correspondence submitted to the HSCB and this should NOT be the patients H &C Number or their initials. (See section 10 – Information Governance)

12.2 Never Events

Never Events are SAIs that are wholly preventable, as guidance or safety recommendations that provide strong systemic protective barriers are already available at a national level and should have been implemented by all health care providers.

Each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a Never Event.

It is important, in the spirit of honesty and openness, that when staff are engaging with Service Users, Families, Carers as part of the SAI process, that in addition to advising an individual of the SAI, they should also be told if the SAI is a Never Event. However it will be for HSC organisations to determine when to communicate this information to Service Users, Families, Carers.

All categories included in the current NHS Never Events list (see associated DoH link below) should now be identified to the HSCB when notifying a SAI.

A separate section within the SAI notification form is to be completed to specify if the SAI is listed on the Never Events list. The SAI will continue to be reviewed in line with the current SAI procedure.

https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

12.3 Reporting Interface Incidents

In line with section 3.4 of this procedure, any organisation alerted to an incident which it feels has the potential to be a SAI should report the incident to the HSCB using the Interface Incident Notification form (Appendix 3) to seriousincidents@hscni.net.

An organisation who has been contacted by the HSCB Governance Team re: an interface incident being reported; will consider the incident in line with section 4.2 of the procedure, and if deemed it meets the criteria of a SAI, will report to the HSCB in line with 12.1 of this procedure.

12.4 Acknowledging SAI Notification

On receipt of the SAI notification the HSCB Governance Team will record the SAI on the DATIX risk management system and electronically acknowledge receipt of SAI notification to reporting organisation; advising

of the HSCB/PHA DRO, HSCB unique identification number, and requesting the completion of:

- SEA Learning Summary Report for Level 1 SAIs within 8 weeks from the date the incident is reported;
- RCA Report for Level 2 SAIs within 12 weeks from the date the incident is reported;
- RCA Report for Level 3 SAIs within the timescale as agreed at the outset by the DRO;

Where relevant, RQIA will be copied into this receipt.

12.5 Designated Review Officer (DRO)

Following receipt of a SAI the Governance Team will circulate the SAI Notification Form to the relevant Lead Officers within the HSCB/PHA to assign a DRO.

Once assigned the DRO will consider the SAI notification and if necessary, will contact the reporting organisation to confirm all immediate actions following the incident have been implemented.

12.6 Review/Learning Summary Reports

Note: Appendices 5 and 7 provide guidance notes to assist in the completion of Level 1, 2 & 3 review reports.

Timescales for submission of review/learning summary reports and associated engagement checklists will be in line with section 6.0 of this procedure.

On receipt of a review/learning summary report, the Governance Team will forward to the relevant DRO and where relevant RQIA.

The DRO will consider the adequacy of the review/learning summary report and liaise with relevant professionals/officers including RQIA (*where relevant*) to ensure that the reporting organisation has taken reasonable action to reduce the risk of recurrence and determine if the SAI can be closed. The DRO will also consider the referral of any learning identified for regional dissemination. In some instances the DRO may require further clarification and may also request sight of the full SEA review report.

If the DRO is not satisfied that a report reflects a robust and timely review s/he will continue to liaise with the reporting organisation and/or other professionals /officers, including RQIA (*where relevant*) until a satisfactory response is received. When the DRO has received all relevant and necessary information the timescale for closure of the SAI will be within 12 weeks, unless in exceptional circumstances which will have been agreed between the Reporting Organisation and the DRO.

12.7 Closure of SAI

Following agreement to close a SAI, the Governance Team will submit an email to the reporting organisation to advise the SAI has been closed, copied to RQIA (where relevant). The email will also indicate, if further information is made available to the reporting organisation (for example, Coroners Reports), which impacts on the outcome of the initial review, that it should be communicated to the HSCB/PHA DRO via the serious incidents mailbox.

This will indicate that based on the review / learning summary report received and any other information provided that the DRO is satisfied to close the SAI. It will acknowledge that any recommendations and further actions required will be monitored through the reporting organisation's internal governance arrangements in order to reassure the public that lessons learned, where appropriate have been embedded in practice.

On occasion and in particular when dealing with level 2 and 3 SAIs, a DRO may close a SAI but request the reporting organisation provides an additional assurance mechanism by advising within a stipulated period of time, that action following a SAI has been implemented. In these instances, monitoring will be followed up via the Governance team.

12.8 Regional Learning from SAIs

It is acknowledged HSC organisations will already have in place mechanisms for cascading local learning from adverse incidents and SAIs internally within their own organisations. However, the management of regional learning and associated assurance is the responsibility of the HSCB/PHA.

Therefore, where regional learning is identified following the review of an SAI, the DRO will refer this for consideration via HSCB/PHA Quality and Safety Structures and where relevant, will be disseminated as outlined in section 8.0.

12.9 Communication

All communication between HSCB/PHA and reporting organisation must be conveyed between the HSCB Governance department and Governance departments in respective reporting organisations. This will ensure all communication both written and verbal relating to the SAI, is recorded on the HSCB DATIX risk management system.

13 EQUALITY

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

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

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

SECTION TWO APPENDICES

APPENDICES

APPENDIX 1

Revised November 2016 (Version 1.1)

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

1. ORGANISATION:	**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE
3. HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)*	**4.** DATE OF INCIDENT: DD / MM / YYYY
5. DEPARTMENT / WARD / LOCATION EXACT *(where incident occurred)*	
6. CONTACT PERSON:	**7.** PROGRAMME OF CARE: *(refer to Guidance Notes)*

8. DESCRIPTION OF INCIDENT:

DOB: DD / MM / YYYY *(complete where relevant)* GENDER: M / F AGE: years

9. IS THIS INCIDENT A NEVER EVENT?				If 'YES' *provide further detail on which never event - refer to DoH link below* https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars
YES		NO		

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING

STAGE OF CARE: *(refer to Guidance Notes)*	DETAIL: *(refer to Guidance Notes)*	ADVERSE EVENT: *(refer to Guidance Notes)*

10. IMMEDIATE ACTION TAKEN TO PREVENT RECURRENCE:

11. CURRENT CONDITION OF SERVICE USER: *(complete where relevant)*

12. HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? *(please select)*	YES	NO	N/A
13. HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED? *(please specify where relevant)*	YES	NO	N/A

14. WHY IS THIS INCIDENT CONSIDERED SERIOUS?: *(please select relevant criteria below)*

serious injury to, or the unexpected/unexplained death of: - a service user (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit) - a staff member in the course of their work - a member of the public whilst visiting a HSC facility.	
unexpected serious risk to a service user and/or staff member and/or member of the public	
unexpected or significant threat to provide service and/or maintain business continuity	
serious self-harm or serious assault *(including attempted suicide, homicide and sexual assaults)* by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service	
serious self-harm or serious assault *(including homicide and sexual assaults)* - on other service users, - on staff or - on members of the public by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the	

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

incident	
suspected suicide of a service user who has a mental illness or disorder *(as defined within the Mental Health (NI) Order 1986)* and/or known to/referred to mental health and related services (*including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident	
serious incidents of public interest or concern relating to: - any of the criteria above - theft, fraud, information breaches or data losses - a member of HSC staff or independent practitioner	

15. IS ANY IMMEDIATE REGIONAL ACTION RECOMMENDED: *(please select)*	YES	NO
if 'YES' (*full details should be submitted*):		

16. HAS THE SERVICE USER / FAMILY BEEN ADVISED THE INCIDENT IS BEING REVIEWED AS A SAI?	YES	DATE INFORMED: DD/MM/YY
	NO	*specify reason:*

17. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(refer to guidance notes e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HCPC etc.) please specify where relevant*	YES	NO
if 'YES' (*full details should be submitted including the date notified*):		

18. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	DATE INFORMED:	OTHERS: *(please specify where relevant, including date notified)*
DoH EARLY ALERT		
HM CORONER		
INFORMATION COMMISSIONER OFFICE (ICO)		
NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)		
HEALTH AND SAFETY EXECUTIVE NORTHERN IRELAND (HSENI)		
POLICE SERVICE FOR NORTHERN IRELAND (PSNI)		
REGULATION QUALITY IMPROVEMENT AUTHORITY (RQIA)		
SAFEGUARDING BOARD FOR NORTHERN IRELAND (SBNI)		
NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP (NIASP)		

19. LEVEL OF REVIEW REQUIRED: *(please select)*	LEVEL 1	LEVEL 2*	LEVEL 3*

* FOR ALL LEVEL 2 OR LEVEL 3 REVIEWS PLEASE COMPLETE AND SUBMIT SECTIONS 2 AND 3 OF THE RCA REPORT TEMPLATE WITHIN 4 WEEKS OF THIS NOTIFICATION REFER APPENDIX 6

20. I confirm that the designated Senior Manager and/or Chief Executive has/have been advised of this SAI and is/are content that it should be reported to the Health and Social Care Board / Public Health Agency and Regulation and Quality Improvement Authority. (*delete as appropriate*)

Report submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

21. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION: *(refer to Guidance Notes)*

Additional information submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

Completed proforma should be sent to: seriousincidents@hscni.net
and (*where relevant*) seriousincidents@rqia.org.uk

APPENDIX 2

Revised November 2016 (Version 1.1)

Guidance Notes
SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

The following guidance designed to help you to complete the Serious Adverse Incident Report Form effectively and to minimise the need for the HSCB to seek additional information about the circumstances surrounding the SAI. This guidance should be considered each time a report is submitted.

1. ORGANISATION: *Insert the details of the reporting organisation (HSC Organisation /Trust or Family Practitioner Service)*	**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE *Insert the unique incident number / reference generated by the reporting organisation.*
3. HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)* *Insert the details of the hospital/facility/specialty/department/ directorate/place where the incident occurred*	**4.** DATE OF INCIDENT: DD / MM / YYYY *Insert the date incident occurred*
5. DEPARTMENT / WARD / LOCATION EXACT *(where incident occurred)*	
6. CONTACT PERSON: *Insert the name of lead officer to be contacted should the HSCB or PHA need to seek further information about the incident*	**7.** PROGRAMME OF CARE: *Insert the Programme of Care from the following: Acute Services/ Maternity and Child Health / Family and Childcare / Elderly Services / Mental Health / Learning Disability / Physical Disability and Sensory Impairment / Primary* ***Health and Adult Community (includes GP's) / Corporate Business(Other)***

8. DESCRIPTION OF INCIDENT:

Provide a ***brief factual description*** *of what has happened and a summary of the events leading up to the incident.* ***PLEASE ENSURE SUFFICIENT INFORMATION IS PROVIDED SO THAT THE HSCB/ PHA ARE ABLE TO COME TO AN OPINION ON THE IMMEDIATE ACTIONS, IF ANY, THAT THEY MUST TAKE.*** *Where relevant include D.O.B, Gender and Age.* ***All reports should be anonymised*** *– the names of any practitioners or staff involved must* ***not*** *be included. Staff should only be referred to by job title.*

In addition include the following:

Secondary Care – *recent service history; contributory factors to the incident; last point of contact (ward / specialty); early analysis of outcome.*

Children – *when reporting a child death indicate if the Regional Safeguarding Board has been advised.*

Mental Health *- when reporting a serious injury to, or the unexpected/unexplained death (including suspected suicide, attempted suicide in an in-patient setting or serious self-harm of a service user who has been known to Mental Health, Learning Disability or Child and Adolescent Mental Health within the last year) include the following details: the most recent HSC service context; the last point of contact with HSC services or their discharge into the community arrangements;*
whether there was a history of DNAs, where applicable the details of how the death occurred, if known.

Infection Control *- when reporting an outbreak which severely impacts on the ability to provide services, include the following: measures to cohort Service Users; IPC arrangements among all staff and visitors in contact with the infection source; Deep cleaning arrangements and restricted visiting/admissions.*

Information Governance –*when reporting include the following details whether theft, loss, inappropriate disclosure, procedural failure etc.; the number of data subjects (service users/staff)involved, the number of records involved, the media of records (paper/electronic),whether encrypted or not and the type of record or data involved and sensitivity.*

DOB: DD / MM / YYYY GENDER: M / F AGE: years
(complete where relevant)

9. IS THIS INCIDENT A NEVER EVENT? Yes/No *(please select)*	If 'YES' *provide further detail on which never event - refer to DoH link below* https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING		
STAGE OF CARE: *(refer to Guidance Notes)* *Insert CCS Stage of Care Code description*	DETAIL: *(refer to Guidance Notes)* *Insert CCS Detail Code description*	ADVERSE EVENT: *(refer to Guidance Notes)* *Insert CCS Adverse Event Code description*

10. IMMEDIATE ACTION TAKEN TO PREVENT RECURRENCE:
Include a summary of what actions, if any, have been taken to address the immediate repercussions of the incident and the actions taken to prevent a recurrence.

