policy perspective and the acquired learning process and may include:

- Revision of Appraisal and Revalidation processes
- Quality Assurance of information processes in relation to Appraisal and Revalidation
- Development of systems and processes that marry professional and clinical governance
- Embedding and providing assurance regarding learning, improvement and communication
- Provide support on Trust communications regarding incident response
- Support triangulation of clinical and social care governance and professional governance information to improve assurance mechanisms
- Support the benchmarking of Trust service developments against regional and national perspectives
- Support liaison and communications with PHA / HSCB and Department of Health on matters relating to the urology incidents

- Support for corporate complaints department

Costs are included in Appendix 1.

Table 3-7 - Professional Governance, Learning and Assurance

Title	Band	WTE
AD Professional Governance, Learning and Assurance	8c	1
Project Lead	7	1
Administrative Support	4	1

Table 3-8 – Claims Management / Medico – Legal Requests (DLS 20%)

It is anticipated that the number of medico-legal requests for patient records and the number of legal claims will significantly increase as a result of the patient reviews and SAIs. This will require support for claims handling, responses to subject access requests and redaction of records.

Title	Band	WTE
Head of Litigation (uplift from band 7)	8a (uplift from band 7)	1
Specialist Claims Handler	7	1
Claims Administrative Support	4	1
Medico – Legal Admin Support	3	1
Service admin support – redaction	4	1
Support Health Professional for redaction – Clinical Nurse Specialist	7	1
2 x Solicitor Consultants (DLS)	sessional	

4.0 Identified Risks

Risk Identified	Mitigation Measure
• Recruitment of experienced staff –	• Complete recruitment documentation as soon as possible • Liaise with Human Resources
• Staff Backfill	• Complete recruitment

Risk Identified	Mitigation Measure
	documentation as soon as possible • Liaise with Human Resources
• Securing Funding	• Liaise with PHA and HSCB regarding additional funding required to support the SAI/Inquiry.
• Volume of calls received by the information line will exceed expectations leading to further complaints	• Monitoring of call volumes • Extending the operational hours to receive calls • Increasing the number of call handlers
• Number of clinics is insufficient to cope with the demand for review appointments	• Monitoring the number of review appointments required • Monitoring clinics and virtual clinics • Increasing the number of virtual clinics
• Current Service Provision will be impacted by the additional clinics being taken forward and Waiting Lists will continue to grow.	• Current provision continues • Utilise independent resources • Provide evening/weekend clinics
• Red flag appointments will not be seen within the required timeframe	• Monitor all current referrals and red flag appointments
• Reputation of Trust	• Provide a response within an agreed timeframe

5.0 Monitoring

Monitoring and reporting will continue throughout the investigation period and will be provided on a weekly basis. Meetings are scheduled on a weekly basis.

Southern Health and Social Care Trust

Quality Care - for you, with you

ROLE DESCRIPTION

JOB TITLE	Independent Consultant Urology Subject Matter Expert
REPORTS TO OPERATIONALLY	Melanie McClements, Acute Director
REPORTS TO PROFESSIONALLY	Dr Maria O'Kane, Medical Director
TIME COMMITMENT	Sessional Work on an ongoing basis

ROLE SUMMARY

To support the ongoing review of urology patients the Southern Health and Social Care Trust requires an independent Consultant Urologist to undertake a range of clinical review and quality assurance processes. The Subject Matter Expert will report operationally to the Director of Acute Services and Professionally to the Medical Director.

ROLE DUTIES

1. To review and quality assure the Trust audit of patients prescribed the medication Bicalutamide taking into account the audit methodology employed, audit findings and where appropriate the proposed changes in medication.

2. To chair a weekly extraordinary Multidisciplinary Team Meeting (MDT) to discuss and review patients which have been identified by independent Consultant Urologist as requiring MDT discussion. MDT will be supported by one additional Consultant Urologist, Consultant Oncologist and where required Consultant Radiologist / Pathologist.

3. To review radiology results (1028 patients) held on Electronically (NIECR System) to ascertain if appropriate action has been taken in response to the radiology results.

4. To review MDT meeting outcomes (271 patients) held on Electronically (NIECR System) to ascertain if appropriate action has been taken in response to the MDT discussions.

5. To quality assure the outcomes and conclusions for all patients that have been reviewed at clinic as part of the urology review to date from all identified workstreams.

6. To assist in the development on parameters for use when triaging patients who contact the patient information line including identification of what constitutes a potential delay in actioning treatments, reviews, referrals and reviews.

Clinical and Social Care Audit Registration Form

Audit Title: Audit of Prescribing of anti-androgen medicine 'Bicalutamide'

Directorate: Acute Services ■ Children & Young People ☐ Older Persons & Primary Care ☐
Mental Health & Disability ☐ Corporate request ☐

Division:

Auditor's name: Mr Mark Haynes **Contact details: (email)** Personal Information redacted by the USI	**Audit Supervisor's Name : Not Applicable**

Is this a: National audit ☐ Regional audit ☐ Trust audit ■ International audit ☐

Proposed audit commencement date 27th October 2020 Proposed audit completion date …/…/….

Audit Aims

To ensure that the anti-androgen medicine 'Bicalutamide' has been prescribed as licensed and in line with NICE guideline NG131 Prostate Cancer: Diagnosis and Management

Audit Objectives

- To ensure that where Bicalutamide is prescribed only where indicated and as per licensed usage
- To ensure that where Bicalutamide is prescribed this is prescribed in the correct therapeutic dosages
- To ensure that patients prescribed Bicalutamide is appropriately reviewed as part of the patients ongoing care
- To ensure that any deviations from prescribing guidance is based on sound evidence based clinical rationale

Audit Standards

The following audit standards obtained from NICE guideline [NG131] Prostate cancer: diagnosis and management

Published date: 09 May 2019.

Audit Criteria	Target	Exceptions	Source of Evidence
Bicalutamide prescribed as per indicated conditions in NICE NG131	100%	Clinical rationale for deviation from guidance	NICE guideline NG131 Prostate Cancer: Diagnosis and Management
Therapeutic doses of anti-androgen monotherapy with bicalutamide are prescribed at recommended dose (150 mg).	100%	Discussions with patient / Clinical rationale	NICE guideline NG131 Prostate Cancer: Diagnosis and Management

Audit Methodology

The following audit methodology will be followed:

- HSCB to provide information on primary care prescriptions of the medication Bicalutamide
- Southern Health and Social Care Trust patients to be identified and a consultant led review of prescribing to take place to identify prescribing of Bicalutamide that is outside of that prescribed in NICE guideline NG131 Prostate Cancer: Diagnosis and Management

Rationale for the audit (please tick all that apply)

Topic is included in the Directorate's clinical audit work-plan ☐ Compliance with standards & guidelines ■

Clinical and Social Care Audit Registration Form

National Healthcare Quality Improvement Partnership (HQIP) audit	☐	Regional RQIA/GAIN audit	☐
Other national / international audit	☐	Trust based audit topic important to team/division	■
Clinical risk	■	Recommendation from national / regional report	☐
Serious Adverse Incident or Adverse Incident review	■	Clinician / personal interest	☐
Incident reporting	☐	Educational audit	☐

Other – please specify ……

Level 1 ☐ **Level 2** ■ **Level 3** ☐ **Level 4** ☐

Has this audit been approved based on the priority level? Yes ■ No ☐

Level 1 - Approval required by Associate Medical Director or Clinical Director or Directorate Governance Forum
Level 2 - Approval required by Associate Medical Director or Clinical Director or Directorate Governance Forum
Level 3 – Approval required by Supervising Consultant
Level 4 – Approval required by Supervising Consultant
Please be advised that the audit cannot proceed without approval as above.

Please Note: The Information Team have advised they will not release data to the requestor unless the clinical audit has been approved as above.
The clinical audit team will also advise contact with Information Governance for any advice required.

The clinical audit team can be contacted via:
Email: Personal Information redacted by the USI
Tel:

Raymond Haffey
Terri Harte
Sandra McLoughlin
Personal Information redacted by the USI

Mary Markey
Roisin Feely
Philip Sullivan
Personal Information redacted by the USI

In submitting this audit registration form, I agree to share the audit findings, recommendations and audit summary template with:the Audit Supervisor, appropriate Divisional/Directorate Committee and the Trust's Clinical audit team

Please submit your audit registration form to: Personal Information redacted by the USI

Priority levels for clinical audit

Level	Audit type - projects identified through	
Level 1 audits, "external must dos" (where the service is applicable to SHSCT)	• National audits (NHS England Quality Accounts List (HQIP), including the National Confidential Enquiry into Patient Outcomes and Deaths (NCEPOD) / Other Confidential Inquires	1
Level 2 audits, other national audits and 'internal must dos'	• National audits not contained within the HQIP list, or other clinical audits arising from: • Clinical risk • Serious untoward incident / internal reviews • National Institute of Clinical Excellence Standards & Guidelines • Complaints • Re-audit • Regional audits initiated by RQIA / GAIN	2
Level 3 audits, 'divisional priorities'	• Local topics important to the division	3
Level 4 audits	• Clinician / personal interest • Educational audits	4

Action Plan Urology Personal Information redacted by

Reference number	Recommendations	Designated responsible person	Action required	Date for completion / timescale	Date recommendation completed with evidence
1	HSCB should link with the electronic Clinical Communication Gateway (CCG) implementation group to ensure it is updated to include NICE/NICaN clinical referral criteria. These fields should be mandatory.	HSCB	See recommendation 5		
2	HSCB should consider GP's providing them with assurances that the NICE guidance has been implemented within GP practices	HSCB			
3	HSCB should review the implementation of NICE NG12 and the processes surrounding occasions when there is failure to implement NICE guidance, to the detriment of patients.	HSCB			
4	GPs should be encouraged to use the electronic CCG referral system which should be adapted to allow a triaging service to be performed to NICE NG12 and NICaN standards. This will also mean systems should be designed that ensure electronic referral reliably produces correct triaging e.g. use of mandatory entry fields.	HSCB			

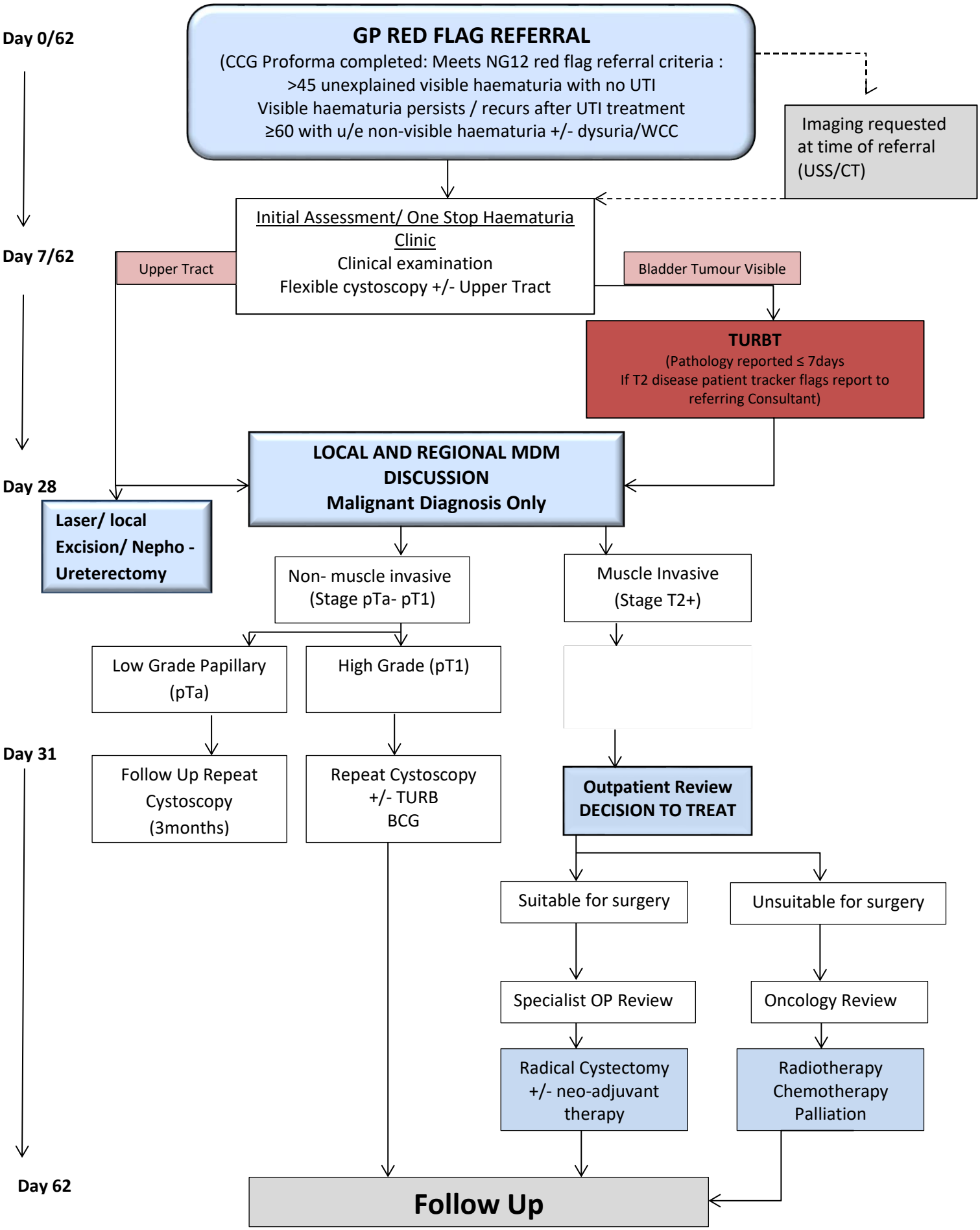
5	**TRUST** Work should begin in communicating with local GPs, perhaps by a senior clinician in Urology, to formulate decision aids which simplify the process of Red-flag, Urgent or Routine referral. The triage system works best when the initial GP referral is usually correct and the secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.	AD surgical/ AMD Primary Care	The urology service hold the view that to enable the referral process to be efficient and effective, the CCG form requires to have mandatory fields which require it to be completed prior to referral from Primary Care.		NiCan pathway.  Bladder Cancer Pathway March 2020  Revised Prostate Diagnostic Pathway D  Female Lower Urinary Tract Sympto  Female Urinary Tract Infection.docx  Male Lower Urinary Tract Symptoms.docx  male urinary tract infections.docx
6	The Trust should re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW.	AD Surgery/ AMD Surgery	Time needs to be made available in consultant job plans to undertake the task of triaging referral letters. Discussions are ongoing with MD and AD	Jan 2021	

7	The Trust will develop written policy and guidance for clinicians on the expectations and requirements of the triage process. This guidance will outline the systems and processes required to ensure that all referrals are triaged in an appropriate and timely manner.	AD surgery	Currently the IEAP protocol is followed The current regional protocol is being updated.	Jan 2021	 Integrated Elective Access Protocol - Apr  Integrated Elective Access Protocol Draft  FW IEAP referral.msg  Booking Centre SOP manual.doc  TRIAGE PROCESS 2. lmca.docx
8	The current Informal Default Triage (IDT) process should be abandoned. If replaced, this must be with an escalation process that performs within the triage guidance and does not allow Red-flag patients to wait on a routine waiting list.	AD Surgery		Nov 2020	
9	Monthly audit reports by Service and Consultant will be provided to Assistant Directors on compliance with triage. These audits should be incorporated into Annual Consultant Appraisal programmes. Persistent issues with triage must be escalated as set out in recommendation 10.	AD surgery	Reports will be sent to AD and AMD/ CD	Nov 2020	
10	The Trust must set in place a robust system within its medical management hierarchy for highlighting	MD			

	and dealing with 'difficult colleagues' and 'difficult issues', ensuring that patient safety problems uncovered anywhere in the organisation can make their way upwards to the Medical Director's and Chief Executive's tables. This needs to be open and transparent with patient safety issues taking precedence over seniority, reputation and influence.				
11	Consultant 1 needs to review his chosen 'advanced' method and degree of triage, to align it more completely with that of his Consultant colleagues, thus ensuring all patients are triaged in a timely manner.	MD			
12	Consultant 1 needs to review and rationalise, along with his other duties, his Consultant obligation to triage GP referrals promptly and in a fashion that meets the agreed time targets, as agreed in guidance which he himself set out and signed off. As he does this, he should work with the Trust to aid compliance with recommendation 6.	MD			

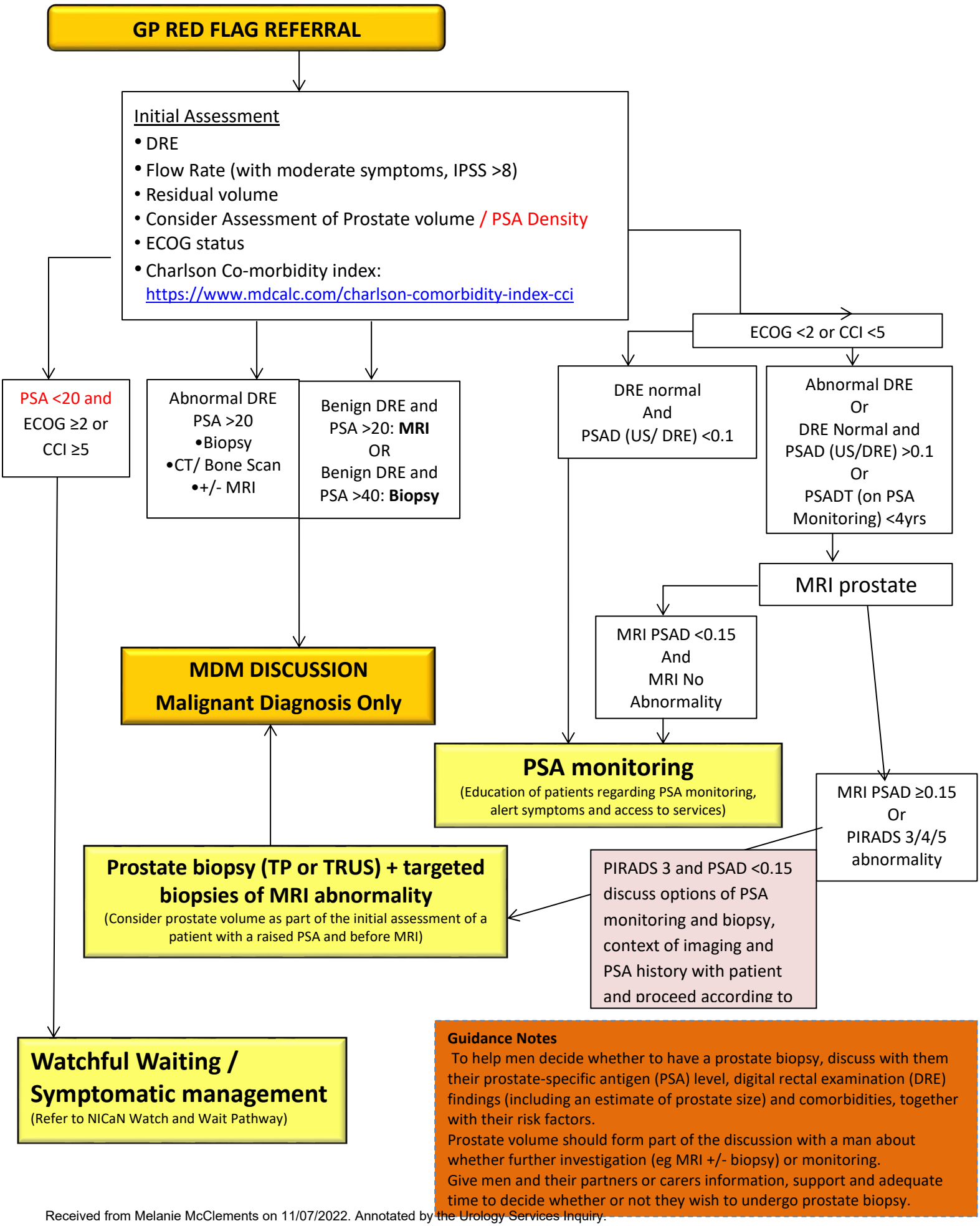
.

NICaN SUSPECT BLADDER CANCER REFERRAL AND DIAGNOSTIC PATHWAY



Final Proposed Prostate Diagnostic Pathway December 2019

NICaN SUSPECT PROSTATE CANCER DIAGNOSTIC PATHWAY



Southern Health and Social Care Trust

Quality Care - for you, with you

Female Lower Urinary Tract Symptoms

History;

- Storage symptoms – Frequency, Urgency, Nocturia, Incontinence
- Voiding symptoms – Hesitancy, Poor flow, Straining, Stop-start void.
- Assessment of Fluid intake

Examination;

- Abdomen
    - Palpable bladder?
- External Genitalia/Pelvic Examination
    - Atrophic Vaginitis
    - Pelvic Organ Prolapse

Investigations;

- Urine Dipstick
    - Glucose
    - Nitrite and Leukocytes
    - Haem
- Blood test
    - Renal profile
    - Glucose (found on Dipstick)
- USS Urinary tract
    - Hydronephrosis?
    - Residual Volume?
    - Pelvic organs?

Primary Care management;

- Lifestyle advice
    - Reduce Caffeine
    - Timing of fluid intake
- Palpabable Bladder
    - refer to Urology
- Atrophic Vagintis
    - Consider oestrogens therapy
- Pelvic Organ Prolapse
    - Refer to Gynae
- Leukocytes
    - manage infection as per Guidelines.
- If Renal Impairment
    - see Nephrology Guidelines

- Ultrasound Urinary tract
    - Hydronephrosis - refer to Urology
    - Residual Volume >150ml – refer to Urology
- Incontinent, residual volume <150ml, storage symptoms
    - If incontinent consider Anticholinergic treatment
    - Symptom review after 3/12 treatment

    If urinary incontinent,

    - If mainly stress incontinent, refer to community
    - Consider anticholinergice treatment – and reassessment after three months

- Others – patients who do not fit into the above two categories
    - Refer to Urology
    - Treat with topical oestrogens.
    - Hydronephrosis → Refer Urology
    - Residual Volume ≥ 300ml → Refer Urology
    - Residual volume 150ml – 300ml → Refer community continence team

Referral;

- Abnormal findings as above
- No symptomatic improvement after 3/12 of medical treatment refer to Urology

Corrigan, Martina

From: McClements, Melanie
Sent: 08 July 2022 18:50
To: Corrigan, Martina
Subject: FW: URGENT :AOB concerns - escalation- oversight meeting request please
Attachments: FW: SHSCT - "Dr Urology Consultant" (84.3 KB); FW: URGENT - : General Medical Council In Response Please Quote SMC/1-22... (23.5 KB); Dr O'Brien – GMC No. [redacted] - SHSCT response to request for info (192 KB)

Importance: High

From: McClements, Melanie [redacted]
Sent: 08 October 2019 16:27
To: Carroll, Ronan [redacted]
Subject: FW: URGENT :AOB concerns - escalation- oversight meeting request please
Importance: High

As discussed Ronan, m

From: OKane, Maria
Sent: 04 October 2019 22:45
To: Khan, Ahmed; Hynds, Siobhan; McClements, Melanie; Haynes, Mark; Corrigan, Martina
Cc: Gibson, Simon; Toal, Vivienne; Weir, Lauren; Reid, Trudy
Subject: URGENT :AOB concerns - escalation- oversight meeting request please
Importance: High

Lauren please arrange meeting for Tuesday as outlined below.

Dear all – unfortunately it wasn't possible for some of us to speak today at 4.15 – Mr Haynes has less flexibility than the rest of us but is available Tues 8th October when he and I have a 1-1 at a time between 1.30-3.30pm .
Can I ask that we try to get a best fit with this please? The GMC ELA has asked for an update on 7th October at 11am.

Unless advised otherwise by yourselves , I am led to believe there have not been any exception reports until this of the 16th September described below.

Agenda:
1. An outline of the escalation plan in relation to managing this and other potential exceptions within the services following on from the MHPS redacted report recommendations.
2. Update please on the recommended review of administrative processes described in the MHPS redacted report and referred to most recently by the GMC in the response attached 27.09.19 .
3. Update on progress of SAI reports which have arrived within the Trust recently and are being reviewed for accuracy
4. Outline of management of any potential risks to patient safety

Regards, Maria

From: Haynes, Mark
Sent: 03 October 2019 14:50
To: Khan, Ahmed; Weir, Lauren

Cc: Gibson, Simon; Hynds, Siobhan; OKane, Maria
Subject: RE: AOB concerns - escalation

Further update...

[redacted] Patient 112 [redacted]

IR1 going in from MDM today. Seen in OP on 16th August after MDM on 27th June (outcome was for Mr O'Brien to review and arrange a renal biopsy. No dictation has been done from the OP appointment, no biopsy has happened. Multiple emails have been sent to Mr O'Brien and his secretary but no update has been provided and no biopsy has occurred. Brought back to MDM today to endeavour to clarify what is happening (has also had enquiry from GP which I contacted Mr O'Brien after to enquire if all was in hand).

Mark

From: Khan, Ahmed
Sent: 03 October 2019 11:13
To: Weir, Lauren
Cc: Gibson, Simon; Hynds, Siobhan; Haynes, Mark; OKane, Maria
Subject: RE: AOB concerns - escalation

Lauran, I would be available between 2-4pm.
Thanks, Ahmed

From: OKane, Maria
Sent: 03 October 2019 00:04
To: Haynes, Mark; Khan, Ahmed; Hynds, Siobhan
Cc: Gibson, Simon; Weir, Lauren
Subject: RE: AOB concerns - escalation

Lauren can you arrange a teleconference for this Friday afternoon from a time from 1pm onwards please to agree next steps please? Many thanks Maria

---

From: Haynes, Mark
Sent: 01 October 2019 19:00
To: Khan, Ahmed; OKane, Maria; Hynds, Siobhan
Cc: Gibson, Simon; Weir, Lauren
Subject: RE: AOB concerns - escalation

The details are at the start of this mail (pasted below)

From: Corrigan, Martina
Sent: 16 September 2019 16:37
To: Khan, Ahmed
Cc: Hynds, Siobhan
Subject: AOB concerns - escalation

Dear Dr Khan

As requested, please see below which I am escalating to you (emails attached showing where I have been asking him to address)

CONCERN 1 –not adhered to, please see escalated emails. As of today Monday 16 September, Mr O'Brien has 26 paper referrals outstanding, and on Etriage 19 Routine and 8 Urgent referrals.

CONCERN 2 – adhered to – no notes are stored off premises nor in his office (this is only feasible to confirm as there have been NO issues raised regarding missing charts that Mr O'Brien had)

CONCERN 3 – not adhered to – Mr O'Brien continues to use digital dictation on SWAH clinics but I have done a spot-check today and:

Clinics in SWAH
EUROAOB – 22 July and 12 August all patients have letters on NIECR
Clinics held in Thorndale Unit, Craigavon Area Hospital
CAOBTDUR - 20 August 2019 had 12 booked to clinic 11 attendances & 1 CND but no letters at all
CAOBUO – 23 August 2019 – 10 attendance and only 1 letter on NIECR
CAOBUO – 30 August 2019 – 12 booked to clinic, 1 CND, 1 DNA and 0 Letters on NIECR
CAOBUO – 3 September – 8 booked to clinic – 0 letters on NIECR

I have asked Katherine Robinson to double-check that these are not in a backlog for typing and I will advise

CONCERN 4 – adhered to – no more of Mr O'Brien's patients that had been seen privately as an outpatient has been listed,

Should you require anything further, please do not hesitate to contact me.

Regards

Martina

Martina Corrigan
Head of ENT, Urology, Ophthalmology and Outpatients
Craigavon Area Hospital

From: Khan, Ahmed
Sent: 01 October 2019 16:13
To: OKane, Maria; Hynds, Siobhan
Cc: Gibson, Simon; Haynes, Mark; Weir, Lauren
Subject: RE: AOB concerns - escalation

Maria, I understand we are awaiting more details from Martina. Just spoke to Mark, he think number of non-adherence to agreed action plan.
Thanks, Ahmed

From: OKane, Maria
Sent: 30 September 2019 12:31
To: Khan, Ahmed; Hynds, Siobhan
Cc: Gibson, Simon; Haynes, Mark; Weir, Lauren
Subject: FW: AOB concerns - escalation

Dear Ahmed and Siobhan – any further updates on addressing the concerns raised by Martina please ? I am meeting with the GMC next Monday and I anticipate they will expect a description of what has occurred and how it has been addressed please? Many thanks Maria

Lauren bf for wed please

From: Weir, Lauren
Sent: 30 September 2019 09:00

To: OKane, Maria
Subject: AOB concerns - escalation

Dr O'Kane,
You asked me to bring this to your attention for today. I have it printed and on my desk for you

Lauren

Lauren Weir
PA to Dr Maria O'Kane – Medical Director's Office,
Southern Health & Social Care Trust
1st Floor, Trust Headquarters, CAH

My Hours of work are: Monday – Friday 9.00am – 5.00pm

☎ Please note my new contact number – External - Personal Information redacted by the USI / Internal ext: Personal Information redacted by the USI

Personal Information redacted by the USI

From: OKane, Maria
Sent: 23 September 2019 13:27
To: Khan, Ahmed
Cc: Weir, Lauren; Hynds, Siobhan; Gibson, Simon
Subject: RE: AOB concerns - escalation

Thank you.

Lauren bf 1 week please

From: Khan, Ahmed
Sent: 23 September 2019 13:04
To: OKane, Maria
Cc: Weir, Lauren; Hynds, Siobhan; Gibson, Simon
Subject: RE: AOB concerns - escalation

Maria, I and Siobhan discussed this case last week. She has already requested more information /clarification from Martina therefore we will wait for this information. Siobhan also informed me trust grievance progress is on hold due to Mr AOB's lengthy FOI requested in progress. I will reply to Grainne Lynn once all this information at hand before contacting her.
Thanks, Ahmed

From: Khan, Ahmed
Sent: 18 September 2019 11:52
To: OKane, Maria
Cc: Weir, Lauren
Subject: FW: AOB concerns - escalation

Maria, see update report & concerns from Martina as Mr OBrien have failed to adhere to 2 elements of agreed action plan. I have requested an urgent meeting with Siobhan and Simon to discuss this issue and other updates as I am unaware of any further progress on his case.
Regards,
Ahmed

From: Khan, Ahmed
Sent: 17 September 2019 09:52
To: Corrigan, Martina; Hynds, Siobhan; Gibson, Simon
Subject: RE: AOB concerns - escalation

Martina, thanks.

Siobhan & Simon, Can we meet to discuss this urgently please. I am can be available tomorrow am or pm.

Thanks,
Ahmed

From: Corrigan, Martina
Sent: 16 September 2019 16:37
To: Khan, Ahmed
Cc: Hynds, Siobhan
Subject: AOB concerns - escalation

Dear Dr Khan

As requested, please see below which I am escalating to you (emails attached showing where I have been asking him to address)

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CONCERN 4 – adhered to – no more of Mr O'Brien's patients that had been seen privately as an outpatient has been listed,

Should you require anything further, please do not hesitate to contact me.

Regards

Martina

Martina Corrigan
Head of ENT, Urology, Ophthalmology and Outpatients
Craigavon Area Hospital

Telephone:
Personal Information redacted by the [redacted] (Internal)
[redacted] (external)
(mobile)

Terms of Reference Southern Health and Social Care Trust

Clinical and Social Care Governance Review

- The purpose of the review is to ensure the Trust has a robust governance structure and arrangements in place which offers assurance on patient safety and that helps people learn.

Objectives

- The Trust is seeking to undertake a comprehensive review of the current governance structure and recommend what a good structure should look like.
- It will review existing governance processes and particularly governance assurance, moving the Trust towards a position where there is a whole governance approach to the organisation. It will include a review of both clinical and social care governance.
- Specifically the work will include:
    - *gaining an understanding of the current governance structure and processes in place*
    - *meeting stakeholders to identify what works well and areas for improvement*
    - *undertaking a benchmarking exercise to identify best practice*
    - *review of existing and draft documentation including a new Governance Assurance Strategy*
- The outcome will be a written report outlining key findings from the review and recommendations.

Clinical and Social Care Governance Review

Draft Report

August 2019

Report Compiled by: **Mrs J Champion, Associate HSC Leadership Centre**

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Executive Summary

In April 2019 the Southern Health and Social Care Trust (the Trust) requested that the Health and Social Care (HSC) Leadership Centre undertake an independent review of clinical and social care governance within the Trust, including governance arrangements within the Medical Directorate and the wider organisation.

The independent review (the Review) was undertaken during the period from mid-May to end August 2019. A total of 15 days were allocated for the Review. The Review was undertaken using standard methodology; review and analysis of documentation and stakeholder meetings (Section 2).

During the course of the Review senior stakeholders provided the context to the development of integrated governance arrangements from the Trust's inception in April 2007 and from recommendations arising from an internal Clinical and Social Care Governance Review that was undertaken during 2010 and implemented in 2013 and the subsequent revisit of the 2010 Review undertaken in April 2015. Senior stakeholders identified that there had been many changes within Trust Board and the senior management team over a number of years which had had a destabilising impact upon the organisation. They cited the number of individuals who had held the Accountable Officer/Chief Executive in Interim and Acting roles as having the most significant impact and welcomed the appointment of the Chief Executive in March 2018. It was also noted that the role of Medical Director had also been in a period of flux since 2011.

There were many areas of good practice outlined during interviews with senior stakeholder including; leadership walk rounds conducted by members of Trust Board, a Controls Assurance Group to continue to focus on systems of internal control and patient and service user experience initiatives including the development of a lessons learned video on engagement with a mother who had been involved in a Serious Adverse Incident review following the death of her child. This video has been used regionally at Department of Health, Inquiry into Hyponatraemia-related Deaths Stakeholder events for shared learning.

The analysis has demonstrated that many of the building blocks for good integrated governance are in place. The Trust has an Integrated Governance Framework incorporating a governance committee structure, a Board Assurance Framework and Corporate Risk Register and a risk management system with underpinning policies and procedures for example adverse incident reporting, health and safety, and complaints and claims management. The analysis has identified good practice across these systems, however, a number of areas for improvement and gaps in control have been identified which will require action. Similarly, there are areas of good practice as identified above which have been developed in operational Directorates which stakeholders consider have not necessarily been shared or applied across the organisation. Some senior stakeholders identified a lack of connectivity across the Integrated Governance Framework. Many stakeholders referred to the lack of a robust streamlined accountability and assurance reporting framework which added to the perception that integrated governance was being delivered in silos.

In considering recommendations for the Trust the Reviewer took account of the Inquiry into Hyponatraemia-related Deaths (IHRD) Report and Recommendations and the ongoing work of the IHRD Implementation Group and Department of Health (DoH) Workstreams.

The Report has identified 48 recommendations to improve the effectiveness and robustness of the integrated governance systems. The recommendations are contained throughout Section 4 (Findings and Analysis) and are broadly categorised under the following themes;

- Board Governance;
- Culture of Being Open;
- Controls Assurance;
- Risk Management Strategy;
- Management of SAIs, Complaints and Legal Services;
- Health & Safety;
- Standards and guidelines;
- Clinical Audit;
- Morbidity & Mortality;
- Learning for Improvement;
- Datix;
- Clinical and Social Care Governance Structures.

A summary of the Recommendations is provided in Appendix 1.

1.0 Introduction

In April 2019 the Southern Health and Social Care Trust (the Trust) requested that the Health and Social Care (HSC) Leadership Centre undertake an independent review of clinical and social care governance within the Trust, including governance arrangements within the Medical Directorate and the wider organisation.

The independent review (the Review) was undertaken during the period from mid-May to end-August 2019. A total of 15 days were allocated for the Review. The Review was undertaken using standard methodology; review and analysis of documentation and stakeholder meetings (Section 2).

2.0 Scope of the Clinical and Social Care Governance Review

2.1 Terms of Reference

The purpose of the review is to ensure the Trust has a robust governance structure and arrangements in place which offers assurance on patient safety and that help people learn.

The following terms of reference were agreed with the Medical Director of the Southern Health and Social Care Trust (SHSCT):

Objectives

- The Trust is seeking to undertake a comprehensive review of the current governance structure including the formulation of recommendations on what a good structure should look like;
- The Review will consider existing governance processes and particularly governance assurance, moving the Trust towards a position where there is a whole governance approach to the organisation rather than in two reporting lines. It will include a review of both clinical and social care governance;

Specifically the work will include;

- *gaining an understanding of the current governance structure and processes in place;*
- *meeting stakeholders to identify what works well and areas for improvement;*
- *undertaking a benchmarking exercise to identify best practice;*
- *reviewing existing and draft documentation including a new Governance Assurance Strategy.*

The outcome will be a written report outlining key findings from the review and recommendations.

2.2 Limitations to Review

As defined within the terms of reference above, the review of integrated governance arrangements within the Trust excluded financial governance. Given the breadth of

the terms of reference and the timeframe allocated to complete this report the review does not claim to provide an exhaustive or exclusive list of all potential gaps in controls or assurance at local level. The Review is intended to be an evaluation of the overarching integrated governance arrangements and related strategies, policies and procedures.

3.0 Methodology

Key to the Review was the examination and analysis of documentary evidence and meetings with key stakeholders.

3.1 Analysis of Documentation

A detailed examination and analysis of a large number of documents was undertaken as part of the fieldwork for this Review.

List of Regional Documents:

- The Inquiry into Hyponatraemia-related Deaths, Volume 3, January 2018;
- Procedure for the Reporting and Follow up of Serious Adverse Incidents, HSCB, November 2016.

List of Core SHSCT Documents:

- Annual Report and Accounts 2017/18;
- Board Assurance Framework, May 2018 and June 2019;
- Clinical Audit Strategy, June 2018;
- Clinical Audit Workplan, June 2018;
- Clinical and Social Care Governance Assurance Strategy, March 2019 (Draft only);
- Clinical and Social Care Governance; Children and Young Peoples Service Directorate;
- Clinical and Social Care Governance Indicator Suite, March 2019 (Draft only);
- Controls Assurance Self-Assessments, February 2019 (Emergency Planning, Governance, Risk Management and Health & Safety);
- Corporate Plan 2017/18 and 2020/21;
- Corporate Risk Register, December 2018;
- Directorate Governance Meetings Sample Agendas;
- Directorate Risk Registers;
- Governance Committee Agendas and Minutes (May & December 2018);
- Governance Arrangements for Social Work & Social Care, SHSCT, February 2019;
- Health & Safety Policy, December 2014;
- Health & Safety Risk Assessment, Version 3, H & S Department, November 2019;
- Incident Management Procedure, October 2014:
- Integrated Governance Framework, September 2017;
- Internal Audit Report, Management of Standards and Guidelines, 2018/19;
- Internal Audit Report, Morbidity & Mortality 2018/19;
- Medical Leadership Review, June 2019;

- Patient Safety Programme SOP, January 2019;
- Policy for the Management of Litigation Claims, November 2018;
- Procedure for the Management of Complaints, November 2018;
- Risk Management Strategy, 2014;
- Risk Management Strategy 2019-2022 (Draft only);
- RQIA Review of Serious Adverse Incidents Process in NI Questionnaire (Draft only);
- Senior Management Team Minutes (Sample from March 2019);
- Social Workers & Social Care Workers: Accountability and Assurance Framework February 2019;
- Standards and Guidelines Monitoring Process – Change Leads;
- Terms of Reference;
    - Audit Committee, February 2018;
    - Governance Committee, February 2018;
    - Health & Safety Committee,
    - Lessons Learned Forum;
    - Quality Improvement Steering Group;
    - Senior Management Team;
- Trust Board Minutes September 2018 - January 2019;
- 'Your Right to Raise a Concern (Whistleblowing) Policy.

3.2 Meetings with internal stakeholders

The following key stakeholders were interviewed as part of this review:

- Chairman of Trust Board;
- Nominated Non-Executive Directors;[1]
- Chief Executive, Executive Directors and Directors and members of the Senior Management Team;
- Director of Pharmacy;
- Interim Assistant Director Clinical and Social Care Governance and key related staff including the Clinical Audit Management and Governance Coordinator;
- Board Assurance Manager;
- Directorate Clinical and Social Care Co-Ordinators;
- Patient Safety & Quality Manger (Standards & Guidelines), Acute Services
- Project Manager, Medical Directorate.

[1] The Chairman of Trust Board nominated three Non-Executive Directors to participate in the Review. The nominated Non-Executive Directors included the Chair of the Governance Committee.

4.0 Findings and Analysis

4.1 Trust Board

The purpose of Trust Boards is to govern effectively and in doing so build patient, public and stakeholder confidence that their health and healthcare is in safe hands. Effective Boards demonstrate leadership by undertaking three key roles; formulating strategy, ensuring accountability by holding the organisation to account for the delivery of strategy by being accountable for ensuring the organisation operatives effectively and with openness and by seeking assurance that systems of control are robust and reliable. The role of the Trust's Board is defined in a number of key documents which are outlined below.[2]

The Trust has an extant approved Standing Orders, Standing Financial Instructions and Scheme of Delegation which in line with best practice is available to staff and the public via the Trust's website.

As defined in the Trust's Standing Orders (SOs), the Trust Board is required to have in place integrated governance structures and arrangements that will lead to good governance and to ensure that decision-making is informed by intelligent information covering the full range of corporate, financial, clinical, social care, information and research governance activities. From 2006, HSC organisations have been encouraged to move away from silo governance and take a holistic view of the organisation and its capacity to meet its legal and statutory requirements and organisational objectives.[3]

The Trust Board is responsible for ensuring that the objectives of the organisation are realised. The Trust has communicated its strategic purpose and corporate objectives in its Corporate Plan 2017/18 to 2020/21.

The Trust Board is responsible for ensuring that the Trust has effective systems in place for governance which are essential for the achievement of organisational objectives. It is also responsible for ensuring that the Trust consistently follows the principles of good governance applicable to HSC organisations and should work actively to promote and demonstrate the values and behaviours which underpin effective integrated governance.[4]

4.1.2 Trust Board Meetings

In line with recommendations from the Francis Report,[5] and best practice, the agenda for Public Trust Board meetings includes an account of a service improvement or learning from a service user experience. Post-Francis, HSC Trust Boards were encouraged to put quality, safety and learning for improvement at the heart of the Board agenda. Learning from service user experience defines the Trust

[2] NHS Leadership Academy '*The Healthy NHS Board: Principles for Good Governance'*. 2013.
[3] Department of Health '*Integrated Governance Handbook'* February 2006.
[4] SHSCT '*Draft Integrated Governance Framework'*, September 2017, Section 4.
[5] *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry.* February 2013. HC 947 London. The Stationery Office.

Board agenda, reminding Members of the organisation's vison and values and acts as a catalyst to continue to strive to improve the quality and safety of care provided.

The Board Assurance Framework, outlining the organisation's principal risks is required to be reviewed by Trust Board a six monthly basis (see Section 4.4 below). This is evidence that the organisation is committed to being open and transparent. It was noted that the Trust has a busy Board agenda and this may not allow for full discussion by the Board of Directors. It was also noted however, that the Corporate Risk Register, is reviewed at the Governance Committees of Trust Board and Senior Management Team meetings (see also Sections 4.2.2 and 4.9.2).

The Trust holds monthly Board Meetings (with the exception of July) which are held alternatively in public session and workshop format. Confidential sessions, when required are held immediately prior to the Board meeting. Senior stakeholders advised that Trust Board and Board Committee agendas are very busy and throughout the year there are a significant number of Board reports, covering a wide range of complex issues, which are presented for approval or assurance. Trust Board workshops allow for detailed discussion on a range of strategic matters including detailed reports for example the Statutory Functions Report and service developments. The Workshops are essential for providing the Board of Directors the time and background information they require to make strategic decisions and fulfil their scrutiny and challenge function. This will be a particularly important in implementing the IHRD recommendations on the Board's Statutory Duty of Quality/Board Effectiveness which have highlighted the need for time for Board effectiveness, development and for understanding patient safety objectives.[6]

The Reviewer has noted that Internal Audit have provided the Trust with a 'Satisfactory Assurance' level for Board Effectiveness. Senior stakeholders advised that they would wish the Internal Audit Board Effectiveness Action Plan to be formally reported and reviewed by a Board Committee for assurance***.***

There is a time allocation for Trust Board Agenda items. It was noted from the minutes of those Trust Board meetings held in public session, that Patient and Client Safety and Quality of Care Reports are included in a standing agenda which also includes Strategic and Operational Performance Reports thus demonstrating a balanced agenda. There is evidence of Non-Executive Director challenge in the area of patient and client safety and quality for example in relation to infection prevention and control training performance and complaints response performance targets. Given the proposal to constitute a Performance Management Trust Board Committee ***it is recommended that the Trust Board review the cycle of Trust Board Reports and the Board of Directors' public meeting agenda.***

The Reviewer can confirm that Trust Board agendas and minutes are readily available on the Trust's website from April 2009 to date.[7]

[6] IHRD Recommendation 55 ~ '*Trust Chairs and Non-Executive Board Members should be trained to scrutinise the performance of Executive Directors particularly in relation to patient safety objective'*.

[7] IHRD Recommendation 70 ~ *'Effective measures should be taken to ensure that minutes of board and committee meetings are preserved'*. The Department of Health IHRD ALB Board Effectiveness Workstream are

4.2 Trust Board Committees

The Trust Board exercises strategic control over the organisation through a system of corporate governance which includes Trust Board Committees:

- Audit Committee;
- Endowments and Gifts Committee;
- Remuneration Committee;
- Governance Committee;
- Patient and Client Experience Committee.

It is recognised that Accounting Officers and Boards have many issues competing for their attention. One of the challenges they and their members face is knowing whether they are giving their attention to the right issues. Key to addressing this is 'assurance', defined as: "an evaluated opinion, based on evidence gained from review, on the organisation's governance, risk management and internal control framework".[8]

Assurance draws attention to the aspects of risk management, governance and control that are functioning effectively and, just as importantly, the aspects which need to be given attention to improve them. An effective risk management framework and a risk-based approach to assurance helps an Accounting Officer and Board to judge whether or not its agenda is focussing on the issues that are most significant in relation to achieving the organisation's objectives and whether best use is being made of resources. The Trust Board Committees, and in particular the Audit and Governance Committees, can help the Accounting Officer and Board to formulate their assurance needs, and then consider how well assurance received actually meets these needs by gauging the extent to which assurance on the management of risk is comprehensive and reliable. Assurance cannot be absolute so the Committees (and Trust Board sub-committees) will need to know that the organisation is making effective use of the finite assurance mechanisms at its disposal, targeting these at areas of greatest risk. The Board Assurance Framework and Corporate Risk Registers and their functions in supporting a risk-based approach are considered in Section 4.9.

4.2.1 Audit Committee

The Audit Committee is the Trust's statutory committee which deals with all aspects of financial governance.[9] The Audit Committee has no executive powers, other than those specifically delegated within the Terms of Reference. The Audit Committee is a non- executive committee of Trust Board and the Director of Finance and representatives from Internal and External Audit will normally attend the meetings. In line with best practice, the Chief Executive is invited to attend at least twice

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reviewing this recommendation and are also considering the ease of access to board and committee information.

[8] Department of Finance '*Audit & Risk Assurance Committee Handbook NI*' April 2018.

[9] Financial governance is not included within the terms of reference for this Review, however, an understanding of the role of the Audit Committee was required to gain an insight into the overall management of integrated governance within the Trust.

annually to discuss the process for assurance that supports the annual Governance Statement. In addition, other directors are required to attend when the Audit Committee is discussing areas of risk that fall within their area of responsibility or accountability.

It was noted from stakeholder meetings that the non-financial risk-based Internal Audit Reports (e.g. Management of Standards and Guidelines) would be tabled at the Governance Committee (see below) for more detailed discussion. The Trust should consider revising the terms of reference for the Audit Committee to enable the Interim Assistant Director for Clinical and Social Care Governance to be in attendance to facilitate the triangulation of integrated governance information.

The Trust has an Internal Audit Forum chaired by the Executive Director of Finance and Procurement. The Internal Audit Forum has successfully significantly increased the number of Internal Audit Plan recommendations that have been follow-up by Management (90% actions were reported as 'undertaken' at the time of Review).

4.2.2 Governance Committee

The Governance Committee is a Non-Executive Committee of the Board and has no executive powers, other than those specifically delegated in the Terms of Reference. The Committee is appointed by the Trust Board from amongst the non-executive directors following recommendation by the Trust Chair and is required to consist of no less than three members. The Trust Board Chair confirmed that she attends Governance Committee meetings when there is a particular item on the agenda that she wants to review in more detail. The following are currently invited to attend; the Chief Executive, Executive Directors (with the exception of the Director of Finance and Estates), members of the Senior Management Team and the Director of Pharmacy. The [Interim] Assistant Director of Clinical and Social Care Governance also attend the committee and provide papers. ***It is recommended that the Director of Finance, Procurement and Estates is also invited to attend the meetings in the interests of integrated governance and also as the Chief Executive has delegated responsibility for Health and Safety Management to this Executive Director***.

The remit of the Committee is to ensure that there are effective and regularly reviewed structures in place to support the effective implementation and continue development of integrated governance and that timely reports are made to Trust Board. The Committee is also responsible for a number of assurance functions including; assessment of assurance systems for effective risk management, ensuring there is sufficient independent and objective assurance as to the robustness of key processes and for ensuring that principal risks and significant gaps in controls and assurance are considered by the Committee and escalated to Trust Board as required. The Chair of the Governance Committee provides an annual report on the undertakings of the Committee to Trust Board which is an example of best practice.

The Agenda for Governance Committee is approved by the Senior Management Team. ***It is recommended that the Chair of the Governance Committee is fully involved in the development of the agenda and the cycle of reports. It is also***

recommended that the cycle of reports is reviewed and submitted to the Committee for approval commencing April 2020.[10]

The annual Governance Statement is brought to Governance Committee for review and approval. The Statement indicates that the Trust adopts an integrated approach to governance and risk management and has an Integrated Governance Framework in place which covers all domains of governance associated with the delivery of health and social care services (see Integrated Governance Section 4.4).

The Corporate Risk Register is presented to Governance Committee on a quarterly basis. From senior stakeholder meetings and review of minutes it is planned to review a small number of corporate risks on a rolling basis to enable a more detailed discussion and afford the Non-Executive Directors the opportunity for scrutiny and challenge is a secure environment (see also Risk Registers Section 4.9).

Regular reports on integrated governance functions are reviewed at Committee including Adverse Incidents, Morbidity and Mortality, Management of Serious Adverse Incidents (SAIs), Claims, Whistleblowing Cases. The Medical Director and Interim Assistant Director Clinical and Social Care Governance are reviewing the format and content of reports to provide high quality intelligence and not just hard data. The Interim Assistant Director has also developed a draft suite of key performance indicators for clinical and social care governance which will help 'triangulate' data with different information sources and should form a key component of future governance reports to Committee. ***It is recommended that the clinical and social care key performance indicators are further developed and submitted for approval through the Senior Management Team.***

The Governance Committee also receives a report on Freedom of Information (FOI), Environmental Regulation and Subject Access Requests (SARs). The Report contains information on performance against timescales for processing requests and information on the nature of the requests which is good practice and there is evidence within the minutes of discussion stimulated by Non-Executive Directors. [11]

The Chief Executive advised that the Trust are to constitute a Performance Management Trust Board Committee (see below). The Governance Committee should therefore review its Terms of Reference. There is a need to focus on the detail of the Board Assurance Framework as well as the Corporate Risk Register on at least an annual basis at either a Trust Board workshop or at Governance Committee.

In line with best practice, the Chairs of the Audit and Governance Committee should meet annually to ensure an integrated approach to governance within the Trust and no overlap with agenda items.

[10] Senior stakeholders suggested that a three year plan should be developed.

[11] This will assist the Trust by forming a basis for implementing IHRD Recommendation 72 ~ *'All Trust publications, media statements and press releases should comply with the requirements for candour and be monitored for accuracy by a nominated non-executive Director'.*

4.2.3 Patient and Client Experience Committee

The Patient and Client Experience Committee was established as a subcommittee of the Trust Board. It has no executive powers, other than those specifically delegated in the Terms of Reference. The role of the Committee is to provide assurance that the Trust's services, systems and processes provide effective measures of patient, client and carer experience and involvement and to identify gaps and areas of opportunity for development to ensure continuous, positive improvement to the patient, client and carer experience and to ensure that patient, client and carer experience improvement initiatives are in place to address identified shortcomings and that these are monitored.

The Chief Executive advised that the terms of reference were being considered in the short term, with a view to refocus the role and responsibility of this Committee.

4.2.4 Performance Management

It has been agreed that a new subcommittee of Trust Board will be constituted during 2019/20 to ensure a strategic focus on performance management.

4.2.5 Senior Management Team/Governance Management Board

The Trust has a Senior Management Team (SMT) that is accountable to the Chief Executive. The Terms of Reference stipulate that the SMT is responsible for the leadership, strategy and priorities of the Trust and to oversee all aspects of Operational activities to ensure that the Trust meets its Statutory Requirement and provides high quality and effective services.

The Terms of Reference provided to the Reviewer are not dated. The Terms of Reference stipulate that all members of the SMT are individually and collectively responsible for the leadership of the following; Strategy and Planning, Delivery and Performance, Communication and Engagement, Governance and Risk Management The Terms of Reference define a model agenda of standing items in Section 8 'Cycle of Business' do not include quality and safety with the exception of Infection Controls within Performance and Delivery. A review of sample agendas confirm that quality and safety is discussed.

The Terms of Reference stipulate that papers, reports and presentations for submission to the Board of Directors will be considered by the SMT at the meeting one week prior to the Board meeting which is standard practice. In respect of Trust Board papers, SOs stipulate that the 'Agenda will be sent to members at least 5 working days before the meeting and supporting papers, whenever possible, shall accompany the agenda, but will be dispatched no later than three working days before the meeting, save in an emergency'.

For SMT meetings the Terms of Reference stipulate that the collation of the agenda, issuing papers/reports are required at least 24 hours in advance of the meeting. Senior stakeholders advised that on occasion there may be a requirement to table an agenda item for urgent consideration and approval after the deadline. The Reviewer recognises that this should be avoided wherever possible to ensure that SMT members have time to review the information, this should be balanced with

potential loss of opportunity and the Terms of Reference should allow for an urgent provision. (See also Weekly Governance Meeting/Debrief Section 4.23.2).

It is recommended that the SMT Terms of Reference are reviewed.

The Terms of Reference also stipulate that once a month the SMT will meet as a Governance Management Board with the staff from the Governance Department in attendance. Section 2 of the SMT Terms of Reference constitute the terms of reference for the Governance Board. Roles and responsibilities include; ensuring the governance framework is fully implemented, monitoring and reviewing the Trust Risk Register and identifying Corporate Risks, reviewing and updating the Board Assurance Framework, escalating risk management issues to Trust Board and approving and reviewing policies that need to go to Trust Board for approval. The SMT Governance Board is also required to monitor patient safety and ensure continuous improvement and receive and approve reports/action plans for presentation to the Governance Committee. ***It is recommended that the remit and responsibilities of the SMT Governance Board are reviewed and a separate Terms of Reference developed to include the purpose, membership and reporting lines to Trust Board via the Governance Committee of Trust Board. (See also Sub Committee Structure proposals at Section 4.2.6). The role of the SMT Governance Board should also be clearly defined in the Integrated Governance Strategy.***

4.2.6 Sub Committees

The Integrated Governance Framework contains an organogram depicting the organisation's high level governance structure including Trust Board, Board Committees, SMT and Directorate and Professional forum[12]. The Reviewer is unable to provide a definitive list of all subcommittee and advisory groups from the written evidence considered. However, from the evidence provided by stakeholders and the review of a number of policies and procedures a number of other integrated Governance Trust Committees, Steering Groups and Advisory Groups have been constituted e.g. Quality Improvement, Health and Safety, Outcomes Review and a Directors' Oversight Group for the implementation of the IHRD Recommendations (see also Integrated Governance Framework Section 4.4 below).

Senior stakeholders advised that current arrangements appeared to lack connectivity. It is difficult currently to define the accountability linkages and reporting arrangements that should be present between the various sub groups and advisory committees to Trust Board via the Senior Management Team. Clear lines of accountability and assurance are crucial to provide the Board of Directors with the assurances that there are robust and transparent governance arrangements in place. Additionally, it is important that staff and stakeholders have clarity on the lines of accountability within the organisation's integrated governance model.

The underlying committee structure which supports the Trust Board's Committees should be reviewed to provide a more cohesive simplified framework of

[12] Integrated Governance Framework 2017, Figure 2.

accountability and assurance. ***It is therefore recommended that the Trust Governance Structures are reviewed as a matter of urgency and Trust Board Sub Committee/Steering Groups are constituted to which the various integrated governance steering groups and committees will report and provide the organisation with a first level of assurance (see Appendix 2).***

A Quality Improvement Steering Group has been constituted which pulls together some of the integrated management functions. The remit of that Steering Group is defined in the draft Terms of Reference provided as being responsible for ensure the Quality Improvement Framework is developed and delivered by the SMT and Trust Board. ***It is recommended that the constitution of Executive Directors/Directors oversight/ steering groups should be considered with the following remits:***

- Clinical and Social Care Governance – Quality Improvement and Safety;
- Corporate Governance;
- Patient and Client Experience and Engagement.

This will effectively group many of the existing sub committees and specialist advisory groups that exist within the organisation and provide a reporting line through the Governance Board of SMT to the respective Trust Board Committees. In considering this sub-committee structure the Trust should ensure that there is no duplication of functionality of groups, forums or advisory committees. The Steering Groups should review the terms of reference of the sub groups and advisory groups on an annual basis and should also provide oversight of progress of any action plans or work plans. ***Terms of Reference and annual work plans/action plans, where applicable should be held centrally***.

In response to all stakeholders who believed that there was a gap in the current framework regarding shared learning the Chief Executive advised that the Steering Groups should be required to report on learning within their Terms of Reference and this would be a vehicle to bring together all aspects of learning from across the integrated governance arrangements including user experience. Senior stakeholders also advised that the role and function of the Lessons Learned Forum should be reviewed as a matter of urgency (see Section 4.20).

It is also recommended that any short term Director's Oversight Groups are added to the Governance Structure for the duration of their remit as 'Task and Finish Groups' e.g. IHRD Directors Oversight Group. This will provide staff and other stakeholders with clarity about the governance assurance and accountability arrangements.

4.2.7 Committee Terms of Reference

A range of terms of reference (ToR) were analysed during the Review. The Audit and Governance Committees use a common template which meet good practice standards. Minutes of Board meetings reflect that their terms of reference are reviewed annually. ***To ensure that all committees provide clarity in their terms of reference, delegated powers and reporting requirements the Trust should***

consider developing a standard template to define the terms of reference for all Board Sub Committees, Steering Groups and Advisory/Specialist Groups.

The terms of reference as a minimum should include the following:

- Constitution;
- Membership (Including chair, deputies and administrative support);
- Remit or high level purpose;
- Frequency of meetings;
- Authority/Delegated Powers;
- Quorum;
- Duties and responsibilities;
- Reporting arrangements;
- Revision dates.

All terms of reference should be reviewed annually and submitted to the relevant overarching Committee for approval. Approved terms of reference should be submitted to the Corporate Clinical and Social Care Governance Department and held in a shared folder.

4.2.8 Role of Board Secretary/Head of Office

The Trust should consider introducing the role of Board Secretary/Head of Office to support the Trust Board and the Integrated Governance Framework.[13] This individual would have the responsibility for ensuring that all Trust Board committees and sub committees are fully serviced and functioning. They should be fully informed of the activity of committees and assist in making decisions on which issues can be resolved at subcommittee level and which issues may represent a high level risk to the organisation and may need to be escalated to the Board for debate and decision.

The Board Secretary/Head of Office should work closely with the Chief Executive, the Chairman of Trust Board and the Non-Executive Directors. They should be a high level appointment with the skills to act at Board level and be an expert in discharging their functions. They should be conversant with the Trust's Standing Orders/Standing Financial Instructions and the Scheme of Delegation. The post holder would hold line management responsibility for the Administrative Team in Trust Headquarters.

4.3 Professional Executive Directors – roles and responsibilities

The Northern Ireland Audit Office (NIAO) Guidance[14] acknowledges that role ambiguity can effect the function and effectivenss of the Board of Directors. executive team (senior managemnt team) and Board Effectiveness. Staff and other stakeholders should be clear on the roles and responsibilities of Executive Directors. The description of Executive Director functions are, by nature, generic in SO/SFIs therefore it is important that the full range of their accountability and responsibility

[13] The role of Company Secretary is described in the DoH (2006) *op. cit* pages 68 and 69 . The evidence for the efficacy of the role were based on discussions that took place with FTSE 100 companies.

[14] Add reference

are adequately outlined in the Trust's strategy and policy documents e.g. the Integrated Governance Framework and Risk Management Strategy. The Chief Executive indicated that the Job Descriptions for the recently appointed Executive Directors (Medical Director and Interim Exectuive Director of Nursing) were strengthened in respect of their integrated governance functions.

The role of the Executive Director Social Work is detailed in a framework entitled 'Governance Arrangements for Social Work and Social Care' for the Trust, which includes clinical and social care governance arrangements in the Children and Young Peoples Services Directorate' dated February 2019 (Section 4.5). The framework sets out clearly the legislative context that underpins social work governance and the Accountability and Assurance Framework for social work and social care. Clarity of role function is particularly important where an executive director has a dual role and has also operational management accountability and responsibility.

The Medical Director is the Executive Director with responsibility for providing assurance to Trust Board that effecive systems and processes for good governance, including those arrangements to support good medical practice. The strategic role of the Executive Medical Director in respect of risk management and clinical and social care governance is considered in more detail below.

The [Interim] Executive Director of Nursing is the lead Director for Nursing and Allied Health Professionals Governance and has responsibility for the strategic leadership for patient and client experience. The Exectuive Director of Nursing provides an annual Professional Nursing and AHP report to Trust Board and also provides a report on Quality Indicators (Nursing) to the Governance Committee. During the Governance Review, she advised that she was developing her strategic vision for Nursing and Midwifery Governance Structures and will be reviewing the Terms of Reference for the Nursing and Midwifery Governance Forum.

Changing and fluid roles which offers a challenge for keeping strategy and policy updated. (see Integrated Governance Framework and Social Care Framework below).

4.4 Integrated Governance

The context for integrated governance in healthcare has its origins in 2004[15] when NHS organisations were urged to; move governance out of individual silos into a coherent and complementary set of challenges, require boards to focus on strategic objectives, but also to know when and how to drill down to critical areas of delivery, require the development of robust assurance and reporting of delegated clinical and operational decision making in line with well-developed controls and to be supported by board assurance products, which provide board members with a series of prompts with which to challenge their objectives and focus.

[15] NHS Confederation Conference Paper by Professor Michael Deighan [and others] : '*The development of integrated governance, NHS Confederation*', May 2004 as summarised by John Bullivant.

The Good Governance Institute 'Integrated Governance Handbook' recognised that in simple terms there is only one governance and that this is the primarily the business of the board. Apart from clinical practice at the point of patient care the board is the key place where all the aspects of governance (clinical, quality, cost, staffing, information etc.), come to play at the same time.[16] Effective governance requires that organisations do not dissipate the composite whole into fragments that never realign. In 2006, integrated governance was defined as the 'systems, processes and behaviours by which Trusts lead and control their functions in order to achieve organisational objectives, safety and quality of services and in which they relate to patients and carers, the wider community and partner organisations'.[17] Key to delivering these systems, processes and behaviours are the Trust's Integrated Governance arrangements clearly articulated in a strategy or framework which also encapsulates the organisation's accountability and assurance arrangements.

The Trust has an Integrated Governance Framework 2017/18 – 2020/2021 which is marked as 'Draft' however, the Board Assurance Manager confirmed that the Framework was endorsed by the Governance Committee. The document is set out in a standard format and details the organisation's governance arrangements to implement an integrated governance model that links financial governance, risk management and clinical and social care governance into one framework. The Framework describes the overarching governance framework, the accountability and responsibility arrangements for the management of governance including the role and function of Trust Board and Board Committees. The document clearly indicates that the Framework should be should be considered with other key Trust documents, in particular the Trust's Risk Management Strategy. It is less definitive about the governance reporting arrangements (complaints, serious adverse incidents, findings of independent review/inquiries and case management reviews etc.) to Trust Board and the operational/directorate governance reporting arrangements through to the Senior Management Team. The Framework should provide a link to the key supporting strategic and policy documents, which have been reviewed and described below.

The Governance Controls Assurance standard requires that there are clear accountability arrangements in place for governance throughout the organisation. The Trust's Standing Orders, Standing Financial Instructions and Scheme of Delegation provide an overview of Trust Board and Board Committees, however, as described above these documents by their nature only provide generic descriptions of roles and responsibilities of Executive Directors. The Reviewer acknowledges the challenges in maintaining a dynamic Integrated Governance Framework as roles and responsibilities of Committees and individuals evolve and change as a result of a number of factors. Senior managerial functions have changed since the Framework was developed in 2017, therefore the Framework does not accurately reflect the accountability or current roles and responsibilities of the Executive Directors.

[16] *Ibid*.
[17] DoH 'Integrated Governance Handbook' 2006.

It is recommended that the Framework is reviewed as a matter of urgency and provides clear descriptions of the roles and responsibilities of key stakeholders. It is also recommended that the Framework provides electronic links to key corporate Trust Strategies and Policies and extant guidance where applicable.

As recommended above (Section 4.2.6), the Trust should also review the governance committee and sub-committee structure revised Framework Governance Structure.[18].

4.5 Social Care Governance

The Integrated Governance Strategy indicates that the Executive Director of Social Work has a dual role also holding operational responsibility for the Children and Young People's Directorate and is responsible to the Chief Executive for the Trust's social work/social care governance arrangements and for the delegation of statutory social care functions and corporate parenting responsibilities. Within the Trust' High Level Governance Structure (Integrated Governance Framework) the only current reference to a social care governance framework is a forum entitled 'Social Work and Social Care Governance Forum'.

In the early stages of the Governance Review the Executive Director Social Work shared a framework entitled 'Governance Arrangements for Social Work and Social Care' for the Trust which includes clinical and social care governance arrangements in the Children and Young Peoples Services Directorate' dated February 2019. The framework sets out clearly the legislative context that underpins social work governance and the Accountability and Assurance Framework. This Framework also identifies roles and functions within the Directorate and across the interfaces. This key document should be cross-referenced and electronically linked with the Integrated Governance Framework (see above).

A review of Trust Board agendas and minutes confirm that the Annual Delegated Statutory Functions Report is tabled at a public meeting of the Trust Board meetings prior to submission to the Health and Social Care Board. During the Review, the Trust Board Chair outlined the process for review by the Non-Executive Directors. Minutes also confirm that the Corporate Parenting Report is also tabled at public Trust Board meetings. The Executive Director also presents a report every two months to Trust Board which provides a summary of activity and developments. Also tabled is the Corporate Patenting Report.

Senior stakeholders expressed some concern regarding Adult Safeguarding arrangements. ***It is recommended that this area of concern is reviewed to identify any potential risks/gaps in control or assurance in this area.***

4.6 Being Open

As outlined in Section 4.2, the Trust Board play a key role in ensuring the organisation operates effectively and with openness and transparency. The National

[18] SHSCT '*Integrated Governance Framework'* Figure 2 page 23.

Patient Safety Agency (NPSA) first issued the 'Being Open Framework' national guidance in 2005.[19] In recognition of changing context in NHS organisations and the altered context, infrastructure and language of patient safety and quality improvement they revised the guidance in 2009. The revision was also based on a listening exercise with healthcare professionals and patient representatives on how organisations could strengthen the principles of being open.

The Trust does not have a current Being Open Policy but has researched existing policies and has established a working group to develop the guidance. The Chair of the IHRD DoH Being Open Sub Group is scheduled to attend the Trust to meet with Board members. The Trust has also participated in the IHRD Programme Duty of Candour/Being Open Stakeholder Events.

The NHS Leadership Academy indicate that effective boards shape a culture for the organisation which is caring, ambitious, self-directed, nimble, responsive, inclusive and encourages innovation. A commitment to openness, transparency and candour means that boards are more likely to give priority to the organisation's relationship and reputation with patients, the public and partners as the primary means by which it meets policy and/or regulatory requirements. As such the Board holds the interest of patients and communities at its heart.[20]

Sir Robert Francis defined openness, transparency and candour as follows:

- Openness: enabling concerns to be raised and disclosed freely without fear and for questions to be answered;
- Transparency: allowing true information about performance and outcomes to be shared with staff, patients and the public;
- Candour: ensuring that patients harmed by a healthcare service are informed of the fact and that an appropriate remedy is offered, whether or not a complaint has been made or a question asked about it.[21]

Post-Francis, the Care Act 2014 introduced a Statutory Duty of Candour for health and social care providers in England i.e. an organisational Duty of Candour.[22] Duty of Candour was introduced by legislation for NHS Trusts in England and the IHRD Report 2018 calls for a Statutory Duty of Candour to be enacted in Northern Ireland (Recommendation 10). The DoH IHRD Duty of Candour Workstream and Being Open Sub Group have delivered a series of stakeholder events to build on the principles of 'being open'. They are also considering the implications of the proposed individual Statutory Duty of Candour. Recommendation 2 seeks for a sanction of "criminal liability" to be attached to a "*breach of this duty and criminal liability should attach to the obstruction of another [member of staff] in the performance of [his/her duty]* ". The Duty of Candour is inextricably linked to the

[19] On 1 June 2012, the key functions of the NPSA were transferred to the NHS Commissioning Board Special Health Authority.[5], later known as NHS England. In April 2016, the patient safety function was transferred from NHS England to the newly established NHS Improvement.
[20] Leadership op cit. Section 2 Roles of the Board – Ensure Accountability
[21] The Mid Staffordshire NHS Foundation Trust Public Inquiry, Chaired by Sir Robert Francis, February 2013
[22] The details of the duty were subsequently set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

policy of 'being open'. The current work on developing an internal Trust 'Being Open' framework is therefore a key element of the Trust's governance arrangements. ***It is recommended that the Trust consider the training implications of implementing the 'Being Open' framework which includes compliance with IHRD Recommendation 69 (i) ~ Trusts should appoint and train Executive Directors with specific responsibility for 'Issues of Candour'***.

4.7 Controls Assurance

The requirement to report annually on Controls Assurances standards ceased in April 2018 and the Trust was required to put in place internal assurance arrangements for each area previously covered by the former Controls Assurance Standards. The Chief Executive outlined the importance of continuing to monitor and review action plans and advised that a Controls Assurance Group had been constituted, he advised that 2018/19 would be a transition year. The Terms of Reference will be reviewed for 2019/20.

The Controls Assurance Group is currently a sub-group of the Senior Management Team and was initially chaired by the Chief Executive and is now chaired by the Director of Finance, Procurement & Estates. The remit of the Group is to drive an implementation plan in the Trust to deliver on the governance framework and assurance model in relation to Controls Assurance. The implementation plan is linked to the annual Governance Statement and Mid-Year Assurance Statement reporting cycles.

Stakeholders raised a concern about a potential gap in the management of medical devices and equipment at operational level. The Reviewer was advised that there were Equipment Controllers in Acute Services. ***It is recommended that the Trust undertakes an audit/review of the Management of Medical Devices and Equipment to provide assurance that systems are in place across the organisation***.

It is the responsibility of the Controls Assurance Group to monitor compliance with best practice guidance, policies and legislation previously contained within the former Controls Assurance Standards regime and agree the process for ensuring assurance on this to the Chief Executive and the Board (and onwards to the Department of Health, where required). Therefore, it is a key component of the Trust's systems of internal control and the integrated governance and assurance framework.

It is recommended that the Trust develop an organisational risk audit and assessment tool with associated audit programme based on the Controls Assurance standards.[23] This will offer additional assurance that core standards and related legislation and statutory duties are embedded across the organisation (see also Section 4.1 Health and Safety Management and Medical Equipment as

[23] The Trust's Health and Safety team have developed a Health and Safety risk audit tool. Comprehensive risk audit and assessment tools have been developed by other HSC Trusts for example Risk Audit and Assessment Tool Northern Trust (RAANT).

above). This development would also underpin the Risk Management Strategy and the Medical Directorate should provide corporate oversight of this process.

4.8 Risk Management Strategy

Managing risk is a key component of good governance and is fundamental to how an organisation is managed at all levels. The Trust's extant Risk Management Strategy is dated January 2014, and the Strategy was based on extant guidance at the time. It is linked to the Corporate Objectives and Values. In line with the Controls Assurance Standard, it contains a Risk Management Policy statement and key definitions including a brief definition of risk appetite. Since 2013/14 there has been more guidance available on how risk appetite should be applied in HSC organisations (see Draft Risk Management Strategy below). As the Strategy was approved 2014, it does not accurately reflect the roles and responsibilities of Committees and Executive Directors within the current governance accountability arrangements. Analysis and evaluation of risk are based on the Regional Matrix including the Regional Impact Table 2013, however, the Regional Risk Matrix was revised in 2016.

At the commencement of the Governance Review 2019, the Reviewer was made aware of a Draft Risk Management Strategy for 2019 – 2022 developed by the Interim Assistant Director of Clinical and Social Care Governance. This version of the Strategy is pending completion of the Review before further consultation and submission to Trust Board for approval.

The Draft Strategy (2019-2022) is based on ISO 31000: 2018, current legislation, and regional and national guidance. It contains a narrative detailing the roles and responsibilities of staff and related processes associated with risk management, including the management of risk registers and the process for the escalation and de-escalation of risk. It defines the role of the Senior Management Team in respect of risk management, including the management of the Corporate Risk Register. The Draft Strategy also provides a clear description of the risk assessment process utilising the most recent version of the Regional Risk Matrix.

The Draft Strategy outlines the role of the Medical Director as the Executive Director with delegated responsibility for risk management and clinical and social care governance. The 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 and national initiatives related to clinical and social care governance are addressed and brought to the attention of appropriate staff;

- Regular clinical and social care reports/information are brought to the Governance Committee (in line with the Governance reporting framework) and to Trust Board.

The Draft contains a detailed Risk Acceptance Framework which includes a Risk Appetite Matrix.[24] The Trust must take risks in order to achieve its aims and deliver beneficial outcomes to stakeholders. Risks should be taken in a considered and controlled manner and exposure to risks should be kept to a level deemed acceptable to the Board. The risk appetite of the Trust is the decision on the appropriate exposure to risk it will accept in order to achieve its strategy over a given time frame. Risk Appetite levels should form the background to the discussion in relation to risk and are nationally considered under four headings; risk to patients, organisational risk, reputational risk and opportunistic risk. Nationally Trusts make an annual statement on risk appetite.

The Draft Risk Management Strategy should show clear links with the Integrated Governance Framework (which should also be revised and updated as outlined in Section 4.4).

It is recommended that the Draft Risk Management Strategy is submitted for approval as a matter of urgency.

It is recommended that the Trust Board consider the application of the Risk Appetite Matrix in respect of the organisation's Corporate Objectives and associated Board Assurance Framework and Corporate Risk Register. This will enable risks throughout the organisation to be managed within the Trust's risk appetite or where this is exceeded, action taken to reduce the risk. This item is also addressed in the Trust's Board Assurance Framework at June 2019.

Some stakeholders identified a current gap in provision of risk management training. Therefore, ***it is also recommended that a risk management training programme should be developed and delivered to underpin the publication of the approved strategy and the training should include risk appetite, risk assessment/evaluation and management of risk registers*** (see Section 4.9).

4.9 Risk Registers including Board Assurance Framework

The Trust is required to be aware of its risk profile and to identify the key areas for investment in risk treatment. The Risk Management Strategy defines the framework for risk registers that comprises both the Directorate and Corporate Risks which underpin the Board Assurance Framework. Well managed risk registers are dynamic documents which log, quantify and rank the risks that threaten the Trust's ability in achieving its aims and objectives.

Currently risk registers are based on Word and Excel documents. The Trust has recently purchased the Datix Risk Register Module which will facilitate risk register reporting at Directorate and Corporate levels.

[24] Good Governance Institute **Risk Appetite** for NHS Organisations: A **Matrix** to support better risk sensitivity in decision taking. January 2012.

4.9.1 Board Assurance Framework

In line with extant guidance the Trust has a Board Assurance Framework.[25] The purpose of the Framework is 'to ensure that the Board can be effective in the delivery of [the Trust's] objectives'. An Assurance Framework seeks to identify and map the main sources of assurance in the Trust and co-ordination them to best effect. The Board Assurance Framework articulates the principal risks to achieving the Trust's objectives and enables the Board to assure itself that all significant risks are being managed effectively and appropriate controls are in place and are place. The Framework should be reviewed by Trust Board on a six-monthly basis. Analysis of Trust Board agendas indicate that the Framework was tabled in June 2018. A review of the minutes does not reflect discussion.

The Board Assurance Manager, on the delegated authority of the Chief Executive, is responsible for maintaining the Corporate Risk Register and Board Assurance Framework and for supporting the Governance Committee and Trust Board in ensuring the provision of regular risk reporting and monitoring information and assurances.[26]

The Framework provides an organisational context and makes a clear link with the delivery of corporate objectives and is underpinned by the Integrated Governance Framework, Risk Management Strategy, Corporate Risk Register and Controls Assurance processes. The figure in Section 5 demonstrates the combined 'top down' and 'bottom up' approach to identifying principal risks.

The Framework contains a high level summary of the Corporate Risk Register, which is also reviewed by the Governance Committee of Trust Board (see below). The format of the Framework has been revised and now includes information on levels of assurance and where independent assurance had been provided i.e. by and Internal Audit or externally by RQIA or Royal College visit etc.

An assessment of the effectiveness of each control measure, based on a RAG rating is included in the Framework.

4.9.2 Corporate Risk Register

The Trust's Corporate Risk Register is linked to the Corporate Objectives as identified within the Trust's Corporate Plan 2017/18 – 2120/21. The Corporate Risk Register is reviewed on a quarterly basis by the Governance Committee. It is the remit of the Senior Management Team to ensure that there is an effective risk register and that risks are escalated to the Board Assurance Framework as appropriate.

The Senior Management Team review the Corporate Risk Register on a six weekly basis and stakeholders advised that there was robust debate and challenge at these meetings. In addition, the Chief Executive advised that at a Directors workshop during 2018/19 members had undertaken an in-depth analysis of two risks (Infection

[25] DHSSPS *'An Assurance Framework: a Practical Guide for Boards of DHSSPS Arm's Length Bodies'.* March 2009. www.dhssps.gov.uk

[26] SHSCT *'Draft Risk Management Strategy'* April 2019.

Prevention and Control (HCAI) and Cyber Security) which had proven to be a useful exercise. It was agreed by the Governance Committee in May 2018 that the Committee would also consider one/two risks in detail on a rotational basis. The minutes of the Governance Committee (September 2018) demonstrate this new approach and capture discussion and challenge by the Non-Executive Directors.

The Chief Executive further advised that the Corporate Risk Register template had also been revised during 2018/19 and that the Senior Management Team continue to monitor the process and seek ways to improve the format e.g. defining the risk description. Senior stakeholders indicated that the revised format was more user friendly. It was noted however, that currently the recorded risk rating is the inherent risk and not the residual risk after the control measures have been applied.

The Register provides a useful summary table of Corporate Risks and in line with best practice the summary table contains trends on the movement of risk levels. It provides a summary of the Risk Assessment Matrix and does not currently contain the impact grid as reviewed by the HSCB in 2016 (see Risk Management Strategy Section 4.8). The Reviewer acknowledges that when the Corporate Risk Register is underpinned by Datix Risk Register software a further review of the risk register process will be required.

It is recommended that the management of the Board Assurance Framework and Corporate Risk Register should be delegated to the Executive Medical Director in line with the Risk Management Strategy.

4.9.3 Directorate Risk Registers

Each Directorate maintains a risk register which is owned by the Director. The Directorates each have a forum in which these Risk Registers are monitored. The Directorate Risk Register is owned by the Director. The Directorate Risk Registers form the basis of the 'bottom up' approach to identifying principal risks as outlined in the Board Assurance Framework.

Directorate Risk Registers are currently in different formats. ***It is recommended that a standardised Directorate risk register template is considered when Datix risk register module is implemented.***

4.10 Management of Adverse Incidents including Serious Adverse Incidents

4.10.1 Management of Adverse Incidents

The Trust Policy supplied to the Review is entitled 'Incident Management Procedure', a 'working draft' dated October 2014. The Procedure sets the context for the management of incident reporting as a fundamental element of the Trust's Risk Management Strategy and focuses on the need to monitor trends and learn from incidents and it does promote the Trust's corporate priorities and values including the need for staff to be open and honest and act with integrity. However, the Procedure does not accurately reflect the current roles and responsibilities of Trust Officers in respect of the management of adverse incidents. The Reviewer was advised that the 2014 Policy was not reviewed as work was ongoing to develop a Regional Adverse Incident Policy which is due to be issued during 2019/20.

The Procedure provides guidance on the risk assessment process which should be applied to all incidents at the time of occurrence to decide the level of investigation that is required. This links with the Procedure for the management of Serious Adverse Incidents outline below.

Adverse incident reports form a key component of the Clinical and Social Care Governance Report to the Trust's Governance Committee. The Governance Committee review incident reporting including serious adverse incidents on a quarterly basis. Senior stakeholders indicated that the report format had been revised during 2017/18. However, the Interim Assistant Director Clinical and Social Care Governance advised that she was currently reviewing and developing the content of reports to provide higher quality intelligence (not just data) that is high level but also allows for appropriate scrutiny and challenge by the Board of Directors.

The Trust mechanism for recording all incidents is Datix web using an electronic incident form. The Trust uses Datix Common Classification System (CCS) codes for the categorisation of incidents. During 2018/19 work was undertaken to align Datix systems and the use of Datix CCS codes across the Region as part of the 'Delivering Together Programme'.[27] The Datix alignment programme was completed by March 2019. Stakeholders advised that there were currently insufficient staff in the Corporate Clinical and Social Care Governance team (Medical Directorate) to quality assure adverse incident data (see Section 4.23.1). This is a function undertaken in the other HSC Trusts. The Reviewer was informed that there were a significant number of incidents in the category 'In Review' which needs to be addressed in the short term.

It is recommended that a Trust flow chart is developed that underpins the Regional Adverse Incident Reporting Policy/Procedure (when disseminated) which accurately reflects local/ Trust roles and responsibilities especially at Executive Director level.

It is recommended that the corporate oversight of the management of adverse incidents is strengthened to include a quality assurance component which will be dependent upon the resources and skills available within the Clinical and Social Care department (see Section 4.23.1)

4.10.2 Serious Adverse Incidents

The extant procedure for the management of Serious Adverse Incidents (SAIs) is the Health and Social Care Board (HSCB) Regional 'Procedure for the Reporting and Follow up of Serious Adverse Incidents'[28]. Stakeholders indicated that the Directorates have adopted local procedures for the management of SAIs and some concern was expressed about a lack of consistency in approach. Stakeholders also advised of a backlog in SAI Reports being submitted to the HSCB within the required timescales which requires urgent attention.

[27] Department of Health, "*Health and Wellbeing 2026: Delivering Together",* October 2016.
[28] Health and Social Care Board '*Procedure for the Reporting and Follow up of Serious Adverse Incidents'*, November 2016.

The Reviewer is aware that the Regional Procedure is subject to imminent review to take account of the recommendations of the IHRD Report in respect of the Management of SAIs. There is also a significant link with the work of the Being Open Workstream (see Section 4.6). Three of the DoH IHRD Implementation Workstreams are considering these recommendations which are summarised as follows;

- *Duty of Quality ALB Board Effectiveness and Quality Clinical and Social Care Subgroups* – learning and trends should form programmes of clinical audit (See Section 4.15), relevant reaching authorities should be informed if findings of investigations show inadequacies in current medical or nursing education programmes and information from investigations should be assessed for potential use in training and retraining, Trusts should ensure that all internal reports, reviews and related commentaries touching upon SAI related deaths are brought to the immediate attention of every Board member (see Section 4.23.1);
- *SAI Workstream* – family engagement, investigations should be subject to multi-disciplinary peer review, each Trust should publish Policy detailing how it will respond to and learn from SAI related patient deaths and each Trust should publish in its Annual Report details of every SAI related patient death.
- *Education and Training* – training in Sai investigation methods and procedures should be provided to those employed to investigate and clinicians should be afforded time to consider and assimilate learning feedback from SAI investigations and within contracted hours (see Section 4.21 Medical leadership);
- *Preparation for Inquest and Death Certification* – Trust employees who investigate an accident should not be involved with related Trust preparation for inquest or litigation (See Sections 4.15 and 4.21).

It is appreciated that for some of these recommendations there have been challenges in defining the objective or principle of the recommendation and for some a Regional approach is being sought, however there are some early indications of travel in terms of family engagement and scrutiny and challenge.

To enable the Trust meets the action required, the following is recommended.

It is recommended that the Trust constitutes an SAI Review Group and/or SAI Rapid Review Group which should provide independent scrutiny and challenge to the SAI process including review of level of investigation, independence of review panel and approval of terms of reference when SAIs are initiated. In addition, the Review Group should oversee completed reports before submission to the HSCB. The Review Group should be chaired by the MD or his/her Deputy and report to a Trust Board Sub Committee. The Review Group should meet on a four weekly basis initially.

It is recommended that the Trust develops a database of SAI Review Panel Chairs who have undertaken SAI/Systems Analysis Training.

The Governance Coordinator highlighted the investment in a recent SAI training programme delivered by an external provider. She also advised that the training programme provided staff with a wide range of investigation tools, techniques and best practice guidance.[29] ***It is recommended that the Trust develops a SAI RCA/Systems Analysis toolkit based on the training provided by the external provider.***

Given the importance and focus on family/service user engagement***, it is recommended that the Trust considers the role of a Service User Liaison Officer [or similar] for engagement with families throughout the SAI process.***

4.11 Health and Safety Management

The Trust has a Health and Safety at Work Policy dated December 2014 which was due for review by December 2016. The Policy indicates that the Chief Executive has delegated responsibility for establishing an monitoring the implementation of the Health and Safety at Work Policy to the Director of Human Resources and Organisational Development with support from the Assistant Director of Estates/Head of Health and Safety. More recently, the responsible was delegated to the Director of Finance, Procurement and Estates and the Health and Safety Team are currently part of the Estate Risks and Sustainability Department and report to the Director of Finance and Estates.

The Team aim to maintain a high visibility and engagement in clinical, non-clinical and social care areas. System based on HSG65 (Health & Safety Executive Managing for Health and Safety) and is centred around: Plan, Do, Check and Act.

The Trust has a Joint Health and Safety Committee and the Chair rotates between the Lead Director and Trade Unions. The Terms of Reference for the Committee are included in Appendix 1 of the Health & Safety Policy and are therefore circa 2014. The membership is indicated as being made-up from Directorate Representatives and Representatives from Trade-Union/Professional Bodies within the Trust. The quorum is four members however, the Terms of Reference do not specific the requirement for an equal representation of staff and management. The current Terms of Reference do not indicate the reporting arrangements to Trust Board and the extant Governance Committee Structure (Integrated Governance Framework Figure 1) does not clearly indicate the reporting and assurance arrangements of this key statutory Committee (See Section 4.2.6). The Lead Director advised that a review of committee membership and agenda was planned. ***It is therefore recommended that the Health and Safety Committee review their Terms of Reference and submit to the relevant Board Sub Committee for approval.***

The Annual Health and Safety Report 2017/18 was provided in evidence to the Review. The 2017/18 Report was presented to the Governance Committee for noting and with a request for feedback on the content and structure of the report so that reports going forward can be reviewed and be as 'meaningful and informative' for the Committee as possible.

[29] Training was provided by CLS Educate @ www.clseducate.com

Stakeholders indicated that attendance at training remains a challenge and this was highlighted in the Annual Report. The 2017/18 Report indicates that Health & Safety audit activity was constrained due to a lack of resources from within the Committee.

The Health & Safety Team have developed a Health & Safety audit tool to evaluate Trust compliance with key areas of health and safety legislation including; accountability, risk assessment, Display Screen Equipment, Management of Violence and Aggression and Slips, Trips and Falls. The aim of the audit is to provide assurance to the Lead Director for Health and Safety. The audit tool is based on a three year cycle which aims to audit all areas of the Trust and cover 15 legislative areas. All audit results are presented to the relevant Director, the Health and Safety Committee and the Governance Committee.

The audit tool is emailed to all Heads of Service (100) within the Trust. The Heads of Service are then required to issue the question sets to their Departmental/Service/Team leads for completion and scoring. Responses are completed on the basis of full compliance, partial compliance or no compliance options for each question. The return rate for the audits at year end 2018 were 78%. Results are collated by Directorate, indicating that 22% of Heads of Service did not submit a return. The Health and Safety Team complete verification audits of 10% of returned audit compliance levels.

From the interviews with stakeholders, the Reviewer found a limited knowledge of the purpose and use of this audit tool. The audit process was evaluated during 2018 using Survey Monkey. A total of 22 Heads of Service responded and some issues were identified including the challenges of competing priorities. This is a useful audit tool which ***could be further developed and used to form the basis of a more comprehensive risk audit and assessment tool as highlighted above (see Section 4.7).***

Senior stakeholders identified some concern regarding assurance of compliance with Health and Safety risk assessments across the organisation. In particular, it was believed that an assessment of compliance with the Control of Substances Hazardous to Health (COSHH) Regulations was required. ***It is recommended that an organisational COSHH audit is undertaken during 2019/20 to be completed before end March 2020.***

4.12 Management of Complaints

The Trust has a Policy for the Management of Complaints which was approved in July 2018. The Policy indicates that the Medical Director is responsible for ensuring that the complaints procedure and approach ensures that appropriate investigations and actions have been competed before a response sent following a formal investigation of a complaint. Further, the Policy indicates that the responsibility for managing the requirements of this policy is delegated to the Assistant Director of Clinical and Social Care Governance. However, the Policy clearly indicates that the Medical Director must maintain an overview of the issues raised in complaints and be assured that appropriate organisational learning has taken place and that action is taken. Stakeholders indicated that the line of corporate oversight by the Medical

Director's Office was now less robust than the Policy envisaged and that this should be revisited.

The [Interim] Assistant Director for Clinical and Social Care Governance is required to work with the Trust's 'operational, executive and corporate Governance leads and support leads on the ongoing development of systems and procedures to monitor the implementation and effectiveness' of changing practice, taking regard of evidence based practice, lessons learned from reviews, complaints, incidents and public inquires and to provide recommendations and advice to SMT Governance on the Governance Action Plan and priorities for action.

The Corporate Clinical and Social Care Governance Team receive complaints and log them into the Datix Complaints module and they are then forwarded to the Operational Directors. The Policy indicates that the Corporate Complaints Officer (CCO) is responsible for screening service user contacts and determining if these are enquiries or complaints and should facilitate either resolution of the enquiry or complaint or facilitate the complainant in the use of the formal complaints procedure. ***It is recommended that the remit of this important role is reviewed in line with the Trust's Complaints Management Policy and as part of the Corporate Clinical and Social Care Governance Department restructure (see Section 4.23)***. The Policy also indicates that the CCO should alert the Directorate governance teams to significant issues. ***It is recommended that the process of screening of complaints is reviewed and parameters for alerts to be clearly defined to include alerts to professional Executive Directors***.

The Operational Directors are responsible and accountability for the proper management of accurate, effective and timely responses to complaints received in relation to the services they manage. There is some variation across the Directorates in approach to the management of complaints. At interview, senior stakeholders outlined continuing challenges in meeting response timescales in particular in areas where a larger volume of complaints are received e.g. Acute Services. It was also identified that some complaints responses remained outstanding for significant periods of time. Senior stakeholders also indicated that there was a significant variation in the quality of responses received for review by the Director, with many responses being returned for further consideration/amendment. This was cited as a particular challenge when a cross Directorate response was required or when an accurate oversight of complaints involving independent sector providers was required.

A recent NI Public Services Ombudsman Report confirmed the concerns expressed by internal stakeholders reiterating the importance of timeliness in responding and the requirement for clear cross directorate/sector linkages, accurate grading of complaints and corporate oversight to ensure that appropriate linkages are made with the Regional SAI process.

There are some good examples of complaints management for example, the CYPS governance team undertook an IHI Quality Improvement Personal Advisors programme which resulted in significant improvement the management of complaints within the Directorate. The improvement initiative included service user feedback on

the complaints process from 353 complaints investigated and responded. The Directorate also undertook an audit from January 2017 to December 2018 from which learning has been identified. A process to improve the management of complaints should be replicated across the organisation to ensure equality in response to service users.

Directorate staff were positive about the use of the Healthcare Complaints Analysis Tool (HCAT) which was developed by the London School of Economics Report July 2018. HCATs is an analytical tool for codifying and assessing the problems highlighted by patients and their families of advocates in letters of complaints. The HCAT codes are considered by Trust staff to be more effective than the Datix CCS Codes and the Reviewer has been advised that it is possible to add an additional field to Datix to capture both sets of codes.

As has been indicated in other key areas of governance (incidents, legal services and M&M), stakeholders indicated a gap in sharing lessons from this process and the need to create a more robust process (see also Section 4.20).

It is not clear from the current High Level Governance Structures where oversight of this element occurs at a level below the SMT.

It is recommended that the Trust constitutes a Director's Oversight Complaints Review Group as a task and finish group to focus on reviewing Policy and Procedure and improving the management of complaints and experience of the service user. Membership should include a Non-Executive Director and/or a Service User(s).

4.13 Litigation Management

The Policy and Procedure for the Management of Litigation Claims provided for the Review indicates that it is operational from November 2018 and due for review in 2021. The Policy does not indicate that it is in draft status however, the Reviewer has been informed that the draft Policy has been submitted to the Policy Scrutiny Committee for approval and subsequent circulation.[30] The Policy provided in evidence states that the Executive Medical Director is the designated officer with responsibility for Clinical Negligence claims and Coronial Services and the Director of Human (HR) and organisational Development (OD) is the designated Director with responsibility for Public and Employer Liability Claims. Each have the associated delegated financial authority accordance with the Trust's SFI and Authorisation and Approvals Framework. From a managerial perspective the Litigation Management Team/Department is the responsibility of the Director of HR and OD.

The Policy clearly articulates the roles and responsibilities of key stakeholders, line managers and staff and in particular the Policy highlights the need for shared learning, being as honest and open with patients/service users and their relatives/carers and the need for staff support in the event of their being involved with a litigation process.

[30] Policy Checklist indicates that the November 2018 Policy Version supersedes the 'Policy for the Management of Litigation and Claims 2007'.

The Litigation team provide reports to the Governance Committee. The Litigation Manager attends Interface Meetings with the Directorates. Stakeholders advised that the opportunities for learning from claims and Inquests both internally across the organisation and externally with the wider health service could be improved.