11. CURRENT CONDITION OF SERVICE USER: *(complete where relevant)*
Where relevant *please provide details on the current condition of the service user the incident relates to.*

12. HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? *(please select)*	YES	NO	N/A
13. HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED *(please select and specify **where relevant**)*	YES	NO	N/A

14. WHY INCIDENT CONSIDERED SERIOUS: *(please select relevant criteria from below)*

serious injury to, or the unexpected/unexplained death of: - a service user (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit) - a staff member in the course of their work - a member of the public whilst visiting a HSC facility.	
unexpected serious risk to a service user and/or staff member and/or member of the public	
unexpected or significant threat to provide service and/or maintain business continuity	
serious self-harm or serious assault *(including attempted suicide, homicide and sexual assaults)* by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service	
serious self-harm or serious assault *(including homicide and sexual assaults)* - on other service users, - on staff or - on members of the public by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident	
suspected suicide of a service user who has a mental illness or disorder *(as defined within the Mental Health (NI) Order 1986)* and/or known to/referred to mental health and related services (*including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident	
serious incidents of public interest or concern relating to: - any of the criteria above - theft, fraud, information breaches or data losses - a member of HSC staff or independent practitioner	

15. IS ANY IMMEDIATE REGIONAL ACTION RECOMMENDED: *(please select)*	YES	NO

if 'YES' *(full details should be submitted)*:

16. HAS THE SERVICE USER / FAMILY BEEN ADVISED THE INCIDENT IS BEING REVIEWED AS A SAI? *(please select)*	YES	DATE INFORMED: DD/MM/YY *Insert the date informed*
	NO	*Specify reason:*

17. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(refer to guidance notes e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HCPC etc.) please specify where relevant*	YES	NO

if 'YES' (*full details should be submitted including the date notified*):

GENERAL MEDICAL COUNCIL **(GMC)**
GENERAL DENTAL COUNCIL **(GDC)**
PHARMACEUTICAL SOCIETY NORTHERN IRELAND **(PSNI)**
NORTHERN IRELAND SOCIAL CARE COUNCIL **(NISCC)**
LOCAL MEDICAL COMMITTEE **(LMC)**
NURSING AND MIDWIFERY COUNCIL **(NMC)**
HEALTH CARE PROFESSIONAL COUNCIL **(HCPC)**
REGULATION AND QUALITY IMPROVEMENT AUTHORTIY**(RQIA)**
SAFEGUARDING BOARD FOR NORTHERN IRELAND **(SBNI)**

OTHER – PLEASE SPECIFY BELOW

18. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	DATE INFORMED:	OTHERS: *(please specify where relevant, including date notified)*
DoH EARLY ALERT		
HM CORONER		
INFORMATION COMMISSIONER OFFICE (ICO)		
NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)		
HEALTH AND SAFETY EXECUTIVE NORTHERN IRELAND (HSENI)		
POLICE SERVICE FOR NORTHERN IRELAND (PSNI)		
REGULATION QUALITY IMPROVEMENT AUTHORITY (RQIA)		
SAFEGUARDING BOARD FOR NORTHERN IRELAND (SBNI)		
NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP (NIASP)		

19. LEVEL OF REVIEW REQUIRED: *(please select)*	LEVEL 1	LEVEL 2*	LEVEL 3*

* FOR ALL LEVEL 2 OR LEVEL 3 REVIEWS PLEASE COMPLETE AND SUBMIT SECTIONS 2 AND 3 OF THE RCA REPORT TEMPLATE WITHIN 4 WEEKS OF THIS NOTIFICATION REFER APPENDIX 6

20. I confirm that the designated Senior Manager and/or Chief Executive has/have been advised of this SAI and is/are content that it should be reported to the Health and Social Care Board / Public Health Agency and Regulation and Quality Improvement Authority. (*delete as appropriate*)

Report submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

21. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION:

Use this section to provide updated information when the situation changes e.g. the situation deteriorates; the level of media interest changes

The HSCB and PHA recognises that organisations report SAIs based on limited information, which on further review may not meet the criteria of a SAI. Use this section to rrequest that a SAI be de-escalated and send to seriousincidents@hscni.net with the unique incident identification number/reference in the subject line. When a request for de-escalation is made the reporting organisation must include information on why the incident does not warrant further review under the SAI process.

The HSCB/PHA DRO will review the de-escalation request and inform the reporting organisation of its decision within 5 working days. The HSCB / PHA may take the decision to close the SAI without a report rather than de-escalate it. The HSCB / PHA may decide that the SAI should not be de-escalated and a full review report is required.

PLEASE NOTE PROGRESS IN RELATION TO TIMELINESS OF COMPLETED REVIEW REPORTS WILL BE REGULARLY REPORTED TO THE HSCB/PHA REGIONALGROUP. THEY WILL BE MONITORED ACCORDING TO AGREED TIMESCALES. IT IS IMPORTANT TO KEEP THE HSCB INFORMED OF PROGRESS TO ENSURE THAT MONITORING INFORMATION IS ACCURATE AND BREECHES ARE NOT REPORTED WHERE AN EXTENDED TIME SCALE HAS BEEN AGREED.

Additional information submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

Completed proforma should be sent to: seriousincidents@hscni.net
and (*where relevant*) seriousincidents@rqia.org.uk

APPENDIX 3
Revised November 2016 (Version 1.1)

HSC INTERFACE INCIDENT NOTIFICATION FORM

1. REPORTING ORGANISATION:	**2. DATE OF INCIDENT: DD / MM / YYYY**
3. CONTACT PERSON AND TEL NO:	**4. UNIQUE REFERENCE NUMBER:**

5. DESCRIPTION OF INCIDENT:

DOB: DD / MM / YYYY **GENDER: M / F** **AGE: years**
(complete where relevant)

6. ARE OTHER PROVIDERS INVOLVED? (e.g. *HSC TRUSTS / FPS / OOH / ISP / VOLUNTARY / COMMUNITY ORG'S*)	**YES**	**NO**
	if 'YES' (*full details should be submitted in section 7 below*)	

7. PROVIDE DETAIL ON ISSUES/AREAS OF CONCERN:

8. <u>IMMEDIATE</u> ACTION TAKEN BY REPORTING ORGANISATION:

9. WHICH ORGANISATION/PROVIDER (*FROM THOSE LISTED IN SECTIONS 6 AND 7 ABOVE*) SHOULD TAKE THE LEAD RESPONSIBILITY FOR THE REVIEW AND FOLLOW UP OF THIS INCIDENT?

10. OTHER COMMENTS:

REPORT SUBMITTED BY: _____ **DESIGNATION:** _____

Email: **Telephone:** **Date: DD / MM / YYYY**

Completed proforma should be sent to: seriousincidents@hscni.net

APPENDIX 4

Revised November 2016 (Version 1.1)

LEVEL 1 – SIGNIFICANT EVENT AUDIT INCLUDING LEARNING SUMMARY REPORT AND SERVICE USER/FAMILY/CARER ENGAGEMENT CHECKLIST

SECTION 1	
1. ORGANISATION:	2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE:
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE:	4. DATE OF INCIDENT/EVENT: DD / MM / YYYY
5. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: YES / NO ***Please select as appropriate***	6. IF 'YES' TO 5. PLEASE PROVDE DETAILS:
7. DATE OF SEA MEETING / INCIDENT DEBRIEF: DD / MM / YYYY	
8. SUMMARY OF EVENT:	

SECTION 2	
9. SEA FACILITATOR / LEAD OFFICER:	10. TEAM MEMBERS PRESENT:
11. SERVICE USER DETAILS: ***Complete where applicable***	
12. WHAT HAPPENED?	
13. WHY DID IT HAPPEN?	

SECTION 3 - LEARNING SUMMARY
14.WHAT HAS BEEN LEARNED:
15.WHAT HAS BEEN CHANGED or WHAT WILL CHANGE?
16.RECOMMENDATIONS (please state by whom and timescale)
17.INDICATE ANY PROPOSED TRANSFERRABLE REGIONAL LEARNING POINTS FOR CONSIDERATION BY HSCB/PHA:
18.FURTHER REVIEW REQUIRED? YES / NO Please select as appropriate If 'YES' complete SECTIONS 4, 5 and 6. If 'NO' complete SECTION 5 and 6.

SECTION 4 (COMPLETE THIS SECTION ONLY WHERE A FURTHER REVIEW IS REQUIRED)	
19.PLEASE INDICATE LEVEL OF REVIEW: LEVEL 2 / LEVEL 3 **Please select as appropriate**	20.PROPOSED TIMESCALE FOR COMPLETION: DD / MM / YYYY
21.REVIEW TEAM MEMBERSHIP *(If known or submit asap)*:	
22.TERMS OF REFERENCE *(If known or submit asap)*:	

SECTION 5	
APPROVAL BY RELEVANT PROFESSIONAL DIRECTOR AND/OR OPERATIONAL DIRECTOR	
23.NAME:	24.DATE APPROVED:
25.DESIGANTION:	

SECTION 6
26.DISTRIBUTION LIST:

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		HSCB Ref Number:	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		
	Comment: ***If multiple service users are involved please indicate the number involved***				
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**		
	If **YES**, insert **date informed**:				
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI				
	a) No contact or Next of Kin details or Unable to contact				
	b) Not applicable as this SAI is not 'patient/service user' related				
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user				
	d) Case involved suspected or actual abuse by family				
	e) Case identified as a result of review exercise				
	f) Case is environmental or infrastructure related with no harm to patient/service user				
	g) Other rationale				
	If you selected c), d), e), f) or g) above please provide further details:				
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**		
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY			
	NO	If **NO**, provide details:			
For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓)					
Content with rationale?	**YES**		**NO**		

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	c) Report not shared but contents discussed ***(if you select this option please also complete 'l' below)***	
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓)				
Content with rationale?	**YES**		**NO**	

SECTION 2							
INFORMING THE CORONERS OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*							
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date report shared**:						
	If **NO**, please provide details:						
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**		**Not Known**
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 5

Revised November 2016 (Version 1.1)

GUIDANCE NOTES
LEVEL 1 – SIGNIFICANT EVENT AUDIT INCLUDING SUMMARY REPORT AND SERVICE USER/FAMILY/CARER ENGAGEMENT CHECKLIST

SECTION 1 (To be submitted to the HSCB)

1. ORGANISATION: *Insert unique identifier number*	2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE: *Self- explanatory*
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE: *Self- explanatory*	4. DATE OF INCIDENT/EVENT: DD / MM / YYYY *Self- explanatory*
5. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: YES / NO ***Please select as appropriate***	6. IF 'YES' TO 5. PLEASE PROVDE DETAILS: *Self- explanatory*
7. DATE OF SEA MEETING / INCIDENT DEBRIEF:	DD / MM / YYYY *Self- explanatory*

8. SUMMARY OF EVENT:

As per notification form. (If the notification form does not fully reflect the incident please provide further detail.)

SECTION 2	
9. SEA FACILITATOR / LEAD OFFICER: *Refer to guidance on Level 1 review team membership for significant event analysis – Appendix 10*	10. TEAM MEMBERS PRESENT: *NAMES AND DESIGNATIONS*
11. SERVICE USER DETAILS: ***Complete where applicable*** *DOB / GENDER / AGE*	
12. WHAT HAPPENED? *(Describe in detailed chronological order what actually happened. Consider, for instance, how it happened, where it happened, who was involved and what the impact was on the patient/service user[1], the team, organisation and/or others).*	
13. WHY DID IT HAPPEN? *(Describe the main and underlying reasons contributing to why the event happened. Consider for instance, the professionalism of the team, the lack of a system or failing in a system, the lack of knowledge or the complexity and uncertainty associated with the event)*	

[1] *ensure sensitivity to the needs of the patient/ service user/ carer/ family member is in line with Regional Guidance on Engagement with Service Users, Families and Carers issued February 2015 (Revised November 2016)*

All sections below be submitted to the HSCB

SECTION 3 - LEARNING SUMMARY

14. WHAT HAS BEEN LEARNED: *(Based on the reason established as to why the event happened, outline the learning identified. Demonstrate that reflection and learning have taken place on an individual or team basis and that relevant team members have been involved in the analysis of the event. Consider, for instance: a lack of education and training; the need to follow systems or procedures; the vital importance of team working or effective communication)*

15. WHAT HAS BEEN CHANGED or WHAT WILL CHANGE? *Based on the understanding of why the event happened and the identification of learning, outline the action(s) agreed and implemented, where this is relevant or feasible. Consider, for instance: if a protocol has been amended, updated or introduced; how was this done and who was involved; how will this change be monitored. It is also good practice to attach any documentary evidence of change e.g. a new procedure or protocol.*

NOTE: Action plans should also be developed and set out how learning will be implemented, with named leads responsible for each action point (Refer to Appendix 7 Minimum Standards for Action Plans).

Action plans for this level of review will be retained by the reporting organisation.

16. RECOMMENDATIONS (please state by whom and timescale) *It should be noted that it is the responsibility of the HSCB/PHA to consider and review all recommendations, of suggested /proposed learning relevant to other organisations, arising from the review of a SAI. In addition, it is the responsibility if the HSCB/PHA to subsequently identify any related learning to be communicated across the HSC and where relevant with other organisations regionally and/or nationally.*

*It is the responsibility of the reporting organisation to communicate to service users, **families and carer's that learning identified** relevant to other organisations (arising from the review of a SAI) and submitted to the HSCB/PHA, to consider and review, may not on every occasion result in regional learning.*

17. INDICATE ANY PROPOSED TRANSFERRABLE REGIONAL LEARNING POINTS FOR CONSIDERATION BY HSCB/PHA:

Self- explanatory

18. FURTHER REVIEW REQUIRED? YES / NO

Please select as appropriate

If 'YES' complete SECTIONS 4, 5 and 6. If 'NO' complete SECTION 5 and 6.