The Head of Communications is notified of pending Coroner's Inquests and Preliminary Hearings. The system will readily allow for compliance with IHRD Recommendation 50 (*The Health and Social Care ('HSCB') should be notified promptly of all forthcoming healthcare related inquests by the Chief Executive of the Trust(s) involved),* when it is formally implemented through the IHRD Implementation Programme.

Senior stakeholders highlighted the proposal to appoint two Medical Leads for litigation management (see Sections 4.21). The paper outlining proposals for Medical Leadership was presented to SMT in June 2019. It is proposed that there will be a Medical Lead for Coroners Services who will work with the Legal Services Manager and Clinical Directors to provide professional and clinical input into the management of Coroner's cases. The role will include the following areas of responsibility; support in the process of obtaining statements from involved staff and advise on action to be taken, support in deciding from whom statements and reports should be sought and review reports and provide a direct liaison and efficient communication with the Coroner's Office. In this respect, the Medical Lead and Legal Services Manager should follow IHRD Recommendation 51 (*Trust employees should not record or otherwise manage witness statements made by Trust Staff and submitted to the Coroner's Office*). As above, more definitive guidance on this Recommendation will be issued via the IHRD Implementation Programme.

The Medical Lead will also provide an extremely important role in supporting Trust staff who are to appear in the Coroner's Court which may mean attending that Court. The Reviewer, acknowledges the challenge that fulfilling this role will entail i.e. balance the Duty of Care to support staff during a stressful experience with any perception that such support could be viewed as influencing staff. Therefore, clear rules of engagement should be developed.

A second Medical Lead for Litigation Services is also proposed. The area of responsibility is not defined in the Medical Leadership Review paper, however, it is understood that this Medical Lead will provide support for the management of professional negligence (clinical negligence) claims and provide a separate line of support and leadership within the Trust's Legal Services Management arrangements.

Stakeholders raised the issue of the management of legal services within the Trust being compliant with IHRD recommendation 36 ~ *Trust employees who investigate an accident should not be involved with related Trust preparation for inquest or litigation.* The Reviewer is aware that the IHRD Death Certification and Preparation for Inquest Workstream have debated this requirement and are currently considering how this recommendation should be implemented in practice. However, the proposed arrangement for appointment of two separate Medical Leadership Management posts is a model which is currently viewed as being reasonable.

Senior stakeholders advised that given the existing workload, delegated authorisation framework and the proposed model of providing medical leadership that the Legal Services team would be best placed with the Corporate Clinical and Social Care Governance team, Medical Directorate.

It is therefore recommended that the management of Legal Services should transfer to the Corporate Clinical and Social Care Governance team, Medical Directorate.

4.14 Policies, Standards and Guidelines

4.14.1 Policy Scrutiny Committee

The Trust has a Policy Scrutiny Committee. Stakeholders involved in the Committee indicated the challenges in maintaining oversight of review and renewal dates given the sheer volume and diversity of Trust Policies and Procedures. Another challenge is that on occasion the Trust Policy has reached the review date and there is a delay as new legislation or regional guidance is pending and/or a regional policy is being developed. In these instances the Trust should consider amending the Policy Procedure Checklist to indicate an extension to review/revision date due to external factors. Some policy authors advised the Reviewer of delay in time from submission to date of approval and dissemination of policies, especially when external deadlines were a factor. During the Review it was noted that version control was not always robust indicating the potential for staff to be working from a dated or draft version of a policy or procedural document. ***It is recommended that the Trust consider options for an electronic policy and procedure management system that is accessible, easy to navigate, contain a search facility and includes the capacity for email notification of new/changed policy and automates a review/revise reminder***.

4.14.2 Management of Standards and Guidelines

Each HSC Trust is accountable and responsible for ensuring that clinical standards and guidelines are effectively managed so that the required recommendations are embedded within local health and social care practice.

The Trust has a process for the management of standards and guidelines which is reliant on both Corporate and Directorate based systems. Standards and guidelines are logged onto the Trust's database system centrally by the Corporate Governance Team and then forwarded on a weekly basis to Directorate Governance Co-Ordinators, Pharmacy Governance and the Medical Directors Office. Each Directorate have developed their own processes for the management of Standards and Guidelines. During the Review stakeholders expressed concern that were there was evidence that Standards and Guidelines were disseminated, however, there was a lack of assurance that they were being implemented as subsequent audit of practice had not always taken place (see Section 4.15). This concern was reiterated by the Chairman and Non-Executive Directors, who identified that this was an area that required focus.

Internal Audit carried out an audit of the Management of Standards and Guidelines during May 2015 when 'Satisfactory' assurance was provided. They audited the process again in September 2018 and provided a Limited level of assurance identifying that although the Trust had good controls to record corporately the receipt and subsequent dissemination of Standards and Guidelines to the directorates there is no corporate overview and reporting of the Trust's overall compliance against Standards and Guidelines.

The Internal Audit also identified weaknesses in relation to the completeness of data held on the Trust's Standards and Guidelines Register and limited ongoing audit/follow up of compliance (as above).

Stakeholders described the challenges in managing the large volume of standards and guidelines that are received from external agencies. During 2017/18, a total of 230 guidelines were received from external agencies, 23 were not applicable to the Trust of the remaining 207 there were 39 that were not applicable to Acute Services. Senior stakeholders identified the challenges in managing standards and guidelines which have cross directorate applicability.

In April 2012, the Trust established a Corporate Standards and Guidelines Risk and Prioritisation group. The aim of this group was to provide a corporate forum to ensure that the Trust has in place a systematic and integrated approach for the implementation, monitoring and assurance of clinical standards and guidelines across all of its care directorates. The Reviewer understands that the Group was stood down in January 2017 to be replaced by monthly meetings between the Corporate Assistant Director Clinical and Social Care and Directorate Governance leads.

All of the Directorates have systems in place for the management of Standards and Guidelines. Acute Services have a robust system in place for the dissemination of Standards and Guidelines which represents a best practice model. The system was developed and is managed by a Patient Safety and Quality Manager (Standards & Guidelines) who is a NICE Scholar and a member of the Acute Services Clinical and Social Care Governance Team. The system includes a Standards and Guidelines Operational Procedures Manual, a reporting schedule, process maps including a process map for clinical change leads and an Accountability Reporting system for Acute Services. The downside of this system is that it is person dependent. The Patient Safety and Quality Manager also identified that the lack of clinical audit in providing assurance that standards and guidelines had been implemented was a systems issue.

Other challenges include identifying a clinical/managerial lead for guidelines – as there is an apprehension surrounding taking on the responsibility/accountability for change lead role.

Positive assurance statements go directly back to HSCB via the Corporate Clinical and Social Care Governance team. Previously they would have been approved by SMT prior to issue. ***It is recommended that a level of corporate oversight is reinstated.***

An 'Accountability Report' of the Trust's compliance with Standards and Guidelines had previously been reported to the Governance Committee on a twice yearly basis. ***It is recommended that the Accountability (Compliance) reporting arrangement is reinstated***.

The Trust will be required to comply with IHRD Recommendation 78 ~ *Implementation of clinical guidelines should be documented and routinely audited*. The challenges in respect of clinical audit are outlined in Section 4.15. It is anticipated that as part of the final stage of the IHRD Implementation Programme Assurance Framework HSC organisations will be required to provide independent assurance of compliance with recommendations.

The Trust, as a matter of urgency, should review the overarching corporate arrangements to provide assurance regarding the effective management of Standards and Guidelines and to facilitate a risk based approach from the triangulation of data from incidents, complaints, claims, service reviews, Morbidity and Mortality reviews and Clinical Audit.

It is recommended that the Trust take the Standards and Guidelines model developed within Acute Services and provide a central management system within the Corporate Clinical and Social Care Team under the leadership of the Medical Director. The Reviewer understands that the IT system currently used within Acute Services may not have the capacity to deal with Trust-wide information.

4.15 Clinical Audit

The Trust's Clinical Audit Strategy was presented to the SMT on 20 June 2018 and was then presented to the Governance Committee on 6 September 2018. The Strategy defined clinical audit as 'a quality improvement cycle that involves the measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes'. Clinical audit is an integral part of the clinical and social care governance framework.

Senior stakeholders advised that Internal Audit had provided Clinical Audit with a 'Limited' assurance level. The Clinical Audit Strategy outlined the strategy and structure for overseeing clinical audit processes to provide an assurance to SMT and Trust Board that clinical audit activity would be appropriately managed and delivered. The paper clearly outlined the key issues and challenges for the organisation which include; ensuring that clinical audit is delivered consistently across all operational directorates, in line with national guidance and ensuring that there is a sufficient number of staff in the corporate clinical audit team and in the operational Directorates to support the delivery of the approved clinical audit programme. The Strategy also describes the prioritisation of clinical audit in line with Healthcare Quality Improvement Partnership (HQIP) proposals that clinical audit programmes are categorised into 4 distinct elements with 'external must do' audits being assigned the highest priority as Level 1 projects.

Clinical Audit will have an increasing and key function in providing corporate assurance that IHRD Recommendations have been implemented. Clinical Audit and

the Morbidity and Mortality Process are intrinsically linked (see Section 4.16). Clinical Audit will be required to provide assurance that clinical standards and guidelines have been implemented (IHRD Recommendation 78 as outlined in Section 4.14). Also Recommendation 76 ~*Clinical standards of care, such as patients might reasonably expect should be published and made subject to regular audit*. Clinical audit will also be required to provide assurance of organisational compliance with clinical standards in IHRD Paediatric Clinical (Recommendations 10-30) for example, patient transfer, on-call rotas and clinical record keeping.

Stakeholders described the dilution of the clinical audit function over a period of time, this experience is similar to that of other HSC Trusts. The Clinical Audit Strategy identified that the current [administrative] staffing levels in the corporate Clinical Audit and M&M team and operational directorates is insufficient to support and deliver the clinical audit work programme. This is covered in more detail in Section 4.23.1 Corporate Clinical and Social Care Governance Department.

The Medical Director has also identified resource issues in the paper entitled 'Medical Leadership Review submitted to SMT in June 2019 (see Section 4.21). The appointment of a Clinical Standards and Audit Lead who will lead the coordination and monitoring of systems and processes to ensure maximum compliance with clinical standards as endorsed or mandated by regional or professional bodies is key. It is envisaged that the role will compliment and support the operational Assistant Medical Director clinical governance responsibilities and accountabilities to their areas of service.

Stakeholders advised that there was a need to demonstrate more robust linkages between clinical audit and quality improvement and the management of serious adverse incidents. ***It is recommended that the integration between quality improvement and the integrated governance function is reviewed to ensure optimum connectivity.***

The 2018 Clinical Audit Strategy and Action Plan should be reviewed and updated.

It is also recommended that the Clinical Audit Committee is reinstated and the reporting arrangements considered in the review of the Trust Board Committee Structure Section 4.2.6 and Appendix 1.

Given the potential increase in focus and demand on clinical audit as outlined above ***it is recommended that the resource implications are reviewed, see Section 4.21 Medical Leadership and Section 4. 23.1 Corporate Clinical and Social Care Governance Department).***

4.16 Clinical Outcomes - Morbidity and Mortality (see also 4. Medical Leadership)

Morbidity and Mortality (M&M) reviews are primarily a tool for identifying opportunities for system level improvement. There was a focus during the IHRD Inquiry into the rationale and mechanics of M&M Review and the significant role this process has in improving outcomes through learning. In November 2016, the DoH

issued guidance on a Regional Mortality and Morbidity Review (RM&MR) process. The aim of the guidance was to provide specific direction for M&M leads and a regional approach as to how M & M meetings should be established, structured managed and assured. RM&MR is hosted on the Northern Ireland Electronic Care Record (NIECR)

As part of the 2018/19 Annual Internal Audit plan, Internal Audit carried out an audit of M & M during October to December 2018. The SHSC Trust was one of four Trusts audited during this period. The Reviewer has noted that the audit focused specifically on the mortality aspects of this guidance. Internal Audit provided a Limited Assurance in respect of the M&M processes. The Internal Audit Report recognised that there were processes however, timescales for Consultant review and discussion at M&M groups was not routinely followed and some deaths had not been reviewed or discussed. Internal Audit did recognised from their observational audit (attendance at three meetings) that deaths were discussed in detail with a level of robust and challenging professionalism among teams visited. Senior stakeholders within the Board of Directors noted an improving culture in the ethos of utilising M&M for shared learning within the organisation.

As a result of the Internal Audit review of four Trusts, a number of concerns have been raised regionally about the adequacy of the regional M&M process and in particular the need for significant investment in order to ensure M&M regional processes are fit for purpose, especially around Learning Lessons. Trust stakeholders have also identified a lack of resources (see also Sections 4.15 and 4.23.1). If the appropriate staff are to attend specialty meetings, they need time out to learn (as indicated above this is also a recommendation from the IHRD Report), this was identified as a particular challenge for non-medics without job plans. Trust senior stakeholders identified that the lack of multidisciplinary participation was a concern and that that was partially as a result of the culture.

In addition, there is a risk in the context that all deaths must be reviewed, that sufficient time will not be spent on those deaths which provide the most opportunity for learning. This would require a screening/risk assessment process to be built into the regional process. There is no central IT system's overview, so the Trust cannot interrogate the system to generate reports and this lack of reporting functionality was a concern raised by Trust officers.

The Trust established an Outcome Review Group, which met for the first time in June 2018. The remit of this Review Group is to provide an assurance that all hospital deaths are monitored and, reviewed and reported, in line with regional guidance and to ensure that lessons learned and actions are implemented to improve outcomes. It is recommended that the Outcome Review Group (see also Trust Board Sub Committee Structures Section 4.2.6).

M&M Chairs have a key function in delivering the RMMR process. Within SHSCT they are responsibility for setting and maintaining the agenda for M&M meetings and for determining, supporting and developing patient safety inputs. They also have a monitoring role which includes; attendance, timely completion of screening templates and medical staff participation in Case Presentation. An M&M Chairs meeting has

also been developed with the purpose of informing the ongoing development of M&M meetings and processes. The M&M Chairs should report to the Outcome Review Group.

Within the Trust, stakeholders highlighted the need for IT and administrative support for the process. With the right investment administrative staff could also reconcile deaths with SAIs thus providing another line of assurance that the process is being implemented. The Internal Audit Report indicates that the minutes and presentations at M&M meetings are held centrally by the Corporate M & M team and Clinical Audit team (see Section 4.23.1).

The M&M Review Process is a core element of the Trust's clinical governance arrangements and patient safety framework. The Clinical Audit/M&M team within the Medical Directorate are a crucial element of the Process. The Outcomes Review Group is an important component of the Trust's assurance framework. I***t is recommended that they are adequately resourced and supported to ensure optimum outputs and clinical engagement. The support will include the development of administrative systems for the central suppository of minutes and attendance logs***.

4.17 Raising Concerns

The Trust's Policy for raising concerns is entitled 'Your Right to Raise a Concern' (Whistleblowing) and is based on Regional guidance. There is no indication of the date the Policy was approved/became operational on the Front Cover. The Lead Director is the Director of Human Resources and Organisational Development.

Board Effectiveness guidance increasingly highlights that the Board of Directors have a role in creating the culture which supports open dialogue. This should include Directors personally listening to complaints, concerns and suggestions from patients and staff, and being seen to act on them fairly (see also Section 4.6 Being Open). The Board should be assured that there is a framework which indicates how staff should raise their concerns and a key element is a clear whistleblowing policy, with support and protection for bona fide whistle blowers. The Reviewer was advised that a Non-Executive Director has been nominated to take a lead in this area.

The aim of the Trust policy is to promote the culture of openness, transparency and dialogue which at the same time; reassures staff that it is safe and acceptable to speak up, upholds patient confidentiality and contributes toward improving services, demonstrates to all staff and the public that the Trust is ensuring its affairs are carried out ethically, honestly and to high standards. The Policy also aims to assist in the prevention of fraud and mismanagement and contains specific guidance and contact details in this respect. The Trust Policy compliments extant Professional Codes and Guidance on responsibilities in raising concerns and clearly states that it is not intended to replace professional codes and mechanisms which also questions about professional competence to be raised.

The Director of HR advised that a gap in awareness training had been identified which would be addressed. She also advised that the use of advocates would be implemented in the medium term. Stakeholders who had participated in

investigation cases indicated that this process was another source of learning for the organisation. The Policy contains a template entitled 'Record of Discussion regarding Confidentiality' which is a very useful tool in those situations where confidentiality is an issue for the member of staff raising the concern.

4.18 Information Governance

The Trust has identified that safeguarding the Trust's information is a critical aspect of supporting the delivery of its objectives. Effective management of information risk is a key aspect of this. The Trust has arrangements in place to manage the risk including; an Information Governance Strategy incorporating Framework, Framework, a Personal Data Guardian to approve data sharing (Medical Director and Director of CYP), a Senior Information Risk Owner (Director of Performance and Reform) and Information Asset Owners in place to reduce the risk to personal information within the Trust and training and advice provided to ensure they were aware of their responsibilities. The Senior Information Risk Owner (SIRO) provides an annual report to the Governance Committee which provides a summary of key aspects of the role, the minutes confirm that the Report was last presented in February 2019.

The Information Governance Strategy incorporating Framework is dated 2014/15 – 2016/17 and is underpinned by a suite of policies, procedures and guidance. The Information Governance Policy is dated January 2015 with a two year default for review. The Policy should be reviewed to take account of extant legislation and guidance in particular General Data Protection Regulations 2018.

Information Governance breeches are required to be reported in line with Trust's Incident Reporting Procedure. Stakeholders have identified that learning from information governance incidents should be included in the Lessons Learned Forum (Section 4.20).

As identified in Section 4.1 Freedom of Information and Data Protection summary compliance data is reported to Trust Board on a quarterly basis to ensure completion within statutory timeframes. An information sharing register is in place which records the details of all episodes of sharing of Trust data with other bodies. Information governance training is mandatory within the Trust.

The Trust had taken action to ensure it was prepared for the General Data Protection Regulations (GDPR) in May 2018. Internal Audit provided 'satisfactory' level of assurance in relation to General Data Protection Regulations (GDPR) Readiness within the Trust during the 2017/18 audit cycle.

Cyber Security remains as a 'High' risk rating on the Corporate Risk Register.

4.19 Emergency Planning and Business Continuity

The Trust has a Corporate Emergency Management Plan incorporating Major Incident and Business Continuity. The Plan was approved by Trust Board in January 2013 and was revised during 2018/19 and is dated 15 February 2019. The lead Director is the Executive Medical Director. The Emergency Planning Policy is dated November 2015, approved by SMT on 9 December 2015 and circulated in February

2016 by the Medical Director. The Business Continuity Policy is dated 2012. An Annual Report on Emergency Planning and Business Continuity is submitted to Trust Board.

The Trust's Controls Assurance Emergency Planning Framework self-assessment has identified that the Trust is largely fully compliant with the core standard. Some actions have been identified including; provision of appropriate resourcing for the Emergency Planning Office; developing an ongoing exercise programme/schedule at directorate and corporate level and a process for implementing actions arising from major incidents/exercises. A training needs analysis is required to identify any gaps in the key competencies and skills required for incident response including chemical, biological, radiological and nuclear defense (CBRN) training. These actions will be monitored by the Trust's Controls Assurance Group (See Section 4.7).

Stakeholders indicated that the development of Business Continuity plans at Directorate level could be improved.

4.20 Shared Learning for Improvement

All of the stakeholders expressed the need for HSC organisations to learn from service user experience and from the analysis of adverse incidents, complaints and claims. The commitment to learn is expressed in the Trust's 'Values' and Corporate Objectives. In the Trust's strategic priority 'Promoting safe, high quality care' the Trust has stated its commitment to 'be a learning and continually developing organisation, where professional standards, best practice and learning from experience share how we improve our services'.

The Trust has a Lessons Learned Forum whose purpose is to provide a corporate cross directorate interface for the identification and sharing of lessons learned from incidents (including near misses), complaints and litigation cases. The Forum is also responsible for identifying areas for improvement in the Trust' management of adverse incident and complaints and if appropriate propose system changes and to provide challenge and scrutiny to the Trust's adverse incident processes. The Forum members are responsible for presenting potential sharing lessons learned from their service areas and for assisting in disseminating the learning within their respective service areas. Stakeholders suggested 'casting the net wider' in respect of sources e.g. systems failures identified in Whistleblowing cases and HR Grievance and Disciplinary investigations (subject to the same rules of working within information governance parameters, maintaining confidentiality and limitations due to ongoing legal processes). Senior stakeholders wanted to see a stronger link between 'Lessons Learned' and Quality Improvement. (See also Section 4.2.6 proposed Trust Board Sub Committee structures.)

Senior stakeholders advised that at times it seemed like the processes for learning were disparate and there was a lack of connectivity for example the learning identified through M&M and learning provided for the Forum. Stakeholders were therefore were keen to ensure that as various Sub Groups are developed within the Trust's integrated governance/assurance framework that duplication of purpose is minimised and the process for shared learning was as streamlined as possible.

During the Review a meeting of the Lessons Learned Forum was held and stakeholders stated that it had been an excellent agenda and provided the organisation with a valuable opportunity to learn. However, the stakeholders were also disappointed at the lack of attendance by medical staff. It is recognised that time to learn is a challenge for clinical staff. This was recognised in the IHRD Report and Recommendation 66 states *'Clinicians should be afforded time to consider and assimilate learning feedback from SAI investigations and within contracted hours'*. The Education and Training Workstream have interpreted clinicians in the boarder term to include nursing, Allied Health Professionals and Social Workers. (See also Medical Leadership Section 4.21).

Stakeholders also indicated that the challenge and scrutiny function of the Forum in ***respect of the management of adverse incidents had not yet been embedded. However, there may be a more appropriate forum for the Trust to undertake this scrutiny challenge (see Section 4.10)***

In reviewing the Terms of Reference the Trust should consider how the Forum could contribute to the implementation of IHRD Recommendation 40 '*Learning and trends identified in SAI investigations should inform programmes of Clinical Audit****' (see also Management of SAIs Section 4.10)***.

4.21 Medical Leadership

Medical leadership was last reviewed in the Trust in 2011 and as the paper indicates, given the length of time since this review and the changes in the health and social care landscape it was agreed that a further review and potential revision of the medical leadership form and function was required.

The findings were presented to the SMT on 11 June 2019. The 'case for change' highlighted three key areas:

- Performance of Frontline Teams;
- Providing a Link from Ward to Board;
- Supporting and influencing Service Planning.

The review emphasised the importance of implementing a Collective Leadership Model and the need to move on from a concept of command and control leadership. The review report also recognises that due to the power and control which doctors possess they may block potential change efforts and confound improvement initiatives. Engaging doctors within the collective leadership model therefore is crucial.

The review process included an independent survey of medical leaders which was carried out to identify the barriers and enablers. Many of these findings reflect the comments from stakeholders during the Governance Review and included the need to clearly define the roles and accountabilities of medical leaders and provide protected time to deliver in their roles and greater integration with operational management teams.

The Medical Leadership Review indicated that if the proposals were approved, all Medical Leadership management posts would be vacated and reappointed collectively.

To support the Medical Director who carries responsibilities in a wide area including; Medical Professional Governance, Clinical and Social Care Governance, Quality Improvement and Audit and Infection Prevention and Control, it is proposed that two Deputy Medical Directors should be appointed. One of the post holders, Deputy Medical Director Quality Improvement will focus on providing strong leadership, systems and process to lead on clinical standards and governance across the organisation, providing expert advice, developing a clinical governance strategy and participating in education and training programmes as required. The Deputy Medical Director will work with the [Interim] Assistant Director Clinical and Social Care Governance in a Collective Leadership model and will provide stronger corporate integrated governance oversight and leadership.

As outlined in Sections 4.14 and 4.15 Standards and Guidelines and Clinical Audit and Sections 4.13 Coroners Service and Litigation Management and Section 4.16 M&M the investment in these Medical Leadership management roles is core to delivering clear accountability arrangements that will provide a robust assurance framework arrangements for integrated governance. In addition, the structure will facilitate the Trust meet the recommendations arising from the IHRD Implementation Programme. To achieve maximum outputs from the Medical Leadership model, the Trust should recognise the need to provide additional administration and clerical support[31] (see also Section 4.23.1)

4.22 Governance Information Management Systems

The Trust currently uses a commercial risk management/patient safety software programme called Datix. Datix is used in all of the Health and Social Care Trusts and the Health and Social Care Board. The Trust currently uses the Incident reporting, Complaints and Claims modules and has just purchased the Risk Register module.

Stakeholders advised that the Clinical and Social Care Governance Coordinator, Mental Health Service had developed statistical reports/Datix dashboards for his own and other operational Directorates which was a much welcomed tool to support data analysis and provision of governance reports.

All of the stakeholders in the Governance and Patient Safety Department and the Directorates who were interviewed were keen that the collective software system was utilised to the maximum capacity to support the patient safety/integrated governance agenda. They were also keen to explore the advantages that more advanced patient safety software can achieve for example Datix Cloud IQ. This is

[3131] SHSCT 'Medical Leadership Review' June 2019. Section 14.11, page 29.

currently being considered by the IHRD DoH Clinical and Social Care Sub Group in respect of the implementation of Recommendations 67, 68 and 80.[32]

To ensure that the Trust maximises it's information for integrated governance it is ***vital that a dedicated Datix systems administrator who can ensure the quality of data provided as this has been identified as a gap at present*** (see also Clinical and Social Care Governance Structures below).

4.23 Structures

4.23.1 Corporate Clinical and Social Care Governance, Medical Directorate

The Corporate Clinical and Social Care Governance Team is managed by the [Interim] Assistant Director for Corporate Clinical and Social Care the support of one very recently appointed Senior Manager (Head of Patient Safety & Improvement). The Team support a large range of functional areas including; delivering the Risk Management Strategy, incident reporting including Serious Adverse Incident reporting, complaints, patient safety data and reporting on Clinical and Social Care to the Governance Committee of Trust Board. Stakeholders advised and as is described in the Sections above that some of the functions are 'light touch' and limited to initial screening or signposting (e.g. complaints). The Reviewer was advised that the Management of Infection Prevention and Control would transfer to the Interim Director. In addition, during the review, the management of Clinical Audit and the M & M system was also transferred from within the Medical Directors Office to the Interim Director and as a result of the Review potentially the management of legal services and risk register would also be considered for transfer. This centralisation is crucial for effective delivery of the integrated governance framework and create a more robust first line of assurance to the Board of Directors on the systems of internal control, to deliver the action to allow Clinical Audit and M & M to implement action plans against the Limited Assurance and to deliver against the recommendations of the IHRD Implementation Programme. However, there are concerns for the staffing of this resource.

The recently appointed Senior Manager (Head of Patient Safety Data and Improvement) role will focus on safety, quality and innovation as key drivers to deliver improved outcomes for patients and clients. This post is responsible for managing the timely and effective provision and communication of a corporate quality and safety analysis service.

The post holder will be responsible for setting the strategic direction for a range of analysis services provided at corporate organisational level within the Trust. This will include Patient Safety, Clinical Audit, Mortality & Morbidity and Trust clinical

[32] Recommendation 67 ~ ' *Should findings from investigation or review imply inadequacy in current programmes of medical or nursing education then the relevant teaching authority should be informed'*. Recommendation 68 ~ '*Information from clinical incident investigations, complaints, performance appraisal, inquests and litigation should be specifically assessed for potential use in training and retraining'*. Recommendation 80 ~ '*Trusts should ensure health care data is expertly analysed for patterns of poor performance and issues of patient safety'*.

guidelines, in line with statutory requirements and national, regional benchmarks, peer accreditation frameworks and standardising Trust best practice.

The Patient Safety Manager will support the Head of Patient Safety Data and Improvement. The post holder is one of the original Institute for Healthcare Improvement (IHI) HSC Safety Forum members and maintains and updates the Forum Extranet and contributes to regional work. There are examples of best practice improvement initiatives in this area for example the Patient Safety Falls Walking Stick and the Pressure Ulcer Safety Cross. The Patient Safety Manager undertakes a large volume of data analysis activity supporting the Trust's Patient Safety Programme. The role is currently supported only by one Band 3 (24 hours). Therefore, this service is dependent on a single manager which is not sustainable. The post holder has limited time to use his expertise at ward/department level in quality improvement initiatives for example Sepsis6.

Clinical Audit (including M&M) is managed by an Acting Band 7 Manager who demonstrated commitment to providing a quality service and provided insight into the challenges of delivering both current and future clinical audit and M&M activity. The team to support Clinical Audit has reduced following the Review of Public Administration (RPA) and currently consists of a B5 WTE x 1 and Band 3 WTE x 3 plus 1 part time.

As outlined above, (Sections 4.15) clinical audit is 'back on the radar'. The role of the team is to support the delivery of the Trust's clinical audit programme which includes key national, regional and local drivers for clinical audit (described as 'top-down') balanced against directorate/service priorities and the interests of individual clinicians (bottom-up) initiatives.[33] The team screen audit proposals prior to registration. The post holder advised that there were also challenges in relation to supporting National Confidential Enquiry into Patient Outcome and Death (NCEPOD) activity which is currently person dependent within the Trust and needs to be re-focused.

Also as above (Section 4.15) the Clinical Audit team have a key role to play in delivering the Regional M&M Review system. Within the current resource there is very limited time for support for M&M Chairs which ideally would include pre and post meeting support and support for the Chairs Forum which meet on a quarterly basis. The rolling audit calendar is a particular challenge as support is required for six meetings at the same time.

The third key challenge for the Clinical Audit team with the current resources is supporting the linkages with quality improvement, the management of standards and guidelines (Section 4.14) and Serious Adverse Incidents (Section 4.10) and providing the SMT and Trust Board with assurance that improvement in practice has been implemented and sustained.

The Governance Coordinator provided insight into core elements of the Clinical and Social Care Governance agenda including; complaints management, adverse

[33] Healthcare Quality Improvement Partnership (HQIP) propose that clinical audit programmes are categorised into 4 distinct elements with 'external must do' audits being assigned the highest priority as Level 1 projects.

incident management (including SAIs) and the use of Datix. She highlighted the lack of the corporate resource required to provide systems-wide quality assurance of these systems.

The range of functional areas for the Corporate Clinical and Social Care Governance team is wide and if proposed corporate governance functions are further integrated will increase significantly. In addition to the day-to-day remit of the functional areas, the Clinical and Social Care Governance Team have to respond to a number of external demands for example the DoH IHRD Workstreams and stocktaking exercises, the RQIA and an ever increasing number of FOI and Media Enquiries. Normally these activities are required in very tight timeframes.

It is the opinion of the Reviewer and senior stakeholders, at director level that the corporate clinical and social care governance function has been under resourced over the past number of years. This underfunding represents a lack of investment in staff and the necessary information technology systems to support integrated governance.

It is recommended that as a matter of urgency the Corporate Clinical and Social Care Governance team is re-structured and two additional Senior Manager posts are considered to provide leadership to related functional areas. It is proposed that there should be a Senior Manager for Clinical and Social Care which will include; management of Serious Adverse Incidents, Complaints and Claims and a Senior Manager for Corporate Governance which will include Risk Management, Risk Registers, Datix Administration, Controls Assurance and training (see Appendix 3). It will be essential to also consider the administrative support required to support the corporate function areas as has been highlighted throughout the report if the Trust is to meet the ever increasing level of scrutiny and demands to provide assurance to Trust Board and external stakeholders of the efficacy of its internal control systems. ***Therefore, it is further recommended that there is an urgent review of the administrative resources and business case development.***

Given the wider remit of the corporate team it is important that each functional area has an annual action plan/work plan which will underpin the Corporate Clinical and Social Care Governance management plan and which can be linked to Corporate Objectives and staff appraisal.

4.23.2 Directorate Governance Arrangements

It was evident that Directors had invested in their Governance structures, however, they all advised that there was still not the capacity to meet the demands of providing information and assurance to internal and external stakeholders on the wide range of integrated governance elements e.g. standards and guidelines, serious adverse incidents and complaints. Additionally, there is an ever growing demand under FOI, Media Inquiries etc.

The extant Integrated Governance Framework requires that each Operational Directorate Governance Forum is responsible for considering all aspects of the

Trust's 'Model of Integrated Governance'.[34] Each directorate have developed governance structures which includes an overarching governance forum/group with terms of reference and sub groups which vary from directorate to directorate. The Reviewer was provided with examples of the structures which show clear lines of accountability and communication lines within the Directorate e.g. Mental Health Services. Governance forum sub groups meet at varying intervals within each Directorate. There is also a slight variation in the directorate governance forum/group meeting agendas and again this is not unusual in a Trust that consists of a range of programmes of care.

The high level governance structure, Figure 2 in the extant Integrated Governance Framework, depicts the directorate governance forum reporting 'organisational and directorate intelligence' to the SMT. It is less clear from a review of the SMT Terms of Reference and Agendas how this operates in practice. ***It is recommended that the directorate governance reporting arrangements are included in a review of Trust Board Sub Committee Structure and the review of the SMT Terms of Reference as above (Sections 4.5 and 4.6).*** Also less clear within the Integrated Governance Framework is the role/link between the Executive Lead for Integrated Clinical and Social Care Governance (Medical Director) and the [Interim] Assistant Director for Clinical and Social Care Governance and the Operational Governance Arrangements (see also Section 4.4). This lack of clarity was confirmed by comments from stakeholders during the Review. ***Clarification of roles and responsibilities should be considered as part of the recommended review of the Integrated Governance Framework following approval of the Governance Review.***

The operational Directorates have appointed Clinical and Social Care Governance Coordinators. They fulfil a key role in supporting Directorates and in collating the Directorate intelligence. There is some variation in the demanding roles and responsibilities of the post holders which have evolved over time to meet the needs of the Directorates. There is also variation from Directorate to Directorate, in the resources allocated to provide support to the Directorate Clinical and Social Care Governance Coordinators. As above, the Directorate Clinical and Social Care Governance Coordinators and teams carry a wide range of roles and responsibilities at local level across the integrated governance functional areas and demand invariable exceeds capacity. Within Acute Services, the Director of Pharmacy has been supporting the role on a temporary basis. This should be reviewed to enable the post holder fulfil her regional role as Chair of the Regional Pharmaceutical Contracting Executive Group for Northern Ireland.

As previously outlined, there are examples of best practice across the Directorates for example work on complaints management, service user engagement and the model for dissemination of standards and guidelines. The Trust should consider how to share the best practice.

4.23.3 Interface between Corporate C&SGC and Directorates

[34] SHSCT 'Draft Integrated Governance Framework 2017/18 – 2020/21'. Section 5 page 21 and Figure 1 page 23.

Weekly Governance Meeting

The Medical Director and Interim Assistant Director Clinical and Social Care Governance have reinstated a weekly Governance Meeting with Directorate Clinical and Social Care Governance Coordinators. The meetings are short, lasting approximately one hour. Currently, the Medical Director where possible, either attends the meeting or joins by teleconference. The Reviewer has been advised that the rationale is to provide an opportunity for both a briefing (e.g. learning and internal safety alerts) and debriefing on newly emerging issues e.g. serious adverse incidents or complaints. These meetings meet the spirit of 'no surprises'. The meetings are currently held on a Thursday and members can currently 'dial in'. There is a mixed reaction to the weekly Governance meeting with stakeholders identifying that the 'dial in' facility is not conducive to debrief meetings. Stakeholders have also identified that due to the nature of Acute Services the agenda can, at times be described as Acute centric. It is important that this interface meeting continues and develops to meet the needs of all concerned. The Interim Assistant Director advised that the process was at an early stage and the agenda was still being tested and evolving. More recently, the membership has increased to include safeguarding, medicines management, litigation management and standards and guidelines.

The Trust has systems in place to brief the Board of Directors of emerging issues in a timely fashion. The output of this meeting will complement existing systems and should be further developed to provide a summary briefing note which when ratified by SMT can be circulated to the Chair and Non-Executive Directors. This will assist the Trust meet IHRD Recommendation 81 ~ *Trust's should ensure that all internal reports, reviews and related commentaries touching upon SAI related deaths within he Trust are brought to the immediate attention or every Board member*.

It is recommended that the agenda, membership and timeliness of the weekly Governance Meeting is reviewed and terms of reference developed. The meetings should be kept as short briefing meetings and held face to face with members. There should be a short summary template report developed which can then be used as an internal communication to NEDs.

Monthly Clinical and Social Care Governance Meeting

The monthly governance meeting provides an opportunity to consider a wider range of integrated governance issues in more detail. In light of the weekly governance meeting, ***it is recommended that a review of the terms of reference including purpose, membership and frequency is undertaken.***

Appendices

Summary of Recommendations **Appendix 1**

Theme/ Rec No	Recommendation	Timescale[35]
Board Governance		
1	The Trust Board should review the cycle of Trust Board Reports and the Board of Directors' public meeting agenda by April 2020. .	M
2	The Director of Finance, Procurement and Estates is also invited to attend the meetings in the interests of integrated governance and also as the Chief Executive has delegated responsibility for Health and Safety Management to this Executive Director.	M
3	The Chair of the Governance Committee should be involved in the development of the agenda and the cycle of reports. It is also recommended that the cycle of reports is reviewed and submitted to the Committee for approval commencing April 2020	S
4	The clinical and social care key performance indicators should be further developed and submitted for approval through the Senior Management Team.	S
5	The SMT Terms of Reference should be reviewed.	M
6	The remit and responsibilities of the SMT Governance Board should be reviewed and a separate Terms of Reference developed to include the purpose, membership and reporting lines to Trust Board via the Governance Committee of Trust Board. (See also Sub Committee Structure proposals at Section 4.2.6). The role of the SMT Governance Board should also be clearly defined in the Integrated Governance Strategy.	M
7	The Trust Governance Structures should be reviewed and Trust Board Sub Committee/Oversight/Steering Groups constituted to which the various integrated governance steering groups, forum and committees will report and provide the organisation with a first level of assurance (see Appendix 2).	S-M
8	The Terms of Reference and annual work plans/action plans (where applicable) for Board Committees and Sub Committees should be held centrally.	M
9	Any short – medium term Director's Oversight Groups should be added to the Governance Structure (Integrated Assurance Framework) for the duration of their remit as 'Task and Finish Groups' e.g. IHRD Directors Oversight Group.	S
10	To ensure that all committees provide clarity in their	M

[35] Short Term (S) action within 3 months, Medium Term (M) action within 6 months, Long Term (L) action within 9-12 months.

Theme/ Rec No	Recommendation	Timescale[35]
	terms of reference, delegated powers and reporting requirements the Trust should consider developing a standard template to define the terms of reference for all Board Sub Committees, Steering Groups and Advisory/Specialist Groups.	
11	The Trust should consider introducing the role of Board Secretary/Head of Office to support the Trust Board and the Integrated Governance Framework.	M
12	The Integrated Governance Framework should be reviewed as a matter of urgency to ensure it provides clear descriptions of the roles and responsibilities of key stakeholders. It is also recommended that the Framework provides electronic links to key corporate Trust Strategies and Policies and extant guidance where applicable.	S
13	Arrangements for Adult Safeguarding should be reviewed to identify any potential risks/gaps in control or assurance in this area.	S
'Being Open'		
14	The Trust should consider the training implications of implementing the 'Being Open' framework which includes compliance with IHRD Recommendation 69 (i) ~ Trusts should appoint and train Executive Directors with specific responsibility for 'Issues of Candour'.	M
Controls Assurance		
15	The Trust should undertake an audit/review of the Management of Medical Devices and Equipment to provide assurance that systems are in place across the organisation.	S-M
16	The Trust should develop an organisational risk audit and assessment tool with associated audit programme based on the Controls Assurance standards.	M-L
Risk Management Strategy		
17	The Draft Risk Management Strategy should be submitted for approval as a matter of urgency.	S
18	The Trust Board should consider the application of the Risk Appetite Matrix in respect of the organisation's Corporate Objectives and associated Board Assurance Framework and Corporate Risk Register.	M
19	A risk management training programme should be developed and delivered to underpin the publication of the approved Risk Management Strategy and the training should include risk appetite, risk assessment/evaluation and management of risk registers	L
20	The management of the Board Assurance Framework and Corporate Risk Register should be delegated to	M-L

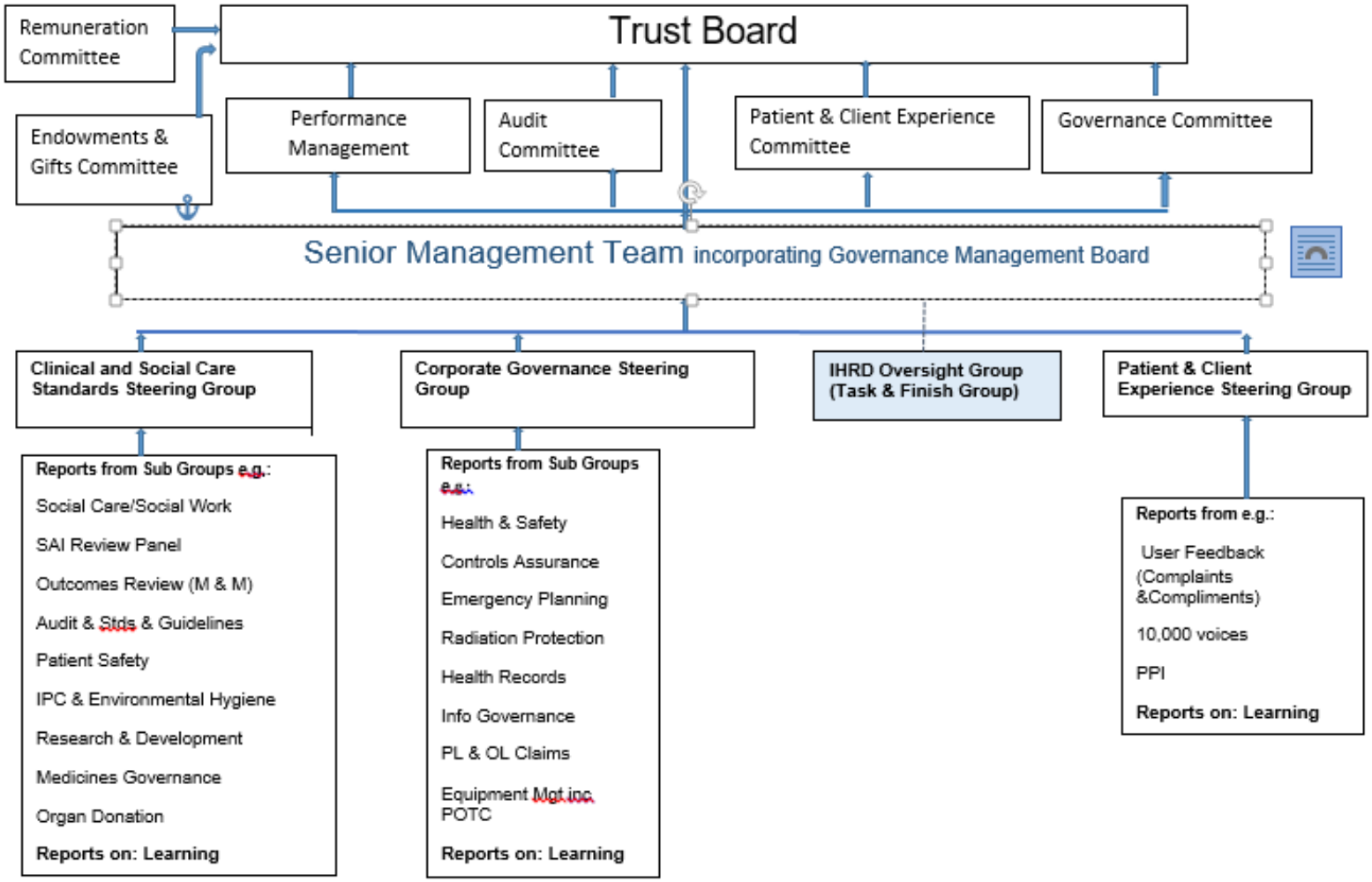
Theme/ Rec No	Recommendation	Timescale[35]
	the Executive Medical Director in line with the Risk Management Strategy.	
21	A standardised Directorate risk register template should be considered when Datix risk register module is implemented.	M
Management of Adverse Incidents including SAIs		
22	A Trust flow chart should be developed to underpin the Regional Adverse Incident Reporting Policy/Procedure (when disseminated) which accurately reflects local/ Trust roles and responsibilities especially at Executive Director level.	L
23	Corporate oversight of the management of adverse incidents should be strengthened to include a quality assurance component which will be dependent upon the resources and skills available within the Clinical and Social Care department (see Section 4.23.1)	S-M
24	The Trust should constitute an SAI Review Group and/or SAI Rapid Review Group [or similar] which should provide independent scrutiny and challenge to the SAI process including review of level of investigation, independence of review panel and approval of terms of reference when SAIs are initiated. In addition, the Review Group should oversee completed reports before submission to the HSCB. The Review Group should be chaired by the MD or his/her Deputy and will report to a Trust Board Sub Committee. The Review Group should meet on a four weekly basis initially.	S
25	The Trust should develop a database of SAI Review Panel Chairs who have undertaken SAI/Systems Analysis Training.	L
26	The Trust should develop an SAI RCA/Systems Analysis toolkit based on the training provided by external provider.	L
27	The Trust should consider developing the role of a Service User Liaison Officer [or similar] for engagement with families throughout the SAI process.	S
Management of Health & Safety		
28	The Trust Health and Safety Committee should review their Terms of Reference and submit to the relevant Board Sub Committee for approval.	S
29	The Trust should review and revise the existing H & S audit tool for use as outlined above in Recommendation 16.	M-L
30	The Trust should undertake an organisational audit of compliance with COSHH Regulations.	M

Theme/ Rec No	Recommendation	Timescale[35]
Complaints Management		
31	The remit of the Corporate Complaints Officer should be reviewed in line with the extant Trust Complaints Management policy.	M
32	The current process of screening of complaints should be reviewed and parameters for alerts to be clearly defined to include alerts to professional Executive Directors	S-M
33	It is recommended that the Trust constitutes a Director's Oversight Complaints Review Group as a task and finish group to focus on reviewing Policy and Procedure and improving the management of complaints and experience of the service user. Membership should include a Non-Executive Director and/or a Service User(s).	M
Litigation Management		
34	The management of Legal Services should transfer to the Corporate Clinical and Social Care Governance team, Medical Directorate.	S-M
Policies, Standards and Clinical Guidelines		
35	The Trust should explore the options for an electronic policy and procedure management system that is accessible, easy to navigate, contains a search facility and includes the capacity for email notification of new/changed policy and automates a review/revise reminder.	L
36	The Corporate oversight of the management of Standards and Guidelines should be reinstated and the former Accountability (Compliance) reporting arrangements are also reinstated.	S
37	The Trust should further develop the Standards and Guidelines model developed within Acute Services and provide a central management system within the Corporate Clinical and Social Care Team under the leadership of the Medical Director.	
38	The Trust should review the Sub Committee Structure to include an oversight committee for the management of Standards and Guidelines either a full time committee or a Task and Finish Sub Committee (see also Recommendation 7).	M-L
Clinical Audit		
39	The 2018 Clinical Audit Strategy and Action Plan should be reviewed and updated.	S
40	The Clinical Audit Committee should be reinstated and the reporting arrangements considered in the review of the Trust Board Committee Structure Section 4.2.6 and	M-L

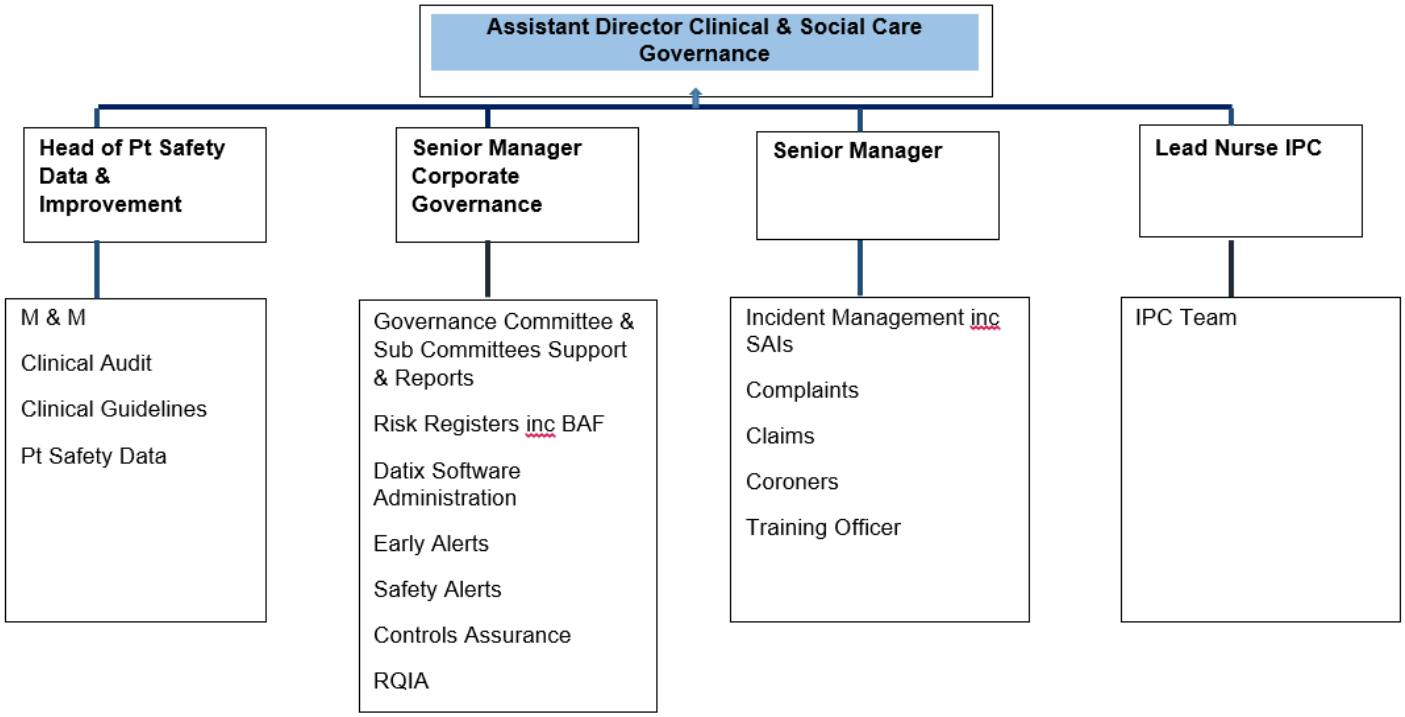
Theme/ Rec No	Recommendation	Timescale[35]
	Appendix 1.	
Morbidity & Mortality – link with Medical Leadership below		
41	The resource implications for the delivery of the RMMR should be considered in line with the proposals for the Medical Leadership model. (Section 4.21 Medical Leadership and Section 4. 23.1 Corporate Clinical and Social Care Governance Department).	S
42	The RMMR process should be adequately resourced and supported to ensure optimum outputs and clinical engagement. This includes the resources required within the Corporate Clinical and Social Care Clinical Audit team to ensure the development of administrative systems for the central suppository of minutes and attendance logs (see also Recommendation 44 and 45 below).	M
Shared Learning for Improvement		
43	The Trust should review the Terms of Reference, including membership, and strengthen the purpose of the Lessons Learned Forum.	S-M
Governance Information Management Systems (Datix)		
44	To ensure that the Trust maximises the potential for the use of patient safety software it is vital that a dedicated Datix systems administrator is appointed who can ensure the quality of data provided as this has been identified as a gap at present (see also Clinical and Social Care Governance Structures below).	S-M
Corporate Clinical and Social Care Governance Structures		
45	It is recommended that the Corporate Clinical and Social Care Governance team is re-structured and two additional Senior Manager posts are considered to provide leadership to related functional areas. Therefore, it is further recommended that there is an urgent review of the administrative resources and business case development.	S
46	The Trust should ensure that the directorate governance reporting arrangements are included in a review of Trust Board Sub Committee Structure and the review of the SMT Terms of Reference as above	M
Corporate & Directorate CSCG Interface		
47	It is recommended that the agenda, membership and timeliness of the weekly Governance Meeting is reviewed and terms of reference developed. The meetings should be kept as short briefing meetings and held face to face with members. There should be a short summary template report developed which can then be used as an internal communication to NEDs.	S-M
48	In light of the weekly governance meeting, it is	M

Theme/ Rec No	Recommendation	Timescale[35]
	recommended that a review of the terms of reference including purpose, membership and frequency is undertaken.	