SECTION 4 (COMPLETE THIS SECTION ONLY WHERE A FURTHER REVIEW IS REQUIRED)

19. PLEASE INDICATE LEVEL OF REVIEW: LEVEL 2 / LEVEL 3 **Please select as appropriate**	20. PROPOSED TIMESCALE FOR COMPLETION: DD / MM / YYYY

21. REVIEW TEAM MEMBERSHIP(If known or submit ASAP):

Refer to section 2 of appendix 7.

22. TERMS OF REFERENCE(If known or submit ASAP):

Refer to section 3 of appendix 7.

SECTION 5 - (COMPLETE THIS SECTION FOR ALL LEVELS OF REVIEW)

APPROVAL BY RELEVANT PROFESSIONAL DIRECTOR AND/OR OPERATIONAL DIRECTOR

23. NAME: *Self- explanatory*	24. DATE APPROVED: *Self- explanatory*

25. DESIGANTION: *Self- explanatory*

SECTION 6

26. DISTRIBUTION LIST:

List of the individuals, groups or organisations the final report has been shared with.

APPENDIX 5

To be submitted to the HSCB

Checklist for Engagement / Communication with Service User[1] / Family / Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		HSCB Ref Number:	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	
	Comment: ***If multiple service users are involved please indicate the number involved***			
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI			
	a) No contact or Next of Kin details or Unable to contact			
	b) Not applicable as this SAI is not 'patient/service user' related			
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user			
	d) Case involved suspected or actual abuse by family			
	e) Case identified as a result of review exercise			
	f) Case is environmental or infrastructure related with no harm to patient/service user			
	g) Other rationale			
	If you selected c), d), e), f) or g) above please provide further details:			
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**	
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY		
	NO	If **NO**, provide details:		
For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓))				
Content with rationale?	**YES**		**NO**	

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

	a) Draft review report has been shared and further engagement planned to share final report	
	b) Plan to share final review report at a later date and further engagement planned	
	c) Report not shared but contents discussed ***(if you select this option please also complete 'l' below)***	
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONERS OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**				**NO**		
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						
2) **If** you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**				**NO**		
	If **YES**, insert **date report shared**:						
	If **NO**, please provide details:						
3) '**If** you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**	**Not Known**	
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 6

Revised November 2016 (Version 1.1)

Insert organisation Logo

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier:

Date of Incident/Event:

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: (M/F) Age: (yrs)

Responsible Lead Officer:

Designation:

Report Author:

Date report signed off:

1.0 EXECUTIVE SUMMARY

2.0 THE REVIEW TEAM

3.0 SAI REVIEW TERMS OF REFERENCE

4.0 REVIEW METHODOLOGY

5.0 DESCRIPTION OF INCIDENT/CASE

6.0 FINDINGS

7.0 CONCLUSIONS

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	
	Comment: ***If multiple service users are involved please indicate the number involved***			
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI			
	a) No contact or Next of Kin details or Unable to contact			
	b) Not applicable as this SAI is not 'patient/service user' related			
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user			
	d) Case involved suspected or actual abuse by family			
	e) Case identified as a result of review exercise			
	f) Case is environmental or infrastructure related with no harm to patient/service user			
	g) Other rationale			
	If you selected c), d), e), f) or g) above please provide further details:			
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**	
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY		
	NO	If **NO**, provide details:		
For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓)				
Content with rationale?	**YES**		**NO**	

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'l' below)***			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓))				
Content with rationale?	**YES**		**NO**	

SECTION 2 **INFORMING THE CORONERS OFFICE** **(under section 7 of the Coroners Act (Northern Ireland) 1959)** *(complete this section for all death related SAIs)*							
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						
2) **If** you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date report shared**:						
	If **NO**, please provide details:						
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**		**Not Known**
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 7
Revised November 2016 (Version 1.1)

Health and Social Care Regional Guidance

for

Level 2 and 3 RCA Incident Review Reports

INTRODUCTION

This document is a revision of the template developed by the DoH Safety in Health and Social Care Steering Group in 2007 as part of the action plan contained within "*Safety First: A Framework for Sustainable Improvement in the HPSS.*"

The purpose of this template and guide is to provide practical help and support to those writing review reports and should be used, in as far as possible, for drafting all **HSC Level 2 and Level 3** incident review reports. It is intended as a guide in order to standardise all such reports across the HSC including both internal and external reports.

The review report presents the work of the review team and provides all the necessary information about the incident, the review process and outcome of the review. The purpose of the report is to provide a formal record of the review process and a means of sharing the learning. The report should be clear and logical, and demonstrate that an open and fair approach has taken place.

This guide should assist in ensuring the completeness and readability of such reports. The headings and report content should follow, as far as possible, the order that they appear within the template. Composition of reports to a standardised format will facilitate the collation and dissemination of any regional learning.

This template was designed primarily for incident reviews however it may also be used to examine complaints and claims.

Insert organisation Logo

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier:

Date of Incident/Event:

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: (M/F) Age: (yrs)

Responsible Lead Officer:

Designation:

Report Author:

Date report signed off:

1.0 EXECUTIVE SUMMARY

Summarise the main report: provide a brief overview of the incident and consequences, background information, level of review, concise analysis and main conclusions, lessons learned, recommendations and arrangements for sharing and learning lessons.

2.0 THE REVIEW TEAM

Refer to Guidance on Review Team Membership

The level of review undertaken will determine the degree of leadership, overview and strategic review required.

- *List names, designation and review team role of the members of the Review Team. The Review Team should be multidisciplinary and should have an Independent Chair.*
- *The degree of independence of the membership of the team needs careful consideration and depends on the severity / sensitivity of the incident and the level of review to be undertaken. However, best practice would indicate that review teams should incorporate at least one informed professional from another area of practice, best practice would also indicate that the chair of the team should be appointed from outside the area of practice.*
- *In the case of more high impact incidents (i.e. categorised as catastrophic or major) inclusion of lay / patient / service user or carer representation should be considered.*

3.0 SAI REVIEW TERMS OF REFERENCE

Describe the plan and scope for conducting the review. State the level of review, aims, objectives, outputs and who commissioned the review.

The following is a sample list of statements of purpose that may be included in the terms of reference:

- To undertake a review of the incident to identify specific problems or issues to be addressed;
- To consider any other relevant factors raised by the incident;
- To identify and engage appropriately with all relevant services or other agencies associated with the care of those involved in the incident;
- To determine actual or potential involvement of the Police, Health and Safety Executive, Regulation and Quality Improvement Authority and Coroners Service for Northern Ireland[2] [3]
- To agree the remit of the review - the scope and boundaries beyond which the review should not go (e.g. disciplinary process) – state how far back the review will go (what point does the review start and stop e.g. episode of care) and the level of review;
- To consider the outcome of the review, agreeing recommendations, actions to be taken and lessons learned for the improvement of future services;
- To ensure sensitivity to the needs of the patient/ service user/ carer/ family member, where appropriate. The level of involvement clearly depends on the nature of the incident and the service user's or family's wishes or carer's wishes to be involved and must be in line with Regional Guidance on Engagement with Service Users, Families and Carers issued November 2016;

[2] *Memorandum of understanding: Investigating patient or client safety incidents (Unexpected death or serious untoward harm)- http://www.dhsspsni.gov.uk/ph_mou_investigating_patient_or_client_safety_incidents.pdf*

[3] *Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults 2009*

3.0 SAI REVIEW TERMS OF REFERENCE

- To agree the timescales for completing and submitting the review report, including the SAI engagement checklist, distribution of the report and timescales for reviewing actions on the action plan;

Methodology to be used should be agreed at the outset and kept under regular review throughout the course of the SAI review.

Clear documentation should be made of the time-line for completion of the work.

This list is not exhaustive

4.0 REVIEW METHODOLOGY

This section should provide an outline of the type of review and the methods used to gather information within the review process. The NPSA's "Seven Steps to Patient Safety[4]" and "Root Cause Analysis Review Guidance[5]" provide useful guides for deciding on methodology.

- Review of patient/ service user records and compile a timeline (if relevant)
- Review of staff/witness statements (if available)
- Interviews with relevant staff concerned e.g.
  - Organisation-wide
  - Directorate Team
  - Ward/Team Managers and front line staff
  - Other staff involved
  - Other professionals (including Primary Care)
- Specific reports requested from and provided by staff
- Outline engagement with patients/service users / carers / family members / voluntary organisations/ private providers
- Review of local, regional and national policies and procedures, including professional codes of conduct in operation at the time of the incident
- Review of documentation e.g. consent form(s), risk assessments, care plan(s), photographs, diagrams or drawings, training records, service/maintenance records, including specific reports requested from and provided by staff etc.

This list is not exhaustive

5.0 DESCRIPTION OF INCIDENT/CASE

Provide an account of the incident including consequences and detail what makes this incident a SAI. The following can provide a useful focus but please note this section is not solely a chronology of events

- Concise factual description of the serious adverse incident include the incident date and

[4] http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787

[5] http://www.nrls.npsa.nhs.uk/resources/?entryid45=75355

5.0 DESCRIPTION OF INCIDENT/CASE

type, the healthcare specialty involved and the actual effect of the incident on the service user and/or service and others;

- People, equipment and circumstances involved;
- Any intervention / immediate action taken to reduce consequences;
- Chronology of events leading up to the incident;
- Relevant past history – a brief description of the care and/or treatment/service provided;
- Outcome / consequences / action taken;
- Relevance of local, regional or national policy / guidance / alerts including professional codes of conduct in place at the time of the incident

This list is not exhaustive

6.0 FINDINGS

This section should clearly outline how the information has been analysed so that it is clear how conclusions have been arrived at from the raw data, events and treatment/care/service provided. This section needs to clearly identify the care and service delivery problems and analysis to identify the causal factors.

Analysis can include the use of root cause and other analysis techniques such as fault tree analysis, etc. The section below is a useful guide particularly when root cause techniques are used. It is based on the NPSA's "Seven Steps to Patient Safety" and "Root Cause Analysis Toolkit".

(i) Care Delivery Problems (CDP) and/or Service Delivery Problems (SDP) Identified

CDP is a problem related to the direct provision of care, usually actions or omissions by staff (active failures) or absence of guidance to enable action to take place (latent failure) e.g. failure to monitor, observe or act; incorrect (with hindsight) decision, NOT seeking help when necessary.

SDP are acts and omissions identified during the analysis of incident not associated with direct care provision. They are generally associated with decisions, procedures and systems that are part of the whole process of service delivery e.g. failure to undertake risk assessment, equipment failure.

(ii) Contributory Factors

Record the influencing factors that have been identified as root causes or fundamental issues.

- Individual Factors (include employment status i.e. substantive, agency, locum voluntary etc.)
- Team and Social Factors
- Communication Factors
- Task Factors
- Education and Training Factors
- Equipment and Resource Factors
- Working Condition Factors
- Organisational and Management Factors
- Patient / Client Factors

This list is not exhaustive

As a framework for organising the contributory factors reviewed and recorded the table in the NPSA's "Seven Steps to Patient Safety" document (and associated Root Cause Analysis Toolkit) is useful. http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/

Where appropriate and where possible careful consideration should be made to facilitate the involvement of patients/service users / carers / family members within this process.

7.0 CONCLUSIONS

Following analysis identified above, list issues that need to be addressed. Include discussion of good practice identified as well as actions to be taken. Where appropriate include details of any on-going engagement / contact with family members or carers.

This section should summarise the key findings and should answer the questions posed in the terms of reference.

8.0 LESSONS LEARNED

Lessons learned from the incident and the review should be identified and addressed by the recommendations and relate to the findings. Indicate to whom learning should be communicated and this should be copied to the Committee with responsibility for governance.

9.0 RECOMMENDATIONS AND ACTION PLANNING

List the improvement strategies or recommendations for addressing the issues highlighted above (conclusions and lessons learned). Recommendations should be grouped into the following headings and cross-referenced to the relevant conclusions, and should be graded to take account of the strengths and weaknesses of the proposed improvement strategies/actions:

- Recommendations for the reviewing organisation
- Suggested /proposed learning that is relevant to other organisations

Action plans should be developed and should set out how each recommendation will be implemented, with named leads responsible for each action point (Refer to Appendix 8 Guidance on Minimum Standards for Action Plans). This section should clearly demonstrate the arrangements in place to successfully deliver the action plan.

It should be noted that it is the responsibility of the HSCB/PHA to consider and review all recommendations, of suggested /proposed learning relevant to other organisations, arising from the review of a SAI. In addition, it is the responsibility if the HSCB/PHA to subsequently identify any related learning to be communicated across the HSC and where relevant with other organisations regionally and/or nationally.

It is the responsibility of the reporting organisation to communicate to service users/families/carers that regional learning identified and submitted to the HSCB/PHA for consideration may not on every occasion result in regional learning.

10.0 DISTRIBUTION LIST

List the individuals, groups or organisations the final report has been shared with. This should have been agreed within the terms of reference.

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		HSCB Ref Number:	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		
	Comment: ***If multiple service users are involved please indicate the number involved***				
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**		
	If **YES**, insert **date informed**:				
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI				
	a) No contact or Next of Kin details or Unable to contact				
	b) Not applicable as this SAI is not 'patient/service user' related				
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user				
	d) Case involved suspected or actual abuse by family				
	e) Case identified as a result of review exercise				
	f) Case is environmental or infrastructure related with no harm to patient/service user				
	g) Other rationale				
	If you selected c), d), e), f) or g) above please provide further details:				
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**		
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY			
	NO	If **NO**, provide details:			
For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓))					
Content with rationale?	**YES**		**NO**		

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**		
	If **YES**, insert date informed:				
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:				
	a) Draft review report has been shared and further engagement planned to share final report				
	b) Plan to share final review report at a later date and further engagement planned				

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	c) Report not shared but contents discussed ***(if you select this option please also complete 'l' below)***	
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓)				
Content with rationale?	**YES**		**NO**	

SECTION 2 **INFORMING THE CORONERS OFFICE** **(under section 7 of the Coroners Act (Northern Ireland) 1959)** *(complete this section for all death related SAIs)*							
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date report shared**:						
	If **NO**, please provide details:						
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**	**Not Known**	
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 8

GUIDANCE ON MINIMUM STANDARDS FOR ACTION PLANS

The action plan must define:

- Who has agreed the action plan
- Who will monitor the implementation of the action plan
- How often the action plan will be reviewed
- Who will sign off the action plan when all actions have been completed

The action plan **MUST** contain the following

1. Recommendations based on the contributing factors	The recommendations from the report - these should be the analysis and findings of the review
2. Action agreed	This should be the actions the organisation needs to take to resolve the contributory factors.
3. By who	Who in the organisation will ensure the action is completed
4. Action start date	Date particular action is to commence
5. Action end date	Target date for completion of action
6. Evidence of completion	Evidence available to demonstrate that action has been completed. This should include any intended action plan reviews or audits
7. Sign off	Responsible office and date sign off as completed

APPENDIX 9

GUIDANCE ON INCIDENT DEBRIEF

• Level 1 - SEA Reviews

For level 1 reviews, the incident debrief can serve the purpose of the SEA review, (these can also be known as 'hot debriefs').

The review should:

- Collect and collate as much factual information on the event as possible, including all relevant records. Also gather the accounts of those directly and indirectly involved, including, where relevant, service user/relatives/carers or other health professionals.

- The incident debrief/significant event meeting should be held with all staff involved to provide an opportunity to:

    - support the staff involved[6]
    - assess what has happened;
    - assess why did it happened;
        - what went wrong and what went well;
    - assess what has been changed or agree what will change;
    - identify local and regional learning.

- The meeting/s should be conducted in an open, fair, honest, non-judgemental and supportive atmosphere and should be undertaken as soon as practical following the incident.

- Write it up – keep a written report of the analysis undertaken using the SEA Report template (see Appendix 4)

- Sharing SEA Report – SEA reports should be shared with all relevant staff, particularly those who have been involved in the incident.

• Level 2 and 3 RCA Reviews

An incident debrief can also be undertaken for level 2 and 3 reviews. This would be separate from the RCA review and should occur quickly after the incident to provide support to staff and to identify any immediate service actions.

[6] *Note: link to ongoing work in relation to Quality 2020 - Task 2 - Supporting Staff involved in SAIs and other Incidents*

APPENDIX 10

LEVEL 1 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

The level of review of an incident should be proportionate to its significance; this is a judgement to be made by the Review Team.

Membership of the team should include all relevant professionals but should be appropriate and proportionate to the type of incident and professional groups involved. Ultimately, for a Level 1 review, it is for each team to decide who is invited, there has to be a balance between those who can contribute to an honest discussion, and creating such a large group that discussion of sensitive issues is inhibited.

The review team should appoint an experienced facilitator or lead reviewing officer from within the team to co-ordinate the review. The role of the facilitator is as follows:

- Co-ordinate the information gathering process
- Arrange the review meeting
- Explain the aims and process of the review
- Chair the review meeting
- Co-ordinate the production of the Significant Event Audit report
- Ensure learning is shared in line with the Learning Summary Report

APPENDIX 11

LEVEL 2 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

The level of review undertaken will determine the degree of leadership, overview and strategic review required. The level of review of an incident should therefore be proportionate to its significance. This is a judgement to be made by the Review Team.

The core review team should comprise a minimum of three people of appropriate seniority and objectivity. Review teams should be multidisciplinary, (or involve experts/expert opinion/independent advice or specialist reviewers). The team shall have no conflicts of interest in the incident concerned and should have an Independent Chair. (*In the event of a suspected homicide HSC Trusts should follow the HSCB Protocol for responding to SAIs in the event of a Homicide – revised 2013*)

The Chair of the team shall be independent of the service area where the incident occurred and should have relevant experience of the service area and/or chairing investigations/reviews. He/she shall not have been involved in the direct care or treatment of the individual, or be responsible for the service area under review. The Chair may be sourced from the HSCB Lay People Panel *(a panel of 'lay people' with clinical or social care professional areas of expertise in health and social care, who could act as the chair of an independent review panel, or a member of a Trust RCA review panel*).

Where multiple (*two or more*) HSC providers of care are involved, an increased level of independence shall be required. In such instances, the Chair shall be completely independent of the main organisations involved.

Where the service area is specialised, the Chair may have to be appointed from another HSC Trust or from outside NI.

Membership of the team should include all relevant professionals, but should be appropriate and proportionate to the type of incident and professional groups involved.

Membership shall include an experienced representative who shall support the review team in the application of the root cause analysis methodologies and techniques, human error and effective solutions based development.

Members of the team shall be separate from those who provide information to the review team.

It may be helpful to appoint a review officer from within the review team to co-ordinate the review.

APPENDIX 12

LEVEL 3 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

The level of review shall be proportionate to the significance of the incident. The same principles shall apply, as for Level 2 reviews. The degree of independence of the review team will be dependent on the scale, complexity and type of the incident.

Team membership for Level 3 reviews will be agreed between the reporting organisation and the HSCB/PHA DRO prior to the Level 3 review commencing.

APPENDIX 13

GUIDANCE ON JOINT REVIEWS/INVESTIGATIONS

Where a SAI involves multiple (*two or more*) HSC providers of care (e.g. a patient/service user affected by system failures both in an acute hospital and in primary care), a decision must be taken regarding who will lead the review and reporting. This may not necessarily be the initial reporting organisation.

The general rule is for the provider organisation with greatest contact with the patient/service user to lead the review and action. There may, however, be good reason to vary this arrangement e.g. where a patient/service user has died on another organisation's premises. The decision should be made jointly by the organisations concerned, if necessary referring to the HSCB Designated Review Officer for advice. **The lead organisation must be agreed by all organisations involved.**

It will be the responsibility of the lead organisation to engage all organisations in the review as appropriate. This involves collaboration in terms of identifying the appropriate links with the other organisations concerned and in practice, separate meetings in different organisations may take place, but a single review report and action plan should be produced by the lead organisation and submitted to the HSCB in the agreed format.

Points to consider:

- If more than one service is being provided, then all services are required to provide information / involvement reports to the review team;
- All service areas should be represented in terms of professional makeup / expertise on the review team;
- If more than one Trust/Agency is involved in the care of an individual, that the review is conducted jointly with all Trusts/Agencies involved;
- Relevant service providers, particularly those under contract with HSC to provide some specific services, should also be enjoined;
- There should be a clearly articulated expectation that the service user (where possible) and family carers, perspective should be canvassed, as should the perspective of staff directly providing the service, to be given consideration by the panel;
- The perspective of the GP and other relevant independent practitioners providing service to the individual should be sought;
- Service users and carer representatives should be invited / facilitated to participate in the panel discussions with appropriate safeguards to protect the confidentiality of anyone directly involved in the case.

This guidance should be read in conjunction with:

- Guidance on Incident Debrief (Refer to Appendix 9)
- Guidance on Review Team Membership (Refer to Appendix 11 & 12)
- Guidance on completing HSC Review Report Level 2 and 3 (Refer to Appendix 7)

APPENDIX 14

PROTOCOL FOR RESPONDING TO SERIOUS ADVERSE INCIDENTS IN THE EVENT OF A HOMICIDE – 2013 (updated November 2016 in line with the HSCB Procedure for the Reporting and Follow up of SAIs)

1. INTRODUCTION AND PURPOSE

1.1. INTRODUCTION

The Health and Social Care Board (HSCB) Procedure for the Reporting and Follow up of Serious Adverse Incidents (SAIs) was issued in April 2010 and revised November 2016. This procedure provides guidance to Health and Social Care (HSC) Trusts and HSCB Integrated Care staff in relation to the reporting and follow up of SAIs arising during the course of business of a HSC organisation, Special Agency or commissioned service.

This paper is a revised protocol, developed from the above procedure, for the specific SAIs which involves an alleged homicide perpetrated by a service user who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident.

This paper should be read in conjunction with Promoting Quality Care – Good Practice Guidance on the Assessment and Management of Risk in Mental Health and Learning Disability Services (Sept 2009 & May 2010).

1.2. PURPOSE

The purpose of this protocol is to provide HSC Trusts with a standardised approach in managing and coordinating the response to a SAI involving homicide.

2. THE PROCESS

2.1. REPORTING SERIOUS ADVERSE INCIDENTS

Refer to the HSCB Procedure for the Reporting and Follow up of Serious Adverse Incidents revised in 2016.

2.2. MULTI-DISCIPLINARY REVIEW

As indicated in Promoting Quality Care (5.0) an internal multi-disciplinary review must be held as soon as practicable following an adverse incident. Where the SAI has resulted in homicide a more independent response is required.

An independent review team should be set up within twenty working days, of the notification of the incident, to the Trust.

2.3. ESTABLISHING AN INDEPENDENT REVIEW TEAM

2.3.1 CHAIR

The Chair of the Review Team should be independent from the HSC Trust, not a Trust employee or recently employed by the Trust. They should be at Assistant Director level or above with relevant professional expertise.

It is the role of the Chair to ensure engagement with families, that their views are sought, that support has been offered to them at an early stage and they have the opportunity to comment on the final draft of the report.

2.3.2 MEMBERSHIP

A review team should include all relevant professionals. The balance of the Team should include non-Trust staff and enable the review team to achieve impartiality, openness, independence, and thoroughness in the review of the incident. [ref: Case Management Review Chapter 10 Cooperating to Protect Children].

The individuals who become members of the Team must not have had any line management responsibility for the staff working with the service user under consideration. The review team must include members who are independent of HSC Trusts and other agencies concerned.

Members of the review team should be trained in the Procedure for the Reporting and Follow up of Serious Adverse Incidents 2016.

3. TERMS OF REFERENCE

The terms of reference for the review team should be drafted at the first meeting of the review team and should be agreed by the HSCB before the second meeting.

The Terms of Reference should include, as a minimum, the following:

- establish the facts of the incident;
- analyse the antecedents to the incident;
- consider any other relevant factors raised by the incident;
- establish whether there are failings in the process and systems;
- establish whether there are failings in the performance of individuals;
- identify lessons to be learned from the incident; and

- identify clearly what those lessons are, how they will be acted upon, what is expected to change as a result, and specify timescales and responsibility for implementation.

4. TIMESCALES

The notification to the Trust of a SAI, resulting in homicide, is the starting point of this process.

The Trust should notify the HSCB within 24hours and the Regulation and Quality Improvement Authority (RQIA) as appropriate.

An independent review team should be set up within twenty working days of the notification of the incident to the Trust.

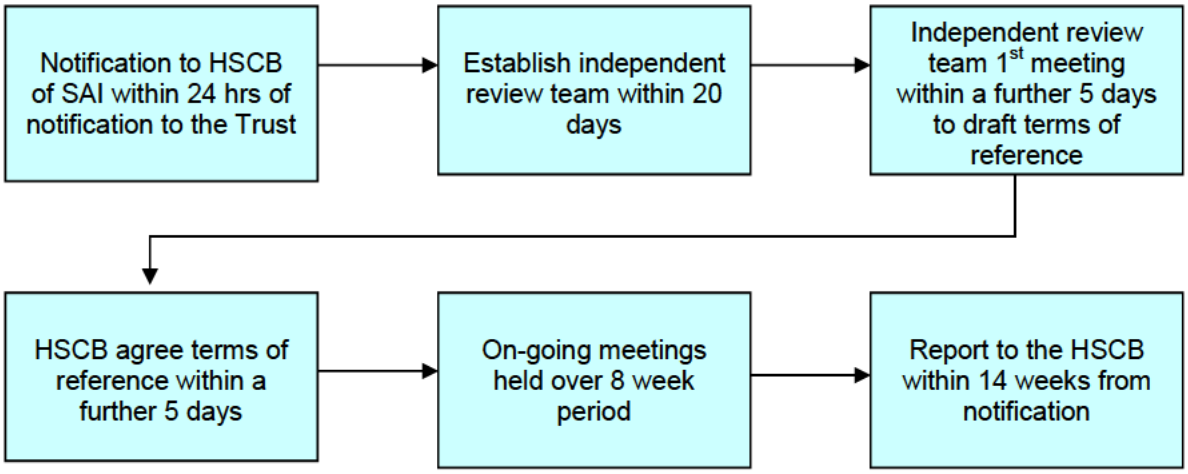
The team should meet to draft the terms of reference within a further five working days (i.e. twenty five days from notification of the incident to the Trust).

The HSCB should agree the terms of reference within a further five working days to enable work to begin at a second meeting.

The review team should complete their work and report to the HSCB within 14 weeks, this may be affected by PSNI investigations.