Appendix 2 Governance Committee and Sub Committee Structures underpinned by Directorate Accountability Arrangements



Appendix 3 Corporate Clinical & Social Care Governance Department Structure reporting to Executive Medical Director



Draft Response to the Clinical and Social Care Governance Review

Southern Health and Social Care Trust

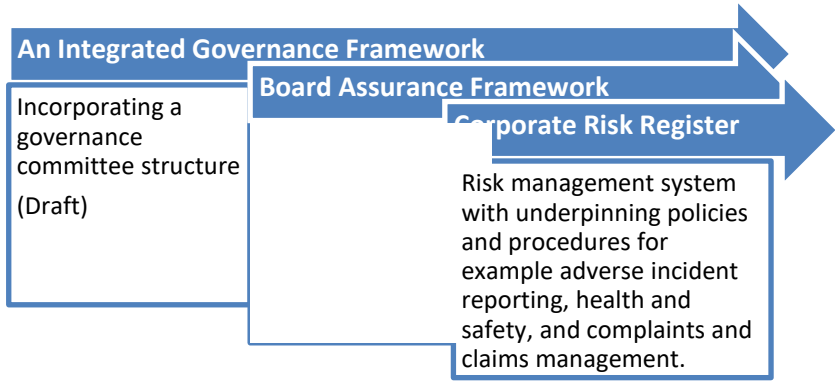
Quality Care - for you, with you

Working together Excellence Openness & Honesty Compassion

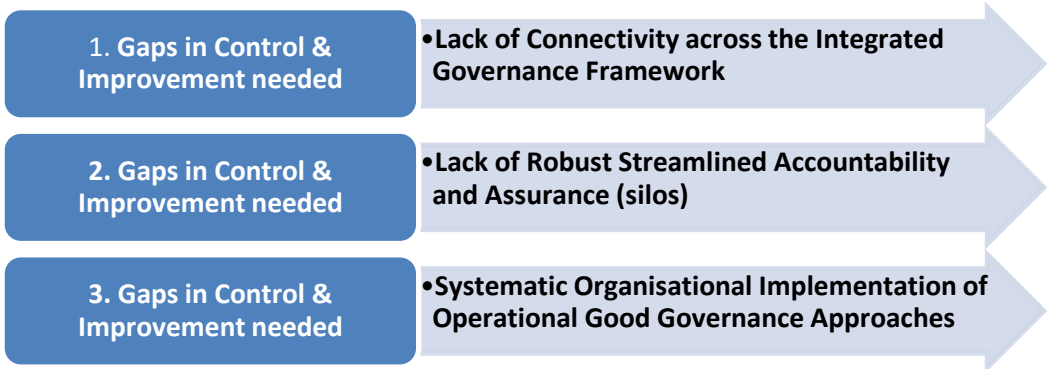
September 2019

Clinical and Social Care Governance Review – Draft August 2019
This draft response comprises of the response to the review report and recommendations (including areas not referenced in the review)
Executive Summary – Key Points (page 3)

- The Context: – Significant previous reviews[1] and of senior executive position turnover at Trust Board / SMT level.
- The review analysis has demonstrated that many of the building blocks for good integrated governance are already in place.



- The review however also identifies gaps in controls assurance and areas of improvement, making 48[2] recommendations across 12 review areas.



[1] 2010 implemented in 2013, re-visited in 2015, Draft IGF, 2017 and further 2019 review
[2] Recommendation on QI connectivity and IGF is noted in the clinical audit section, but not listed in Appendix 1.

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*Short Term (S) action within 3 months, Medium Term (M) action within 6 months, Long Term (L) action within 9-12 months.

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Report Section No:	Review Extract & Response				
2.0 Scope 2.1 ToR & Objectives (page 5)	**Terms of Reference** The purpose of the review is to ensure the Trust has a robust governance structure and arrangements in place which offers assurance on patient safety and that help people learn. The Trust is seeking to undertake a comprehensive review of the current governance structure including the formulation of recommendations on what a **good structure** should look like; The Review will consider existing governance processes and particularly governance assurance, moving the Trust towards a position where there is a **whole governance approach** to the organisation rather than in two reporting lines. It will include a review of both clinical and social care governance.				
2.2 Limitations (page 5)	Given the breadth of the terms of reference and the timeframe allocated to complete this report **does not claim to provide an exhaustive or exclusive list of all potential gaps in controls or assurance at local level.** The Review is intended to be **an evaluation of the overarching integrated governance arrangements and related strategies, policies and procedures.**				
Draft Response to the Scope and Limitations	The limitations as clearly set out in the report mean that the review ToR and objectives **have not been fully met**. In this draft response to the review cognisance has taken that: 1. What a 'Good' structure would look like is not clearly evident and as a consequence what a 'whole' governance approach to the organisation (or options for achieving this) are not defined. 2. An analysis of the gaps in assurance of two reporting lines in comparison to any benefits of a re-structured whole governance approach (which integrates the current corporate C&CSG and operational functions) is absent. The 48 review recommendations which are responded to below need to be viewed in the context of these two significant deficits from the original objectives.				
4.0.	**Review Recommendations:**	**Draft**	**Improvement /**	**Dependency / Pre-Requisite**	**Priority**

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Findings & Analysis / Timescale *	Board Governance	Response Opinion Accepted / Not Accepted	Gap Identified		
1. M	The Trust Board should review the cycle of Trust Board Reports and the Board of Directors' public meeting agenda by April 2020.	Accepted	Improvement in accountability and assurance	Consideration given to linkages to existing and proposed committees	Completed – new schedule approved by TB on 29/08/2019
2. M	The Director of Finance, Procurement and Estates is also invited to attend the meetings in the interests of integrated governance and also as the Chief Executive has delegated responsibility for Health and Safety Management to this Executive Director.	Accepted	Improvement in IGF connectivity and accountability and assurance	Not Applicable	Implemented
3. S	The Chair of the Governance Committee should be involved in the development of the agenda and the cycle of reports. It is also recommended that the cycle of reports is reviewed and submitted to the Committee for approval commencing April 2020	Accepted	Improvement in accountability and assurance	Proposed reporting cycle to be developed, including assurance indicators and agreed with safety science Director level training (as per IHRD)	High – delivery potential long term
4. S	The clinical and social care key performance indicators should be further developed and submitted for approval through the Senior Management Team.	Accepted	Improvement in accountability and assurance	-Strategy development through engagement -KPI development -Collation and analysis investment	High – delivery potential long term

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				-Audit and Quality Improvement programmes	
5. M	The SMT Terms of Reference should be reviewed.	Accepted	Improvement in accountability and assurance Improvement in IGF connectivity	SMT Workshop to review ToR for individual and collective responsibilities (pg. 13 4.2.5)	High
6. M	The remit and responsibilities of the SMT Governance Board should be reviewed and a separate Terms of Reference developed to include the purpose, membership and reporting lines to Trust Board via the Governance Committee of Trust Board. (See also Sub Committee Structure proposals at Section 4.2.6). The role of the SMT Governance Board should also be clearly defined in the Integrated Governance Strategy.	Accepted	Improvement in accountability and assurance	-ToR -Specification of the assurance reporting required. -Capacity (experts, admin support and ICT infrastructure) to support the information and assurance. -Could be included with SMT workshop (above)	High – delivery potential long term
7. S - M	The Trust Governance Structures should be reviewed and Trust Board Sub Committee/Oversight/Steering Groups constituted to which the various integrated governance steering groups, forum and committees will report and provide the organisation with a first level of assurance (see Appendix 2).	Accepted	Improvement in accountability and assurance Improvement in IGF connectivity	-ToR -Specification of the assurance reporting required. -Capacity (experts, admin support and ICT infrastructure) to support the information and assurance. -Trust Board Workshop	High – delivery potential long term
8.0 M	The Terms of Reference and annual work plans/action plans (where applicable) for Board Committees and Sub Committees	Accepted	Improvement in accountability and assurance	-ToR and annual work plans / action plans will require assurance (expert evaluated	High

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	should be held centrally.		Improvement in IGF connectivity	opinion) and administrative support to ensure that accurate and timely records can be held centrally.	
9. S	Any short – medium term Director's Oversight Groups should be added to the Governance Structure (Integrated Assurance Framework) for the duration of their remit as 'Task and Finish Groups' e.g. IHRD Directors Oversight Group.	Accepted	Improvement in accountability and assurance Improvement in IGF connectivity	Any short term group requires: -ToR -Specification of the assurance reporting required. -Capacity (experts, admin support and ICT infrastructure) to support the information and assurance.	High
10. M	To ensure that all committees provide clarity in their terms of reference, delegated powers and reporting requirements the Trust should consider developing a standard template to define the terms of reference for all Board Sub Committees, Steering Groups and Advisory/Specialist Groups.	Accepted	Improvement in accountability and assurance	Engagement in template development and implementation and centralisation.	High
11. M	The Trust should consider introducing the role of Board Secretary/Head of Office to support the Trust Board and the Integrated Governance Framework.	For further consideration			Office of Chief Executive
12. S	The Integrated Governance Framework should be reviewed as a matter of urgency to ensure it provides clear descriptions of the roles and responsibilities of key stakeholders. It is also recommended that the Framework provides electronic links to	Accepted	Improvement in accountability and assurance Improvement in IGF connectivity	The review does not consider the investment required to undertake an urgent review of the integrated governance framework. This would include:	High

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Clinical and Social Care Governance Review – Draft August 2019
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	key corporate Trust Strategies and Policies and extant guidance where applicable.			Systems and structures to deliver integrated governance, processes and behaviours. The timescale suggested is therefore likely to be independent of these considerations. This urgent review however would be essential to help remedy the limitations identified under section 2.0 (pg2.0)	
13. S	Arrangements for Adult Safeguarding should be reviewed to identify any potential risks/gaps in control or assurance in this area.	Accepted	Improvement in accountability and assurance	-Develop methodology / approach to gap identification -Cross directorate stakeholder engagement	

Summary of Section & Potential Weakness 1.0 – 11.0	These 11 recommendations all relate to Trust Board, Board Sub-Committee and SMT structures, meetings and procedures.
	- The ToR and annual work plans / action plans will require assurance (expert evaluated opinion) and administrative support to ensure that accurate and timely records can be held centrally.
	- The assurance information provided needs to be of the required quality and standard. As per IHRD recommendation 80, HSCTS are required to ensure that healthcare data is expertly analysed for poor performance and issues of patient safety. Sufficient time is required on TB agenda and sub-committee agendas to allow the TB to carry out it's effectiveness function for Governance / Risk scrutiny by Directors.
	- The report does not reflect the requirements of reporting and information gathering and expert analysis that would be required to adequately service the SMT Governance Board.
	  - The report recommends two new steering Groups – Clinical and Social Care Standards and Corporate Governance Standards Group.
	  - The report recommends 17 sub-groups to these steering groups (existing and new)
	However no consideration is outlined in the review as to the requirements of reporting and information gathering and analysis that would be required to adequately service these sub-groups, steering groups through to SMT Governance Board				

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	- Whilst all these recommendations contain as aspect of 'housekeeping' which is in addition to the key function of assurance. Robust housekeeping arrangements for Trust Board and delegated sub-committees and SMT will require support streamlined terms of reference, administration and central repository - Recommendation 11 requires the investment and the development of job role and function on which other recommendations would be reliant.
12.	The review does not consider the investment required to undertake an urgent review of the integrated governance framework. (Integrated Governance is defined as: "The systems, processes and behaviours by which Trusts lead, direct and control their functions in order to achieve organisational objectives, safety and quality of services and in which they relate to patients and carers, the wider community and partner organisations." (Integrated Governance Handbook, Department of Health February 2006). This would include an appraisal of the systems and structures to deliver integrated governance, processes and behaviours. The timescale suggested is therefore likely to be independent of these considerations. The recommendation of an urgent review however **would be essential to help remedy the limitations identified under section 2.0, page 2 of this draft response.**
13.	This recommendation would lead to improvement in systematic approaches to cross directorate governance. However the report stops short of describing the methodology / approach that would be required to identify potential risks and gaps in control or assurance in ASG to take this recommendation forward within the 3 month timescale. Underpinning these recommendations is the requirement for Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs)

4.0. Findings & Analysis / Timescale	**Review Recommendation:** **Being Open**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**Priority**
14. M	The Trust should consider the training implications of implementing the 'Being Open' framework which includes	Accepted	Systematic Improvement in	Regional 'Being Open'	High

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	compliance with IHRD Recommendation 69 (i) ~ Trusts should appoint and train Executive Directors with specific responsibility for 'Issues of Candour'.		cross-directorate approaches	Guidance	
Potential Weakness	- The report refers to both the development of the 'Being Open' Framework and the Training requirements for Being Open. However the recommendation deals only with the training implications. - The framework development is both dependent on the regional working group and local implementation structures to progress to final implementation. Our current plans are to develop an interim solution and the review does not outline the resourcing required to bring this recommendation to full implementation				
4.0. Findings & Analysis / Timescale	**Review Recommendations:** **Controls Assurance**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**Priority**
15. S-M	The Trust should undertake an audit/review of the Management of Medical Devices and Equipment to provide assurance that systems are in place across the organisation.	For further consideration			Finance, Procurement & Estates Directorate
16. M-L	The Trust should develop an organisational risk audit and assessment tool with associated audit programme based on the Controls Assurance standards.	For further consideration			Finance, Procurement & Estates Directorate
4.0. Findings & Analysis / Timescale	**Review Recommendations:** **Risk Management Strategy**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**Priority**
17. S	The Draft Risk Management Strategy should be submitted for approval as a matter of urgency.	Accepted	Improvement in accountability and assurance	See potential weakness section below	High
18. M	The Trust Board should consider the application of the	Accepted	Improvement in	See potential	

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	Risk Appetite Matrix in respect of the organisation's Corporate Objectives and associated Board Assurance Framework and Corporate Risk Register.		accountability and assurance	weakness section below	
19. L	A risk management training programme should be developed and delivered to underpin the publication of the approved Risk Management Strategy and the training should include risk appetite, risk assessment/evaluation and management of risk registers	Accepted	Improvement in accountability and assurance	See potential weakness section below	
20. M-L	The management of the Board Assurance Framework and Corporate Risk Register should be delegated to the Executive Medical Director in line with the Risk Management Strategy.	Accepted	Improvement in accountability and assurance	See potential weakness section below	
21. M	A standardised Directorate risk register template should be considered when Datix risk register module is implemented.	Accepted	Improvement in accountability and assurance	See potential weakness section below	
Potential Weakness	- Whilst these 5 recommendations reflect the elements necessary to implement the risk management strategy they do not consider the pre-requisite resource aspects required to deliver upon them. The training cost, release of staff time, investment in Datix, as the risk management system and required supporting staff. - The review of the integrated governance framework (recommendation 12) would need to examine the linkages for operationally and corporately reporting assurance on risk. - The report does not reflect how the Board Assurance Framework and Corporate Risk Register integrate. - The housekeeping nature of recommendation 5 will require engagement across directorates for template design and system development, otherwise the opportunity for standardisation will not be realised. - Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs)				
4.0. Findings & Analysis / Timescale	**Review Recommendations:** **Management of Adverse Incidents including SAIs**	**Draft Response Opinion Accepted /**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**Priority**

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		Not Accepted			
22. L	A Trust flow chart should be developed to underpin the Regional Adverse Incident Reporting Policy/Procedure (when disseminated) which accurately reflects local/ Trust roles and responsibilities especially at Executive Director level.	Accepted	Improvement in accountability and assurance	Regional process agreement and dissemination	High
23 S-M	Corporate oversight of the management of adverse incidents should be strengthened to include a quality assurance component which will be dependent upon the resources and skills available within the Clinical and Social Care department (see Section 4.23.1)	Accepted	Improvement in accountability and assurance	-Datix investment -Datix Team -Training -Reporting specification	High
24 S	The Trust should constitute an SAI Review Group and/or SAI Rapid Review Group [or similar] which should provide independent scrutiny and challenge to the SAI process including review of level of investigation, independence of review panel and approval of terms of reference when SAIs are initiated. In addition, the Review Group should oversee completed reports before submission to the HSCB. The Review Group should be chaired by the MD or his/her Deputy and will report to a Trust Board Sub Committee. The Review Group should meet on a four weekly basis initially.	Accepted	Improvement in accountability and assurance	- ToR -Specification of the assurance reporting required. -Capacity (SAI experts, admin support and ICT infrastructure) to support the information and assurance.	High
25 L	The Trust should develop a database of SAI Review Panel Chairs who have undertaken SAI/Systems Analysis Training.	Accepted	Improvement in accountability and assurance	-ICT investment	High
26 L	The Trust should develop an SAI RCA/Systems Analysis toolkit based on the training provided by external provider.	Accepted	Improvement in accountability and assurance	-Training resourcing	High
27 S	The Trust should consider developing the role of a Service User Liaison Officer [or similar] for engagement with families throughout the SAI process.	Accepted	Improvement in accountability and assurance	-Role development, funding, recruitment and training.	High

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Potential Weakness	-These 6 recommendations will require significant additional training costs in SAI, RCA, and Human Factors, release of staff time, investment in IT support. -No consideration is outlined in the review as to the requirements of reporting and information gathering and analysis that would be required to adequately service the AI oversight function and SAI Rapid Review Group with pre-requisites of ToR, clinical engagement, specification of the assurance reporting required, capacity (i.e. the experts, admin support and ICT infrastructure) to support the information and assurance. -The implementation of these recommendations will be influenced by the 21 IHRD recommendations relating to SAI including family engagement etc. - Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs)				
4.0. Findings & Analysis / Timescale	**Review Recommendations:** **Management of Health & Safety**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**Priority**
28. S	The Trust Health and Safety Committee should review their Terms of Reference and submit to the relevant Board Sub Committee for approval.	For further consideration			Finance, Procurement & Estates Directorate
29. M-L	The Trust should review and revise the existing H & S audit tool for use as outlined above in Recommendation 16.	For further consideration			Finance, Procurement & Estates Directorate
30. M	The Trust should undertake an organisational audit of compliance with COSHH Regulations.	For further consideration			Finance, Procurement & Estates Directorate
4.0. Findings & Analysis /	**Review Recommendations:** **Complaints Management**	**Draft Response Opinion Accepted / Not**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**Priority**

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Timescale		Accepted			
31. M	The remit of the Corporate Complaints Officer should be reviewed in line with the extant Trust Complaints Management policy.	Accepted	Systematic Improvement in cross-directorate approaches	See potential weakness section below	High
32. S-M	The current process of screening of complaints should be reviewed and parameters for alerts to be clearly defined to include alerts to professional Executive Directors	Accepted	Systematic Improvement in cross-directorate approaches	See potential weakness section below	High
33. M	It is recommended that the Trust constitutes a Director's Oversight Complaints Review Group as a task and finish group to focus on reviewing Policy and Procedure and improving the management of complaints and experience of the service user. Membership should include a Non-Executive Director and/or a Service User(s).	Accepted	Systematic Improvement in cross-directorate approaches	See potential weakness section below	High
Potential Weakness	-These 3 recommendations will require significant additional investment in what 'Good' complaints management and alert systems would require in terms of engagement with stakeholder groups of staff, service user and families and external agencies. -No consideration is outlined in the review as to the requirements of reporting and information gathering and analysis that would be required to adequately service the Director's oversight complaints review group, with pre-requisites of ToR, PPI engagement, training requirements and the specification of the assurance reporting required, capacity (i.e. the experts, admin support and ICT infrastructure) to support the information and assurance. -Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs)				
4.0. Findings & Analysis / Timescale	**Review Recommendation:** **Litigation Management**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**Priority**
34. S-M	The management of Legal Services should transfer to the Corporate Clinical and Social Care Governance team,	Not Accepted	IHRD recommendation No.	Not Applicable	Not Applicable

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	Medical Directorate.		36		
4.0. Findings & Analysis / Timescale	**Policies, Standards and Clinical Guidelines**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre Requisite**	**Priority**
35. L	The Trust should explore the options for an electronic policy and procedure management system that is accessible, easy to navigate, contains a search facility and includes the capacity for email notification of new/changed policy and automates a review/revise reminder.	Accepted	Improvement in accountability and assurance, IGR connectivity and systematic improvement in cross directorate approaches	-system investment, support and training	High
36. S	The Corporate oversight of the management of Standards and Guidelines should be reinstated and the former Accountability (Compliance) reporting arrangements are also reinstated.	Accepted	Improvement in accountability and assurance, IGR connectivity and systematic improvement in cross directorate approaches	See potential weakness section below	High
37.	The Trust should further develop the Standards and Guidelines model developed within Acute Services and provide a central management system within the Corporate Clinical and Social Care Team under the leadership of the Medical Director.	Accepted	Improvement in accountability and assurance, IGR connectivity and systematic improvement in cross directorate approaches	See potential weakness section below	High

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38. M-L	The Trust should review the Sub Committee Structure to include an oversight committee for the management of Standards and Guidelines either a full time committee or a Task and Finish Sub Committee (see also Recommendation 7).	Accepted	Improvement in accountability and assurance, IGR connectivity and systematic improvement in cross directorate approaches	See potential weakness section below	High
Potential Weakness	- The oversight of Standards and Guidelines management requires significant additional investment in ICT systems, trained personnel, release of clinician time (change lead) and assurance mechanisms for receipt, allocation, dissemination, implementation and audit above the current baseline of S & G investment. - IHRD recommendations nos. 57, 77 & 78 reference standards and guidelines and the connectedness to publication and audit of standards to provide assurance of implementation. - S&G oversight committee will have pre-requisites of ToR, clinical engagement, specification of the assurance reporting required, capacity (i.e. the experts, admin support and ICT infrastructure) to support the information and assurance. - Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs)				
4.0. Findings & Analysis / Timescale	**Clinical Audit**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre Requisite**	**Priority**
39. S	The 2018 Clinical Audit Strategy and Action Plan should be reviewed and updated.	Accepted	Improvement in accountability and assurance	See potential weakness section below	High
40. M-L	The Clinical Audit Committee should be reinstated and the reporting arrangements considered in the review of the Trust Board Committee Structure Section 4.2.6 and Appendix 1.	Accepted	Improvement in accountability and assurance	See potential weakness section below	High
Potential Weakness	- Page 10 of the review 'assurance', defined as: "an evaluated opinion, based on evidence gained from review, on the organisation's governance, risk management and internal control framework". The function of clinical audit is required to provide an evaluated				

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	opinion, with recommendations driving learning and improvement processes in safety and quality. The assurance information provided by clinical audit needs to be of the required quality and standard and performed systematically across the organisation and supporting the necessary multi-disciplinary involvement. The resourcing and form of this function or options for it are not described or benchmarked to undertake national and local studies, and assurance of the implementation of audit recommendations including NCEPOD. - The review does not reference the organisation's governance, risk management and internal control framework for RQIA inspections, audit and assurances regarding implementation of recommendations. - The increasing assurance role for audit in IHRD recommendations is referenced (19, 40, 48, 76, 78 and 90), but its significant resource implications for staffing and training are not defined. - **Although not contained in appendix 1 - the review does recommend that the integration between quality improvement and the integrated governance function is reviewed to ensure optimum connectivity.** - Clinical audit committee re-instatement has pre-requisites of ToR, clinical engagement, specification of the assurance reporting required, capacity (i.e. the experts, admin support and ICT infrastructure) to support the information and assurance. - Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs)				
4.0. Findings & Analysis / Timescale	**Review Recommendations:** **Morbidity & Mortality**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre Requisite**	**Priority**
41. S	The resource implications for the delivery of the RMMR should be considered in line with the proposals for the Medical Leadership model. (Section 4.21 Medical Leadership and Section 4. 23.1 Corporate Clinical and Social Care Governance Department).	Accepted	Improvement in accountability and assurance Improvement in IGF connectivity	See potential weakness section below	High
42. M	The RMMR process should be adequately resourced and supported to ensure optimum outputs and clinical engagement. This includes the resources required within the Corporate Clinical and Social Care Clinical Audit team to ensure the development of administrative	Accepted	Improvement in accountability and assurance Improvement in IGF	See potential weakness section below	High

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	systems for the central suppository of minutes and attendance logs (see also Recommendation 44 and 45 below).		connectivity		
Potential Weakness	- The review acknowledges that adequate resourcing is required to optimise the learning outputs from M&M forums. This will require an exercise to benchmark against other models of M&M facilitation and embedding learning, as well as the assurance function to be provided by the Oversight Group on the systematic review of all deaths. - The review does not reference a requirement for an additional level of objective review of mortality and morbidity cases which is currently being considered regionally and has implications for clinician review time, training and ICT infrastructure to aggregate themes across an organisational system. - Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs)				
4.0. Findings & Analysis / Timescale	**Review Recommendations:** **Shared Learning for Improvement**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**Priority**
43. S-M	The Trust should review the Terms of Reference, including membership, and strengthen the purpose of the Lessons Learned Forum.	Partially accepted	Systematic Improvement in cross-directorate approaches Improve Connectivity across the Integrated Governance Framework	See potential weakness below	High
Potential Weakness	The review does not reflect the elements and pre-requisites necessary for the sharing and implementation of 'lessons learned' systematically across the organisation and supporting the necessary multi-disciplinary involvement.				

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	- The resourcing and form of this function or options for it are not described - The implementation of this recommendations will be influenced by the 6 IHRD recommendations which refer to 'learning' including clinician being afforded time to consider and assimilate learning and feedback from SAI investigations within contracted hours and Director level training - The lessons learned forum will have pre-requisites of clinical engagement to review the ToR, specification of the assurance reporting required, capacity (i.e. the experts, admin support, ICT infrastructure) to support the information and assurance. - Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs)				
4.0. Findings & Analysis / Timescale	**Review Recommendations:** **Governance Information Management Systems (Datix)**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**Priority**
44. S-M	To ensure that the Trust maximises the potential for the use of patient safety software it is vital that a dedicated Datix systems administrator is appointed who can ensure the quality of data provided as this has been identified as a gap at present (see also Clinical and Social Care Governance Structures below).	Accepted	Improvement in accountability and assurance	Engagement, specification of the assurance reporting required, capacity (i.e. the experts, admin support and Datix and other IT infrastructure investment) to support the information and	High

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				assurance.	
Potential Weakness	The review acknowledges that adequate resourcing is required to optimise the potential for the use of patient safety software. Pre-requisites. - Specification of the assurance reporting required and capacity (experts in data and safety science, admin support and ICT infrastructure) to support the information and assurance. - Data collection and reporting infrastructure (Datix, QlikView etc.) - Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs)				
4.0. Findings & Analysis / Timescale	**Review Recommendations:** **Corporate Clinical and Social Care Governance Structures**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**PriorityH**
45. S	It is recommended that the Corporate Clinical and Social Care Governance team is re-structured and two additional Senior Manager posts are considered to provide leadership to related functional areas. Therefore, it is further recommended that there is an urgent review of the administrative resources and business case development.	**Partially accept**	Improvement in accountability and assurance Improvement in IGF connectivity	See potential weakness below	**High**
46. M	The Trust should ensure that the directorate governance reporting arrangements are included in a review of Trust Board Sub Committee Structure and the review of the SMT Terms of Reference as above	Accepted	Improvement in accountability and assurance Improvement in IGF connectivity	See potential weakness below	**High**
Potential Weakness	- The review does not describe what a 'Good' structure would look like and as a consequence what a 'whole' governance approach to the organisation (or options for achieving this) is not defined. The review does not reference the requirement for robust safety measurement, indicators or expertise to provide assurance.				

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	Prerequisites include - A review of the integrated governance framework. This would include an appraisal of the systems and structures to deliver integrated governance, processes and behaviours. The timescale suggested is therefore likely to be independent of these considerations. However this **would be essential to help remedy the limitations identified under section 2.0, page 2 of this draft response.** This will allow for triangulation of information and assurance. The review does not consider the investment required to undertake such a review. - Specification of the assurance reporting required and capacity (experts, admin support and ICT infrastructure) to support the information and assurance. - Engagement and development of ToR. This could be included with SMT workshop (above) - Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs) are not described in the review				
4.0. Findings & Analysis / Timescale	**Review Recommendations:** **Corporate & Directorate CSCG Interface**	**Draft Response Opinion Accepted / Not Accepted**	**Improvement / Gap Identified**	**Dependency / Pre-Requisite**	**Priority**
47. S-M	It is recommended that the agenda, membership and timeliness of the weekly Governance Meeting is reviewed and terms of reference developed. The meetings should be kept as short briefing meetings and held face to face with members. There should be a short summary template report developed which can then be used as an internal communication to NEDs.	**Accepted**	Improvement in accountability and assurance Improvement in IGF connectivity	See potential weakness below	**High**
48. M	Monthly Clinical and Social Care Governance Meeting -In light of the weekly governance meeting, it is recommended that a review of the terms of reference including purpose, membership and frequency is undertaken.	**Accepted**	Improvement in accountability and assurance Improvement in IGF connectivity	See potential weakness below	**High**
Potential	The review acknowledges that there are existing systems in place which should be further developed to provide a briefing summary to				

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Weakness	SMT, the Chair and Non-Executive Directors, however does not reflect the pre-requisites required to support the information and assurance Pre-requisites - A review of the integrated governance framework. This would include an appraisal of the systems and structures to deliver integrated governance, processes and behaviours. The timescale suggested is therefore likely to be independent of these considerations. However this **would be essential to help remedy the limitations identified under section 2.0, page 2 of this draft response.** The review does not consider the investment required to undertake such a review - ToR, engagement, specification of the assurance reporting required, capacity (i.e. the experts, admin support and ICT infrastructure) to support the information and assurance - Capacity and Demand Modelling for the Governance areas vs Manpower (any benchmark comparisons to other HSCs or NHSFTs) are not described in the review

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31 Day Cancer Performance Target = 98% (Red denotes breach of target) Urology Tumour Site													
Fiscal Year	**April**	**May**	**June**	**July**	**August**	**September**	**October**	**November**	**December**	**January**	**February**	**March**	**Full Year Cumulative Performance**
2018/2019	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	92.86%	100.00%	100.00%	100.00%	**99.41%**
2019/2020	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	91.30%	100.00%	100.00%	100.00%	100.00%	95.83%	**98.93%**
2020/2021	92.86%	94.44%	100.00%	94.44%	94.44%	83.33%	100.00%	100.00%	91.67%	84.62%	100.00%	100.00%	**94.65%**
2021/2022	95.65%	100.00%	100.00%	100.00%	100.00%	100.00%	92.31%	100.00%	100.00%	85.71%	100.00%	100.00%	**97.81%**

62 Day Cancer Performance Target = 95% (Red denotes breach of target) Urology Tumour Site													
Fiscal Year	**April**	**May**	**June**	**July**	**August**	**September**	**October**	**November**	**December**	**January**	**February**	**March**	**Full Year Cumulative Performance**
2018/2019	80.00%	50.00%	65.85%	68.00%	65.22%	81.48%	45.71%	35.29%	26.09%	44.44%	53.85%	37.04%	**54.41%**
2019/2020	84.21%	50.00%	59.09%	41.18%	66.67%	33.33%	27.03%	34.38%	26.09%	25.81%	29.63%	21.62%	**41.59%**
2020/2021	13.04%	10.53%	60.00%	45.83%	64.29%	53.33%	40.74%	33.33%	8.70%	9.09%	16.67%	29.63%	**32.10%**
2021/2022	29.63%	6.67%	33.33%	66.67%	48.00%	16.67%	20.00%	27.27%	23.06%	21.05%	12.50%	20.69%	**27.13%**

Information Source - Business Objects, Completed Waits Report ran at 16/05/2022

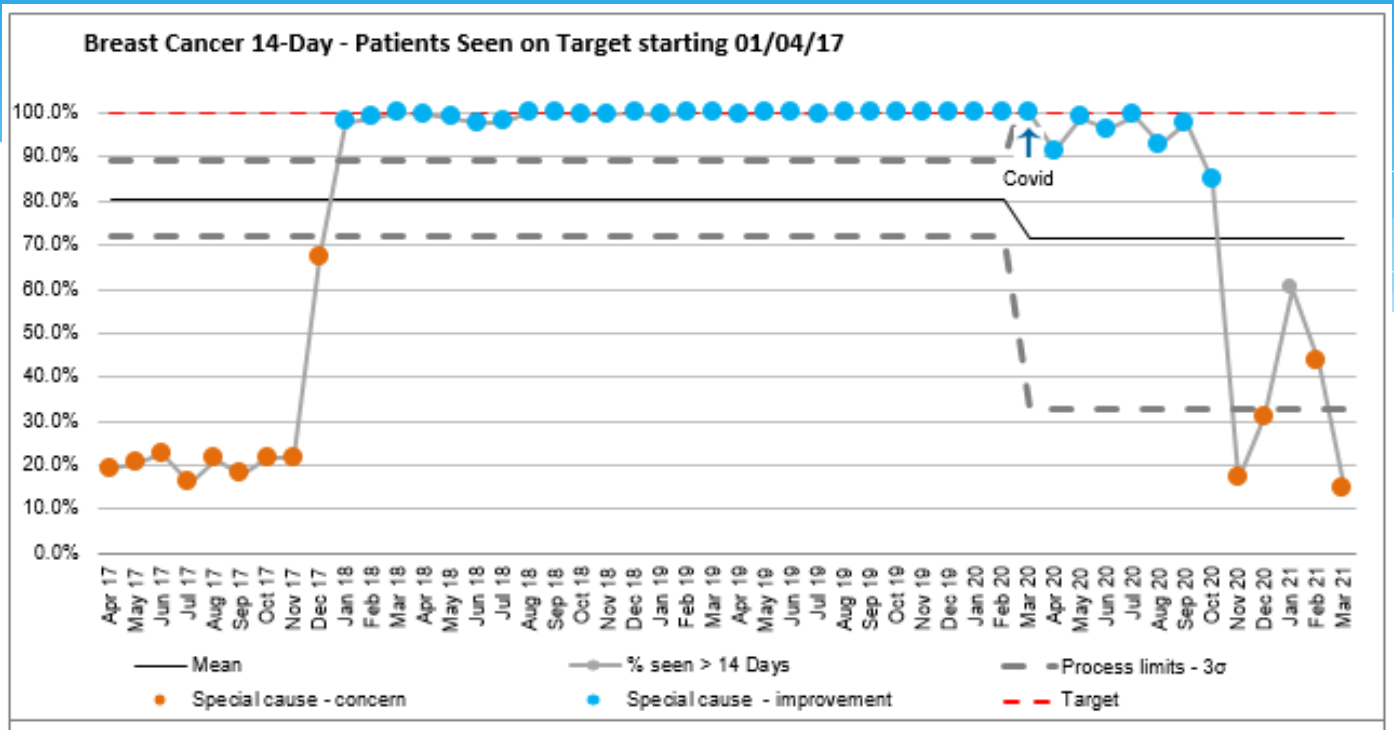
Southern Health and Social Care Trust
Performance Committee

Agenda Focus: Cancer Services

Acute Services Directorate

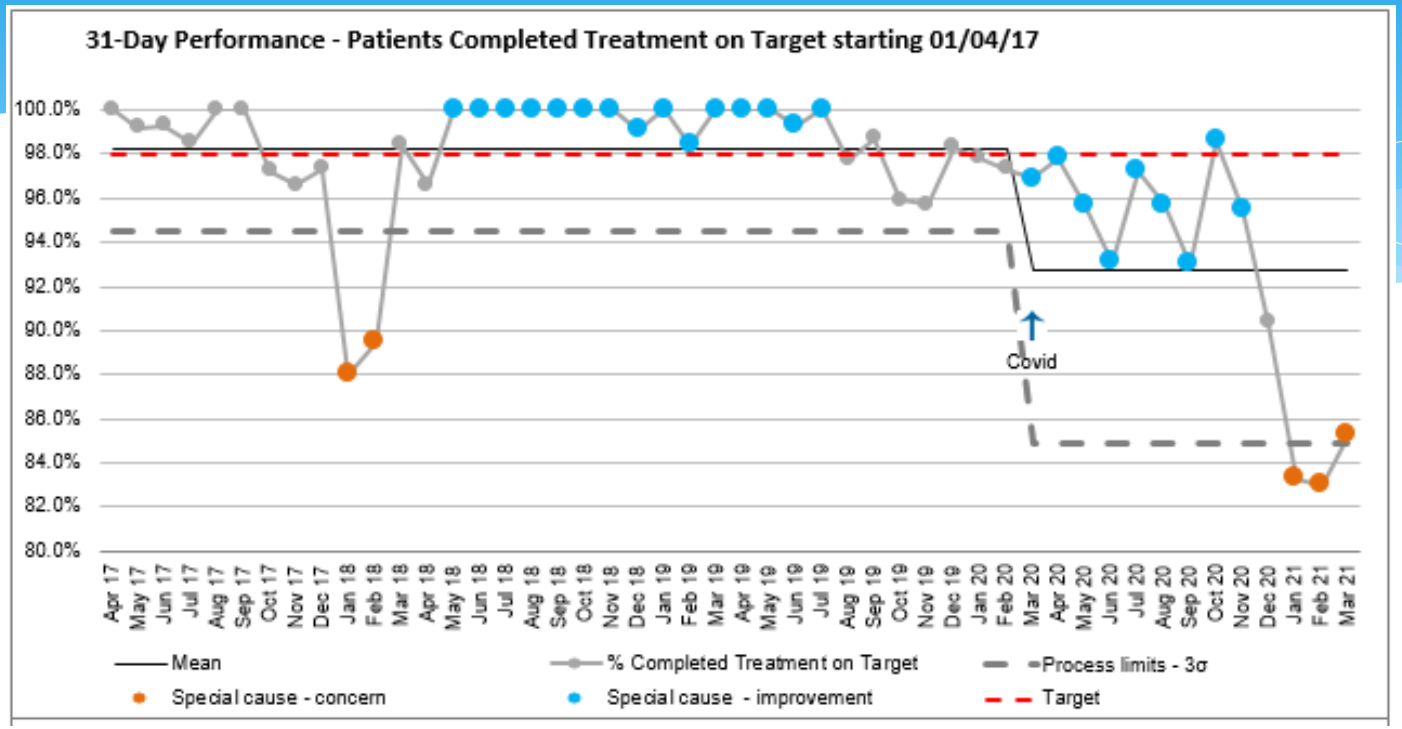
20 May 2021 – Performance Committee

Elective Access OGI



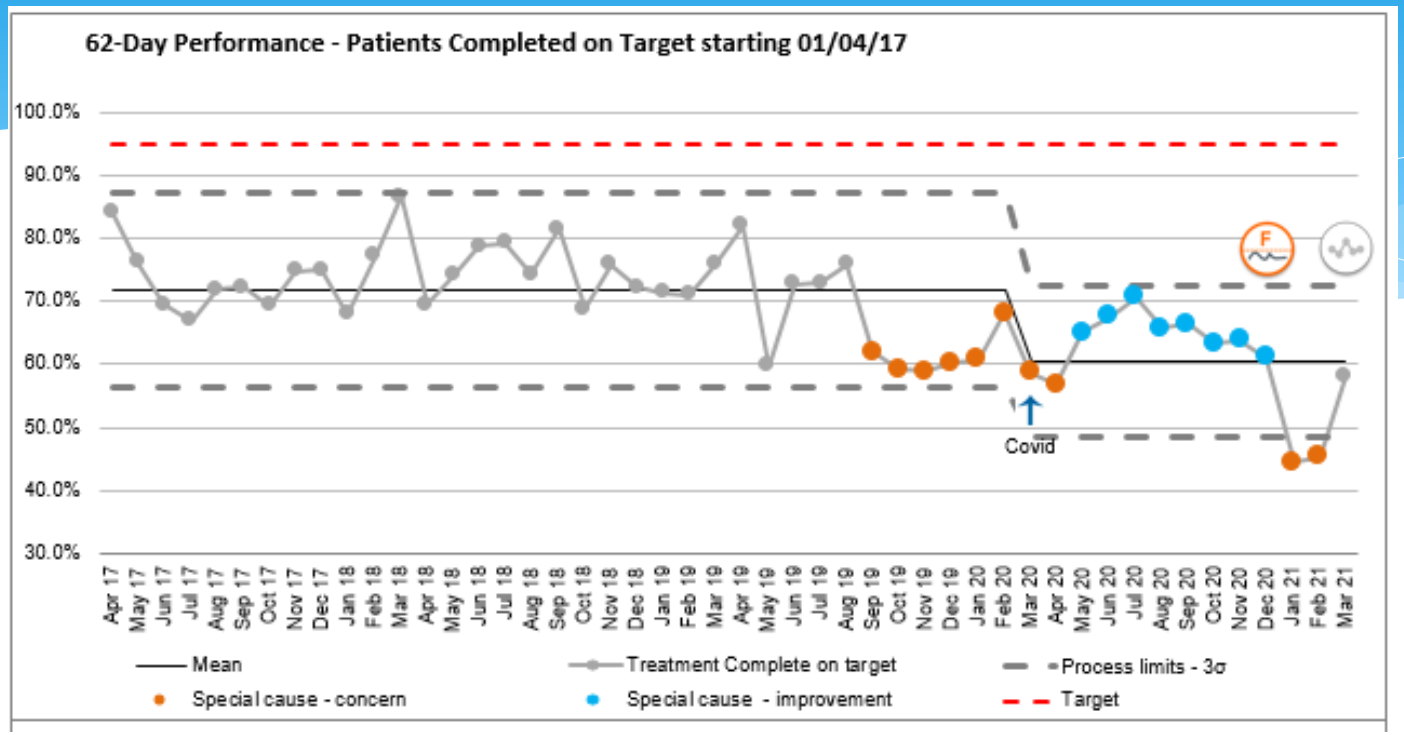
Target	January 2019	January 2020 (Pre-Covid)	January 2021 (Covid Surge 3)
14-Day	99% (268 out of 270)	100% (252 out of 252)	60.2% (154 out of 256)

Elective Access OGI



Target	January 2019	January 2020 (Pre-Covid)	January 2021 (Covid Surge 3)
31-Day	100%	98%	83%

Elective Access OGI

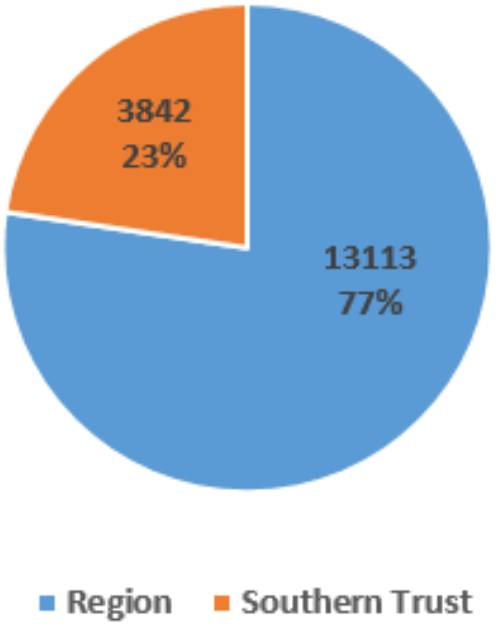


Target	January 2019	January 2020 (Pre-Covid)	January 2021 (Covid Surge 3)
62-Day	71% Longest wait 356-days	61% Longest wait 213-days	44% Longest wait 456-days

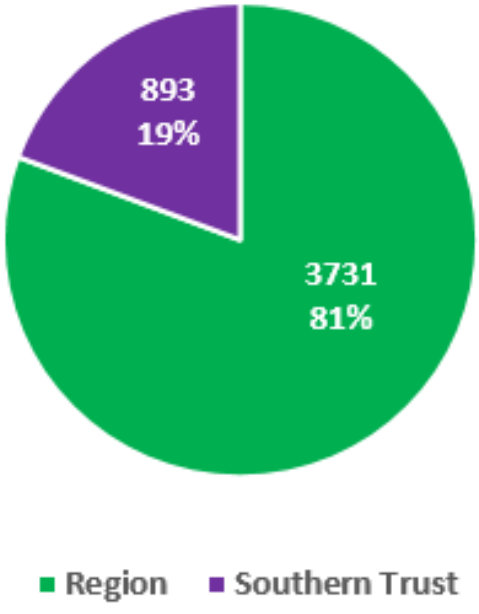
Regional Performance

Southern Trust Actively Tracking 5,170 patients on Cancer Pathways
(3,840 62-Day and 1,330 31-Day Pathway)

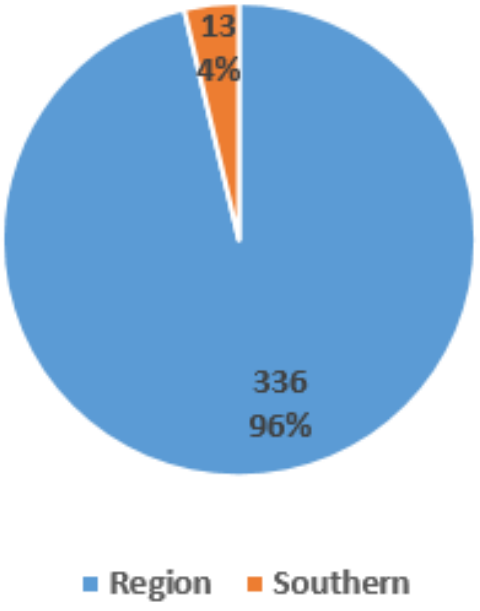
62-Day



>85-Days

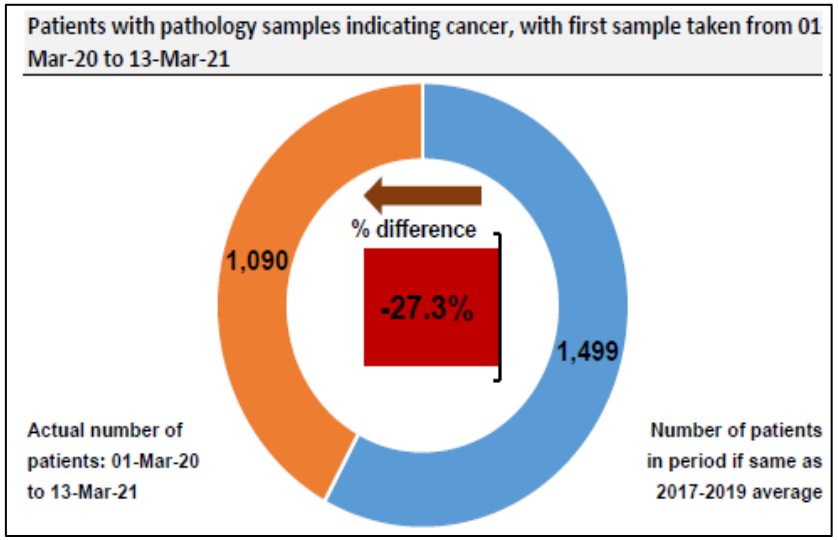


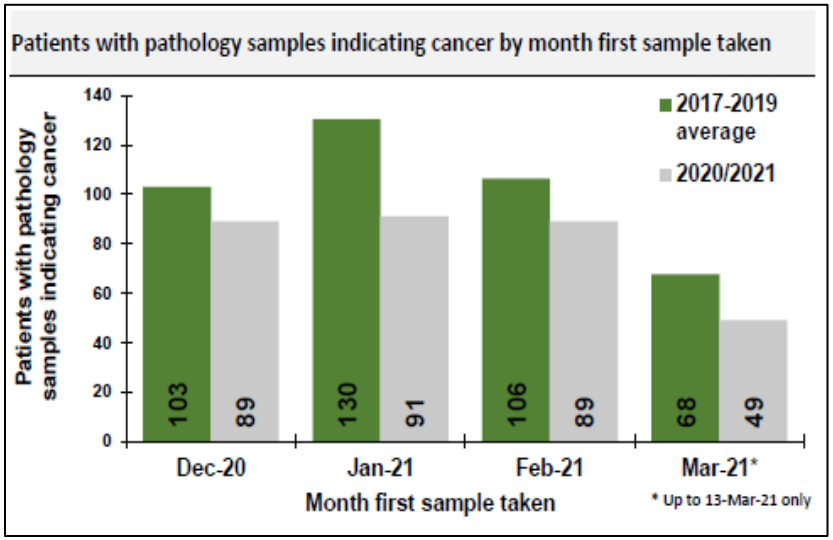
31-Day



62-Day Longest Wait Southern @ 469-Days / Regional @ 532-Days

NI Cancer Registry





Cancer Services Issues / Actions

* **Issues:**
  - Decrease in referrals during Pandemic
  - 'Missing' patients
  - Backlogs and increased volumes patients waiting longer
  - Capacity gaps pre-Covid – scopes; CT; out-patients
  - Service vulnerability pre-Covid – oncology and haematology
  - Theatre nursing constraining surgical developments
  - Changing profile of patients

Cancer Services Issues / Actions

* **Actions: Local –**
  - Fortnightly Cancer Checkpoint Meetings with multidisciplinary team representative from tumour sites, assessing pressures and actions
  - Weekly clinically led Theatre Priority Group
  - Balance between virtual and face-to-face consultations
  - Straight to test for certain patient groups
  - Radiology investigations expedited, eg, patients waiting CT guided biopsy
  - Q-Fit implemented for risk stratification on LGI & LGI pathways
  - Clinic templates adjusted to see more red flag patients
  - Close links with Regional Cancer Reset Cell
* **Actions: Regional -**
  - 3-year costed plan covers entire pathway except surgical
  - Aligned to draft recommendations in cancer strategy
  - Significant programme of modernisations focusing on improving patient outcomes and experience
  - 11 key work streams
  - Aims to create a smoother and more efficient pathway; and ensuring patients have equitable access to diagnostics; care; treatment; and support

Regional Recovery Plan Workstreams

1. Supporting People
2. Screening
3. Awareness and Early Detection
4. Safety Netting and Patient Flow
5. Diagnostic - Imaging
6. Diagnostics – Colposcopy
7. Diagnostics – Endoscopy
8. Diagnostics – Pathology
9. Prehabilitation and Rehabilitation
10. Oncology and Haematology
11. Palliative Care

Cost

- Recurrent cost 3 years £82.53m
- Non-recurrent cost £20.23m
- Capital investments £11.31m

Challenges

- Workforce
- Infrastructure
- Broader context

Next Steps

- RMB for ratification
- Subject to RMB support – to be presented to the NI Executive

Professional Issues

* Medical Staffing – Workforce Issues for oncology & haematology

* Nursing – Major theatre nursing challenges

* Technical – Tracking Resource Pressures – recognition Regionally of challenges and recent approval for non-recurrent funding to maintain required resources

Any Questions?

Record of Regional Prioritisation Oversight Group: 4 October 2021

Attendees:

SET	Ian McAllister, Chris Allam and Rachel Deyemond,
BHSST	Stephen Boyd and Samantha Sloan
NHSCT	Barry McAree and Lorraine Mc Donnell
WHSCT	Geraldine McKay and Alex MacLeod
HSCB	David McCormick and Sorcha Dougan

Elective Cell Clinical Representatives: Mark Haynes and Rosie Hogg

Apologies: Lisa Mc Williams, Mark Taylor, Ted McNaboe, David Robinson

Minutes of Last Meeting

1.0 Minutes of the meeting were agreed.

2.0 Outstanding Actions

It was noted that good progress made to resolve the outstanding coding issues pertaining to the P2 waiting list data in Belfast Trust. However the Trust was still using an "absolute priority" code which included procedures such as flexible cystoscopies and circumcisions. It was agreed that this data should be reviewed and priority patients recorded as either P2A, P2B or P2D.

Action 1: Belfast Trust to review and recode absolute priority patients

It was noted that RPOG had previously discussed the issue of Orthopaedic P2 patients. It was highlighted that this cohort of patients normally had access to dedicated theatres and beds and therefore were not competing for other theatre capacity. It had been previously agreed that these waits would be separately monitored outwith the normal P2 returns. It was agreed that each Trust needed to record orthopaedic waits in the same way to ensure data consistency.

Action 2 – Each Trust to review and identify their orthopaedic P2 waiters. Belfast to update any briefings internally and for external parties that currently include Orthopaedics within their P2 numbers.

It was advised that the Southern Trust had reviewed their P2 colorectal patients and had identified that a number of these patients were either at different stages of pre-operative treatment or not medically fit. The Trust confirmed that the remaining patients could be managed within the HSC. It was agreed that there was a possibility that there may be other P2 Patients who are currently on the waiting list but not ready for surgery.

Action 3 – Trusts should ensure that the P2 waiting lists are validated

It was noted that UIC have been approached to secure further theatre capacity for paediatric surgery. It was also confirmed that the Southern Trust could accommodate paediatric surgery on the DHH site but would require additional nurses to support the service and medical patients moved out of recovery beds. It was agreed that the HSCB would provide an update on the work force appeal.

Action 4 – HSCB to provide an update on work force appeal at next RPOG meeting

Prioritisation Data

3 The Trust returns as at Friday 1 October indicates that there are approximately 4,714 priority 2 patients currently waiting for a treatment date in theatre. In addition there were a further 365 P2 patients waiting on Belfast only specialist services. The breakdown of the 4,714 P2 patients by Trust was as follows: Belfast 2,688, SET 626, Western 493, Southern 474 and Northern 433.

It was also noted that approximately 30% of all Belfast P2 waits were ENT (ie 981) and this volume of patients was far greater than the ENT P2s recorded in other Trusts. It was also highlighted that the number of P2 ENT patients was not reflective of the internal allocation of theatre capacity in Belfast Trust where only one list had been allocated to ENT out of the 70+ lists.

Action 5 – Belfast Trust to review prioritisation of ENT patients

Emerging Pressures

4 All Trusts reporting the same pressures with lack of access to theatres and in-patient beds. It was acknowledged that the lack of nursing was a key limiting factor in preventing the expansion of surgical capacity.

It was agreed that RPOG representation was required on the Critical Care Network to ensure that the redeployment of nursing staff, currently used to support critical care, better reflects the changing covid conditions and allows greater agility in service provision. The ability to react quickly to downturns in the current and subsequent surges will ensure that Trusts are able to flex their surgical capacity and ensure that throughput on green sites and across green pathways is maximised.

Action 6: The HSCB to liaise with the Critical Care Hub, via Paul Cavanagh, to confirm elective cell representation.

In-house Capacity – Week Beginning 11 October

5 Across the region there are approximately 255 theatre lists scheduled for the week of 11 October

6 Belfast Trust plan is to have 81 lists scheduled ie BCH – 40 sessions, RVH – 41 sessions and no elective lists in MPH.

7 Northern Trust is scheduling 35 theatre sessions (20 IP and 15 day case) ie Causeway site – 17 lists (11 GA and 6 day case), Antrim 14 sessions (9 GA and 5 day case) and Whiteabbey site – 4 lists.

8 SET is scheduling 67 urgent theatre lists (30 IP and 37 day case) of which 31 will be released for regional specialties. Ulster – 36 lists (17 tertiary), LVH – 19 day case lists (4 tertiary and 6 regional) and Downe – 12 elective lists (10 regional).

9 The Southern Trust is scheduling 13 theatre sessions (8 IP and 5 day case) ie CAH- 6 GA lists, CAH – 2 day case lists and DHH – 5 day case/IP lists.

10 The Western Trust is scheduling 59 lists (19 IP and 40 day case) ie AAH – 16 GA lists and 21 day case lists, Omagh 18 day case and SWAH – 3 GA lists and I day case list.

IS Capacity – Week Beginning 18 October 2021

11 For the period 18 October, 6 GA theatre lists have been confirmed in UIC and 1 GA and 3 LA lists in KPH.

12 It was agreed that the 7 GA theatre lists will be prioritised for urology - 3 lists, Breast - 2 lists and gynae - 2 lists with the other 3 LA lists allocated to neurosurgery, ophthalmology and urology. The allocation by Trust was as follows: Belfast – 7 lists and Southern Trust – 3 lists

13 Southern Trust confirmed that £700k had been allocated to support a regional TURP initiative which would enable patients to be treated in Hermitage Dublin. It was noted that these were likely to be catheterised patients who will need care assessment to identify suitable patients. It was agreed that urgent TURP waiting list data would be extracted to ensure equitable allocation of capacity.

Action 7: PMSID to extract data from Urgent TURPs Waiting List

14 In relation to the Musgrave House orthopaedic initiative, Western Trust noted there was a hold up in drugs license and final steps had been taken to resolve the outstanding issues. Once signed off should move at pace. Again this capacity would be allocated on an equitable basis to reflect the current waiting lists across the region

15 The HSCB confirmed that they had contacted Mark Regan to arrange a meeting to discuss the proposed increased capacity in the North West Independent Hospital site. HSCB agreed to feedback once meeting had taken place

Action 8: PMSID to update on NWIH capacity

Activity Delivered (w/c 27 September)

14 For the week beginning 27 Sept, there were approximately 40 procedures undertaken in the 11 GA theatre lists and 1 LA lists which had been made available by the IS for regional priority patients.

15 In addition there were 3,268 procedures undertaken in-house. The inpatient activity equates to 454 and the breakdown by Trust and Trust of residence is detailed below.

Residence	Belfast	Northern	SET	Southern	Western	TOTAL
Belfast	66	1	17			84
Northern	64	45	4		11	124
SET	45		40			85
Southern	37		6	38		81
Western	17			1	62	80
Total	**229**	**46**	**67**	**39**	**73**	**454**

Rescheduling of Cancelled Cancer Patients

15 For patients scheduled to be admitted during the period 26 July – 3 October 2021, there were 655 (suspect or confirmed) cancer procedures cancelled by HSC Trusts. Of these, 99 are still waiting on a confirmed treatment date.

Lisa McWilliams

Southern Health and Social Care Trust

Quality Care - for you, with you

SHSCT Urology Cancer Service

---Annual Report---

(1st January 2019 to 31 December 2019)

Report Author	Mr Anthony Glackin
Position	Clinical Lead for Urology Cancer Team
Organisation	Southern Health & Social Care Trust
Signature	Personal Information redacted by the USI
Date to be Approved at AGM	5th November 2020

This Annual Report is to be reviewed and approved by the Urology MDT following the annual general meeting held on 5th November 2020. Following approval the report will be circulated to the members as a final approved version.

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1.0 INTRODUCTION

This annual report relates to the operational period 01/01/2019 – 31/12/2019 for the Southern Trust Urology Multi-disciplinary Team (MDT) and the clinical data presented relates to patients diagnosed in this period.

2.0 KEY ACHIEVEMENTS

The main achievements for the service during 2019 were:

- Funding secured to recruit x2 B7 nurses, one with a focus on cancer and one for benign disease
- Equipment secured to enable the delivery of Transperineal (TP) prostate biopsy

3.0 KEY CHALLENGES

Oncology and Radiology

The greatest challenge for the MDT during the past year has been the inadequacy of the availability of a clinical oncologist and or a radiologist at all MDMs. The inadequacy in both cases has essentially been due to the inability to recruit adequate numbers of clinical oncologists and radiologists to the post where they are required. The inadequacy has been addressed with the appointment authorities.

Red Flag Referrals

There has been an increase in the number of Red Flag referrals throughout Northern Ireland during the past few years. In Southern trust there was a 16% increase of red flag referrals from 2017 to 2018 with a slight reduction of 8% in 2019.

Breakdown of Red Flag Referrals 2017-2019

	2017	2018	2019
62D RF	1640	1925	1791
Other - 31D	418	531	479
Total	**2058**	**2456**	**2270**

Performance

For 2019, the 31 day performance for the SHSCT was 98.4% and the 62 day performance was 47.9% - this reflects the marked increase in GP red flag referrals for the trust.

As there has been an increase in Red Flag referrals over the past few years, this has been reflected in the Cancer Performance data. The monthly average waits for an appointment between September-December 2019 were as follows:

Prostate: 70 day wait
Haematuria: 49 day wait
Others: 28 day wait

The diagnostic and operative activity has been reflected in an increase in the numbers of specimens received by the Cellular Pathology Laboratory at Craigavon Area Hospital up to 2017. Tissue specimens increased from 903 in 2016 to 932 in 2017, but there has been a decrease in 2018 (898) and in 2019 (859).

Even though not all tissue specimens were known, suspected or found to be cancerous, the analysis of the tissue type below demonstrates the varied spread of organ biopsies and resections. Biopsies and resections of prostate and bladder comprise the bulk of urological pathological diagnostic activity.

SPECIMENS	2012	2013	2014	2015	2016	2017	2018	2019
Prostate Biopsies	345	225	248	340	318	347	335	293
TURP	158	141	163	176	147	112	142	117
Bladder Biopsies	182	253	224	205	180	180	146	170
TURBT	78	70	115	120	123	158	163	146
Testis Biopsies	-	-	4	8	5	7	4	7
Testis	28	37	36	38	32	27	30	28
Renal Biopsies	-	-	24	14	12	12	7	11
Kidney	28	33	46	76	77	74	56	72
Penile Biopsies	6	9	13	13	7	13	13	10
Penis	4	3	1	3	2	2	2	5

It is notable that there has been a decrease in the numbers of Prostate biopsies in 2019 which reflects the use of MRI to avoid unnecessary TRUS biopsy.

The increase in kidney biopsies is in part due to cases being referred from outside the Southern Trust.

Operative Capacity

The main limiting factor in providing a complete cancer service is operating theatre capacity and operator time. Though the MDT has provided for the increased demand on Red Flag pathways, it has been at the expense of patients having, or suspected of having, recurrent bladder tumours, and those awaiting prostatic resection to facilitate their progress to radical radiotherapy for prostatic carcinoma having to wait increasingly longer periods of time for surgery, in addition to all those with non-cancerous pathology. This is a common and concerning experience across Northern Ireland, and will remain an increasing challenge until operative capacity is increased.

Conduct of MDM

The quality of the conduct of MDM has been a singular achievement these past six years. The quality of participation has been enhanced by increasing the number of persons chairing, and by having time allocated for preview.

Development Priorities

In addressing the concerns raised at Peer Review and the findings of Patient Satisfaction Surveys, it has been agreed that the team would endeavour to make substantial progress in the implementation of Key Worker, Holistic Needs Assessment, Communication and having a Permanent Record of Patient Management. With the appointment of two more Nurses to the Thorndale Unit and Clerical Staff, all newly diagnosed patients should have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner. It is intended that patients newly diagnosed as inpatients will be included.

Conclusion

While a firm MDM foundation has now been established, and while much success has been achieved during the past year, there remain inadequacies and challenges which are to be addressed in the coming year.

4.0 MDT ATTENDANCE 2019

The Urology MDM takes place every Thursday from 2.15 pm to 5 pm (at the latest) in Tutorial Room 1, Craigavon Area Hospital, with videoconferencing available to Daisy Hill Hospital. The attendance is monitored by the MDT Coordinator. There were 43** meetings held in 2019. The dates of the MDT meetings can be seen in **Appendix 1** along with an attendance spread-sheet for core members and extended members.

there were 43 MDT meetings and a further 8 virtual meetings held to progress the care of patients

Table 1: Urology MDT Attendance record January 2019 – December 2019

Name	Role	Attended	DNA	% Attended	% Attendance by core /cover
	Surgeon				**100%**
Mr A Glackin*	Surgeon	35	8	81	
Mr M Haynes	Surgeon	37	6	86	
Mr A O'Brien	Surgeon	33	10	77	
Mr J O'Donoghue	Surgeon	29	14	67	
	Radiologist				**70%**
Dr M Williams	Radiologist	25	18	58	
Cover	Radiologist	5	38	12	
	Pathologist				**95%**
Dr G McClean	Pathologist	39	4	91	
Dr R Shah	Pathologist	1	42	2	
Dr A Ervine	Pathologist	1	42	2	
Clinical oncologist representation(regional)	**Clinical Oncologist**	2	41	5	**5%**
	Urology Specialist Nurse				**98%**
Kate O'Neill**	Urology Specialist Nurse	39	4	91	
Leanne McCourt	Urology Clinical Sister	29	14	67	
	Palliative Nurse Specialist				**95%**

Stephanie Reid	Palliative Nurse Specialist	33	10	77	
A Palliative Nurse Specialist	Palliative Nurse Specialist	8	35	19	
	MDT Co-ordinator				**100%**
Shauna McVeigh	MDT Co-ordinator	36	7	84	
A MDT Co-Ordinator	MDT Co-ordinator	7	36	16	

- *Responsible for clinical trials & research
- **Responsible for users issues and patient information

The MDT quorum for 2019 was 2% as there was only 1 meeting that was quorate. There were two meetings that had Clinical Oncology representation at the MDT meetings.

4.1 Attendance at Network Clinical Reference Group Meetings

There were 4 meetings of the Urology Clinical Reference Group (CRG) held during 2019. Details of the attendees are listed below.

DATE of CRG MEETING	***ATTENDEES***
5/03/19	Mark Haynes; Gareth McClean; Mary Haughey; Kate O'Neill; Leanne McCourt
18/06/19	Mark Haynes; Kate O'Neill; Leanne McCourt
24/09/19	Mark Haynes; Gareth McClean; Kate O'Neill; Leanne McCourt
03/12/19	Mark Haynes; Gareth McClean; Kate O'Neill; Leanne McCourt

5.0 MDT Workload January to December 2019

Workload	**Number**
Meetings	51
Number of discussions	1286
Number of patients	845
Number of new patients	806

5.1 Number of New Diagnoses 2019

Final MDM Diagnosis	Number
Prostate	286
Bladder	134
Kidney	83
Testicular	13
Penile	8
Ureter/ureteric orifice	3
Total	**527**

5.2 Cancers by referral source 2019

Referral type	No. of referrals
GP Red Flag	**1537**
Consultant Upgrade	**254**
Other consultant referrals	**479**
Total	**2270**

5.3 Breakdown of first definitive treatments in 2019

The table below provides a breakdown of first definitive treatments of Urology patients on 31 and 62 day pathways during 2019.

Breakdown of first definitive treatment Jan-Dec 2019

Treatment	31 Day	62 Day	Total
Surgery	61	93	154
Palliative	1	0	1
Chemo	3	3	6
Radiotherapy	9	16	25
Brachytherapy	3	8	11
Hormone Therapy	43	110	153
Other treatment	3	0	3
No treatment	1	0	1
Active monitoring	37	35	72
Watchful waiting	9	3	12
Total	**170**	**268**	**438**

5.4 Breakdown of cancer waiting times performance

The table below summarizes the performance of Urology patients on 31 and 62 day pathways. Cancer Access Standards mandate that 98% of patients have their definitive treatment within 31 days of decision to treat (when the treating consultant agrees the treatment with the patient) and 95% of patients on a 62 day pathway are given their first definitive treatment within 62 days of suspect GP referral or consultant upgrade. The 31 day performance for the SHSCT was 98.4% in 2019 and the 62 day performance was 47.9%. Pathway breaches are considered at Trust Performance meetings and reasons detailed and escalated as appropriate. The majority of breach reasons are due to the complexity of the pathway, with multiple investigations and discussions often required to obtain a diagnosis and agree a treatment plan.

31 day and 62 day performance from Jan-Dec 2019

	31 Day Performance				62 Day Performance			
	Over Target	**Within Target**	**Total**	**% Within Target**	**Over Target**	**Within Target**	**Total**	**% Within Target**
Jan-19	0	30	31	**96.8**	12.5	11.5	24	**47.9**
Feb-19	1	22	23	**95.7**	6	8	14	**57.1**
Mar-19	0	21	21	**100.0**	8.5	5	13.5	**37.0**
Apr-19	0	22	22	**100.0**	3	16	19	**84.2**
May-19	0	26	26	**100.0**	9	9	18	**50.0**
Jun-19	0	35	35	**100.0**	9	14	23	**60.9**
Jul-19	0	26	26	**100.0**	10	7	17	**41.2**
Aug-19	0	27	27	**100.0**	5.5	11	16.5	**66.7**
Sep-19	0	33	33	**100.0**	16	8	24	**33.3**
Oct-19	2	22	24	**91.7**	13.5	6	19.5	**30.8**
Nov-19	1	25	26	**96.2**	10.5	3.5	14	**25.0**
Dec-19	0	21	21	**100.0**	8.5	4	12.5	**32.0**
Totals	**4**	**310**	**315**	**98.4**	**112**	**103**	**215**	**47.9**

Trends for breaches

- Delay in 1st out-patient appointment
- Delay in reporting of MRI scans / delay in discussion at MDT due to no radiologist being present
- Accessing TRUSB appointments due to capacity issues
- Complex cases requiring multiple MDT discussion

6.0 Advanced communication skills training

This has been identified as an area for development. The following members of the MDT have participated in Advanced Communication Skills training and the remaining core members will be offered a position when courses are available in the trust:

NAME	ROLE
Aidan O'Brien	Consultant Urologist
Kate O'Neill	Clinical Nurse Specialist
Stephanie Reid	Palliative Nurse Specialist
Tony Glackin	Consultant Urologist
John O'Donoghue	Consultant Urologist
Leanne McCourt	Clinical Sister

7.0 Patient Experience

The Public Health Agency with support from Macmillan Cancer Support commissioned a second regional Cancer Patient Experience Survey (CPES) in 2018. A total of 6,256 patients who had received treatment for cancer during March 2017 to October 2017 were included in the sample for the regional Cancer Patient Experience Survey 2018. The response rate for NI was 57% (3,478) and 473 questionnaires returned were from Southern trust patients. Reports are available at regional and trust levels.

Respondents by Tumour Group

Tumour Group	Number of respondents*
Urological	79
Prostate	17

Summary of results for Urological patients

Overview of positive results (Trust score higher than NI score >5%)

Q12. Given written information about their cancer when told they had cancer
Q14. Possible side effects explained in a way they could understand
Q15. Before treatment, they were given written information about the side effects
Q16. Before treatment, they were told about future side effects
Q17. Thought they were involved as much as wanted to be in decisions about their care and treatment
Q18. Were given the name of a CNS who would support them through treatment
Q19. Found it easy to contact CNS
Q27. After the operation staff explained how it had gone in a way they could understand
Q40. Were given written information about what they should / shouldn't do after leaving
Q44. While being treated, they were able to find someone on the staff to discuss worries and fears**
Q50. Had all of the information they needed about their chemotherapy
Q51. Were given information about if chemotherapy was working in an understandable way
Q52. Staff gave family / friends information they needed to help care for you at home
Q58. Were offered a needs assessment and care plan**

Q60. Were happy with length of time waiting when attending clinics and appointments

Overview of declined results (Trust score lower than NI score by > 5%)

Q21. Hospital staff gave information about support or self-help groups
Q23. Hospital staff gave information about how to get financial help or any benefits
Q33. Had confidence and trust in the ward nurses treating them
Q38. Thought the hospital staff did everything they could to help control their pain
Q39. Overall, felt they were treated with respect and dignity while in the hospital
Q48. Given information about if radiotherapy was working in an understandable way
Q61. Since diagnosis someone discussed whether they would like to take part in cancer research

7.1 Regional results for Prostate patients

- Majority of NI scores were more than 75% (34 questions)
- 10 questions scored less than 75%

Scores which are 75% or lower:

Q12. When told they had cancer, they were given written information about their cancer
Q16. Before treatment were told about future side effects
Q23. Hospital staff gave information about how to get financial help or any benefits
Q37. During hospital visit was able to find a staff member to discuss their worries and fears
Q48. Were information about if radiotherapy was working in an understandable way
Q52. Staff gave family / friends the information they needed to help care for you at home
Q53. During treatment, felt they were given enough care & support from health / social services
Q54. Once treatment finished, felt they were given enough care & support from health / social services
Q58. Were offered a needs assessment and care plan
Q61. Since diagnosis, did some discuss whether they would like to take part in cancer research

Regional priorities for improvement:

- Care plans & Needs Assessment – Key CNS role
- Engagement with GPs
- Communication around worries & fears
- Side effects
- Research & Clinical trials

Due to the low response rate from patients with a urological cancer, including prostate cancer, a local patient experience survey was rolled out in March 2020 to 118 patients who were diagnosed with a prostate, renal or bladder cancer in the preceding 12 months. There was a response rate of 58% (i.e.68 patients).

Further details from the CPES survey, the local patient survey and the resulting action plan are available in **Appendices 2,3 and 4.**

8.0 Communication of diagnosis to GPs

When a patient is given a diagnosis of Urological Cancer, the aim of the MDT is that the patient's GP is informed by the end of the next working day of the consultation via a typed letter from the responsible consultant. An audit of GP timeliness of communication was carried out. Please refer to **Appendix 5** for results of the audit.

9.0 Clinical Trials

The Urological clinical research activity in Craigavon during 2019 is detailed below:

Urology open studies:

UKGPCS: The UK Genetic Prostate Cancer Study (formerly Familial Prostate Cancer Study)
50 patients

See **Appendix 6** for further details of open trials from the NI Cancer Trials Network

10.0 Audit

The MDT reviews its data and discusses the progress of its audits annually as part of the MDT annual report at one of the MDT business meetings.

Please refer to **Appendix 7** for results of the following audits:

- TRUS Biopsy Audit 2018: Sr Kate O'Neill, presented January 2019

- Bladder Cancer Pathway Audit: Mr A Glackin & Mr M Evans, presented February 2019:

(*A snapshot audit of compliance with NICE guidelines for bladder cancer, areas for improvement identified a long lead time from referral to theatre for TURBT*)

The team had previously submitted data to the Nephrectomy dashboard, the British Association of Urological Surgeons (BAUS) data & audit database but are not able to contribute to the dashboard due to the current Northern Ireland data governance legislation in relation to secondary use of data. A change in this legislation is awaited.

Appendix 1: MDT Attendance spreadsheet 2019

MDM Dates	Mr Mark Haynes	Mr Anthony Glackin	Mr Aidan O'Brien	Mr John O'Donoghue	Mr M Tyson	Mr G Solt	CONSULTANT UROLOGIST	Dr Gareth McClean	Dr Rajeev Shah	Dr Aaron Ervine	CONSULTANT PATHOLOGIST	Dr Marc Williams	CONSULTANT RADIOLOGIST	CONSULTANT ONCOLOGIST	Ms Kate O'Neill	Mrs Leanne McCourt	CLINICAL NURSE SPECIALIST	Stephanie Reid	PALLIATIVE NURSE SPECIALIST	Miss Shauna McVeigh	MDT CO-ORDINATOR/TRACKER	Quorate
03/01/2019	1	1	1	1	0	0	1	1	0	0	1	0	0	1	1	0	1	1	1	0	1	No
10/01/2019	1	1	0	1	0	0	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
17/01/2019	1	0	1	1	0	0	1	1	0	0	1	0	1	0	1	1	1	1	1	1	1	No
24/01/2019	1	1	1	1	0	0	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
31/01/2019	1	1	1	0	0	0	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
07/02/2019	1	1	1	1	0	0	1	1	0	0	1	0	1	0	1	1	1	1	1	1	1	No
14/02/2019	0	1	1	1	0	0	1	1	0	0	1	1	1	1	1	0	1	1	1	0	1	No
21/02/2019	0	1	1	1	0	0	1	1	0	0	1	0	0	0	1	0	1	1	1	1	1	No
28/02/2019	1	1	1	0	0	0	1	1	0	0	1	0	0	0	0	1	1	1	1	1	1	No
07/03/2019	1	1	0	1	0	0	1	1	0	0	1	0	1	0	1	1	1	0	1	1	1	No
14/03/2019	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	
21/03/2019	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	
28/03/2019	1	1	1	0	0	0	1	1	0	0	1	1	1	0	1	0	1	1	1	1	1	No
04/04/2019	1	1	0	1	0	0	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
11/04/2019	1	1	1	1	0	0	1	0	1	0	1	1	1	0	1	1	1	1	1	1	1	No
18/04/2019	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	
25/04/2019	1	1	0	0	0	0	1	1	0	0	1	0	1	0	0	1	1	1	1	1	1	No
02/05/2019	1	0	1	1	0	0	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
09/05/2019	1	0	1	1	0	0	1	0	0	1	1	0	0	0	1	0	1	1	1	1	1	No
16/05/2019	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	
23/05/2019	1	1	1	1	0	0	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
30/05/2019	1	1	1	1	0	0	1	1	0	0	1	0	0	0	1	1	1	1	1	1	1	No
06/06/2019	1	1	0	1	0	0	1	1	0	0	1	0	0	0	1	1	1	1	1	1	1	No
13/06/2019	1	0	0	1	0	0	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
20/06/2019	1	1	1	1	1	0	1	1	0	0	1	1	1	0	1	1	1	0	1	1	1	No
27/06/2019	1	0	1	1	0	0	1	1	0	0	1	0	0	0	1	1	1	1	1	1	1	No
04/07/2019	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	
11/07/2019	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	
18/07/2019	1	0	1	1	0	1	1	0	0	0	0	0	1	0	1	0	1	1	1	1	1	No
25/07/2019	1	1	1	1	0	1	1	0	0	0	0	1	1	0	1	0	1	0	1	1	1	No
01/08/2019	1	1	1	1	0	0	1	1	0	0	1	0	0	0	1	1	1	0	0	1	1	No
08/08/2019	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	
15/08/2019	1	0	1	0	0	0	1	1	0	0	1	1	1	0	1	0	1	0	0	1	1	No
22/08/2019	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	Virtual MDM	
29/08/2019	0	1	1	1	0	0	1	1	0	0	1	1	1	0	1	1	1	0	1	0	1	No
05/09/2019	1	1	1	0	0	1	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
12/09/2019	0	1	1	0	0	0	1	1	0	0	1	1	1	0	0	1	1	1	1	1	1	No
19/09/2019	1	1	1	0	0	0	1	1	0	0	1	1	1	0	1	0	1	1	1	0	1	No
26/09/2019	1	1	1	0	0	0	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
03/10/2019	1	1	0	1	0	0	1	1	0	0	1	0	0	0	1	1	1	0	1	1	1	No
10/10/2019	1	1	0	0	0	0	1	1	0	0	1	1	1	0	1	1	1	0	1	1	1	No
17/10/2019	1	0	1	0	0	0	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
24/10/2019	1	1	0	1	0	0	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	No
31/10/2019	1	1	1	1	0	0	1	1	0	0	1	1	1	0	1	1	1	0	1	0	1	No
07/11/2019	1	1	1	1	0	0	1	1	0	0	1	0	0	0	1	1	1	1	1	0	1	No
14/11/2019	0	1	1	1	0	0	1	1	0	0	1	0	0	0	1	0	1	1	1	0	1	No
21/11/2019	1	1	1	0	0	0	1	1	0	0	1	1	1	0	1	0	1	1	1	1	1	No
28/11/2019	1	1	1	0	0	0	1	1	0	0	1	1	1	0	0	1	1	0	1	1	1	No
05/12/2019	0	1	0	1	0	0	1	1	0	0	1	0	0	0	1	1	1	1	1	1	1	No
12/12/2019	1	1	1	1	0	0	1	1	0	0	1	1	1	0	1	0	1	1	1	0	1	No
19/12/2019	1	1	1	0	0	0	1	1	0	0	1	0	0	0	1	1	1	1	1	1	1	No
26/12/2019	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	No MDM	
Grand Total	37	35	33	29	1	3	43	39	1	1	41	25	30	2	39	29	43	33	41	35	43	

Appendix 2: Feedback from the NI Cancer Patient Experience Survey 2018

	Q9. When first told you had cancer, were you told you could bring a family member or friend?			Q10. How do you feel about the way you were told you had cancer?			Q11. Did you understand the explanation of what was wrong with you?		
Cancer Type	This Trust 2015	This Trust 2018	N.I.	This Trust 2015	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	75%	75%	*	86%	85%	*	77%	77%
Prostate	*	*	79%	*	*	86%	*	*	79%

NI CPES 2018: Southern trust results for Urology Pts & Regional results for Prostate Pts

Finding out what's wrong

	Q12. When you were told you had cancer, were you given written information about your cancer?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	66%	61%
Prostate	*	*	74%

Deciding The Best Treatment For You

	Q13. Before your cancer treatment started, were your treatment options explained to you?			Q14. Were the possible side effects explained in a way you could understand?			Q15. Before your treatment, were you given written information about the side effects?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	82%	86%	*	79%	70%	*	83%	71%
Prostate	*	*	90%	*	*	78%	*	*	81%

	Q16. Before your treatment, were you also told about future side effects?			Q17. Were you involved as much as you wanted to be in decisions about your care and treatment?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	65%	51%	*	84%	78%
Prostate	*	*	68%	*	*	84%

Trust 2015 Tumour Group scores provided for information only, comparison not statistically valid

Clinical Nurse Specialist

	Q18. Were you given the name of a CNS who would support you through your treatment?	Q19. How easy or difficult has it been for you to contact your CNS?	Q20. When you asked important questions to your CNS, could you understand the answers?

Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	73%	66%	-	95%	89%	*	95%	93%
Prostate	*	*	83%	-	*	91%	*	*	93%

Support For People With Cancer

	Q21. Did hospital staff give you information about support or self-help groups?			Q22. Did staff discuss with / give you information about the impact cancer could have?			Q23. Did hospital staff give you information about how to get financial help or any benefits?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	63%	69%	*	77%	72%	*	35%	44%
Prostate	*	*	89%	*	*	89%	*	*	66%

Operations

	Q26. Beforehand, did you have all the information you needed about your operation?			Q27. After the operation, did staff explain how it had gone in a way you could understand?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	-	93%	91%	*	84%	78%
Prostate	-	*	97%	*	*	83%

Hospital Care As An Inpatient

	Q30. Did groups of doctors and nurses talk in front of you as if you weren't there?			Q31. Did you have confidence and trust in the doctors treating you?			Q32. If your family or someone else close to you wanted to talk to a doctor, were they able to?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	-	76%	80%	*	86%	91%	*	73%	71%
Prostate	-	*	89%	*	*	89%	*	*	82%

	Q33. Did you have confidence and trust in the ward nurses treating you?			Q34. In your opinion, were there enough nurses on duty to care for you in hospital?			Q35. While you were in hospital did thestaff ask what name you prefer to be called by?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	74%	84%	*	67%	72%	*	76%	73%
Prostate	*	*	89%	*	*	82%	*	*	77%

	Q36. Were you given	Q37. During your hospital	Q38. Do you think the

	enough privacy when discussing your condition or treatment?			visit, did you find staff member to discuss your worries and fears?			hospital staff did everything they could to help control your pain?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	83%	88%	*	50%	49%	*	63%	74%
Prostate	*	*	95%	*	*	75%	*	*	85%

	Q39. Overall, did you feel you were treated with respect and dignity while you were in the hospital?			Q40. Were you given written information about what you should / shouldn't do after leaving?			Q41. Did staff tell you who to contact if you were worried after you left?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	79%	89%	*	90%	81%	*	83%	85%
Prostate	*	*	95%	*	*	85%	*	*	94%

Hospital Care As A Day Patient/Outpatient

	Q44. While being treated, did you find someone on the staff to discuss your worries and fears?			Q45. Last time you had an outpatients appointment, did they have the right documents?			Q47. Beforehand, did you have all of the information you needed about your radiotherapy?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	-	82%	68%	*	100%	100%	-	100%	90%
Prostate	-	*	77%	*	*	98%	-	*	94%

	Q48. Were you given information about if radiotherapy was working in an understandable way?			Q50. Beforehand, did you have all of the information you needed about your chemotherapy?			Q51. Were you given information about if chemotherapy was working in an understandable way?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	-	67%	83%	-	95%	76%	-	88%	71%
Prostate	-	*	70%	-	*	88%	-	*	76%

Home Care And Support

	Q52. Did staff give your family / friends the information they needed to help care for you at home?			Q53. During treatment, were you given enough care & support from health / social services?			Q54. Once treatment finished, were you given enough care & support from health / social services?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	69%	62%	-	56%	58%	-	48%	48%
Prostate	*	*	68%	-	*	55%	-	*	56%

Care From Your General Practice

	Q55. Was your GP given enough information about your condition and treatment?			Q56. Did the staff at your general practice do all they could while you were having treatment?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	97%	94%	*	66%	70%
Prostate	*	*	96%	*	*	77%

Your Overall Care

	Q57. Did the different people treating and caring for you work well together?			Q58. Have you been offered a needs assessment and care plan?			Q59. Overall, how would you rate the administration of your care?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	*	71%	71%	*	29%	19%	-	95%	91%
Prostate	*	*	78%	*	*	22%	-	*	95%

	Q60. How do you feel about the length of time waiting when attending clinics and appointments?			Q61. Since diagnosis, has anyone discussed whether you would like to take part in cancer research?			Q62. Overall, how would you rate your care?		
Cancer Type	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.	This Trust 2015 $	This Trust 2018	N.I.
Urological	-	83%	77%	*	4%	5%	-	8.74	8.80
Prostate	-	*	80%	*	*	31%	-	*	9.14

Respondents by Tumour Group

Tumour Group	Number of respondents*
Urological	79
Prostate	17

These figures will not match the numerator for all questions in the comparisons by tumour group section of this report because not all questions were answered by all responders.

****Trust 2015 Tumour Group scores provided for information only, comparison not statistically valid***

Summary of results for Urological patients

- Trust scores were higher than NI scores for 25 questions (14 were higher by >5%)
- Trust scores were lower than NI scores for 13 questions (6 were lower by >5%)

Overview of positive results (Trust score higher than NI score >5%)

Q12. Given written information about their cancer when told they had cancer
Q14. Possible side effects explained in a way they could understand

Q15. Before treatment, they were given written information about the side effects
Q16. Before treatment, they were told about future side effects
Q17. Thought they were involved as much as wanted to be in decisions about their care and treatment
Q18. Were given the name of a CNS who would support them through treatment
Q19. Found it easy to contact CNS
Q27. After the operation staff explained how it had gone in a way they could understand
Q40. Were given written information about what they should / shouldn't do after leaving
Q44. While being treated, they were able to find someone on the staff to discuss worries and fears**
Q50. Had all of the information they needed about their chemotherapy
Q51. Were given information about if chemotherapy was working in an understandable way
Q52. Staff gave family / friends information they needed to help care for you at home
Q58. Were offered a needs assessment and care plan**
Q60. Were happy with length of time waiting when attending clinics and appointments

Overview of declined results (Trust score lower than NI score by > 5%)

Q21. Hospital staff gave information about support or self-help groups
Q23. Hospital staff gave information about how to get financial help or any benefits
Q33. Had confidence and trust in the ward nurses treating them
Q38. Thought the hospital staff did everything they could to help control their pain
Q39. Overall, felt they were treated with respect and dignity while in the hospital
Q48. Given information about if radiotherapy was working in an understandable way
Q61. Since diagnosis someone discussed whether they would like to take part in cancer research

Regional results for Prostate patients

- Majority of NI scores were more than 75% (34 questions)
- 10 questions scored less than 75%

Scores which are 75% or lower:

Q12. When told they had cancer, they were given written information about their cancer
Q16. Before treatment were told about future side effects
Q23. Hospital staff gave information about how to get financial help or any benefits
Q37. During hospital visit was able to find a staff member to discuss their worries and fears
Q48. Were information about if radiotherapy was working in an understandable way
Q52. Staff gave family / friends the information they needed to help care for you at home
Q53. During treatment, felt they were given enough care & support from health / social services
Q54. Once treatment finished, felt they were given enough care & support from health / social services
Q58. Were offered a needs assessment and care plan
Q61. Since diagnosis, did some discuss whether they would like to take part in cancer research

Regional priorities for improvement:

- Care plans & Needs Assessment – Key CNS role
- Engagement with GPs
- Communication around worries & fears
- Side effects
- Research & Clinical trials

Appendix 3

Urology Service: Patient Experience Survey

March 2020

The Urology cancer team, as part of their service improvement plan to seek feedback from patients on the urology service, issued a patient feedback survey to 118 patients who were diagnosed with a prostate, bladder or renal cancer over the previous 12 months. There was a response rate of 58% (i.e. 68 patients completed and returned the survey).

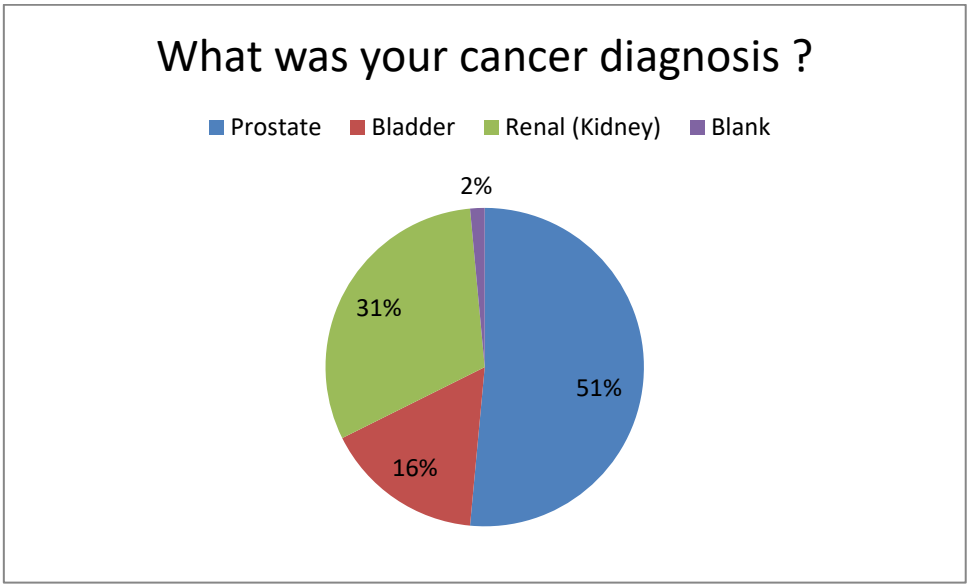
The survey asked questions in relation to their hospital visit and the results from the survey along with the feedback from the NI Cancer Patient Experience Survey (2018) will help the team to look at the service currently provided and to plan for the future to make sure they are meeting the on-going needs of patients and families.