FLOWCHART OF PROCESS WITH TIMESCALES

NB Days refers to working days from the date of notification of the incident to the Trust



5. THE HEALTH AND SOCIAL CARE BOARD RESPONSIBILITY

On receipt of the completed Trust review report the HSCB will consider the findings and recommendations of the report and must form a view as to whether or not an Independent Inquiry is required.

The HSCB must advise the Department of Health, (DoH) as to whether or not an Independent Inquiry is required in this particular SAI.

APPENDIX 15

ADMINISTRATIVE PROTOCOL

REPORTING AND FOLLOW UP OF SAIs INVOLVING RQIA MENTAL HEALTH/LEARNING DISABILITY AND INDEPENDENT/REGULATED SECTOR

On receipt of a SAI notification and where a HSC Trust has also copied RQIA into the same notification, the following steps will be applied:

1. HSCB acknowledgement email to Trust advising on timescale for review report will also be copied to RQIA.

2. On receipt of the review/learning summary report from Trust, the HSCB Governance Team will forward to the HSCB/PHA Designated Review Officer (DRO).

3. At the same time, the HSCB Governance Team will also forward the review report/learning summary report[1] to RQIA, together with an email advising of a **3 week** timescale from receipt of review report/learning summary report, for RQIA to forward comments for consideration by the DRO.

4. The DRO will continue with his/her review liaising (where s/he feels relevant) with Trust, RQIA and other HSCB/PHA professionals until s/he is satisfied SAI can be closed.

5. If no comments are received from RQIA within the 3 week timescale, the DRO will assume RQIA have no comments.

6. When the SAI is closed by the DRO, an email advising the Trust that the SAI is closed will also be copied to RQIA.

All communications to be sent or copied via:

HSCB Governance Team: ***seriousincidents@hscni.net***
and RQIA: **seriousincidents@rqia.org.uk**

[1] **For Level 1 SAIs the HSCB only routinely receive the Learning Summary Report. If RQIA also wish to consider the full SEA Report this should be requested directly by RQIA from the relevant Reporting Organisation.**

HSC Regional Impact Table – with effect from April 2013 (updated June 2016)

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

HSC REGIONAL RISK MATRIX – WITH EFFECT FROM APRIL 2013 (updated June 2016)

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

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

APPENDIX 17

CHILD AND ADULT SAFEGUARDING AND SAI PROCESSES

The Procedure for the Reporting and Follow up of Serious Adverse Incidents (Revised November 2016) provides guidance to Health and Social Care organisations in relation to the reporting and follow up of Serious Adverse Incidents arising during the course of their business or commissioned service.

The guidance notes that the SAI review should be conducted at a level appropriate and proportionate to the complexity of the incident under review.

The guidance notes that there are three possible levels of review of an SAI and specifies the expected timescale for reporting on a review report as follows:

Level 1 Review – Significant Event Audit (SEA). To be completed and a Learning Summary Report sent to the HSCB within 8 weeks of the SAI being reported.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review timescales for completion of the RCA will be determined following submission of the Learning Summary Report to the HSCB.

Level 2 Review – Root Cause Analysis (RCA). The final report to be submitted to the HSCB within 12 weeks from the date the incident was notified.

Level 3 Review – Independent Review. Timescales for completion to be agreed by the DRO.

It should be noted that not every referral to child or adult safeguarding processes will proceed to the completion of an SAI report. Within Children's Services, the most complex cases and those that involve death or serious injury to a child, where concerns about how services worked together exist, will be notified to the HSCB as an SAI and may be assessed as meeting the criteria for a Case Management Review (CMR) in which case they will be managed out of the SAI system. The CMR report will highlight the learning from the case.

However, the timescales for the completion of SAI reviews at Level 2 and 3 have proved to be challenging for the cases that do not reach the threshold for a CMR or which result from allegations of abuse of an adult. These are more likely to be some of the more complex cases, and generally involve inter- and multi- agency partnership working.

In responding to allegations of the abuse, neglect or exploitation of a child or vulnerable adult where it is suspected that criminal offence may have been committed, the Health and Social Care Trusts operate under the principles for joint working with the PSNI and other agencies as set out in

- Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults (2009);

- Sharing to Safeguard (DoH Revised HSCC 3/96 and currently being revised by DoH);
- Co-operating to Safeguard Children (DoH 2003); and
- Protocol for joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse – Northern Ireland (2013)

The Memorandum of Understanding: Investigating patient or client safety incidents (2013) states that in cases where more than one organisation may/should have an involvement in investigating any particular incident, then:

"The HSC Organisation should continue to ensure patient or client safety, but not undertake any activity that might compromise any subsequent statutory investigations."

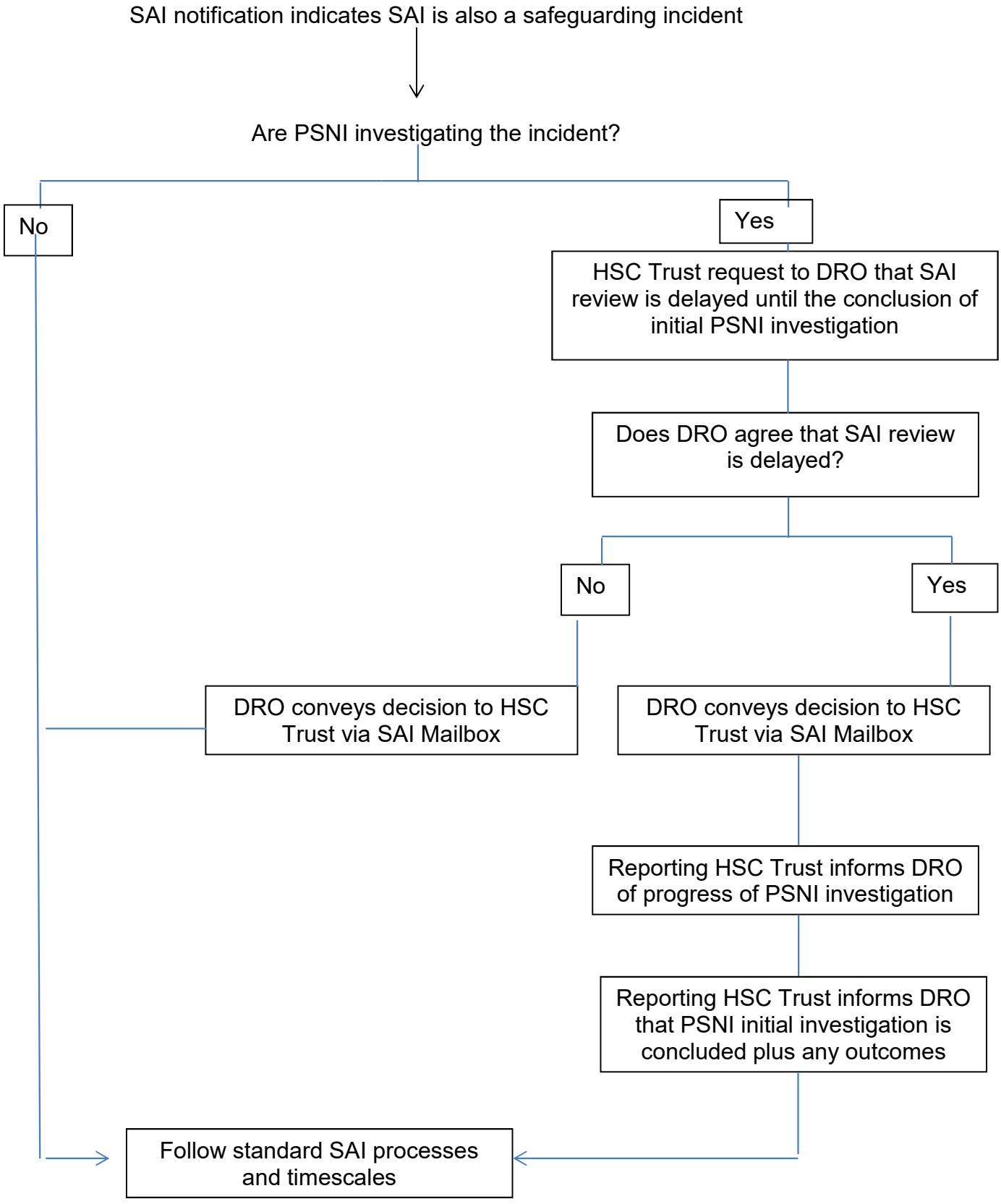
In addition "Achieving Best Evidence: Guidance on interviewing victims and witnesses, the use of special measures and the provision of pre-trial therapy" (revised in 2012), sets out clear protocols for interviewing vulnerable witnesses or victims, whether they are children or adults. This guidance ensures that interviews with vulnerable witnesses and victims are led by specially trained staff, conducted at the victims pace and take place in an environment that is conducive to the needs of the victim.

Clearly, there is an inter-dependency between PSNI and HSC investigations/reviews in complex cases involving multi-agency approaches and protocols. The identification and analysis of learning from these events is likely to be incomplete until both the PSNI and HSC have completed their separate and joint investigations/reviews using the protocols outlined above, and it is unlikely that this can be achieved within the timescales set out for both Level 1 and Level 2 reviews under the SAI procedure.

In such circumstances, the following process should be used:

- Trust report SAI to HSCB using the SAI Notification Form;
- The SAI Notification Form or section 22 of the notification form i.e. 'additional information following initial notification, should indicate the following:
  - The SAI is also a Safeguarding incident
  - PSNI are conducting an investigation of the circumstances surrounding the SAI
  - SAI evaluation will commence at the conclusion of the initial PSNI investigation;
  - Set out the arrangements for keeping the DRO informed of the progress of the PSNI initial investigation;
- If satisfied, the DRO will advise the Trust via the SAI Mailbox that he/she is in agreement with the proposal to delay the SAI review until the conclusion of the initial PSNI investigation;
- The reporting HSC Trust will inform the DRO as soon as the initial PSNI investigation has concluded, along with any outcomes and advise the SAI evaluation has commenced;
- The SAI will continue to be monitored by HSCB Governance team in line with timescales within the Procedure for the Reporting and Follow up of SAIs;
- If the DRO is **not** in agreement with the proposal to delay the SAI review, the reasons for this will be clearly conveyed to the Trust via the SAI Mailbox. Possible reasons for this may include, for example, situations where a criminal incident has occurred on HSC Trust premises but does not involve HSC Trust staff, or an incident involving a service user in their own home and a member of the public is reported to the PSNI by HSC Trust staff.

CHILD AND ADULT SAFEGUARDING AND SAI PROCESSES



Received from SHSCT on 05 May 2023. Annotated by the Urology Services Inquiry.

SECTION THREE ADDENDUM

ADDENDUM

ADDENDUM 1

A Guide for Health and Social Care Staff

Engagement/Communication with the Service User/Family/Carers following a Serious Adverse Incident

November 2016
Version 1.1

Contents

Notes on the Development of this Guidance

This guidance has been compiled by the Health and Social Care Board (HSCB) and Public Health Agency (PHA) working in collaboration with the Regulation and Quality Improvement Authority (RQIA), the Patient Client Council (PCC) and Health and Social Care (HSC) Trusts.

This guidance has been informed by:

- National Patient Safety Agency (NPSA) Being Open Framework (2009)
- Health Service Executive (HSE) – Open Disclosure National Guidelines (2013)

Please note the following points:

- *The term 'service user' as used throughout this guidance includes patients and clients availing of Health and Social Care Services from HSC organisations and Family Practitioner Services (FPS) and/or services commissioned from the Independent Sector by HSC organisations.*

- *The phrase 'the service user / family' is used throughout this document in order to take account of all types of engagement scenarios, and also includes a carer(s) or the legal guardian of the service user, where appropriate. However, when the service user has capacity, communication should always (in the first instance) be with them (see appendix 1 for further guidance).*

A review / re-evaluation of this guidance will be undertaken one year following implementation.

1.0 Introduction

When an adverse outcome occurs for a service user it is important that the service user / family (as appropriate) receive timely information and are fully aware of the processes followed to review the incident.

The purpose of a Serious Adverse Incident (SAI) review is to understand what occurred and where possible improve care by learning from incidents. Being open about what happened and discussing the SAI promptly, fully and compassionately can help the service user / family cope better with the after-effects and reduce the likelihood of them pursuing other routes such as the complaints process or litigation to get answers to their questions.

It is therefore essential that there is:

- full disclosure of a SAI to the service user / family,
- an acknowledgement of responsibility,
- an understanding of what happened and a discussion of what is being done to prevent recurrence.

Communicating effectively with the service user / family is a vital part of the SAI process. If done well, it promotes person-centred care and a fair and open culture, ultimately leading to continuous improvement in the delivery of HSC services. It is human to make mistakes, but rather than blame individuals, the aim is for all of us to identify and address the factors that contributed to the incident. The service user / family can add valuable information to help identify the contributing factors, and should be integral to the review process, unless they wish otherwise.

2.0 Purpose

This is a guide for HSC staff to ensure effective communication with the service user / family, following a SAI, is undertaken in an open, transparent, informed, consistent and timely manner.