68/118 Responses (58%)

Summary of results:

- The majority of respondents had a prostate cancer (51%), followed by a renal cancer (31%) and then a bladder cancer (16%)
- 87% of respondents rated the hospital signage directing them to the unit as excellent or very good, 83% rated the reception / waiting area as excellent or very good and 57% rated the disabled parking (if applicable) as excellent or very good
- 100% of respondents indicated that staff introduced themselves when they first met.
- 97% rated the level of politeness and courtesy shown to them as excellent or very good
- 95% rated the level of privacy and dignity when being examined or when discussing treatment as excellent or very good
- 74% of respondents advised they were asked which name they would prefer to be called by.
- 92% of respondents were told sensitively that they had cancer
- 94% of respondents were given easy to understand written information about their cancer.
- 85% of respondents were able to find / offered a staff member to discuss any worries or fears.
- The majority of respondents (88%) said they were given the name of their CNS.
- 82% were definitely told about future side effects before treatment.

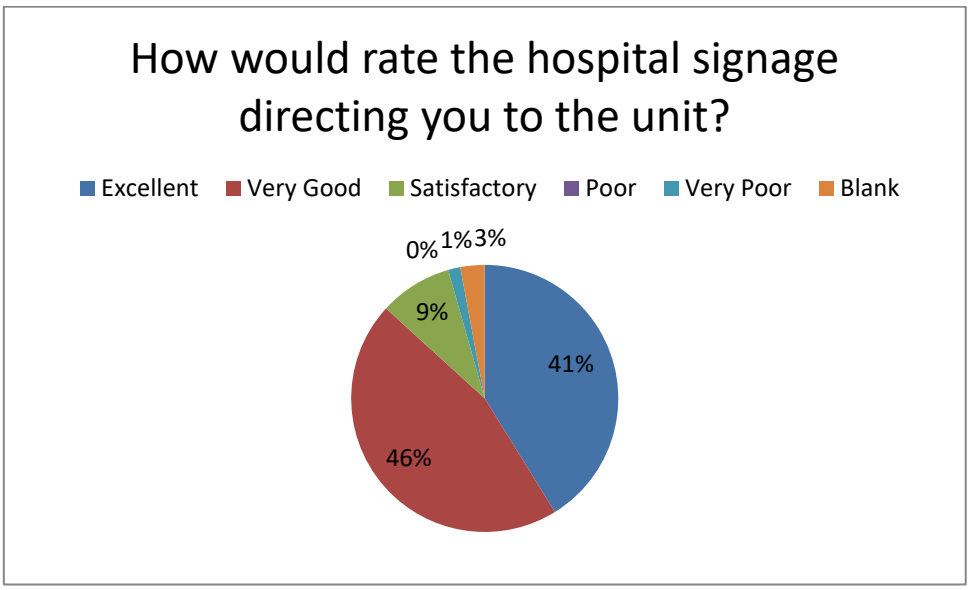
ABOUT YOU (The Patient)



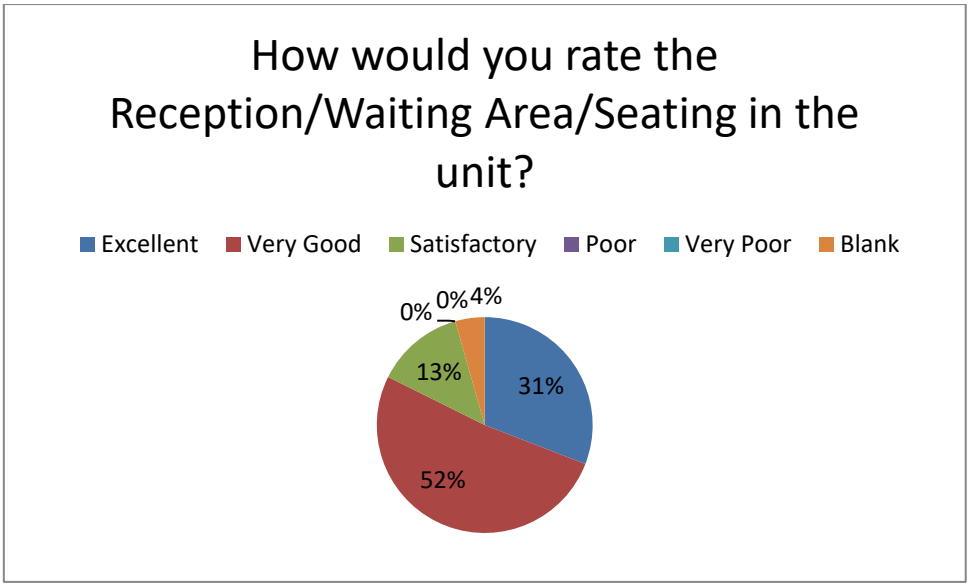
- 35 of respondents had a prostate cancer
- 11 had a bladder cancer
- 21 had a renal cancer

1 person didn't answer the question

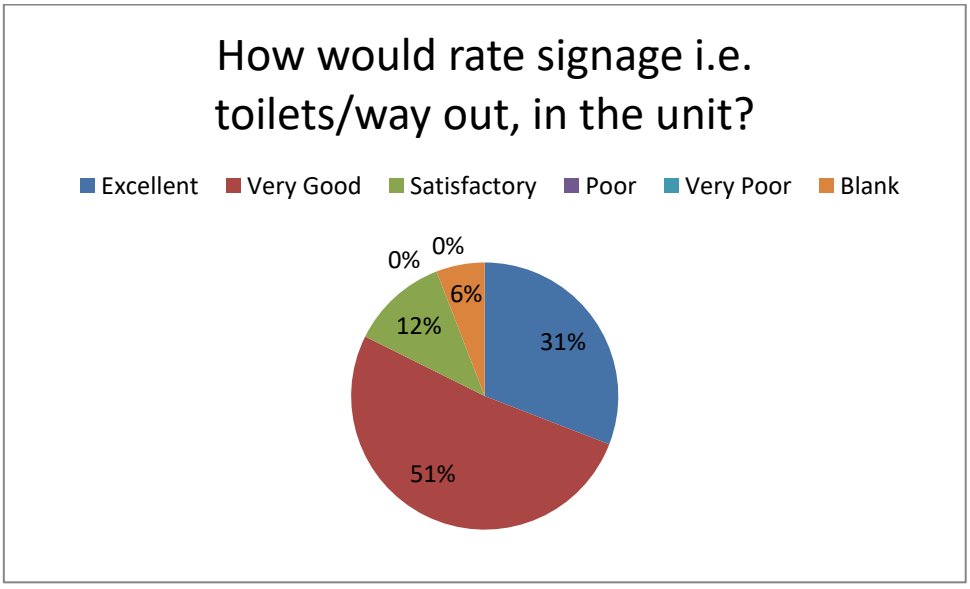
First Impressions



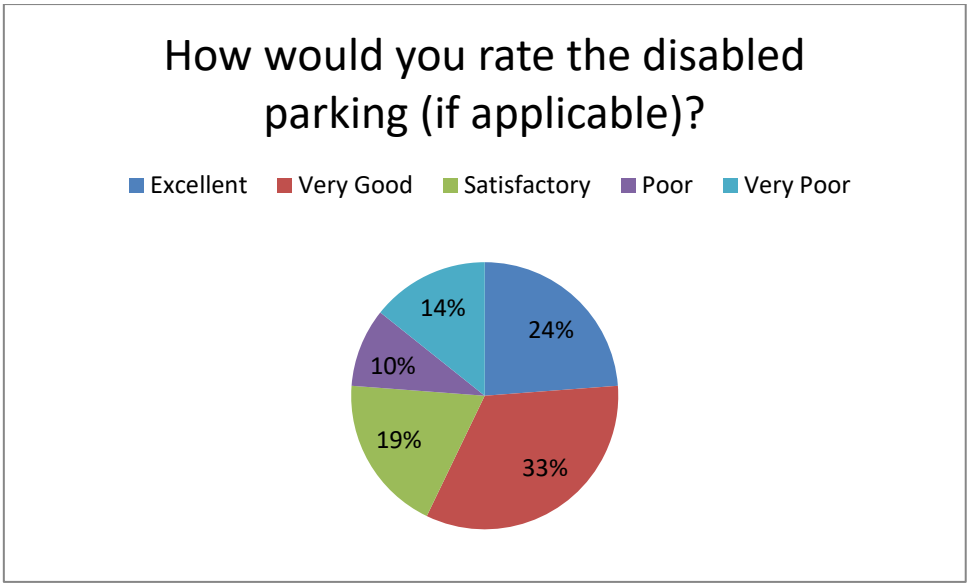
The majority of respondents (59/68) rated the hospital signage directing them to the unit as Excellent or Very Good, with only 1 respondent rating this as Very Poor.



The majority of respondents (56/68) rated the reception/waiting area/seating in the unit as Excellent or Very Good.



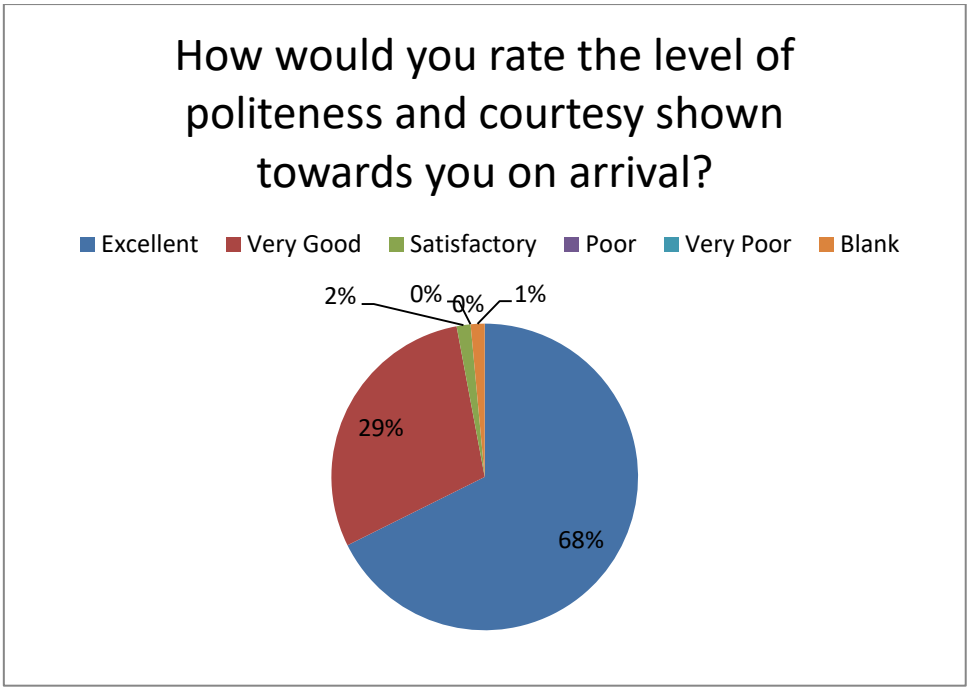
The majority of respondents (56/68) rated the signage in the unit as Excellent or Very Good.



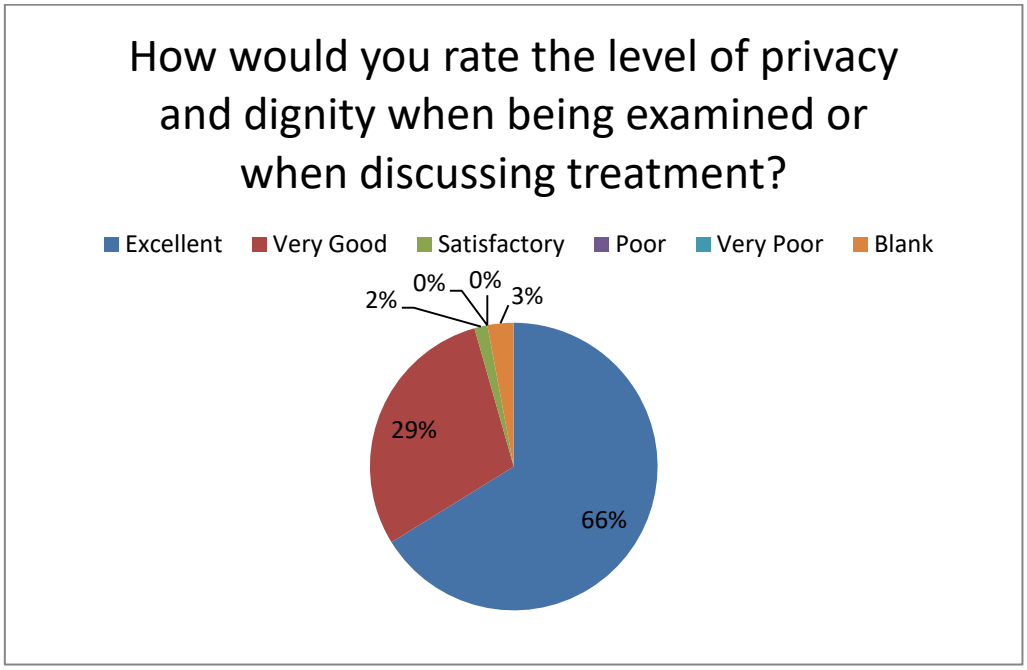
21 of the respondents answered the above question with 57% rating this as excellent or very good.

Our Staff

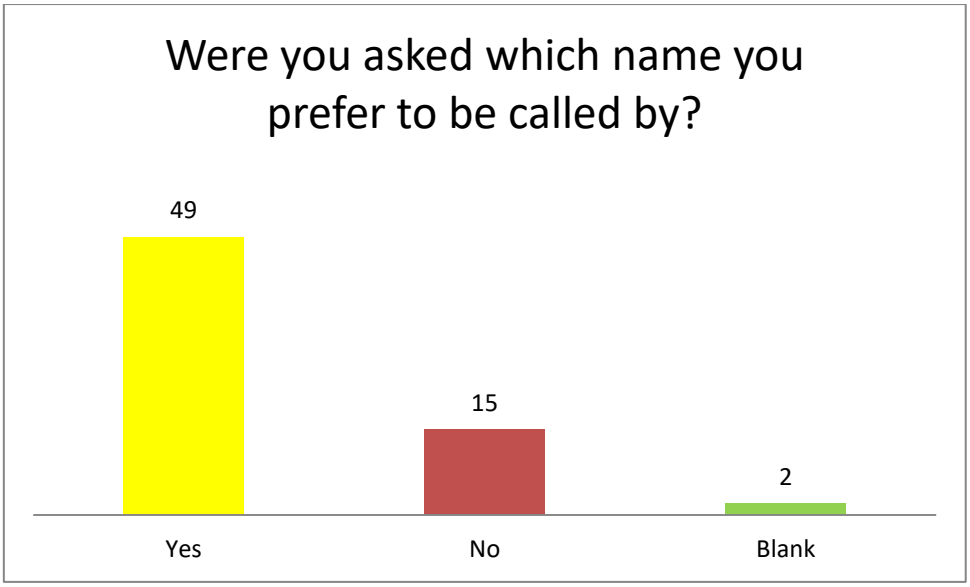
All of the respondents that answered this question indicated that staff introduced themselves when they first met.



The majority of respondents (97%) rated the level of politeness and courtesy shown to them on arrival as excellent or very good.



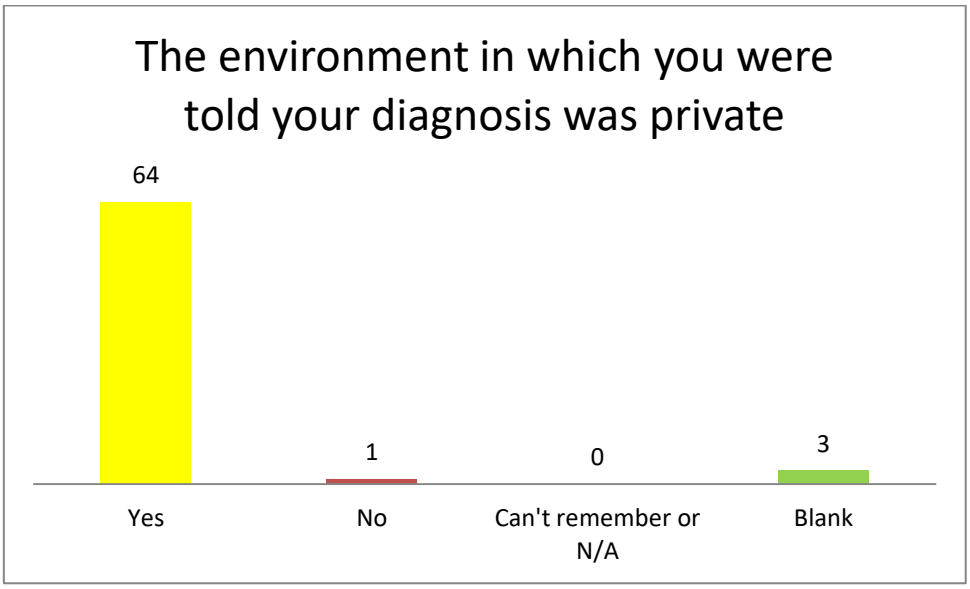
The majority of respondents (65/68) rated the level of privacy and dignity when being examined or when discussing treatment as Excellent or Very Good.



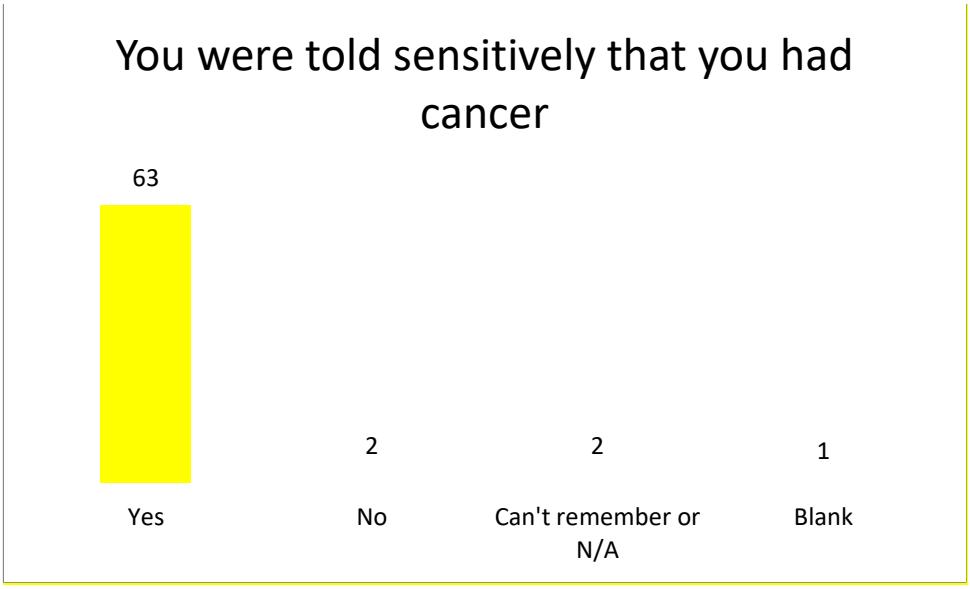
74% of respondents advised they were asked which name they would prefer to be called by.

This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES Urology responses was 76% and the NI score was 73%.

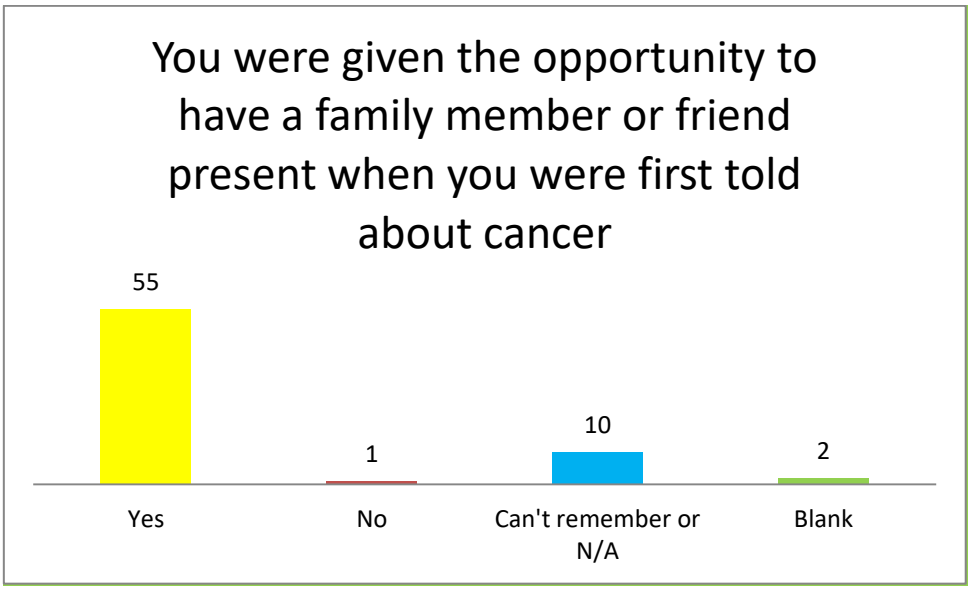
With regard being told your diagnosis, how would you describe the following:



94% of respondents agreed the environment where they were told their diagnosis was private

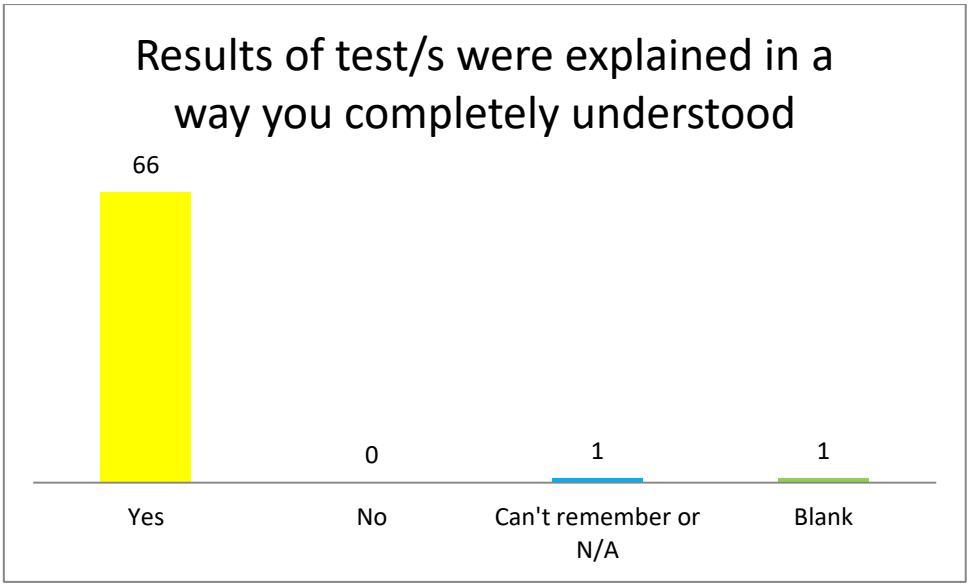


92% of respondents were told sensitively that they had cancer

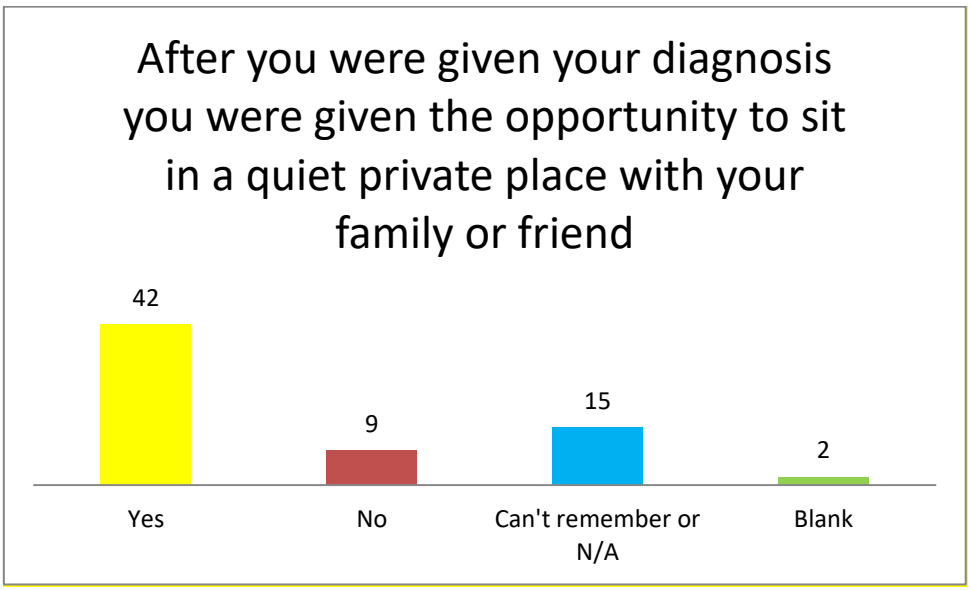


81% of respondents were given the opportunity to have a family member or friend present when they were first told about cancer.

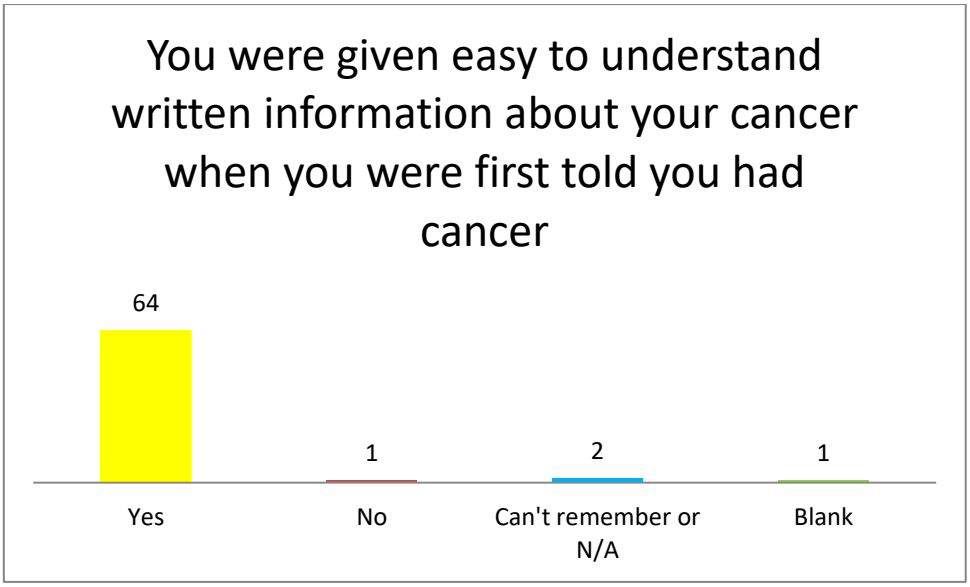
This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT urology responses was 75% the same as the NI score. The score for the regional Prostate responses was 79%.



97% of respondents indicated that results of tests were explained in a way they completely understood

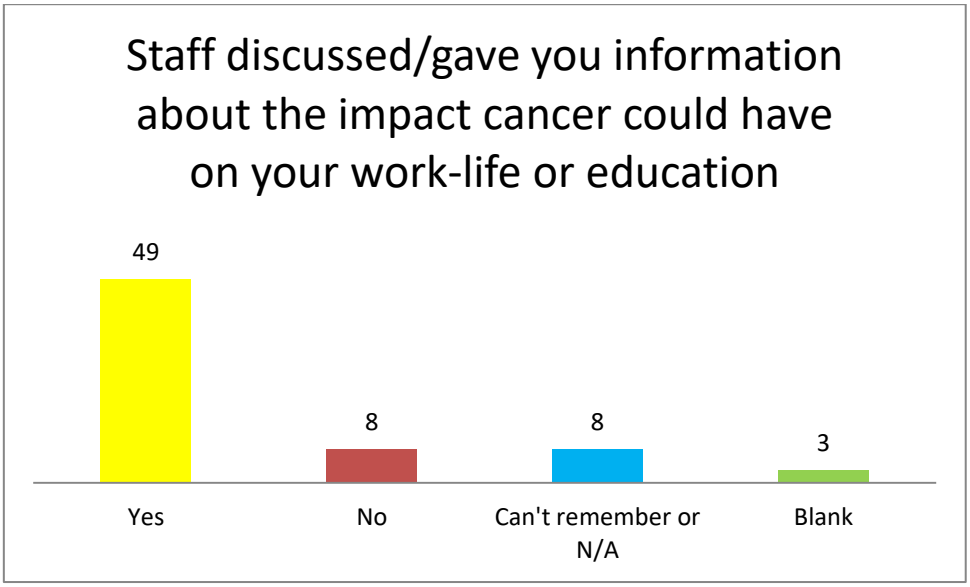


62% of respondents were given the opportunity to sit in a quiet private place with a family member or friend



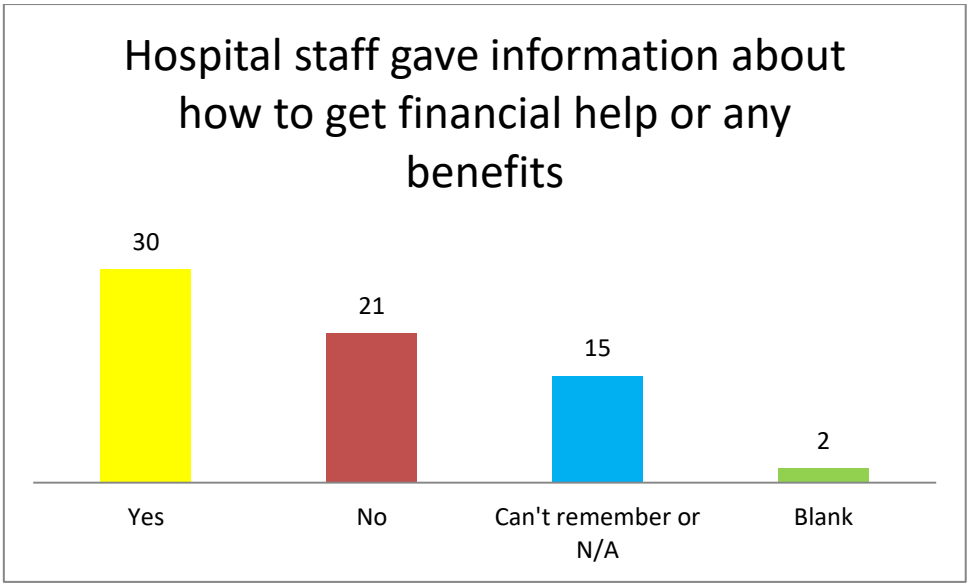
94% of respondents were given easy to understand written information about their cancer.

This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 66%, the NI score was 61% and the regional prostate CPES response rate was 74%.



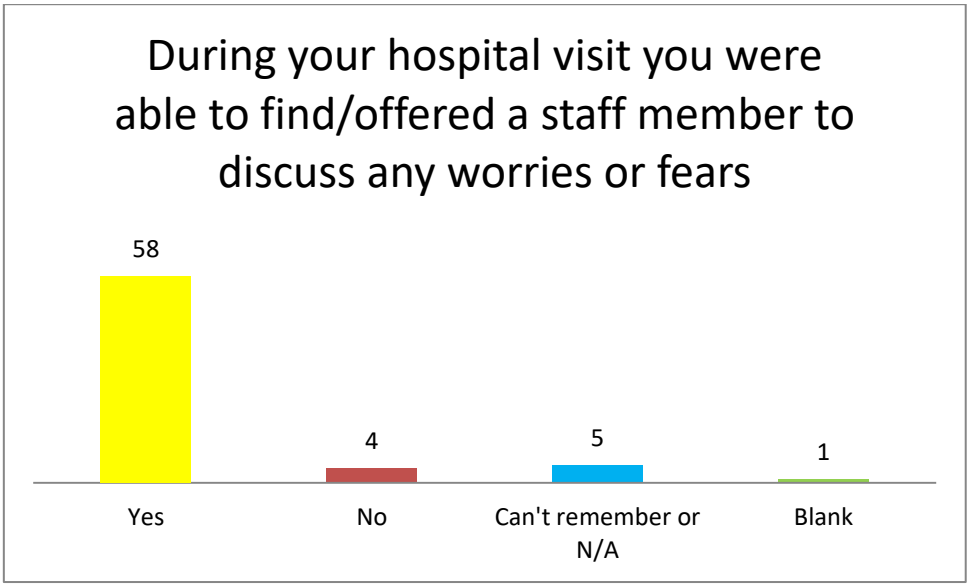
72% of respondents indicated that staff discussed or gave them information about the impact cancer could have on their work-life or education.

This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 77%, the NI score was 72% and the regional prostate CPES response rate was 89%.



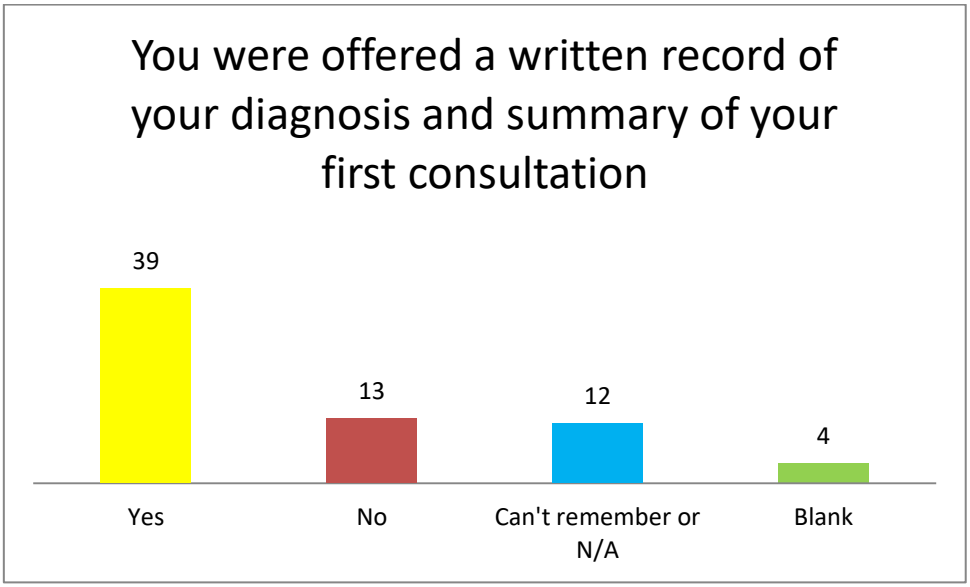
44% of respondents indicated that hospital staff gave information about how to get financial help or any benefits.

This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 35%, the NI score was 44% and the regional prostate CPES response rate was 66%.

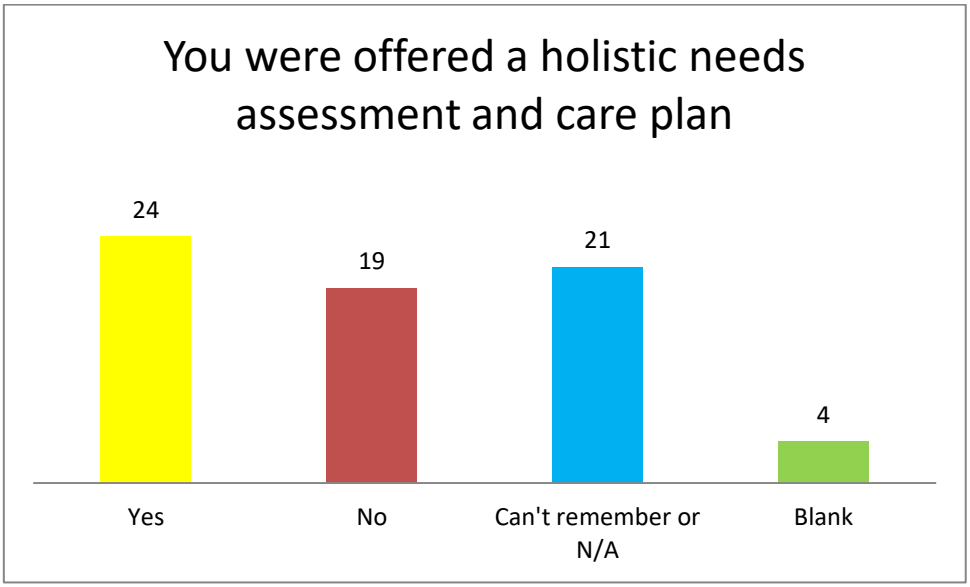


85% of respondents were able to find / offered a staff member to discuss any worries or fears.

This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 50%, the NI score was 49% and the regional prostate CPES response rate was 75%.



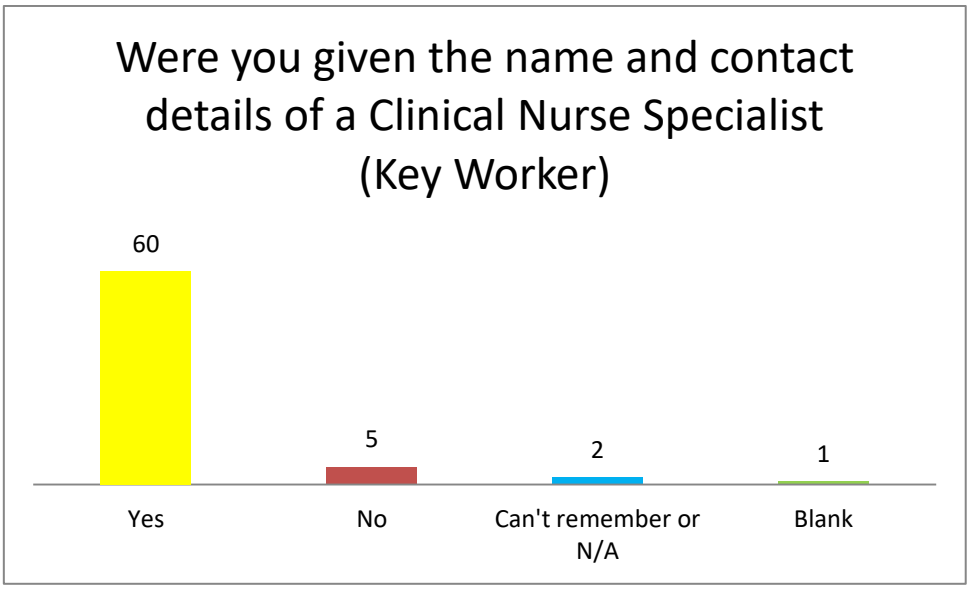
57% of respondents were offered a written record of their diagnosis and summary of their first consultation.



35% were offered a holistic needs assessment and care plan
31% can't remember
28% indicated that they were not offered a holistic needs assessment and care plan

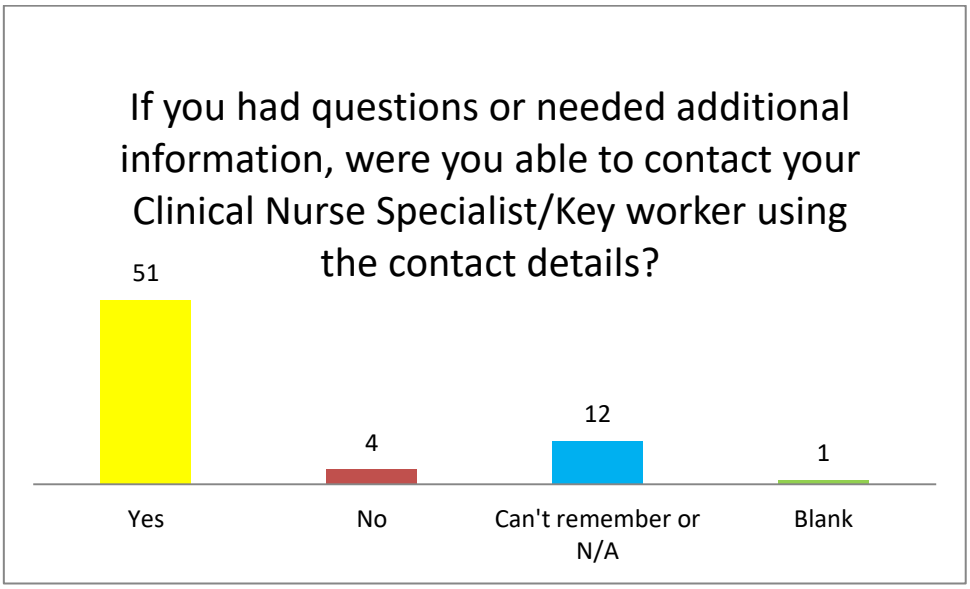
This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 29%, the NI score was 19% and the regional prostate CPES response rate was 22%.

About your Clinical Nurse Specialist (Key Worker)

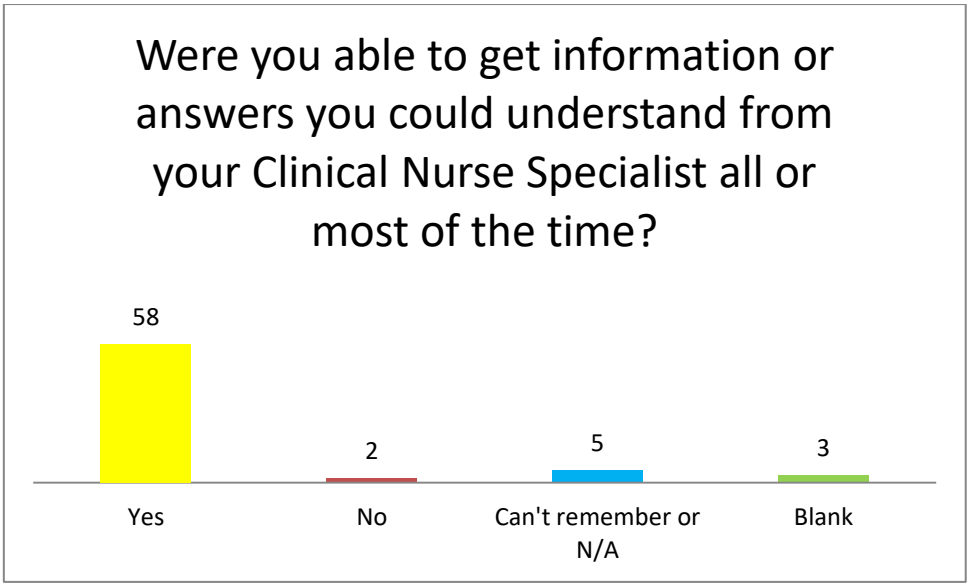


The majority of respondents (88%) said they were given the name of their CNS.

This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 73%, the NI score was 66% and the regional prostate CPES response rate was 83%.

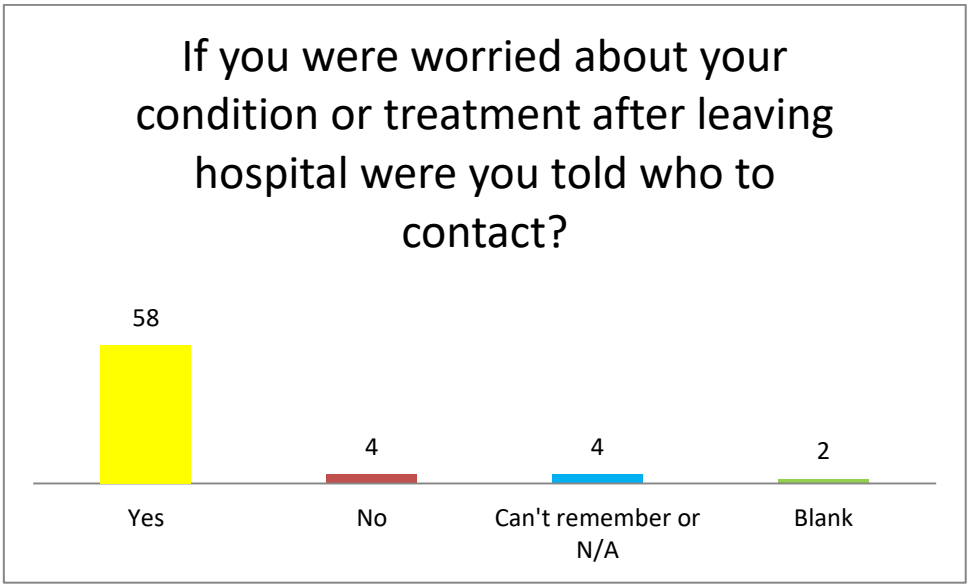


75% of respondents were able to contact their CNS or key worker if they had questions or needed additional information



85% were able to information or answers from their CNS they could understand all or most of the time.

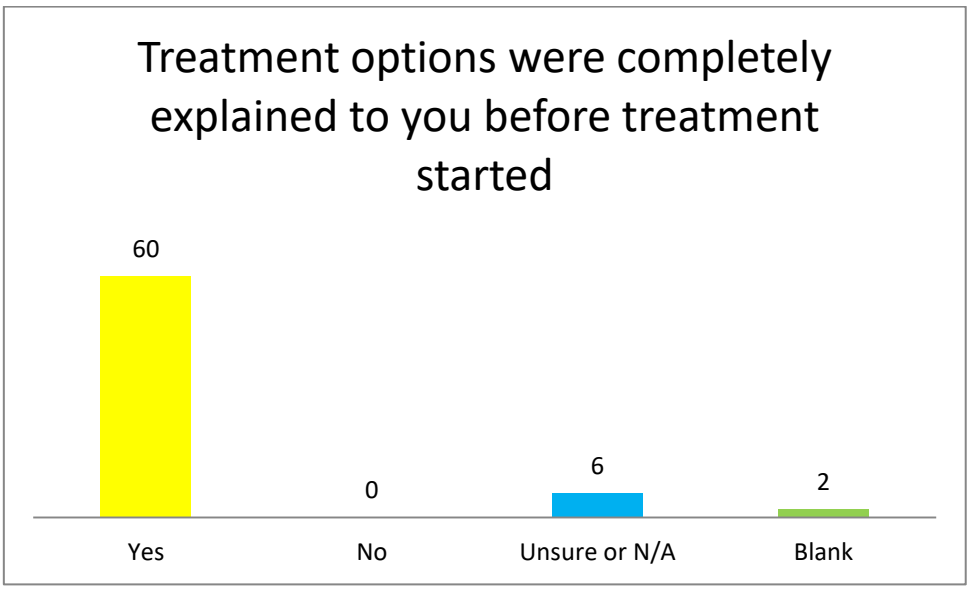
This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 95%, the NI score was 93% and the regional prostate CPES response rate was 93%.



85% of respondents were told who to contact if they were worried after leaving hospital.

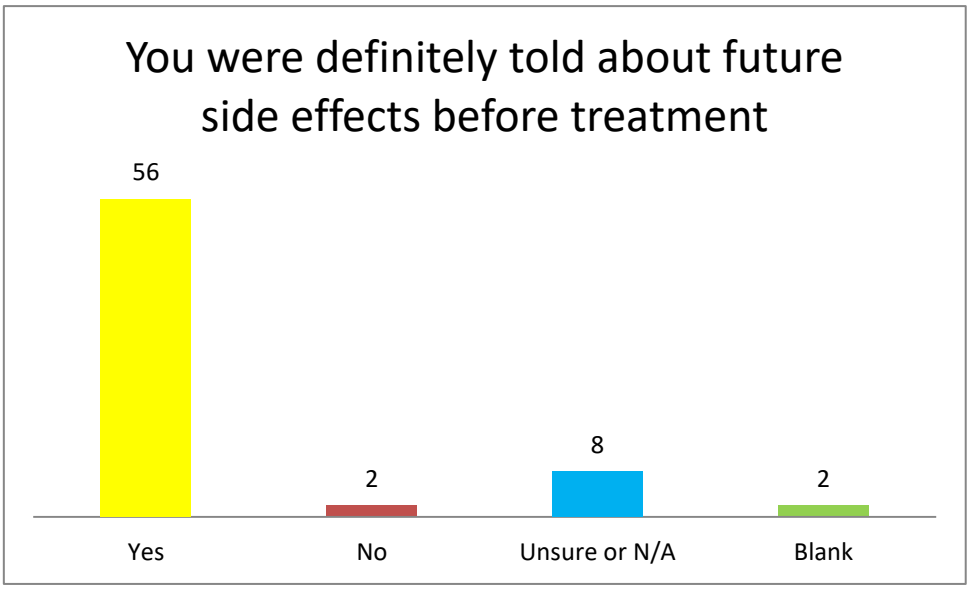
This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 83%, the NI score was 85% and the regional prostate CPES response rate was 94%.

With regard deciding the best treatment available for you, how would describe the following:



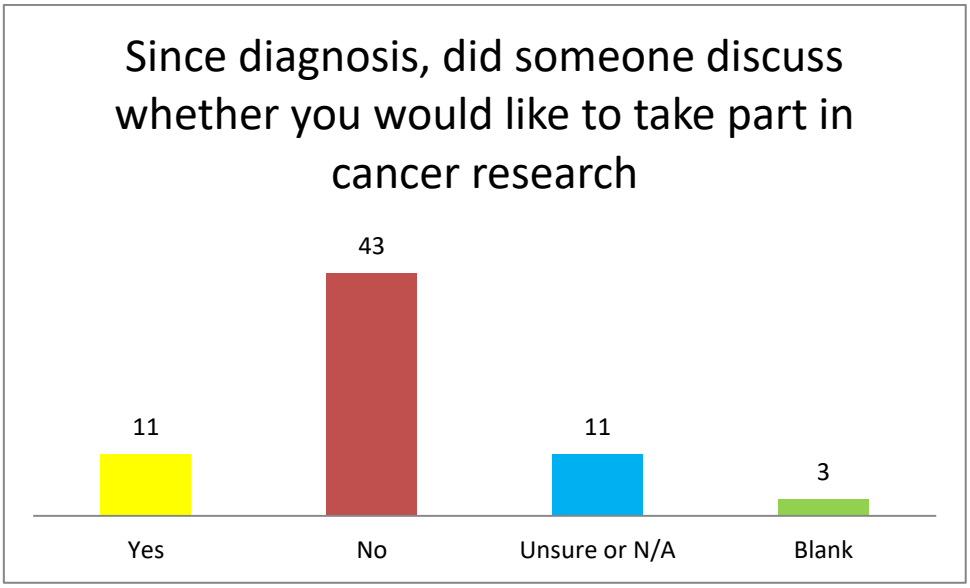
88% of respondents indicated that treatment options were completely explained to them before treatment started.

This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 82%, the NI score was 86% and the regional prostate CPES response rate was 90%.



82% were definitely told about future side effects before treatment.

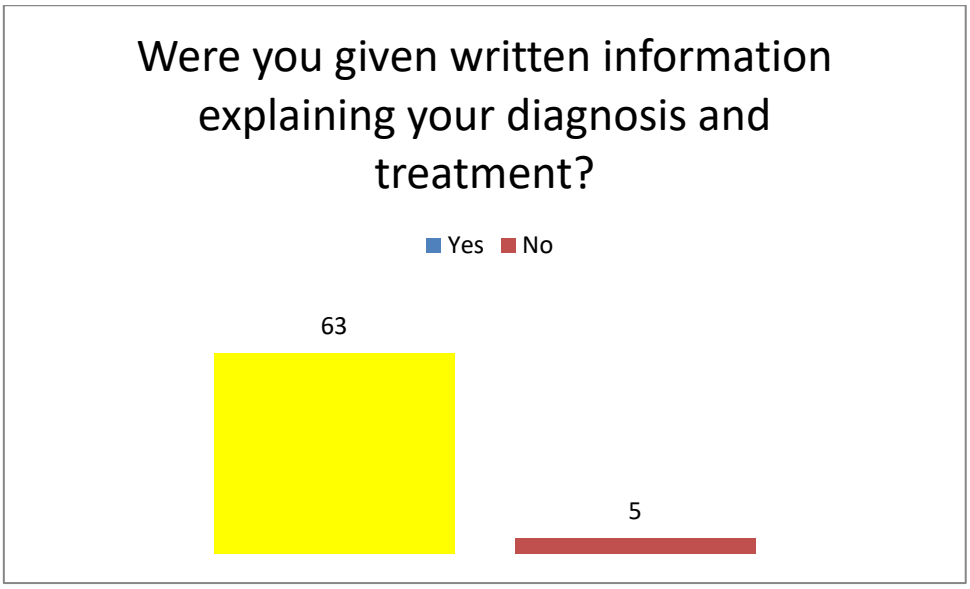
This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 65%, the NI score was 51% and the regional prostate CPES response rate was 68%.



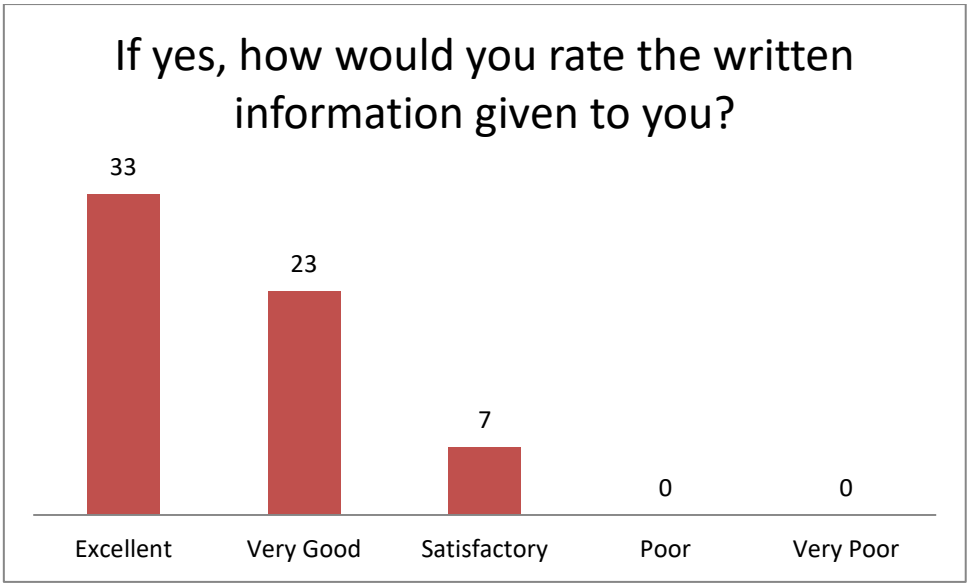
16% of respondents said they asked if they would like to take part in Cancer Research.

This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 4%, the NI score was 5% and the regional prostate CPES response rate was 31%.

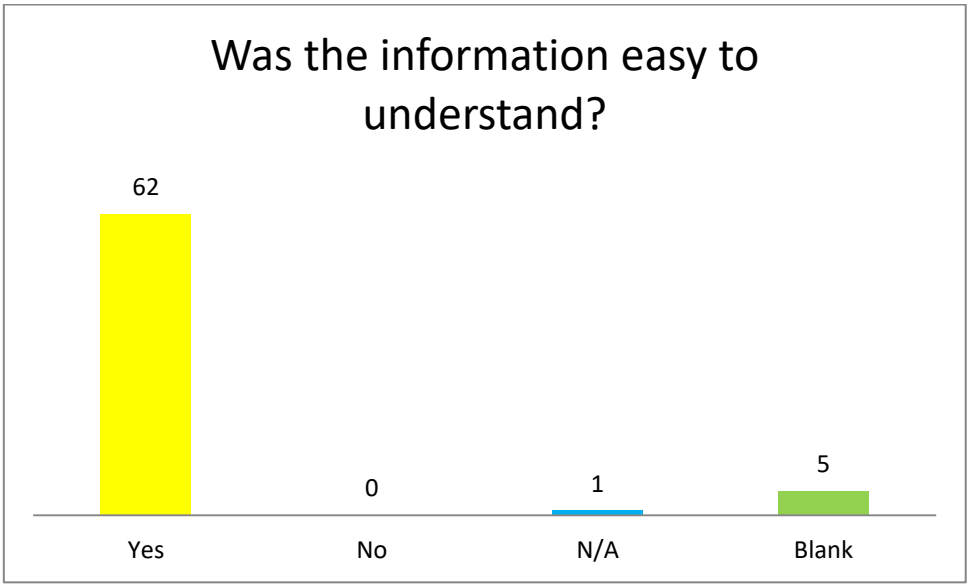
Information



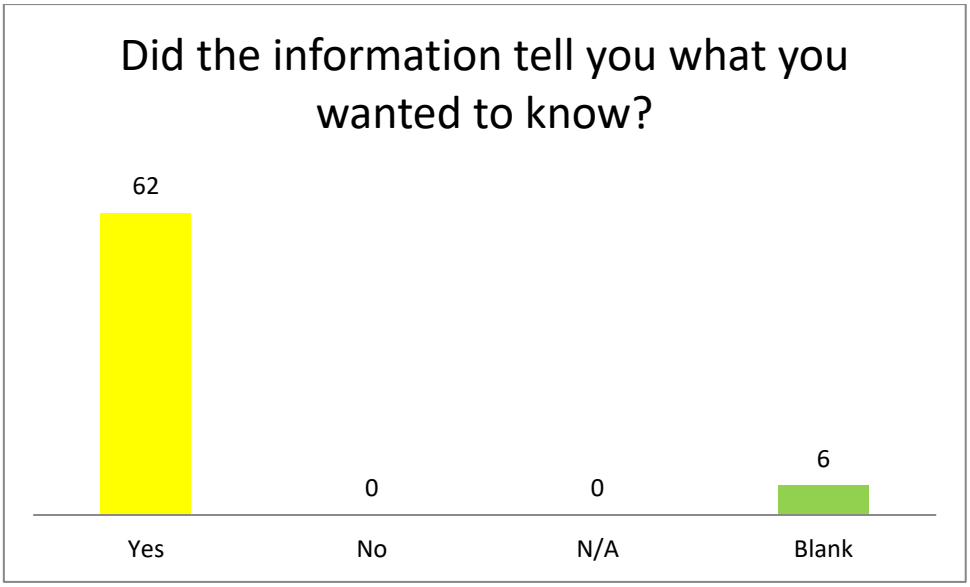
92% of respondents were given written information explaining their diagnosis and treatment.



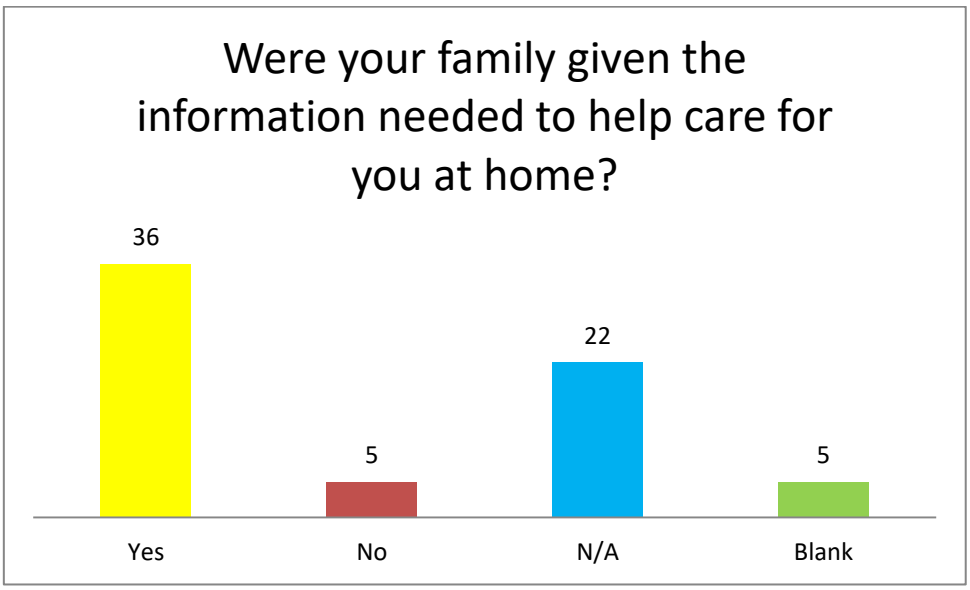
The majority of respondents (89%) rated the written information given to them as Excellent or Very Good.



91% found the information easy to understand.

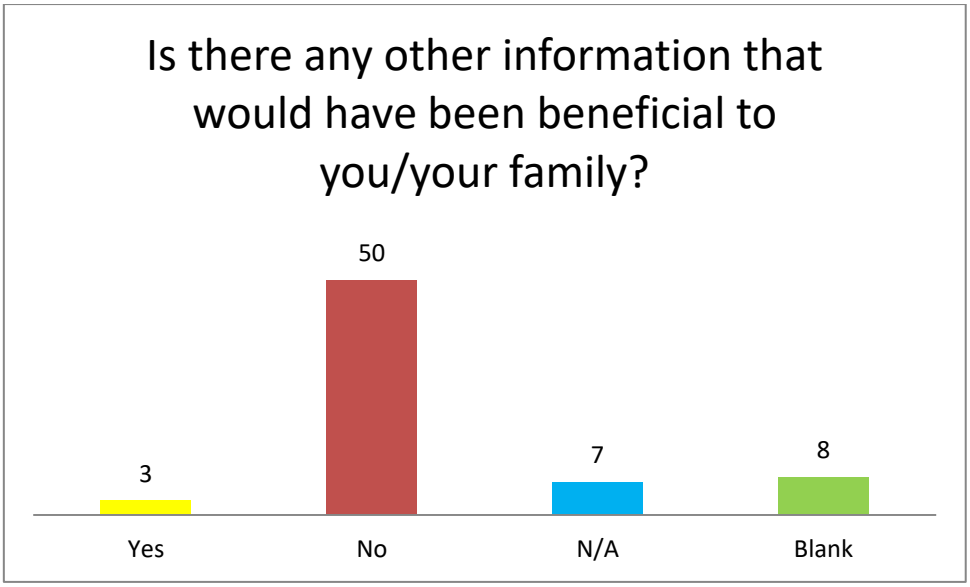


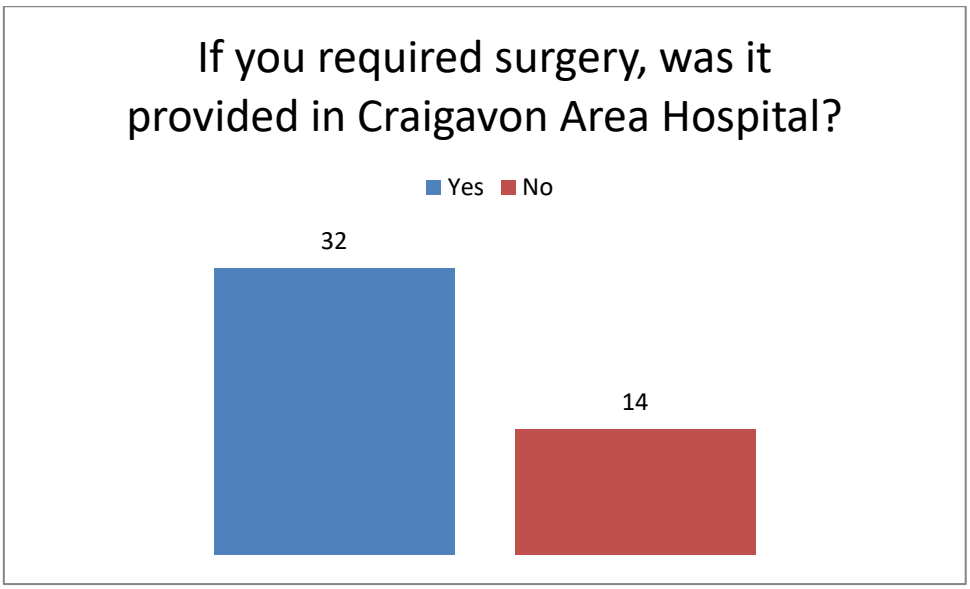
100% of respondents who answered this question (n=62) said the information told them what they wanted to know.



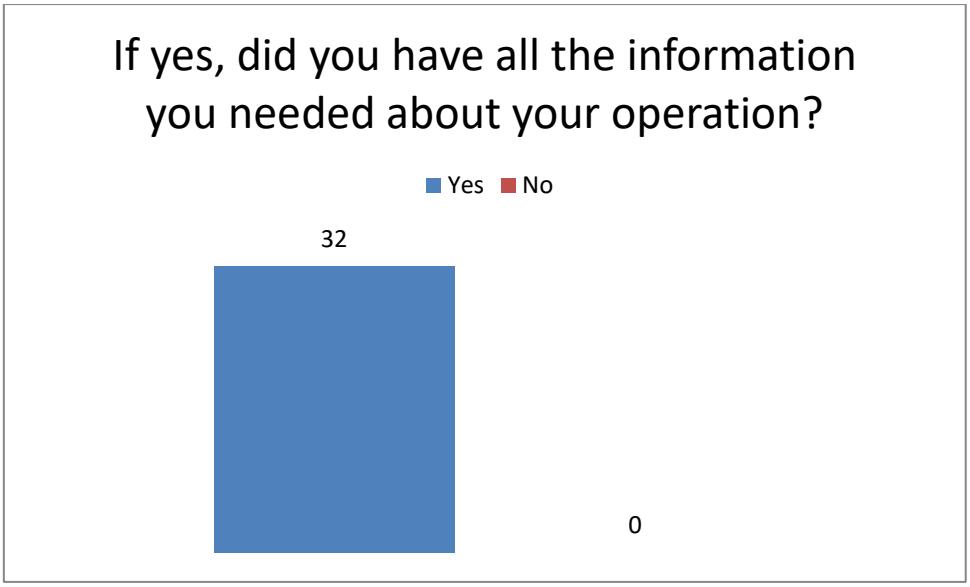
57% of respondents indicated that their families were given information to help care for them at home.

This is a question that was asked in the 2018 regional Cancer Patient Experience Survey. The score for the SHSCT CPES urology responses was 69%, the NI score was 62% and the regional prostate CPES response rate was 68%.





70% of respondents who required surgery, had this completed in CAH (32/46)

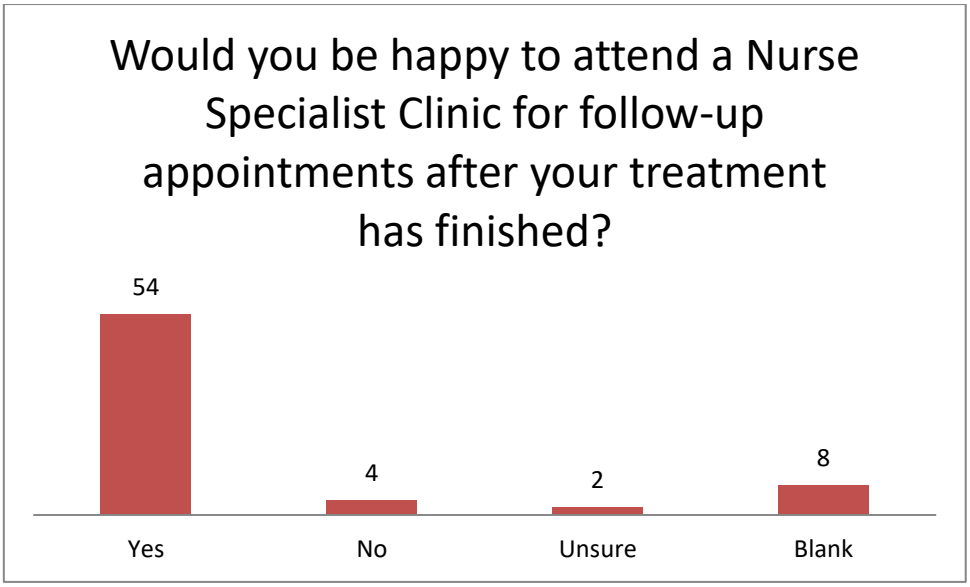


100% of respondents had all the information they needed about their operation.

Future Service Developments

At the end of the survey, patients were asked for feedback on future service developments in the Urology Cancer Service in relation to the provision of a Clinical Nurse Specialist clinic to get results of investigations and to attend a nurse-led clinic for follow-up appointments:

79% of respondents were happy to attend a Nurse Specialist clinic for results of investigations, 7% would not be happy, 4% were unsure, 13% did not answer.



79% of respondents were happy to attend a Nurse Specialist clinic for results of investigations, 6% would not be happy, 3% were unsure, 12% did not answer

Patients were invited to add any other comments/suggestions for improvement:

- Very satisfied with all the care and treatment I received during my kidney operation - May 2019 - Cannot give enough praise to the Consultants, nurses etc. during my 3 day stay in the Urology department.
- Can some of it be done from STH?
- When I went to the Mater Private Hospital I seen every person involved in my operation on the day. Instead of individual appointments. Doctor first. After care nurse second. Anaesthetist third. ECG and blood results all back in the one day. Maybe the way forward.
- Very impressed with care given by medical and nursing staff both at Outpatient and inpatient services.
- I travel too far to Craigavon Hospital without seeing my Consultant
- No complaints
- Went to City Hospital under Mr xxxx, a gentleman, explained everything to our family all doing well since treatment.
- Build a bigger carpark!
- Since my diagnosis is incomplete and treatment not yet started I cannot decide the best option.
- We were very happy that Mr xxxx spoke with us. We would prefer to speak with Mr xxxxx. We have an appointment with him for 31st March. The provision of chilled, filter water.
- No complaints whatsoever everything was just fine thank you.
- I had a very positive and supportive experience as a patient under Mr xxxxx in CAH. Both Mr xxxxx and Nurse xxxxx took me and my husband through a difficult diagnosis with great care and professionalism. Thank you so much.
- 8 weeks from removal of kidney tumour. Awaiting regular long term follow up with scans when are these expected……?

Appendix 4: Service Improvement Action plan based on patient feedback 2020

Urology Patient Experience feedback & action plan 2020

The Public Health Agency with support from Macmillan Cancer Support commissioned a second regional Cancer Patient Experience Survey (CPES) in 2018. A total of 6,256 patients who had received treatment for cancer during March 2017 to October 2017 were included in the sample for the regional Cancer Patient Experience Survey 2018. The response rate for NI was 57% (3,478) and 473 questionnaires returned were from Southern trust patients. Reports are available at regional and trust levels.

At the Urology business meeting on 23rd January 2020, it was agreed to carry out a local patient survey using some of the CPES questions. A patient survey was issued during March 2020 to 118 patients who were diagnosed with a prostate, renal or bladder cancer in the preceding 12 months. There was a response rate of 58% (i.e.68 patients).

The results of the local patient survey and CPES results were reviewed and a local action plan developed to address some of the areas highlighted by patients. Where applicable, the scores of the CPES local and regional scores are provided along with the local patient survey results.

Issues for Consideration		Action Required	Person Responsible	Date for Completion
Finding out what was wrong with you				
1	74% of respondents were asked which name they prefer to be called by **CPES SHSCT: 76% (NI 73%)**	Continue to ensure that all staff ask patient what name they preferred to be called by	All staff	Ongoing
2	62% of respondents were given the chance to sit in a private place after being given their diagnosis	Continue to ensure that patients are offered the opportunity to sit in a private place after diagnosis	All staff	Ongoing

3	72% of respondents advised that staff discussed or gave them information about the impact of cancer on their work-life or education. **CPES SHSCT – 77% (NI – 72%)**	Written information is available and offered to patients as appropriate Patients who are continuing to work or are in education are given information about the impact of cancer/treatment Patients are referred to Macmillan information and support centre for further information	CNS / Consultant core members	Ongoing
4	44% of respondents advised that hospital staff gave information about how to get financial help or any benefits **CPES SHSCT – 35% (NI – 44%)**	Written information is available about the Macmillan Benefits Service and offered to patients as appropriate Patients who are continuing to work or are in education are given information about the impact of cancer/treatment Patients are referred to Macmillan information and support centre for further information	CNS / Consultant core members	Ongoing
4	57% of respondents were offered a written record of their diagnosis and summary of first consultation	Ensure all patients are offered a Permanent Record of Consultation at diagnosis This was previously piloted by the team. Following the business meeting in January 2020, it was agreed to review and implement.	CNS / Consultant core members CNS's M.Haughey	Ongoing
5	35% of respondents advised they were offered a holistic needs	Due to staffing levels in the Unit, the two CNS's have not been able to fully implement this for all newly diagnosed patients. A recruitment process is currently underway for an additional x2 Nurse	CNS's	To be reviewed in 6 months

	assessment and care plan **CPES SHSCT – 34% (NI – 28%)**	Specialists which will enable this to be fully implemented. Formal HNA clinics will be set up as part of this.		
6	85% of respondents advised that they were able to find/offered a staff member to talk about their worries and concerns **CPES SHSCT – 50% (NI –49%)**	The CNS will ensure to see as many patients as possible on the ward before and after their surgery in order to discuss with patients any worries or concerns in relation to their diagnosis, prognosis, treatment and care	CNS's	Ongoing
8	82% of respondents were definitely told about future side effects before treatment **CPES SHSCT – 65% (NI – 51%)**	Continue to give Information on possible future side effects of treatment Encourage patients to attend information session (if appropriate) prior to commencement of treatment Educate on late effects of treatment through health and wellbeing events	All core members CNS's	Ongoing
9	57% of respondents thought their family were given all the information needed to help care for them at home **CPES SHSCT – 69% (NI – 62%)**	Ensure that families are given appropriate and adequate information to help care at home and are provided with details of who to contact if they have any concerns or queries Families are signposted to relevant support services as appropriate	Consultant / Ward staff / CNS	Ongoing

Appendix 5: Audit of Communication of Diagnosis to GPs

Standard

One of the local peer review measures outlined by NICaN relates to communication with the patient's GP following the diagnosis of a cancer; the standard states:

"The MDT should have an agreed policy whereby after a patient is given a diagnosis of cancer the patient's general practitioner (GP) is informed of the diagnosis by the end of the follow working day"

Methodology

To test if the MDT is meeting this standard and if GPs are receiving timely information on all patients diagnosed with cancer an audit was carried out. 10 patients from the Southern Trust who were discussed at the MDT held between January and December 2016 were selected at random. The audit was carried out by using the Northern Ireland Electronic Care Record (NIECR) to establish when the patient was given their diagnosis, when the letter was typed and then by phoning the GP practices to establish when the letter was received.

Results

One GP practice out of 10 received notification of the patient's diagnosis within 2 days. The letters of five patients were received by GP Practices within3-5 days, the letter of three patients were received within 8-9 days and one patient letter was received within 18 days. Five of the letters were typed within 1 day of the patient being given their diagnosis and therefore these would have been available on the NIECR for the GP to view. Two letters were typed within 2 days, two were typed within 4-7 days and one letter was typed within 15 days.

Time between patient being informed of diagnosis and GP receiving Clinic letter:

	Southern Trust
Shortest time	2 days
Longest time	18 days
Median	6 days

Time between diagnosis given to patient and letter typed:

	Southern Trust
Shortest time	1 day
Longest time	15 days
Median	2 days

Appendix 6: Clinical Trial Activity 2019

UROLOGY CANCER TRIAL ACTIVITY 2019

Prostate Open Cancer Trials 2019

Southern Trust:

Acronym	Full title	Date open at Southern Trust	2019 Status at Southern Trust	Recruitment at Southern Trust in 2019	Overall Recruitment at end 2019 Southern Trust
UKGPC	UK Genetic Prostate Cancer Study (formerly Familial Prostate Cancer Study)	21/01/2009 PI Dr Judith Carser	Open	0	50

Belfast Trust:

Acronym	Full title	Date open at Belfast Trust	2019 Status at Belfast Trust
UKGPC	UK Genetic Prostate Cancer Study (formerly Familial Prostate Cancer Study)	27/10/2006	Open
STAMPEDE	Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy	16/12/2005	Open
ADRRAD	Neo-adjuvant Androgen Deprivation Therapy, Pelvic Radiation and RADium-23 for new presentation of T1-4 N0/1 M1B adenocarcinoma of prostate (ADRRAD Trial)	21/01/2016	Closed 29/04/19
SPORT	A Randomised Feasibility Study Evaluating Stereotactic PrOstate RadioTherapy in High-Risk Localised Prostate Cancer with or without Elective Nodal Irradiation (SPORT High-Risk Trial)	18/01/2016	Open
IMMUNE GENE	How does radiotherapy affect immune gene expression and the tumour microenvironment in men with localised prostate cancer?	04/01/2017	Open
RE-AKT	A randomised Phase II study of enzalutamide (MDV3100) in combination with AZD5363 in Patients with Metastatic Castrate-Resistant	15/06/2017	Open

	Prostate Cancer		
Add-Aspirin Trial (Prostate Cohort)	A phase III, double blind, placebo controlled, randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours	01/11/2017	Open
CORE	A randomised trial of conventional care versus radioablation (stereotactic body radiotherapy) for extracranial metastases	05/12/17	Closed 01/03/19
ACE	ACE: Proof of concept Phase I/II trial of the CXCR2 antagonist AZD5069, administered in combination with enzalutamide, in patients with metastatic castration resistant prostate cancer(mCRPC)	14/05/2018	Open
CTC-STOP	Utilising Circulating Tumour Cell (CTC) Counts to Optimise Systemic Therapy of Metastatic Prostate Cancer	01/06/2018	Closed 02/05/19
TrueNTH Registry	TrueNTH Global Registry- Prostate Cancer Outcomes	29/06/2018	Closed 31/08/19
GAP 4 INTERVAL	INTense Exercise foR survival among men with Metastatic Castrate-Resistant Prostate Cancer (INTERVAL – MRCPC): A Multicenter, Randomized, Controlled, Phase III Study	23/01/2019	Open
PIVOTALboost	A phase III randomised controlled trial of prostate and pelvis versus prostate alone radiotherapy with or without prostate boost	25/10/2019	Open
Also 3 studies in early phase portfolio open to advanced solid tumours			

Other Urological Open Cancer Trials 2019

Belfast Trust:

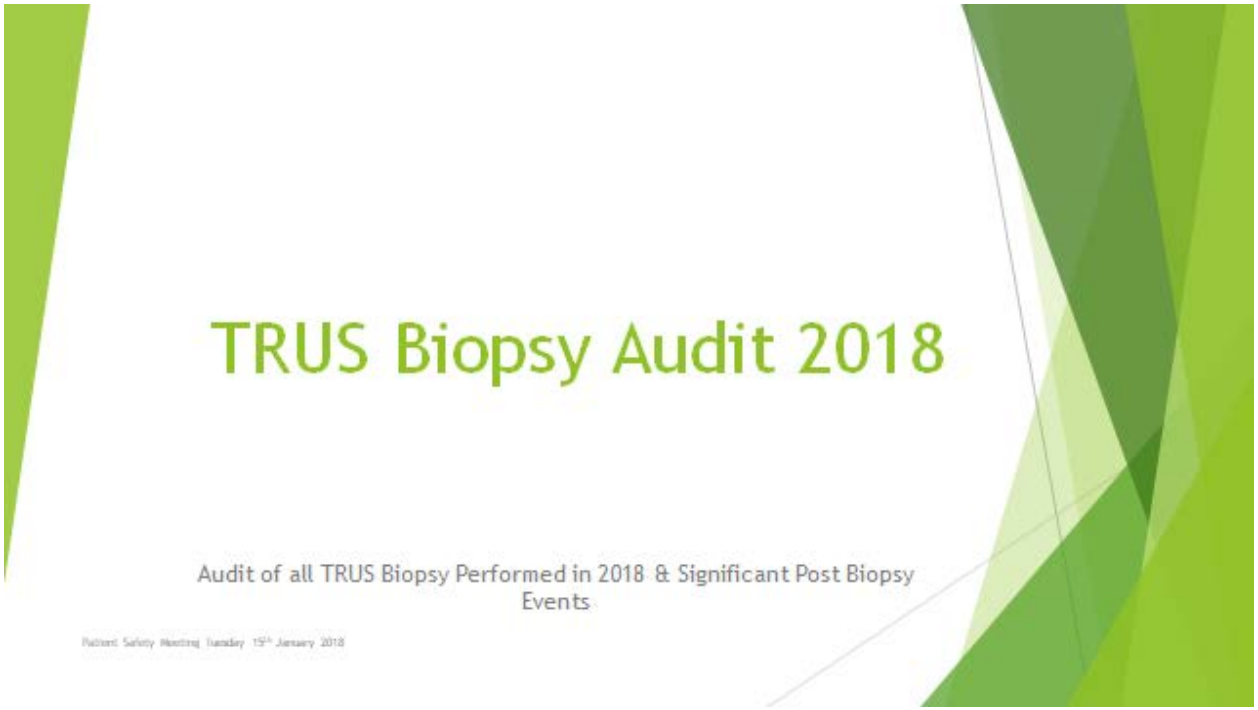
Cancer Type	Acronym	Full title	Date open at Belfast Trust	2019 Status at Belfast Trust
Bladder	**RAIDER**	A Randomised phase II trial of Adaptive Image guided standard or Dose Escalated tumour boost Radiotherapy in the treatment of transitional cell carcinoma of the bladder	24/11/2017	Open
Germ	**UK**	A randomised phase 3 trial of accelerated versus standard BEP chemotherapy for patients with intermediate and poor-risk	04/10/2019	Open

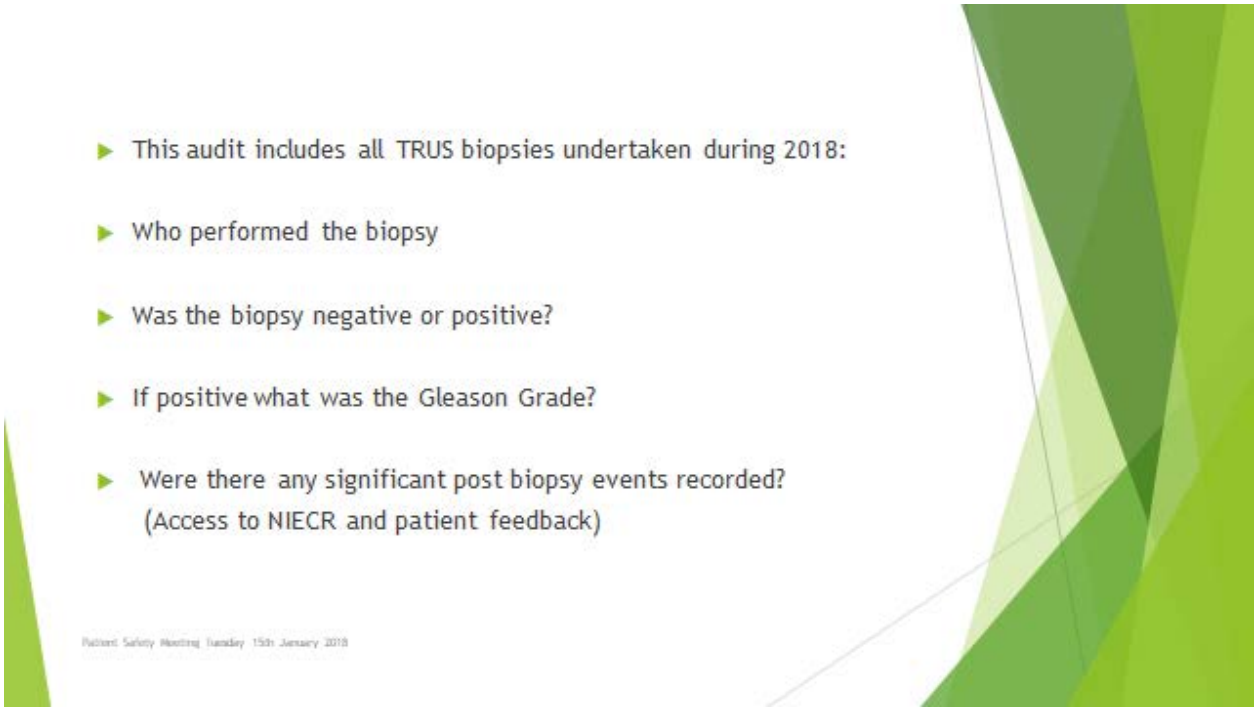
Cell	**P3BEP**	metastatic germ cell tumours		

Urology Clinical Trials in Set-up at Belfast Trust 2019

TRAP	Targeted Radiotherapy in Androgen-suppressed Prostate cancer patients
VISION	An International, Prospective, Open-Label, Multicenter, Randomized Phase 3 Study of 177Lu-PSMA-617 in the Treatment of Patients with Progressive PSMA-Positive Metastatic Castration Resistant Prostate Cancer (mCRPC)
BAYER 16996	A Phase 4 long-term follow-up study to define the safety profile of radium-223 dichloride
IRONMAN	Prostate Cancer Outcomes: An International Registry to Improve Outcomes in Men with Advanced Prostate Cancer
PACE-C	International randomised study of laparoscopic prostatectomy vs stereotactic body radiotherapy (SBRT) and conventionally fractionated radiotherapy vs SBRT for early stage organ-confined prostate cancer
Pembrolizumab Extension Study	A Multicenter, Open label, Phase III Extension Trial to Study the Long-term Safety and Efficacy in Participants with Advanced Tumors Who Are Currently on Treatment or in Follow-up in a Pembrolizumab Trial

Appendix 7 AUDITS





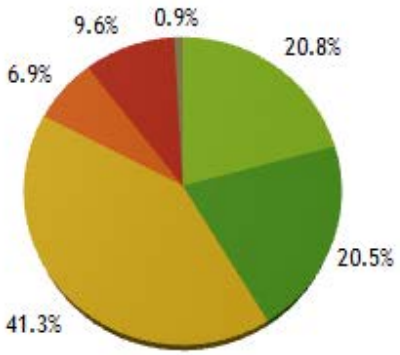
Biopsies Performed

(Jan 18 - Dec 18)

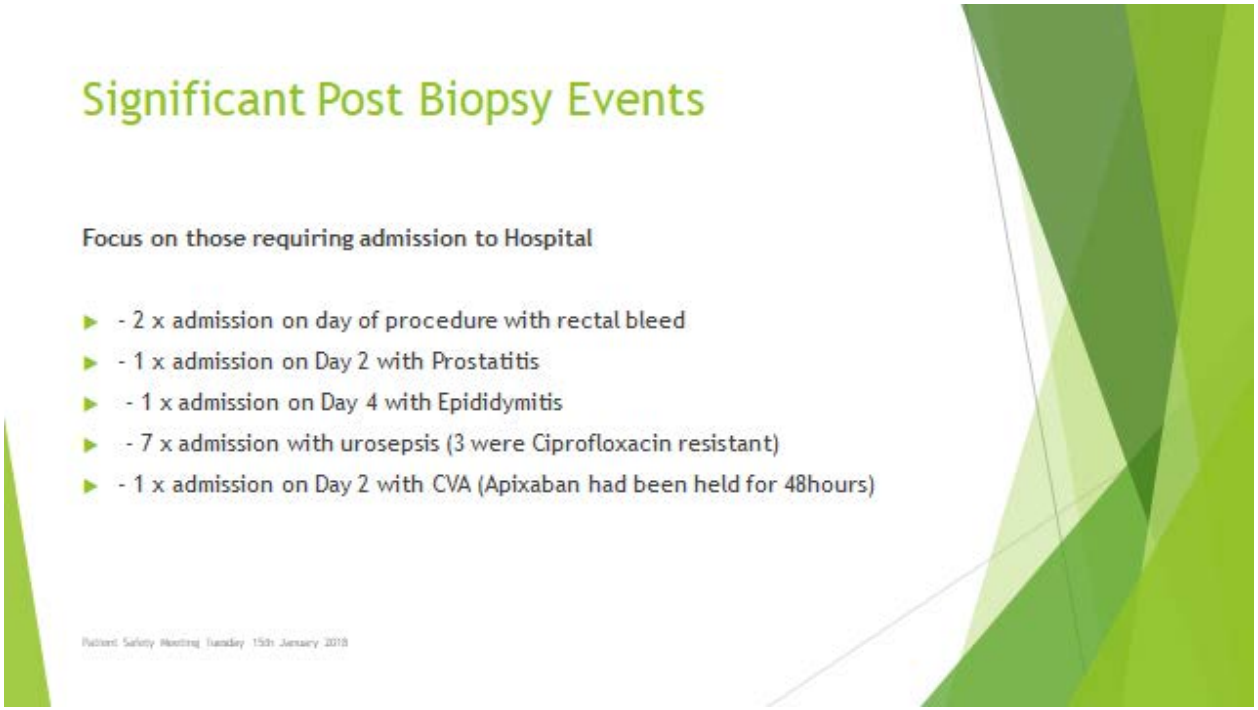
Professional	TRUS	GA- Biopsy	Total	Percentage
Consultant Urologist	35	22	57	17.2%
Consultant Radiologist	64	N/A	64	19.3%
Nurse Specialist	211	N/A	211	63.5%
Overall Total			332	

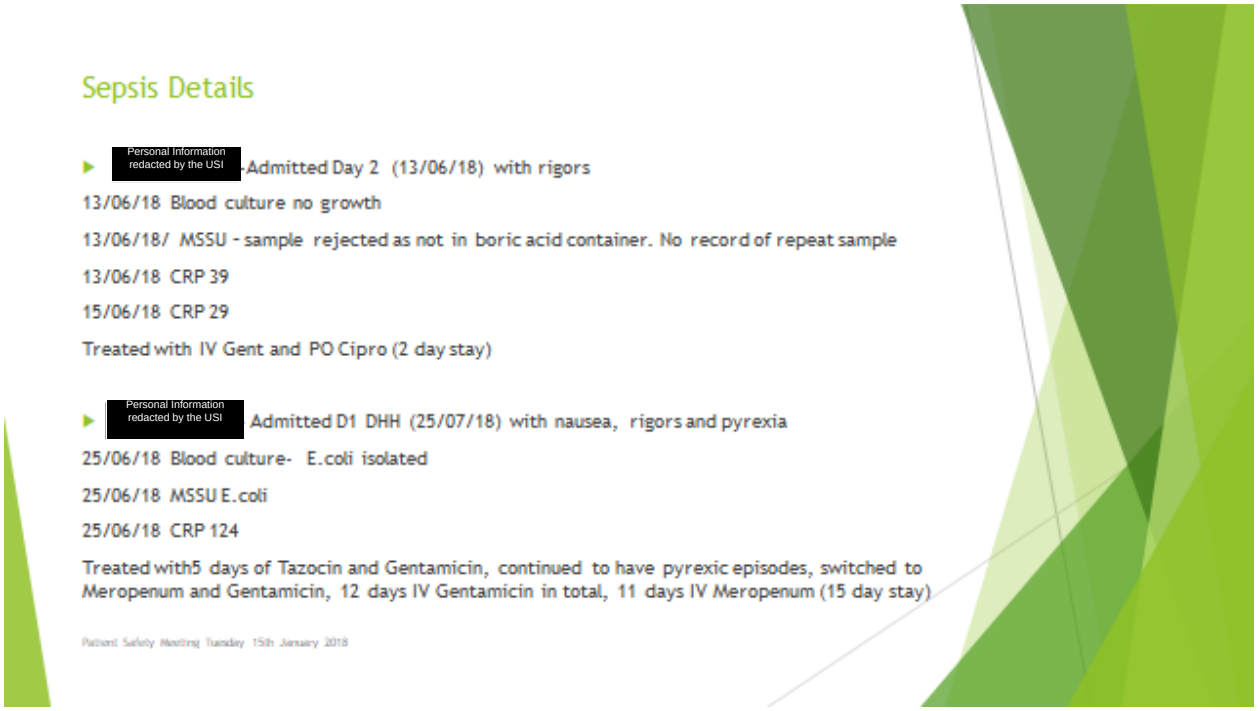
Patient Safety Meeting Tuesday 15th January 2019

GRADING



- Benign n=69
- G 6 n=68
- G 7 n=137
- G 8 n=23
- G 9 n=32
- G 10 n=3





Sepsis Details

- Personal Information redacted by the USI Admitted Day 1 (08/08/18) with altered mental status and pyrexia

08/0818- blood cultures- no growth

08/08/18- MSSU not significant though >50 pus cells (3 x MSSU sent on 8th Aug)

09/08/18 CRP 36

Treated with IV gentamicin for 5 days and then changed to PO Ciprofloxacin (5 day stay)

- Personal Information redacted by the USI Admitted Day 2 (17/10/18)with rigors, shivering and generally feeling unwell

17/10/18- Blood cultures- E.coli **(CIPROFLOXACIN RESISTANT)**

17/10/18- MSSU- not significant

17/10/18 CRP

23 20/10/18 CRP 63

Treated with Gent then switched to IV Aztreonam, switched to oral Cefalexin (7 day course) (6 day stay)

Patient Safety Meeting Tuesday 15th January 2018

Sepsis Details

- Personal Information redacted by the USI Admitted Day 3 (01/11/18) with fever, chills, nausea, vomiting, urinary frequency

Blood cultures 01/11/18- E.coli (CIPROFLOXACIN RESISTANT)

02/11/18 MSSU- not significant

01/11/18 CRP 60 02/11/18 CRP 243

Treated with IV ABx (Meropenem then Tazocin) and patient improved clinically

12/11/18- Blood cultures- no growth

12/11/18 MSSU - E.coli

12/11/18 CRP 58 (prev 13)

14/11/18 CRP 65

He was readmitted following day with rigors, aches and feeling unwell

Urine cultures grew E. Coli demonstrating a moderate level of resistance to oral antimicrobials