It is important this guidance is read in conjunction with the regional Procedure for Reporting and Follow up of SAIs (November 2016) and any subsequent revisions relating to the SAI process that have or may be issued in the future. This will ensure the engagement process is closely aligned to the required timescales, documentation, review levels etc. *To view the SAI Procedure please follow the link below* http://www.hscboard.hscni.net/download/PUBLICATIONS/policies-protocols-and-guidelines/Procedure-for-the-reporting-and-follow-up-of-SAIs-2016.pdf.

The HSCB Process works in conjunction with all other review processes, statutory agencies and external bodies. Consequently, there may be occasions when a reporting organisation will have reported an incident via another process before or after it has been reported as a SAI. It is therefore important that all existing processes continue to operate in tandem with the SAI procedure and should not be an obstacle to the engagement of the service user / family; nor should an interaction through another process replace engagement through the SAI process.

In that regard, whilst this guidance is specific to 'being open' when engaging with the service user / family following a SAI, it is important HSC organisations are also mindful of communicating effectively with the service user / family when investigating adverse incidents. In these circumstances, organisations should refer to the NPSABeingOpenFramework www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726 which will provide assistance for organisations to determine the level of service user / family engagement when investigating those adverse incidents that do not meet SAI criteria.

The Being Open Framework may also assist organisations with other investigative processes e.g. complaints, litigation, lookback exercises, and any other relevant human resource and/or risk management related policies and procedures.

3.0 Principles of Being Open with the Service User / Family

Being open and honest with the service user / family involves:

- Acknowledging, apologising and explaining that the organisation wishes to review the care and treatment of the service user;
- Explaining that the incident has been categorised as a SAI, and describing the review process to them, including timescales;
- Advising them how they can contribute to the review process, seeking their views on how they wish to be involved and providing them with a leaflet explaining the SAI process (see appendix 2);
- Conducting the correct level of SAI review into the incident and reassuring the service user / family that lessons learned should help prevent the incident recurring;
- Providing / facilitating support for those involved, including staff, acknowledging that there may be physical and psychological consequences of what happened;

- Ensuring the service user / family have details for a single point of contact within the organisation.

It is important to remember that saying sorry is not an admission of liability and is the right thing to do.

The following principles underpin being open with the service user / family following a SAI.

3.1 Acknowledgement

All SAIs should be acknowledged and reported as soon as they are identified. In cases where the service user / family inform HSC staff / family practitioner when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all professionals.

In certain circumstances e.g. cases of criminality, child protection, or SAIs involving theft, fraud, information breaches or data losses that do not directly affect service users; it may not be appropriate to communicate with the service user / family. When a lead professional / review team make a decision, based on a situation as outlined above, or based on a professional's opinion, not to disclose to the service user / family that a SAI has occurred, the rationale for this decision must be clearly documented in the SAI notification form / SAI review checklist that is submitted to the HSCB.

It is expected, the service user / family will be informed that a SAI has occurred, as soon as possible following the incident, for all levels of SAI reviews. In very exceptional circumstances, where a decision is made not to inform the service user / family, this decision must be reviewed and agreed by the review team, approved by an appropriate Director or relevant committee / group, and the decision kept under review as the review progresses. In these instances the HSCB must also be informed:

- **Level 1 reviews - on submission of Review Report and Checklist Proforma**
- **Level 2 and 3 reviews - on submission of the Terms of Reference and Membership of the review team.**

3.2 Truthfulness, timeliness and clarity of communication

Information about a SAI must be given to the service user / family in a truthful and open manner by an appropriately nominated person (see 4.2.2). The service user / family should be provided with an explanation of what happened in a way that considers their individual circumstances, and is delivered openly. Communication should also be timely, ensuring the service user / family is provided with information about what happened as soon as practicable without causing added distress. Note, where a number of service users are involved in one incident, they should all be informed at the same time where possible.

It is also essential that any information given is based solely on the facts known at the time. Staff should explain that new information may emerge as an incident review is undertaken, and that the service user / family will be kept informed, as the review progresses. The service user / family should receive clear information with a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff, and the use of jargon, should be avoided.

3.3 Apology / Expression of Regret

When it is clear, that the organisation / family practitioner is responsible for the harm / distress to the service user, it is imperative that there is an acknowledgement of the incident and an apology provided as soon as possible. Delays are likely to increase the service user / family sense of anxiety, anger or frustration. Relevant to the context of a SAI, the service user / family should receive a meaningful apology – one that is a sincere expression of sorrow or regret for the harm / distress that has occurred as a result of the SAI.

3.4 Recognising the expectations of the Service User / Family

The service user / family may reasonably expect to be fully informed of the facts, consequences and learning in relation to the SAI and to be treated with empathy and respect.

They should also be provided with support in a manner appropriate to their needs. Specific types of service users / families may require additional support (see appendix 1).

In circumstances where the service user / family request the presence of their legal advisor this request should be facilitated. However, HSC staff

should ensure that the legal advisor is aware that the purpose of the report / meeting is not to apportion liability or blame but to learn from the SAI. Further clarification in relation to this issue should be sought from Legal Services.

3.5 Professional Support

HSC organisations must create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report SAIs. Staff should feel supported throughout the incident review process because they too may have been traumatised by being involved. There should be a culture of support and openness with a focus on learning rather than blame.

HSC organisations should encourage staff to seek support where required form relevant professional bodies such as the General Medical Council (GMC), Royal Colleges, the Medical Defence Union (MDU), the Medical Protection Society (MPS), the Nursing and Midwifery Council, the Northern Ireland Association for Social Work (NIASW) and the Northern Ireland Social Care Council (NISCC).

3.6 Confidentiality

Details of a SAI should at all times be considered confidential. It is good practice to inform the service user / family about those involved in the review and who the review report will be shared with.

3.7 Continuity of Care

In exceptional circumstances, the service user / family may request transfer of their care to another facility; this should be facilitated if possible to do so. A member of staff should be identified to act as a contact person for the service user / family to keep them informed of their on-going treatment and care.

4.0 Process

Being open with the service user / family is a process rather than a one-off event. There are 5 stages in the engagement process:

- Stage 1 – Recognition
- Stage 2 - Communication
- Stage 3 – Initial Meeting
- Stage 4 – Follow up Discussions

- Stage 5 – Process Completion

The duration of this process depends on the level of SAI review being undertaken and the associated timescales as set out in the Procedure for the Reporting and Follow up of SAIs (2013).

4.1 Stage 1 - Recognition

As soon as the SAI is identified, the priority is to prevent further harm / distress. The service user / family should be notified that the incident is being reviewed as a SAI.

4.1.1 Preliminary Discussion with the Service User / Family

On many occasions it will be at this stage when the lead professional / family practitioner responsible for the care of the service user will have a discussion with the service user / family, advising of the need to review the care and treatment. This preliminary discussion (which could be a telephone call) will be in addition to the formal initial meeting with the service user / family (see 4.3).

A Level 1 review may not require the same level of engagement as Levels 2 and 3 therefore the preliminary discussion may be the only engagement with service user / family prior to communicating findings of the review, provided they are content they have been provided with all information.

There may be occasions when the service user / family indicate they do not wish to engage in the process. In these instances the rationale for not engaging further must be clearly documented.

4.2 Stage 2 – Communication

4.2.1 Timing of Initial Communication with the Service User / Family

The initial discussion with the service user / family should occur as soon as possible after recognition of the SAI. Factors to consider when timing this discussion include:

- service user's health and wellbeing;
- service user / family circumstances, preference (in terms of when and where the meeting takes place) and availability of key staff *(appendix 1 provides guidance on how to manage different categories of service user / family circumstances);*

4.2.2 Choosing the individual to communicate

The person[7] nominated to lead any communications should:

- Be a senior member of staff with a comprehensive understanding of the facts relevant to the incident;
- Have the necessary experience and expertise in relation to the type of incident;
- Have excellent interpersonal skills, including being able to effectively engage in an honest, open and transparent manner, avoiding excessive use of jargon;
- Be willing and able to offer a meaningful apology / expression of regret, reassurance and feedback.

If required, the lead person communicating information about the SAI should also be able to nominate a colleague who may assist them with the meeting and should be someone with experience or training in communicating with the service user / family.

The person/s nominated to engage could also be a member/s of the review team (if already set up).

[7] *FPS SAIs involving FPS this will involve senior professionals/staff from the HSCB Integrated Care Directorate.*

4.3 Stage 3 - Initial Meeting with the Service User / Family

The initial discussion is the first part of an on-going communication process. Many of the points raised here should be expanded on in subsequent meetings with the service user / family.

4.3.1 Preparation Prior to the Initial Meeting

- The service user / family should be given the leaflet - What I Need to Know About a SAI (see appendix 2);
- Share with the service user / family what is going to be discussed at the meeting and who will be in attendance.

4.3.2 During the Initial Meeting

The content of the initial meeting with the service user / family should cover the following:

- Welcome and introductions to all present;
- An expression of genuine sympathy or a meaningful apology for the event that has occurred;
- The facts that are known to the multidisciplinary team;
- Where a service user has died, advising the family that the coroner has been informed (where there is a requirement to do so) and any other relevant organisation/body;
- The service user / family are informed that a SAI review is being carried out;
- Listening to the service user's / families understanding of what happened;
- Consideration and formal noting of the service user's / family's views and concerns;
- An explanation about what will happen next in terms of the SAI review, findings, recommendations and learning and timescales;
- An offer of practical and emotional support for the service user / family. This may involve getting help from third parties such as charities and voluntary organisations, providing details of support from other organisations, as well as offering more direct assistance;
- Advising who will be involved in the review before it takes place and who the review report will be shared with;
- Advising that all SAI information will be treated as confidential.

If for any reason it becomes clear during the initial discussion that the service user / family would prefer to speak to a different health / social

care professional, these wishes should be respected, and the appropriate actions taken.

It is important during the initial meeting to try to avoid any of the following:

- Speculation;
- Attribution of blame;
- Denial of responsibility;
- Provision of conflicting information from different health and social care individuals.

It should be recognised that the service user / family may be anxious, angry and frustrated, even when the meeting is conducted appropriately. It may therefore be difficult for organisations to ascertain if the service user / family have understood fully everything that has been discussed at the meeting. It is essential however that, at the very least, organisations are assured that the service user / family leave the meeting fully aware that the incident is being reviewed as a SAI, and knowing the organisation will continue to engage with them as the review progresses, so long as the service user / family wish to engage.

Appendix 3 provides examples of words / language which can be used during the initial discussion with the service user / family.

4.4 Stage 4 – Follow-up Discussions

Follow-up discussions are dependent on the needs and wishes of the service user / family.

The following guidelines will assist in making the communication effective:

- The service user / family should be updated if there are any delays and the reasons for the delays explained;
- Advise the service user / family if the incident has been referred to any other relevant organisation / body;
- Consideration is given to the timing of the meetings, based on both the service users / families health, personal circumstances and preference on the location of the meeting, e.g. the service users / families home;
- Feedback on progress to date, including informing the service user / family of the Terms of Reference of the review and membership of the review panel (for level 2 and 3 SAI reviews);
- There should be no speculation or attribution of blame. Similarly, the health or social care professional / senior manager communicating the SAI must not criticise or comment on matters outside their own experience;
- A written record of the discussion is kept and shared with the service user / family;
- All queries are responded to appropriately and in a timely way.

4.5 Stage 5 – Process Completion

4.5.1 Communicating findings of review / sharing review report

Feedback should take the form most acceptable to the service user / family. Communication should include:

- a repeated apology / expression of regret for the harm / distress suffered;
- the chronology of clinical and other relevant factors that contributed to the incident;
- details of the service users / families concerns;
- information on learning and outcomes from the review
- Service user / family should be assured that lines of communication will be kept open should further questions arise at a later stage and a single point of contact is identified.

It is expected that in most cases there will be a complete discussion of the findings of the review and that the final review report will be shared with

the service user / family. In some cases however, information may be withheld or restricted, for example:

- Where communicating information will adversely affect the health of the service user / family;
- Where specific legal/coroner requirements preclude disclosure for specific purposes;
- If the deceased service users health record includes a note at their request that he/she did not wish access to be given to his/her family.

Clarification on the above issues should be sought form Legal Services.

There may also be instances where the service user / family does not agree with the information provided, in these instances Appendix 1 (section 1.8) will provide additional assistance.

In order to respond to the timescales as set out in the Procedure for the Reporting and Follow up of SAIs (November 2016) organisations may not have completed stage 5 of the engagement process prior to submission of the review report to HSCB. In these instances, organisations must indicate on the SAI review checklist, submitted with the final review report to the HSCB, the scheduled date to meet with the service user / family to communicate findings of review / share review report.

4.5.2 Communicating Changes to Staff

It is important that outcomes / learning is communicated to all staff involved and to the wider organisation as appropriate.

4.6 Documentation

Throughout the above stages it is important that discussions with the service user / family are documented and should be shared with the individuals involved.

Documenting the process is essential to ensure continuity and consistency in relation to the information that has been relayed to the service user / family.

Documentation which has been produced in response to a SAI may have to be disclosed later in legal proceedings or in response to a freedom of information application. It is important that care is taken in all communications and documents stating fact only.

Appendix 4 provides a checklist which organisations may find useful as an aide memoire to ensure a professional and standardised approach.

5.0 Supporting Information and Tools

In addition to this guidance, supporting tools have been developed to assist HSC organisations with implementing the actions of the NPSA's Being Open Patient Safety Alert.

Training on being open is freely available through an e-learning tool for all HSC organisations.

Information on all these supporting tools can be found at: www.**npsa**.nhs.uk/**beingopen** and www.nrls.**npsa**.nhs.uk/**beingopen**/.

Guidance on sudden death and the role of bereavement co-ordinators in Trusts can be found at:
http://webarchive.proni.gov.uk/20120830110704/http://www.dhsspsni.gov.uk/sudden-death-guidance.pdf

List of Acronyms and Abbreviations

FPS	-	Family Practitioner Services
GMC	-	General Medical Council
HSC	-	Health and Social Care
HSCB	-	Health and Social Care Board
HSE	-	Health Service Executive
MDU	-	Medical Defence Union
MPS	-	Medical Protection Society
NIASW	-	Northern Ireland Association for Social Work
NISCC	-	Northern Ireland Social Care Council
NMC	-	Nursing and Midwifery Council
NPSA	-	National Patient Safety Agency
PCC	-	Patient Client Council
PHA	-	Public Health Agency
RC	-	Royal colleges
RCA	-	Root Cause Analysis
RQIA	-	Regulation and Quality Improvement Authority
SAI	-	Serious Adverse Incident
SEA	-	Significant Event Audit

Particular Service user Circumstances

The approach to how an organisation communicates with a service user / family may need to be modified according to the service user's personal circumstances.

The following gives guidance on how to manage different categories of service user circumstances.

1.1 When a service user dies

When a SAI has resulted in a service users death, the communication should be sensitive, empathetic and open. It is important to consider the emotional state of bereaved relatives or carers and to involve them in deciding when it is appropriate to discuss what has happened.

1.2 Children

The legal age of maturity for giving consent to treatment is 16 years old. However, it is still considered good practice to encourage young people of this age to involve their families in decision making.

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the communication process after a SAI.

The opportunity for parents / guardians to be involved should still be provided unless the child expresses a wish for them not to be present. Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents / guardians alone or in the presence of the child. In these instances the parents' / guardians' views on the issue should be sought.

1.3 Service users with mental health issues

Communication with service users with mental health issues should follow normal procedures unless the service user also has cognitive impairment (see1.4 Service users with cognitive impairments).

The only circumstances in which it is appropriate to withhold SAI information from a service user with mental health issues is when advised to do so by a senior clinician who feels it would cause adverse psychological harm to the service user. However, such circumstances are rare and a second opinion may be required to justify withholding information from the service user.

In most circumstances, it is not appropriate to discuss SAI information with a carer or relative without the permission of the service user, unless in the public interest and / or for the protection of third parties.

1.4 Service users with cognitive impairment

Some individuals have conditions that limit their ability to understand what is happening to them.

In these cases communication would be conducted with the carer / family as appropriate. Where there is no such person, the clinicians may act in the service users best interest in deciding who the appropriate person is to discuss the SAI with.

1.5 Service users with learning disabilities

Where a service user / family has difficulties in expressing their opinion verbally, every effort should be made to ensure they can use or be facilitated to use a communication method of their choice. An advocate / supporter, agreed on in consultation with the service user, should also be identified. Appropriate advocates / supporters may include carer/s, family or friends of the service user or a representative from the Patient Client Council (PCC).

1.6 Service users with different language or cultural considerations

The need for translation and advocacy services and consideration of special cultural needs must be taken into account when planning to discuss SAI information. Avoid using 'unofficial translators' and / or the service users family or friends as they may distort information by editing what is communicated.

1.7 Service users with different communication needs

Service users who have communication needs such as hearing impaired, reduced vision may need additional support.

1.8 Service users who do not agree with the information provided

Sometimes, despite the best efforts the service user/family/carer may remain dissatisfied with the information provided. In these circumstances, the following strategies may assist:

- Facilitate discussion as soon as possible;
- Write a comprehensive list of the points that the service user / family disagree with and where appropriate reassure them you will follow up these issues.
- Ensure the service user / family has access to support services;
- Offer the service user / family another contact person with whom they may feel more comfortable.
- Use an acceptable service user advocate e.g. PCC or HSC layperson to help identify the issues between the HSC organisation and the service user / family and to achieve a mutually agreeable solution;

There may be occasions despite the above efforts the service user/family/carer remain dissatisfied with the HSC organisation's attempts to resolve their concerns. In these exceptional circumstances, the service user/family/carer through the agreed contact person, should be advised of their right to approach the Northern Ireland Public Services Ombudsman (NIPSO). In doing so, the service user/family requires to be advised by the HSC organisation that the internal procedure has concluded (within two weeks of this process having been concluded), and that the service user/family should approach the NIPSO within six months of this notification.

The contact details for the NIPSO are: Freephone 0800 34 34 34 or Progressive House, 33 Wellington Place, Belfast, BT1 6HN.

1.9 Service Users who do not wish to participate in the engagement process

It should be documented if the service user does not wish to participate in the engagement process.

Health and Social Care Board

Public Health Agency

What I need to know about a Serious Adverse Incident

Information for Service Users, Family Members and Carers

Insert Name of Organisation

This leaflet is written for people who use Health and Social Care (HSC) services and their families.

**The phrase service user / family member and carer is used throughout this document in order to take account of all types of engagement scenarios. However, when a service user has capacity, communication should always (in the first instance) be with them.*

Introduction

Events which are reported as Serious Adverse Incidents (SAIs) help identify learning even when it is not clear something went wrong with treatment or care provided.

When things do go wrong in health and social care it is important that we identify this, explain what has happened to those affected and learn lessons to ensure the same thing does not happen again. SAIs are an important means to do this. Areas of good practice may also be highlighted and shared, where appropriate.

What is a Serious Adverse Incident?

A SAI is an incident or event that must be reported to the Health and Social Care Board (HSCB) by the organisation where the SAI has occurred. It may be:

- an incident resulting in serious harm;
- an unexpected or unexplained death;
- a suspected suicide of a service user who has a mental illness or disorder;
- an unexpected serious risk to wellbeing or safety, for example an outbreak of infection in hospital;

A SAI may affect services users, members of the public or staff.

Never events are serious patient safety incidents that should not occur if the appropriate preventative measures have been implemented by healthcare providers. A small number of SAIs may be categorised as never events based on the Department of Health Never Events list.

SAIs, including never events, occurring within the HSC system are reported to the HSCB. You, as a service user / family member / carer, will be informed where a SAI and/or never event has occurred relating to treatment and care provided to you by the HSC.

Can a complaint become a SAI?

Yes, if during the follow up of a complaint the (**insert name of organisation)** identifies that a SAI has occurred it will be reported to the HSCB. You, as a service user / family member and carer will be informed of this and updated on progress regularly.

How is a SAI reviewed?

Depending on the circumstance of the SAI a review will be undertaken. This will take between 8 to 12 weeks depending on the complexity of the case. If more time is required you will be kept informed of the reasons.

The (**insert name of organisation**) will discuss with you how the SAI will be reviewed and who will be involved. The (**insert name of organisation**) will welcome your involvement if you wish to contribute.

Our goal is to find out what happened, why it happened and what can be done to prevent it from happening again and to explain this to those involved.

How is the service user or their family/carer involved in the review?

An individual will be identified to act as your link person throughout the review process. This person will ensure as soon as possible that you:

- Are made aware of the incident, the review process through meetings / telephone calls;
- Have the opportunity to express any concerns;
- Know how you can contribute to the review, for example share your experiences;
- Are updated and advised if there are any delays so that you are always aware of the status of the review;
- Are offered the opportunity to meet and discuss the review findings;
- Are offered a copy of the review report;

- Are offered advice in the event that the media make contact.

What happens once the review is complete?

The findings of the review will be shared with you. This will be done in a way that meets your needs and can include a meeting facilitated by **(insert name of organisation)** staff that is acceptable to you.

How will learning be used to improve safety?

By reviewing a SAI we aim to find out what happened, how and why. By doing this we aim to identify appropriate actions which will prevent similar circumstances occurring again.

We believe that this process will help to restore the confidence of those affected by a SAI.

For each completed review:

- Recommendations may be identified and included within an action plan;
- Any action plan will be reviewed to ensure real improvement and learning.

We will always preserve your confidentiality while also ensuring that opportunities to do things better are shared throughout our organisation and the wider health and social care system. Therefore as part of our process to improve quality and share learning, we may share the anonymised content of the SAI report with other HSC organisations'

Do families get a copy of the report?

Yes, a copy of the review report will be shared with service users and/or families with the service user's consent.

If the service user has died, families/carers will be provided with a copy of the report and invited to meet with senior staff.

Who else gets a copy of the report?

The report is shared with the Health and Social Care Board (HSCB) and Public Health Agency (PHA). Where appropriate it is also shared with the Coroner.

The Regulation and Quality Improvement Authority (RQIA) have a statutory obligation to review some incidents that are also reported under the SAI procedure. In order to avoid duplication of incident notification and review, RQIA work in conjunction with the HSCB / PHA with regard to the review of certain categories of SAI including the following:

- All mental health and learning disability SAIs reportable to RQIA under Article 86.2 of the Mental Health (NI) Order 1986.

- Any SAI that occurs within the regulated sector for example a nursing, residential or children's home (whether statutory or independent) for a service that has been commissioned / funded by a HSC organisation.

In both instances the names and personal details that might identify the individual are removed from the report. The relevant organisations monitor the (**insert name of organisation)** to ensure that the recommendations have been implemented. The family may wish to have follow up / briefing after implementation and if they do this can be arranged by their link person within the (**insert name of organisation**).

All those who attended the review meeting are given a copy of the anonymised report. Any learning from the review will be shared as appropriate with relevant staff/groups within the wider HSC organisations.

Further Information

If you require further information or have comments regarding this process you should contact the nominated link person - name and contact details below:

Your link person is ……

Your link person's job title is……..

Contact number ……

Hours of work……

Prior to any meetings or telephone call you may wish to consider the following:

Think about what questions and fears/concerns you have in relation to:

(a) What has happened?
(b) Your condition / family member condition
(c) On-going care

You could also:

- Write down any questions or concerns you have;
- Think about who you would like to have present with you at the meeting as a support person;
- Think about what things may assist you going forward;
- Think about which healthcare staff you feel should be in attendance at the meeting.

Patient and Client Council

The Patient Client Council offers independent, confidential advice and support to people who have a concern about a HSC Service. This may include help with writing letters, making telephone calls or supporting you at meetings, or if you are unhappy with recommendations / outcomes of the reviews.

Contact details:
Free phone number: 0800 917 0222

Appendix 3

Examples of communication which enhances the effectiveness of being open	
Stage of Process	**Sample Phrases**
Acknowledgement	"We are here to discuss the harm that you have experienced/the complications with your surgery/treatment" "I realise that this has caused you great pain/distress/anxiety/worry" "I can only imagine how upset you must be" "I appreciate that you are anxious and upset about what happened during your surgery – this must have come as a big shock for you" "I understand that you are angry/disappointed about what has happened" "I think I would feel the same way too"
Sorry	"I am so sorry this has happened to you" "I am very sorry that the procedure was not as straightforward as we expected and that you will have to stay in hospital an extra few days for observation" "I truly regret that you have suffered xxx which is a recognised complication associated with the x procedure/treatment." "I am so sorry about the anxiety this has caused you" "A review of your case has indicated that an error occurred – we are truly sorry about this"
Story	**Their Story** "Tell me about your understanding of your condition" "Can you tell me what has been happening to you" "What is your understanding of what has been happening to you" **Your understanding of their Story: (Summarising)** "I understand from what you said that" xxx "and you are very upset and angry about this"

	Is this correct? (i.e. summarise their story and acknowledge any emotions/concerns demonstrated.) "Am I right in saying that you……." **Your Story** "Is it ok for me to explain to you the facts known to us at this stage in relation to what has happened and hopefully address some of the concerns you have mentioned? "Do you mind if I tell you what we have been able to establish at this stage?" "We have been able/unable to determine at this stage that……." "We are not sure at this stage about exactly what happened but we have established that ……. We will remain in contact with you as information unfolds" "You may at a later stage experience xx if this happens you should ……."
Inquire	"Do you have any questions about what we just discussed?" "How do you feel about this?" "Is there anything we talked about that is not clear to you?"
Solutions	"What do you think should happen now?" "Do you mind if I tell you what I think we should do?" "I have reviewed your case and this is what I think we need to do next" "What do you think about that?" "These are your options now in relation to managing your condition, do you want to have a think about it and I will come back and see you later?" "I have discussed your condition with my colleague Dr x we both think that you would benefit from xx. What do you think about that?"
Progress	"Our service takes this very seriously and we have already started a review into the incident to see if we can find out what caused it to happen" "We will be taking steps to learn from this event so that we can

	try to prevent it happening again in the future" "I will be with you every step of the way as we get through this and this is what I think we need to do now" "We will keep you up to date in relation to our progress with the review and you will receive a report in relation to the findings and recommendations of the review team" "Would you like us to contact you to set up another meeting to discuss our progress with the review." "I will be seeing you regularly and will see you next in….days/weeks. "You will see me at each appointment" "Please do not hesitate to contact me at any time if you have any questions or if there are further concerns – you can contact me by……" "If you think of any questions write them down and bring them with you to your next appointment." "Here are some information leaflets regarding the support services we discussed – we can assist you if you wish to access any of these services"

Appendix 4

Organisations may find this checklist useful an aide memoire to ensure a professional and standardised approach

Before, During and After Communication / Engagement Documentation Checklist

BEFORE	***Note taking***
Service users full name	
Healthcare record number	
Date of birth	
Date of admission	
Diagnosis	
Key HSC professional(s) involved in service user's care	
Date of discharge (if applicable)	
Date of SAI	
Description of SAI	
Outcome of SAI	
Agreed plan for management of SAI	
Agreed professional to act as contact person with the service user / family	

Service user / family informed incident is being reviewed as a SAI: • Date • By Whom • By what means (telephone call / letter / in person)	
Date of first meeting with the service user / family	
Location of first meeting (other details such as room booking, arrangements to ensure confidentiality if shared ward etc)	
Person to be responsible for note taking identified	
Person Nominated to lead communications identified	
Colleague/s to assist nominated lead	
Other staff identified to attend the disclosure meeting	
Anticipated service user / family concerns queries	
Meeting agenda agreed and circulated	
Additional support required by the service user / family, if any?	
The service user / family has been advised to bring a support person to the meeting?	
The service user consented to the sharing of information with others such as designated family members / support person?	