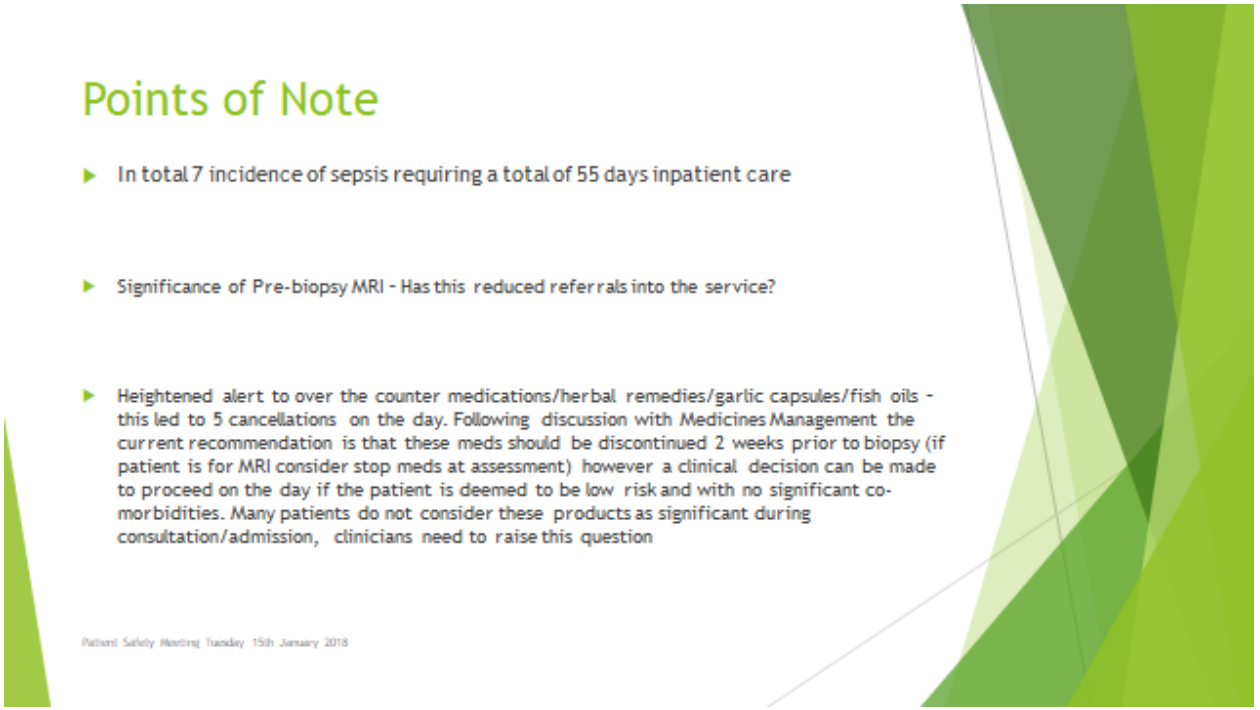
blood cultures grew nil

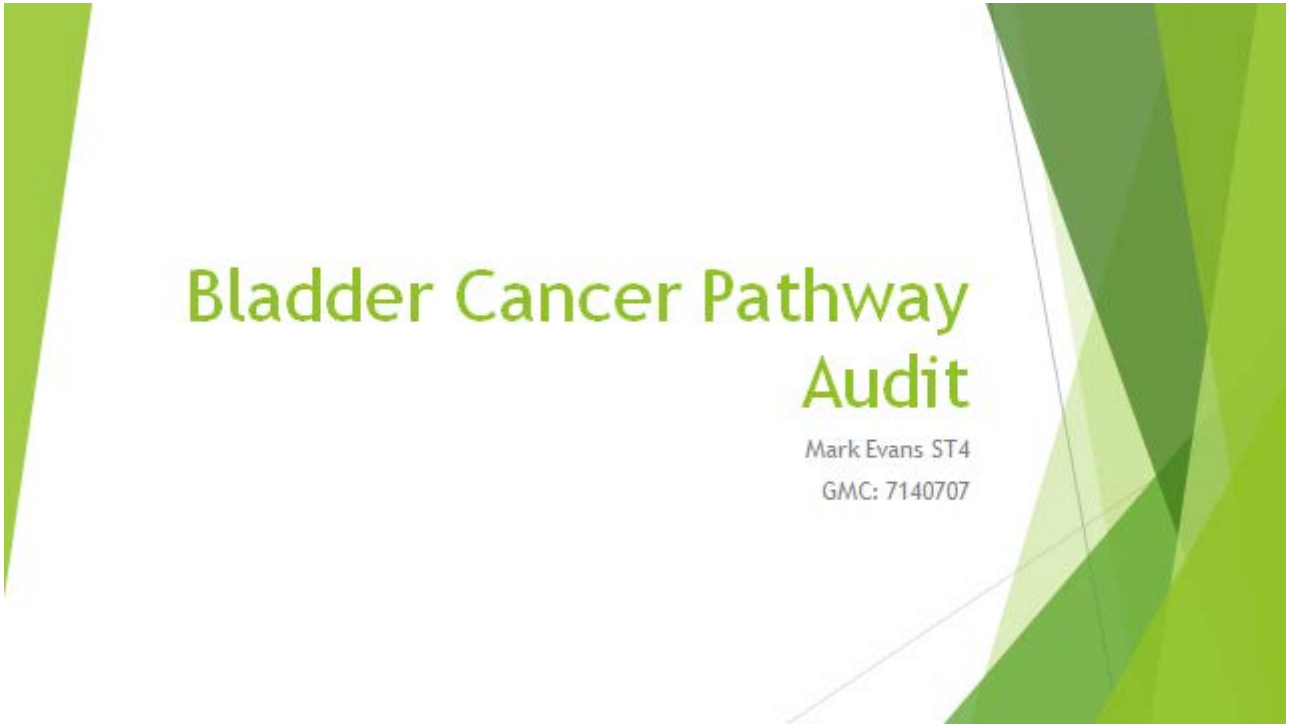
Placed on IV TAZ, discussed with the microbiology team - given the rapid readmission following Meropenem therapy it was advised to continue IV TAZ

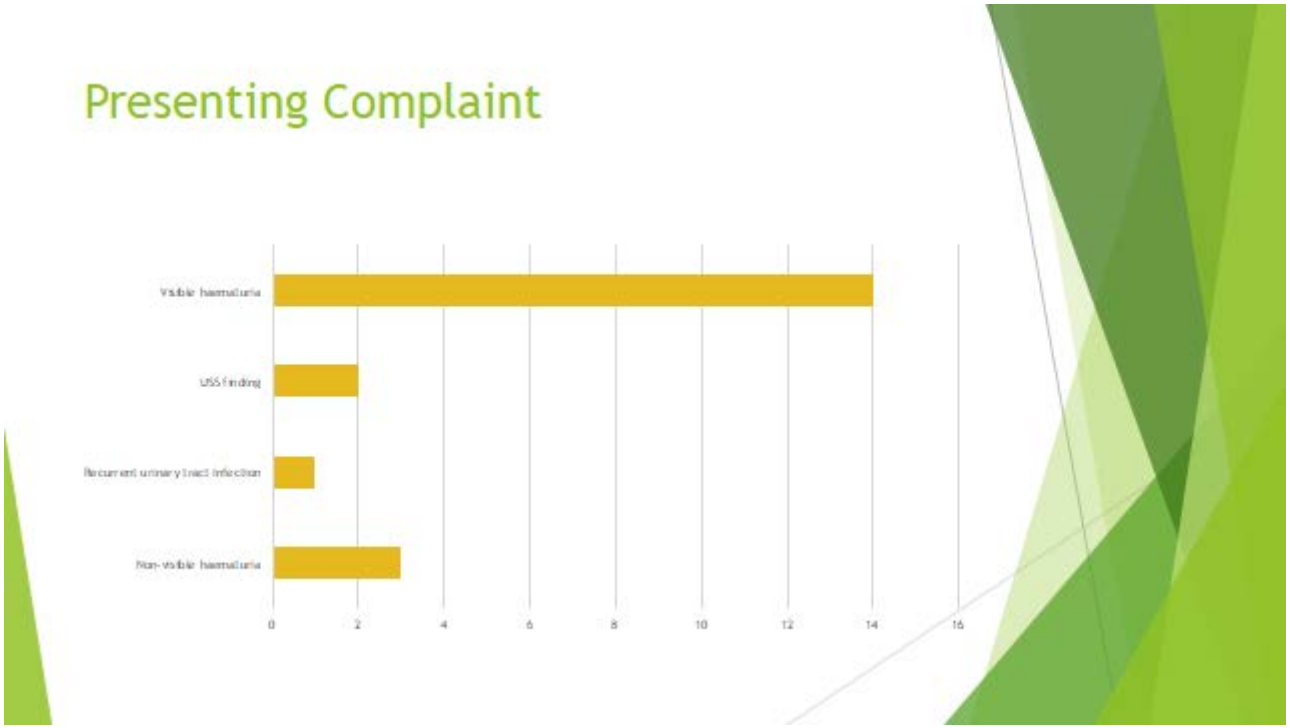
Positive urine cultures and negative blood cultures suggested a local infective recurrence

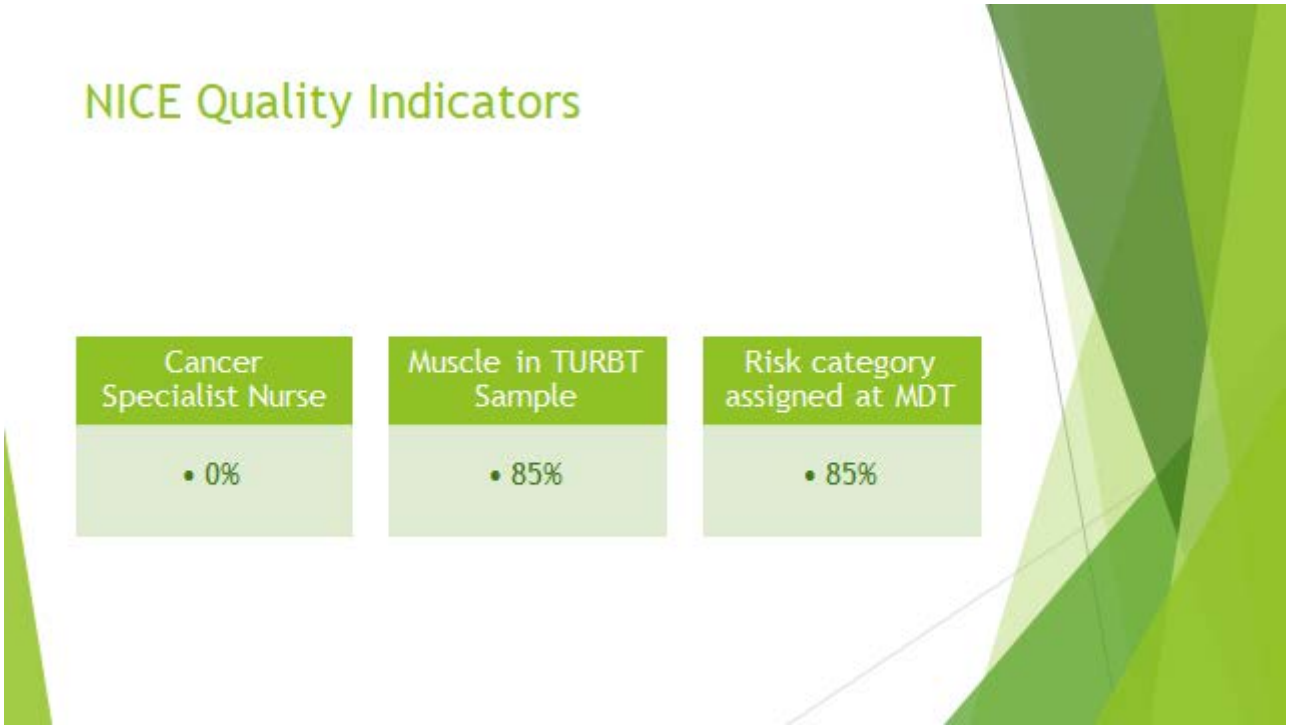
Discharged home on a 7 day course of oral Pivmecillinam (2 admissions total 14 day stay)

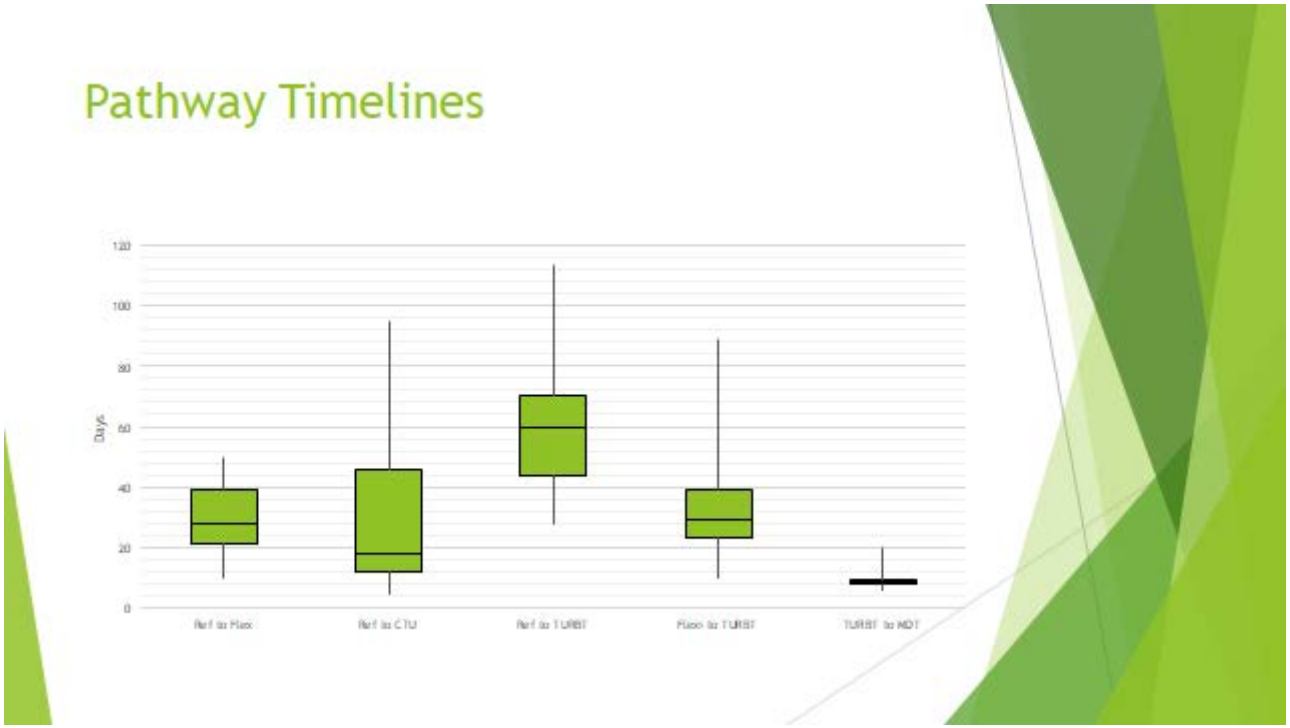
Patient Safety Meeting Tuesday 15th January 2018

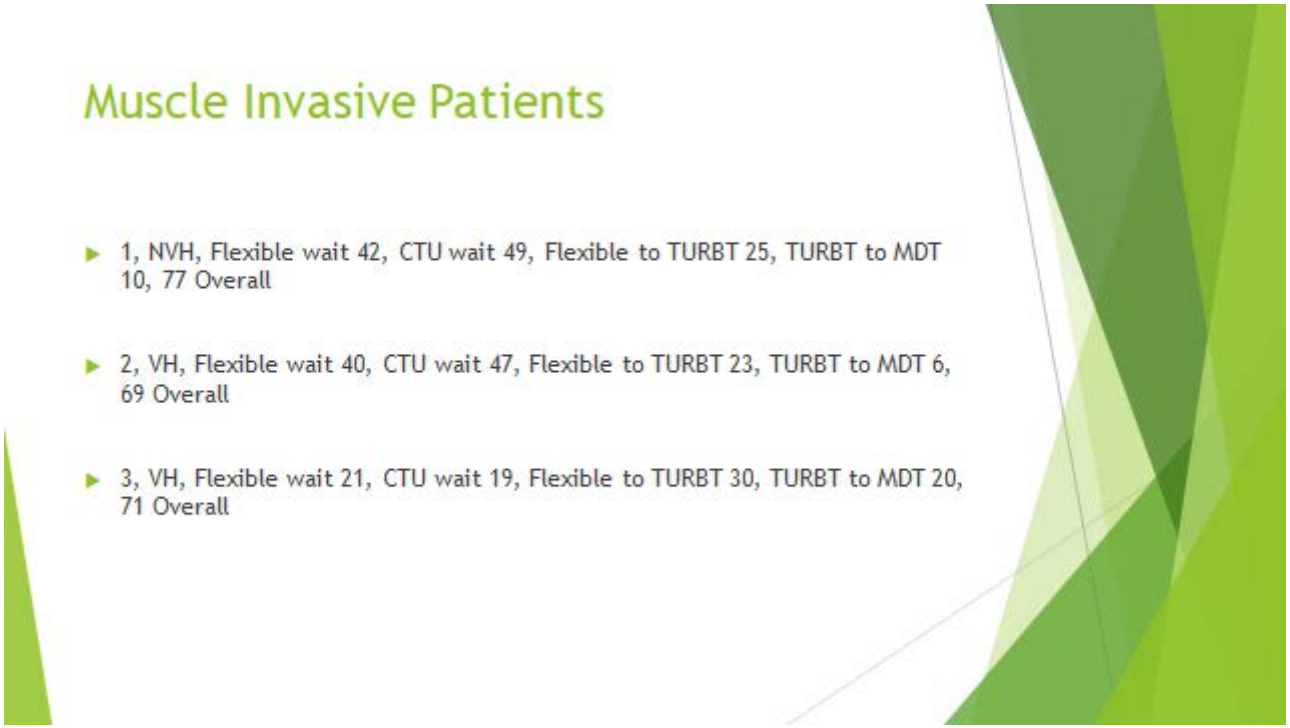












Action Plan Internal Lookback Steering Group | 2021/2022

Stage 2: Identifying and Tracing Service Users at Risk "Regional Guidance for Implementing A Lookback Review Process, DOH, July 2021

Action Required	What is Required to Action?	Action Owner	Required By	Action to Date	Action Completed & Date	RAG
2.1 The Steering Group Agrees the Scope and TOR of the Service Review/ Audit and Recall Stages of the Lookback Review Process	• TOR for Internal steering group and External Assurance Group to be agreed	• Internal Steering Group and External Assurance Group	• Dec 2021 for Internal • Jan 2022 for External	• **Internal TOR confirmed at meeting 6.12.21** TOR Internal Lookback Steering Gr	**6.12.21**	
2.2 The Steering Group Develops a Lookback Review Action/ Work Plan to Inform the Audit and Recall Stages of the Lookback Review Process	• All patients included in the 2019-2020 cohort are identified • Patients are separated into cohorts: **1. Patients Clinical Record Reviewed and Nil Issues** **2. Patients Clinical Record Review and Issues Identified/ Requires Further Investigation** **3. Patients Clinical Record Reviewed and Subject of SJR** **4. Patients who have not had any form of review** **5. Any RIP patient in any of the above .**	• Head of Clinical Assurance • Clinicians Reviewing Internally and Externally • Steering Group	• Letters to be completed by Week Ending 19.12.2021 • Action plan/ Work Log ongoing at fortnightly meetings	• Activity to Date		

	• The Steering Group will be provided with details of the issues identified as the process continues at each meeting to ensure new risks identified are escalated and decision to progress to stage 3 is identified and agreed at earliest opportunity.					
2.3 A Database is Established to Collate and Track the Information Gathered by the Lookback Review Process	• Database of all patients within the 2019-2020 cohort is completed with details of review, concerns identified, death indicator, addresses, DOB and contact number. • As the Lookback process continues the Database will be kept up to date. Clinicians reviewing patients either F2F/ Telephone or Virtually will complete the clinical review form and/or inform Head of Clinical Assurance so that patients journey can be tracked and database maintained so up to date data on Lookback can be provided at each group meeting and feed into Assurance Group.	• Head of Clinical Assurance • Clinicians Reviewing Internally and Externally • Steering Group	• Dec 2021 • Database update ongoing • 2019-2020 patients to be addressed by End March 2022	• **Database completed to reflect the current position of Lookback exercise.** • **Includes Date of calls from Liaison and all attempts/ messages left** • **Datix Number recorded for SCRR patients** • **Type of Letter sent and date of sending recorded** • **Contact from Info Line and actions taken recorded** • **Additional Review Clinic details recorded (cons & date)**	**Yes- 3.12.21 and ongoing as progresses**	
2.4 The Service Review/ Audit is Undertaken by a Nominated Team of	• External Team appointed for SJR • Internal screening process for patients identified by Clinical	• Head of Clinical Assurance	• Dec 2021 • SJR process pending to	• 49 records uploaded onto EGRESS and section 1 completed on SCRR form.		

Experts Commissioned by the Steering Group	Review process for potential SJR following SAI screening process. • Outcomes of SJR to be reflected in an Action Plan of recommendations to address	• Internal and External Clinicians • Governance Team • Internal Steering Group	commence Dec 21/ Jan 22	Sent to X2 Consultants 21.1.22 to commence process. 3rd Consultant confirmed 27.1.22 and a further 10charts sent to upload 7.2.22. As per Stephen Wallace 15.2.22. 3rd batch of 10 records uploaded 11.3.22 and 4th batch uploaded 26.4.22. WE now have 10 records back with completed SCRR. •  Structured Clinical Record Review Form. • • 13 records to be uploaded. (7 have had the cover page completed and with Dawn King the remaining 6 are not ready to go yet) • Contract complete in draft for SCRR process.. The contract for the Clinical Record review & subsequent reviews/ diagnostics is also nearing completion. Spoke to 3Five2 last week and draft contracts discussed and will attempt to cost based on the basic processes contained. Also having Consultants review the SCRR form. • Discussion of issues with IS committing to the process as Consultants do not want		

				to be involved in a Public Inquiry & pilot commencing this week (wed 25th) • No access to NIECR in IS and this is being worked through with Contracts team and BSO. This is essential for any contract (clinical record review & SCRR) which will be in the next phase of lookback. Meeting 20.5.22 with Contracts & BSO about NIECR access. • Requested by Dawn King via IT a report of all patients coded under AOB from Jan 2015 to Jan 2019 with a breakdown of per year and if possible the category (eg ED admission, outpatient referral etc)		

2.5 The Service Review/ Audit Identified Persons Affected to be Included in the Recall Stage	• Database of all patients within the 2019-2020 cohort is completed with details of review, concerns identified, death indicator, addresses, DOB and contact number. • Screening of the database to identify the cohorts of patients and the themes of issues. Updating as further patients/ records are reviewed and clinical review forms completed. • Recording of the type of letter sent to patient and date sent • Fortnightly meetings to update on new issues identified and number of patients within each.	• Head of Clinical Assurance • Clinicians Reviewing Internally and Externally • Steering Group	• Ongoing but to have current cohort of patients completed by end March 2022	• **Database completed to reflect the current position of Lookback exercise.** • **Includes Date of calls from Liaison and all attempts/ messages left/ action taken** • **Datix Number recorded for SCRR patients** • **Type of Letter sent and date of sending recorded** • **Contact from Info Line and actions taken recorded** • **Additional Review Clinic details recorded (cons & date)** • **Review Forms and detail included.**	**Yes- 3.12.21 and ongoing as progresses**	
2.6 The Helpline/ Information Line is Established by the Steering Group	• The Helpline numbers are functional. Separate numbers are established for general Urology Inquiry Helpline and SJR Helpline. • The Helpline is staffed by persons who are suitable to manage the potential issues coming through the line. The SJR Helpline will be staffed by Liaison Staff trained to provide further support through this process. • The staff managing the Helplines will be provided with "script" of support for speaking to patients/ families/ carers. These will be different for both general Urology Helpline and SJR Helpline.	• Head of Clinical Assurance • Admin Team • Liaison Team • Urology Team • Steering Group	• Week ending 12.12.21	• **IS Admin Team (x2 staff) allocated to commence week beginning 13.12.21 to staff the general Urology Helpline** • **See attached Activity to date detailing change in Liaison Staff. Will have to update/ amend leaflets for patients. Fiona Sloan currently ringing all SAI patients to advise of the change and pass on new details.** • **Liaison Team have "script" in place including process for recording contact and managing distress.**	**Complete end Dec 21**	

	• All patients will be provided with the details of the Helpline within their letters. • SJR patients will be contacted prior to letters going out to advise, answer what questions they can and direct back to clinical team for further information. • The general Urology Helpline will have a database established to record the name, DOB, contact number and nature of query. This will allow for prioritisation of reviews (F2F or telephone)			• **Details of Helpline for general Urology and SJR completed for sending in letters.** • **To now we have had no further calls and CNS has supported the return of all remaining calls.** • **Script for new batch SCRR patients & need for Liaison to attend clinic review. Need steer on letter templates to support the info to the patient**		

Rag Rate Description	
	Not Commenced
	In Process
	Completed

Southern Health and Social Care Trust

Quality care – for you, with you

BOARD REPORT SUMMARY SHEET

Meeting: Date:	Trust Board 12th November 2020
Title:	Urology Update
Lead Director:	Dr Maria O'Kane, Medical Director Melanie McClements, Director of Acute Services
Purpose:	Information

Overview:

The purpose of this paper to provide an update to Trust Board (November 2020) on the ongoing review of urology services relating to Consultant A

Key areas for SMT / Committee consideration:

- Update on review progress to date (10th November 2020)
- Formation of Department of Health Oversight group and details of planned ministerial statement to the NI Assembly
- Update on the progress of identified Serious Adverse Incidents and Public Health Agency advice regarding a proposed 'Clinical Investigation' model for future identified urology incidents
- Update on engagement with the Independent Sector Provided engagement to provide review appointments for 236 oncology backlog patients
- Update on review of prescribing of the medication Bicalutamide, an Anti-androgen drug, to date there have been 26 patients out of 300 identified as needing an urgent appointment.

Human Rights/Equality:

None to declare

Background to Review

A review of clinical processes has been undertaken, the background and current status of the ongoing review is provided below. The necessity of a further review of clinical care is being discussed with the Royal College of Surgeons.

Elective Care	The review has identified that Consultant A had operated on 334 patients, and out of these 120 patients were found to have undergone delays in dictation of their discharge with a further 36 patients having no record of their discharge on the Trust's electronic care record (NIECR). **Of the 36 patients, there have been 2 incidents identified that meet the threshold for SAI reviews.**
Management of Pathology and Cytology Results	The review has identified 50 out of 168 patients that require review as a result of un-actioned Pathology or Cytology results. **Of the 50 patients requiring review there have been 3 incidents identified that meet the threshold for SAI reviews with a further 5 requiring a review follow-up to determine if these patients have come to harm.**
Management of Radiology Results	The review has identified 1536 radiology results which require review to ascertain if appropriate action was taken. A review of the 1536 cases is ongoing.
Actions required as a result of Multidisciplinary Team Meetings	There were 271 patients under Consultant A's care whose cases were discussed at Multidisciplinary Team Meetings. A review of these patient records is being undertaken. To date there are currently **3 confirmed SAI's and a further 1 needing a review follow-up** to determine if these patients have come to harm. This exercise is ongoing.
Oncology Review Backlog	236 review oncology outpatients will be seen face to face by an Urologist in the independent sector for review. To date there has been **one SAI confirmed** from this backlog as the patient presented to Emergency Department and he has been followed up as a result of this attendance.
Patients on Drug "Bicalutamide"	There are concerns regarding Consultant A's prescribing of androgen deprivation therapy outside of established NICE guidance regarding the diagnosis and management of prostate cancer[1]. *Bicalutamide is an Anti-androgen that has a number of recognised short term uses in the management of prostate cancer. In men with metastatic prostate cancer NICE Guidance states;* *'1.5.9 For people with metastatic prostate cancer who are willing to*

[1] Prostate cancer: diagnosis and management. National Institute for Health and Care Excellence. NICE guideline 131. May 2019.

	accept the adverse impact on overall survival and gynaecomastia with the aim of retaining sexual function, offer anti-androgen monotherapy with bicalutamide[6] (150 mg). ***[2008]*** *1.5.10 Begin androgen deprivation therapy and stop bicalutamide treatment in people with metastatic prostate cancer who are taking bicalutamide monotherapy and who do not maintain satisfactory sexual function.* ***[2008]'*** All patients currently receiving this treatment are being identified by a number of parallel processes utilising Trust and HSC / Primary Care systems in order to facilitate a review to ascertain if the ongoing treatment with this agent is indicated or if an alternative treatment / management plan should be offered.

Department of Health Oversight Group

The Permanent Secretary has established a Department of Health level of external oversight and assurance group to review progress and guide the way forward in terms of the Trust's management plan. Currently the Urology Assurance Group has begun to meet weekly. Michael O'Neill, Acting Director of General Healthcare Policy, is leading on this in the Department and providing secretariat for the group.

Ministerial Statement

The Minister for Health issued a written statement to the NI Assembly on the 26th October. The Trust has been advised a further statement from the Minister to the NI Assembly will be made on 17th November 2020 which will provide additional details. The Trust is preparing proactive communication arrangements in anticipation of this announcement.

Serious Adverse Incidents (SAI) Update

The SAI panel membership has been agreed Terms of Reference have been internally agreed and have been forwarded to the HSCB. All 9 patients/families identified through the SAI process have been spoken to this week with some of them being offered a further appointment with a Consultant Urologist, taking place this week. During the initial consultations with one family there appears to be some discrepancies in what the families understanding of what had been said by the consultant and what the expert reviewer has indicated.

Four out of the five patients/ families, along with the index patient of the previous SAI's, have also been spoken to. The family of the fifth patient's family (RIP) is still outstanding as this is being

clinically considered due to the recent death of the patient. The Chair of the SAI panel is also going to meet with these patients and this is currently being organised.

Given the number of patient cases from this review period (January 2019 to June 2020), this review exercise continues to be ongoing, and the above information is the current position at this point in the review.

The Health and Social Care Board / PHA have advised that any additional incidents that are identified as meeting the threshold for an SAI review should be paused will be managed via a separate 'clinical investigation' process. The Public Health Agency has indicated that this process will be independent of the Trust and will be guided by and have parameters set by the HSCB/PHA/Department of Health.

Consultants Private Practice

It was requested at the Department of Health Oversight Group meeting on 6th November 2020 that the Trust write to the Consultant to gain assurances surrounding their private practice for the last 5 years. Either of the options below are to be offered:

- A written assurance from the Consultant to the Trust that they will make arrangements for their private patients to be reviewed by an independent urologist; or
- The Consultant provides details of their private practice and the Trust will make arrangements for the review of these patients and recharge the cost to them / their medical insurer

Summary of Activity for Patient Facing Information Line

The Trust established since 26th October 2020 a patient information line available for patients who may have questions or concerns regarding their care. The details of contacts made to date:

- **Total calls – 153 (up to and including Tuesday 10 November)**
- **2** patients are being seen as part of the oncology review backlog in Independent Sector
- **1** patient was on Bicalutamide and was seen at clinic on Monday 2 November
- **1** patient was picked up as not having been added to any system for a Red Flag Flexible Cystoscopy and has an appointment for Monday 9 November 2020

The Trust has also set up an accompanying GP information line for GP's who may wish to find out more information regarding patients who have been referred to Trust urology services. The details of contacts made to date:

- **1** GP has called the **GP Information line** - communication has been sent by HSCB

Independent Sector Clinics

A total of **236** oncology patients were deemed to be part of a backlog relating to Oncology Reviews. These patients will be seen for review by an Urologist in the Independent Sector. There have been **191** oncology review patients transferred to the Independent Sector and clinics are fully booked for the month of November for these patients. To date one case has been identified as meeting the threshold for an SAI review from this backlog.

- **131** patients have been offered and accepted an appointment over the next four weeks.
- **39** patients still to be contacted (not answering phone) so a letter has been sent asking them to ring to arrange an appointment
- **21** patients have been returned to Trust
    - 8 patients have advised that they no longer require an appointment and happy to be discharged
    - 1 patient has moved to Scotland
    - 12 patients not willing to travel so will be offered an appointment in the Southern Trust by end of November 2020.

Bicalutamide Audit

There are concerns regarding Consultant A's prescribing of a particular drug, which appears to be outside of established NICE guidance, regarding the diagnosis and management of prostate cancer. The drug is Bicalutamide, an Anti-androgen drug, which has a number of recognised short term uses in the management of prostate cancer. All patients currently receiving this treatment are currently being identified by the Trust, in order to facilitate a review to ascertain if their ongoing treatment with this drug is indicated or if an alternative treatment management plan should be offered. To date there have been 26 patients out of 300 identified as needing an urgent appointment.

- **26** patients identified from the first review of the patients:
- Two all-day clinics (Monday 2nd & Tuesday 3rd November) were held in Craigavon Hospital clinical team (1 x Consultant, 2 x Specialist Nurses and 1 x Pharmacist in attendance)
- **26** patients were contacted and offered an appointment:
- **9** patients attended the hospital
- **2** patients cancelled on the day
- **1** patient did not attend

- **14** patients (or their main carer) declined face to face appointment and these patients will be followed up by a telephone consultation

General Medical Council

The Trust is continuing to liaise with the General Medical Council regarding professional issues.

Royal College of Surgeons Invited Review Service

The Trust has approached the Royal College of Surgeons (RCS) Invited Review service to request a review of Trust urology services in relation to consultant A's practice. This engagement is at an initial stage and a meeting with a clinical lead from the RCS is being scheduled for this week / beginning of next week.

Grievance Hearing

The outcome of the formal grievance hearing was communicated to Consultant A on 26th October 2020 by report.

The panel was constituted by an external HR professional and a senior medic not previously involved in the case from within the Trust.

Overall, the panel did not find Consultant A's grievance upheld. Consultant A has subsequently lodged an appeal.

Additional Subject Matter Expertise / Consultant Reviews

The Trust via the Royal College of Surgeons has engaged with the British Association of Urological Surgeons (BAUS) who have provided two subject matter expert Consultant Urologists to assist with the ongoing work. One subject matter expert is providing independent expertise for the SAI process with the second expert engaged to assist with the review of electronic patient records.

Investment Proposal Template (IPT) HSCB

The HSCB have advised that the Trust develop and submit an IPT to cover additional costs associated with current and projected future work relating to the Urology review. This work will include clinical, managerial and governance oversight costs.

Comments concerning the RCA Report on Review of SAI [redacted]

In submitting this commentary regarding the RCA Report of SAI [redacted], I have reviewed all retained correspondence relating to the issue of triage, all retained documentation relating to other issues impacting upon triage and all retained documentation relating to other issues referred to by others interviewed during the course of the Root Cause Analysis. Having done so, I believe that the Recommendations outlined in the Report are its most important component, though I believe that at least one additional recommendation is required to ensure that the others could be effectively implemented. I have endeavoured to be concise.

Having been interviewed by Dr. Johnston and having read the above Report, I do believe that the singular and significant flaw of the Review has been to investigate the failure to triage urgent and routine referrals in isolation of other pressures and clinical priorities which I believe are evidently more important. As a clinician and a clinical department, I believe that these greater clinical priorities cannot be compromised for the sake of triage, as they have been and continue to be.

Urologist / Consultant of the Week

While agreeing that triage is indeed a serious issue and very important, I was concerned to being expected to agree that triage of referrals has 'number one ranking in the overall scheme of things'. I believe that it is vitally important to fully appreciate the significance of this claim, especially as triage has been aligned with the duties of the Urologist of the Week (UOW). If, as has been my experience during my last week as UOW, one does a ward round from 09.00 am to 11.30 am, prior to going to theatre to undertake seven emergency / urgent operations, is triage the most important concern that day, or the day after, if it is similar?

I most earnestly urge the Review Team to review the wording of Recommendation 6, urging the Trust to re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW. I believe that it is important to appreciate that the Trust has never examined or assured itself in the first place, never mind do so again. I believe that it is crucially important that the duties and priorities of the CoW and the expectations of the Trust of the CoW in the conduct of those duties and priorities, be clearly agreed and expressed in a written Memorandum of Understanding, or similar. I do so as there has been an ambiguity since its inception as to those duties and priorities.

Following a long period of gestational discussion, the UOW came into existence in late 2014. The major reason for the length of that gestational discussion was the belief, particularly on the part of our Lead Clinician, that the duties of the UOW could not possibly take up a whole day. This belief was borne out of his perception that the UOW would essentially be on call. When subsequently persuaded and convinced that it would be a good for inpatient management that the UOW would conduct an ward round each morning, it was then proposed that we could then undertake a clinic in the afternoon each day, as the duties of UOW could be confined to the morning, as one would rarely be called to theatre in an emergency. When successfully disabused of that proposal which would have necessitated the disorderly cancellation of outpatient attendances, the proposal of

being able to undertake triage of all referrals while UOW was born, as it could be undertaken at any flexible time.

There is no doubt that the clinical and operative demands upon the UOW have evolved and increased during the past five years. Nevertheless, there persists a lack of clarity as to its very purpose, and I have no doubt that there persists a dichotomy of Urologist on Call and Urologist of the Week. It had been my understanding ab initio that its raison d'etre was to provide hands-on, clinical management of all inpatients within our department, whether acutely or electively admitted, to provide advice and management to patients attending and referred from other Departments at Craigavon Area, Daisy Hill and South West Acute Hospitals, and to undertake emergency and urgent surgical intervention so far as is possible. To do so effectively in pursuit of optimal clinical outcomes requires knowing patients, often with complex comorbidities, in detail, and that requires time. However, this has not always been the case.

I have experienced a patient being unnecessarily and inappropriately discharged when it would have been entirely possible for them to have had surgical intervention while inpatients, only to be acutely readmitted, sicker than previously and for another UOW to manage. I have witnessed patients undergoing surgery by Registrars (while the UOW triaged referrals) with outcomes inferior to those I believe would have been achieved had the UOW been operating, or at least attending in supervision. I have been requested by Nursing Staff to assess inpatients who had never been seen by a UOW. Indeed, the most frequently occurring practice which persists is that of the UOW not coming to the hospital at all, particularly over weekends, unless 'called' of course, or not undertaking ward rounds even if present in the hospital.

And while it has been and continues to be easier to undertake triage while being 'on call', I have also no doubt whatsoever that the expectation to undertake triage of all referrals lends itself to being Urologist on Call rather than UOW. Indeed, a senior executive manager of the Trust has written that UOW was introduced to facilitate triage! If that is one understanding, there certainly needs to be a discussion and an agreement in the first instance of the duties of the UOW.

In 2018, following discussion amongst our colleagues, it was agreed that we would set aside a whole day, Monday 24 September 2018, to meet with senior management to discuss this very issue, among others. We were requested to submit those issues which we wanted to have discussed (I have separately attached my submission). No clinical commitments were arranged for that day. The meeting was cancelled, with loss of all clinical activity that could have been scheduled. The meeting was rescheduled for Monday 03 December 2018, again with no clinical commitments scheduled. No senior management personnel could attend. I therefore have no confidence whatsoever that Recommendation 6 will be addressed.

Triage and Waiting Times

I also do contend that it is not possible to deal adequately with the very important issue of triage without consideration of waiting times, and how this could or should affect the nature of the triage conducted. Dr. Johnston was of the view that the Red Flag referrals were not an issue as they 'go straight into the system'. However, the recent waiting time for a first consultation for a patient suspected of having prostatic carcinoma is 107 days. We have recently been circulated with the details of twelve patients referred as, or upgraded to, Red Flags as they were suspected

of having prostatic carcinoma. They were triaged, without any consideration of any form of preliminary investigation being requested. It would have taken less than one minute to ascertain their Red Flag status, and 'they go straight into the system', and wait almost four months for a first consultation. The further ignominy is that, on attending almost four months later, some have waited all of that time just to have a serum PSA repeated, before deciding whether to proceed with Investigative imaging, such as MRI scanning, prior to prostatic biopsies. Lest there be any doubt, the reason for the conduct of triage in such a manner is the lack of time to do otherwise, coupled with a determination that triage will be completed on completion of the period of UOW. As indicated above, I have witnessed such minimalist triage being conducted instead of undertaking ward rounds.

In March 2015, I endeavoured as Lead Clinician of Urology MDT to have my colleagues agree to advanced / enhanced triage of Red Flag patients alone. The purpose of doing so was to facilitate patients progressing along the diagnostic and therapeutic pathway in the timeliest manner possible. I did not succeed, as they declined to commit to doing so, and the reason given then was the lack of adequate time while being UOW. I have retained a written record which can be provided if requested. As a persistent consequent, a patient recently referred with a renal tumour detected on ultrasound scanning, waited for a first consultation before having staging CT scanning performed, and which could have been requested if time had been taken or available to do so, to request the scan, informing the patient (and referrer) that it had been requested.

The issue of the referrals which are actually triaged as urgent and routine is even more pressing. It is worth asserting that a referral triaged as urgent may be as life threatening, except that it is presumed that it will not be threatened by a malignancy. However, as has been a recent experience, last year's pyelonephritis was actually a renal cell carcinoma, and she was not even referred, never mind triaged. The recent waiting time for a first consultation for an urgent appointment was 85 weeks. For a routine consultation, it is over three years! Scrotal swellings considered benign by the referrer are routinely triaged by most as routine, without any imaging requested. Yet, seven of 77 such referrals (9%) have been found in a recent audit to have testicular tumours.

Apart from the lack of adequate time to conduct optimal triage while UOW, an additional disincentive is that the UOW will be responsible for the receipt of any investigations requested, and without any additional administrative time allocated to do so. During my last period as UOW, I requested 47 scans. I did so, mainly in the days following completion of the period as UOW. Today, I have received the result of a CT Urogram indicating that the patient probably has pancreatic carcinoma with hepatic secondaries. I will arrange an outpatient consultation for this patient in coming days.

Yet, despite repeated claims to the contrary, the Trust does not have a policy regarding urological triage, and particularly in the context of such waiting times, and with respect to an ongoing expectation that triage will be conducted by the UOW while being the UOW. It remains the case that the Trust is happy with and prefers that the referral is triaged as quickly as possible, so that they are in the system, without investigation and irrespective of the periods of time waiting for a first consultation. It is now almost three years since I recommended in my report concerning the index case Personal Infor that the Trust should meet with us to discuss and agree who should undertake triage, when it should be conducted, and the nature of the triage to be conducted. There has been

no response to date. Two attempts to arrange meetings with senior Trust management in late 2018 did not materialise. I have come to the view that the Trust is only interested in the avoidance of any shared responsibility for these issues, preferring instead that they will be the sole responsibility of the clinician, without provision of the time to do so.

To conclude this section, the Report implies that, irrespective of the difficulties and pressures which my colleagues did have in conducting triage while UOW, they did so, and that there were no negative consequences in there doing so. Inpatient care or the quality of triage suffered to varying degrees, and particularly in the context of long waiting times. I have personally experienced a number of cases of delayed diagnoses of cancer following triage by my colleagues since 2017.

Number One Ranking in the Overall Scheme of Things

Number one ranking in the overall scheme of things for any urological department should be the provision of acute care to those most urgently in need of it; hence, the concept of the UOW. Of course, triage is a method of selecting those patients who may next most urgently need such care. Meanwhile, patients languish on ever increasingly long lists awaiting elective admission, some 600 awaiting urgent elective admission for surgery, some now waiting over five years.

We collectively have over 640 patients awaiting admission for prostatic resection. At least 10% of these patients will be found to have prostatic carcinoma. A recent review has reported an incidence of 13.4% in men aged less than 65 years, and of 28.7% of men older than 65 years. One third of the younger patients required curative or palliative treatment. So, we have a situation where at least 64 patients are waiting for years to have a diagnosis of prostatic carcinoma found. Such a figure contrasts profoundly with the five cases found due to the failure to upgrade to Red Flag status, the subject of the Report. Yet, these patients have been assessed by our Department, placed on waiting lists, with a significant risk of having a cancer diagnosis, some requiring treatment with either curative or palliative intent. Which guidelines, goals, objectives, root cause analyses, SAIs apply to these patients? None, but for our concern for them.

Factual Inaccuracies

AMD1 reported that referrals were not triaged by me in the early 90s, that referrals were being kept in a ring binder and were not on any waiting list, that I stopped the practice when challenged, and would then slip back etc. This is untrue. I was a single handed urologist from 1992 to 1996. I triaged all referrals, sorting them into urgent, soon and routine. Each category had a ring binder of referrals. I had my secretary allocate appointments for patients from each category, in commensurate numbers, to every clinic. I continued to do so until the appointment of Mr. Michael Young in 1998 when it was more appropriate to have an appointments office make appointments.

I find it difficult to believe that patients were waiting 10 years for a first appointment., as claimed by DAS2. It has been my experience that the current waiting times are the longest we have ever had. Of course there were no serious clinical issues due to the effective triage that had been conducted.

DAS1 claimed that I struggled to adapt to the modernisation and change resulting from the Regional Transformation of Urology Services. This is particularly untrue. I can provide for you on request my written submission to the Regional Review Team in 2009, detailing my concerns regarding the future provision of urological services outside of Belfast, my views concerning the lack of a Urological Department at Antrim Area Hospital, and where radical prostatectomies and radical cystectomies should be undertaken in the future. I was particularly concerned regarding the 'centralisation' of radical cystectomies for bladder cancer to Belfast. Even then, I did not entirely appreciate the negative consequences of that centralisation, in that our Department continues to have patients suffering and dying due to their not having radical cystectomies performed.

I was particularly concerned at interview that HOS1 claimed that she had discovered over 700 untriaged referral letters in my filing cabinet, having gained permission to enter my office. I also found that Dr. Johnston appeared to struggle to accept that I had advised HOS1 of the whereabouts of the letters of referral, in the third drawer of the filing cabinet in my office. They were not discovered, or uncovered. Moreover, they were all copies of the originals, as the originals or copies were retained by the Appointments Office for appointment in chronological order in accordance with the Informal Default System (IDS) introduced in 2014.

The Report does acknowledge that I had advised colleagues and management that I had found it impossible to conduct non-Red Flag referrals while UOW, while continuing to triage Red Flag referrals, as detailed in my annual appraisal. It is inconceivable that a IDS was introduced to deal with the lack of triage of non-Red Flag referrals without management being aware that they were not being done, or claiming not to have been informed or aware. The Report implies that it was my sole responsibility, and that Trust management did not bear any responsibility for either their claimed lack of awareness, or its failure to address the issue in a constructive, agreed manner, and which it has still failed to do.

Recommendation 10

The Trust is recommended to set in place a robust system for highlighting and dealing with 'difficult colleagues' and 'difficult issues'. I entirely agree. I believe that it should be included in this Recommendation that any such systems should conform with and be implemented in compliance with national guidelines.

The Report is entirely silent on any Recommendation as to how clinicians, individually or collectively, are to deal with 'difficult management', and particularly management which has repeatedly and consisted failed to address issues of concern for clinicians. The absence of such a Recommendation implies an asymmetry unworthy of the Report.

Recommendations 11 and 12

Recommendation 11 advises that I review my chosen 'advanced' method and degree of triage, to align it more completely with that of my Consultant colleagues. This is itself inconsistent with the claim on Page 18 of the Report that other members of the consultant team were also 'ordering

investigations, providing treatment recommendations and adding patients directly to waiting lists, similar to outcomes achieved from Cons 1's advanced triage'.

Nevertheless, I believe that this recommendation should be amended. I believe that I should triage in the manner agreed with and expected by the Trust in a written policy for urological referral. That way, there will be no room for variance in how or when triage is conducted, and the trust will bear responsibility for any negative consequences, provided clinicians have conducted triage in accordance with the agreed policy. In doing so, Recommendation 12 will have been complied with.

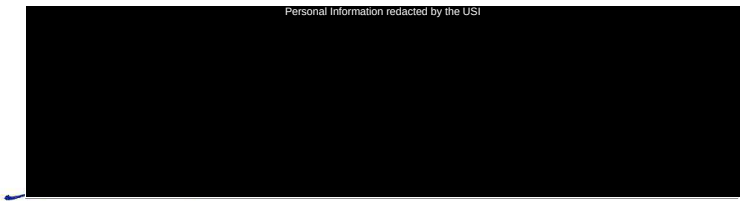
Conclusions

I do agree with the Recommendations contained in the Report, with a number of caveats. I do believe that it is crucially important that Recommendation be amended to ensure that the Trust develop a clear, agreed, written policy of its expectations, duties and performance of the Urologist of the Week, before it consider whether it is feasible to undertake triage while Urologist of the Week. Qualitatively and quantitatively defining and describing its expectations of the complexity of triage without firstly doing so for UOW will lead to a fudged failure.

I believe that no Consultant Urologist should be expected to concern him or herself with reviewing their conduct of triage to align themselves with his or her colleagues, especially when the colleagues claim to be conducting triage in a similar manner. That proposal wil be replaced by a clear, agreed, written policy of the Trust concerning the conduction of triage. Then each Consultant only has to comply with the policy, and not with conduct of his or her colleagues, real or imagined.

Lastly, the report should include a Recommendation concerning the establishment of systems enabling clinicians, and particularly clinical departments, deal with difficult or dysfunctional management.

I look forward to receiving a revised report in due course. I have little confidence that it will have been significantly amended. I have less confidence that any of its Recommendations will be implemented.



Aidan O'Brien

11 December 2019