It has been established that the service user / family requires an interpreter? If yes, provide details of language and arrangements that have been or to be made.	

Signature: _____

***Date*:** _____

DURING	***Note taking***
There has been an acknowledgment of the SAI in relation to the service user / family experience.	
An apology / expression of regret provided	
The service user / family was provided with factual information regarding the adverse event	
The service user / family understanding of the SAI was established	
The service user / family was provided with the opportunity to: - Tell their story - Voice their concerns and - Ask questions	
The next steps in relation to the service user's on-going care were agreed and the service user was involved in the decisions made.	
The service user / family was provided with information in relation to the supports available to them.	
Reassurance was provided to the service user / family in relation to the on-going communication of facts when the information has been established and available – continuity provided.	
Next meeting date and location agreed	

Signature: _____

***Date*:** _____

AFTER

Circulate minutes of the meeting to all relevant parties for timely verification.
Follow through on action points agreed.
Continue with the incident review.
Keep the service user included and informed on any progress made – organise further meetings.
Draft report to be provided to the service user in advance of the final report (if agreed within review Terms of Reference that the draft report is to be shared with the service user prior to submission to HSCB/PHA).
Offer a meeting with the service user to discuss the review report and allow for amendments if required.
Follow through on any recommendations made by the incident review team.
Closure of the process is mutually agreed.
When closure / reconciliation was not reached the service user was advised of the alternative courses of action which are open to them i.e the complaints process.

Signature: _____

***Date*:** _____

Stinson, Emma M

From: Kingsnorth, Patricia
Sent: 09 February 2021 10:01
To: Andrew.Anthony[Personal Information redacted by the USI]
Subject: RE: reequested information confidential [TS-Live.FID694915]
Attachments: Datix [Personal Information redacted by USI] Service user A.pdf; datix [Personal Information redacted by] 1Service User B.pdf; datix Service User C.pdf; Datix [Personal Information redacted by USI] Service User D.pdf; datix [Personal Information redacted by USI] Service user E.pdf; datix Service User F.pdf; Datix [Personal Information redacted by USI] Service user G.pdf; Datix [Personal Information redacted by USI] Service User H.pdf; datix [Personal Information redacted by USI] Service User I.pdf

Dear Mr Anthony
Please see attached.

Kind regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
[Personal Information redacted by the USI]

From: Kingsnorth, Patricia
Sent: 09 February 2021 09:46
To: 'Andrew Anthony'
Subject: RE: reequested information confidential [TS-Live.FID694915]

Dear Mr Anthony
That's what I plan to do. I will have them to you shortly.

Kind regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
[Personal Information redacted by the USI]

From: Andrew Anthony [redacted]
Sent: 09 February 2021 09:42
To: Kingsnorth, Patricia
Subject: RE: reequested information confidential [TS-Live.FID694915]

Thanks

Perhaps the most straightforward way would be to rename the PDF to call it “Datix Service User A” etc?

Kind regards,

Andrew

ANDREW ANTHONY
Partner
[redacted]
T: [redacted]
M:
D:

Tughans / Marlborough House, 30 Victoria Street, Belfast BT1 3GG

From: Kingsnorth, Patricia [redacted]
Sent: 09 February 2021 09:39
To: Andrew Anthony [redacted]
Subject: RE: reequested information confidential [TS-Live.FID694915]

Dear Mr Anthony
Thank you for letting me know.
Apologies. I will resend the datix assigned to service users.

The TOR were approved as attached.

Regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
[redacted]

From: Andrew Anthony [redacted]
Sent: 09 February 2021 09:28
To: Kingsnorth, Patricia
Subject: RE: reequested information confidential [TS-Live.FID694915]

Dear Ms Kingsnorth,

I confirm the NIECR records have arrived, thank you for forwarding them.

I assume the terms of reference were approved in the same format as the draft previously provided, please confirm.

Is it possible for you to identify the Datix to the Service User in the TOR?

Kind regards,

Andrew

ANDREW ANTHONY
Partner
[redacted]
T: [redacted]
M:
D:

Tughans / Marlborough House, 30 Victoria Street, Belfast BT1 3GG

From: Kingsnorth, Patricia [redacted]
Sent: 08 February 2021 16:40
To: Andrew Anthony [redacted]
Subject: reequested information confidential

Dear Mr Anthony
As requested please see attached datix forms (9).
The Terms of reference were approved by the board on 12 December 2021 following family engagement.
Dr Hughes will forward the remaining questions this week.
I can confirm the documents from NIECR were sent from our office recorded delivery on Friday 6 February. The majority of these records are included in the medical notes previously sent.

Kind regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
[redacted]

Datix

Carly Connolly

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details
ID & Status

Incident Reference ID	121045
Submitted time (hh:mm)	12:59

Incident IR1 details

Notification email ID number	Personal Information
Incident date (dd/MM/yyyy)	31/10/2019
Time (hh:mm)	16:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	No
Does this incident involve a Staff Member?	Yes
Description Enter facts, not opinions. Do not enter names of people	Diagnosed with locally advanced prostate cancer August 2019. MDM 31st October 2019 recommended ADT and refer for EBRT. Not referred for EBRT and hormone treatment not as per guidance. March 2020 rising PSA and local progression (urinary retention). Re-staged June 2020 and developed metastatic disease.
Action taken Enter action taken at the time of the incident	Patient and family have been seen in outpatients and the diagnosis and future management plan discussed. Family asked if earlier treatment with EBRT would have changed the course and I have advised them that the care would be looked into.
Learning Initial	Concern MDM outcome not followed and patient has subsequently developed progression of disease.
Reported (dd/MM/yyyy)	14/07/2020
Reporter's full name	[redacted]
Reporter's SHSCT Email Address	[redacted]
Opened date (dd/MM/yyyy)	22/07/2020
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	[redacted]

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Thorndale Unit
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery

Staff initially notified upon submission

Management of Incident

Reasons for Rejection - History

No records to display.

Linked records

No Linked Records.

Coding

Datix Common Classification System (CCS)

Category	Treatment, procedure
Sub Category	
Detail	

Datix CCS2

Type	Patient Incidents
Category	Administrative Processes (Excluding Documentation)
Sub-Category	Referrals
Detail	Referral delayed
Is this a Haemovigilance /Blood Transfusion or Labs-related Incident?	No
Is this an incident relating to confidentiality? This may include inappropriate access / disclosure, loss or theft of records etc	No

SAI / RIDDOR / NIAIC?
Click here To Help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

SAI?

Click To help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

Is this incident RIDDOR reportable?

Below are the 5 categories which qualify a RIDDOR Reportable incident (click on blue links for further definition):
1. Employee or self-employed person working on Trust premises is killed or suffers a major injury
2. A member of the public on Trust premises is killed or taken to hospital
3. An incident connected with the Trust where an employee, or self-employed person working on Trust premises, suffers an "over 3 day injury (being incapacitated to do their normal duties for more than three consecutive days (not counting the day of the accident but including weekends and rest days). Incapacitation means that the member of staff is absent or unable to do their normal work e.g. placed on lighter duties which are not part of their normal work)
4. Dangerous Occurence attributable to the work of the Trust
5. A doctor has notified you in writing that a Trust employee suffers from a reportable work-related disease

Is this a NIAIC Incident

NIAIC (Northern Ireland Adverse Incident Centre) incidents relate to medical devices. If a medical device is involved in an incident consider the list below to identify if the incident is NIAIC reportable;
- design or manufacturing problems
- inadequate servicing and maintenance
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice

[redacted]

Investigation

Investigator

Date started (dd/MM/yyyy) [redacted]

Actual Impact/Harm: Catastrophic

This has been populated by the reporter. To be quality assured by the investigating manager.

Risk grading

Click here
When the incident has a Severity (actualimpact/harm, grading of insignificant to moderate, you need to plot on the matrix oppositethe Potential impact/harm. Deciding what are the chances of the incidenthappening againunder similar circumstances. (Likelihod) and multiply that by the potential impact if it were to reoccur (consequence) The overall risk grading for the event will be determined by plotting: consequence multiplied by likelihood = risk grading. Refer to impact table here:

	Consequence				
Likelihood of recurrence	Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain (Expected to occur daily)	O	O	O	O	O
Likely (Expected to occur weekly)	O	O	O	O	O
Possible (Expected to occur monthly)	O	O	O	O	O
Unlikely (Expected to occur annually)	O	O	O	O	O
Rare (NOT expected to occur for years)	O	O	O	O	O
	Grade:				

Action taken on review

Enter here any actions you have taken as a result of the incident occurring; e.g. communicating with staff / update care plan / review risk assessment (corrective and preventative action)

Action Plan Required?

A formal action plan is required for all Moderate to Catstrophic incidents. If you tick yes an "Action plan" section will appear below. Use this to create your action plan.

Action Plan

No actions.

Lessons learned

Notepad

Communication

Medication details

Falls Information
Please Quality Assure all information as part of your investigation

Pressure Ulcers

Equipment details

Documents added

People Affected

Employees

No Employees

Other Contacts

No Other Contacts

Datix

Carly Connolly

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details
ID & Status

Incident Reference ID	121851
Submitted time (hh:mm)	14:08

Incident IR1 details

Notification email ID number	Personal information redacted by the USI
Incident date (dd/MM/yyyy)	31/10/2019
Time (hh:mm)	15:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	No
Does this incident involve a Staff Member?	Yes
Description Enter facts, not opinions. Do not enter names of people	Initial assessment May 2019. Clinically felt to have a malignant prostate. Commenced on Bicalutamide 50mg OD, TURP arranged (Benign pathology). Reviewed in outpatients in July 2019. Planned for repeat PSA and further review. Emergency Department attendance May 2020 resulting in catheterization. Rectal mas investigated and diagnosed as locally advanced prostate cancer. Commenced on Hormone treatment July 2020 and staging investigations arranged.
Action taken Enter action taken at the time of the incident	Discussed at MDM and prompt Outpatient review and commencement of treatment arranged.
Learning Initial	Concern TURP is not a diagnostic investigation for suspected prostate cancer and no prostate biopsies were performed despite clinical suspicion of locally advanced prostate cancer. Dose of bicalutamide patient commenced on below dose for standard antiandrogen monotherapy and no plan to utilize at this dose as cover for commencement of LHRHa therapy. No additional staging investigations arranged despite clinical impression of locally advanced prostate cancer. Patient subsequently re-presented with complications of local progression of untreated prostate cancer.
Reported (dd/MM/yyyy)	28/07/2020
Reporter's full name	[redacted]
Reporter's SHSCT Email Address	[redacted]
Opened date (dd/MM/yyyy)	30/07/2020
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	[redacted]

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Urology Clinic
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery

Staff initially notified upon submission

Management of Incident

Reasons for Rejection - History

Linked records

Coding

Datix Common Classification System (CCS)

Datix CCS2

SAI / RIDDOR / NIAIC?
Click here To Help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

SAI?

Click To help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

Is this incident RIDDOR reportable?

Below are the 5 categories which qualify a RIDDOR Reportable incident (click on blue links for further definition):
1. Employee or self-employed person working on Trust premises is killed or suffers a major injury
2. A member of the public on Trust premises is killed or taken to hospital
3. An incident connected with the Trust where an employee, or self-employed person working on Trust premises, suffers an "over 3 day injury (being incapacitated to do their normal duties for more than three consecutive days (not counting the day of the accident but including

weekends and rest days). Incapacitation means that the member of staff is absent or unable to do their normal work e.g. placed on lighter duties which are not part of their normal work)
4. Dangerous Occurrence attributable to the work of the Trust
5. A doctor has notified you in writing that a Trust employee suffers from a reportable work-related disease

Is this a NIAIC Incident

NIAIC (Northern Ireland Adverse Incident Centre) incidents relate to medical devices. If a medical device is involved in an incident consider the list below to identify if the incident is NIAIC reportable;
- design or manufacturing problems
- inadequate servicing and maintenance
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice

Investigation

Investigator

Date started (dd/MM/yyyy)

Actual Impact/Harm: Major

This has been populated by the reporter. To be quality assured by the investigating manager.

Risk grading

Click here
When the incident has a Severity (actualimpact/harm, grading of Insignificant to moderate, you need to plot on the matrix oppositethe Potential Impact/harm. Deciding what are the chances of the incidenthappening againunder similar circumstances. (Likelihood) and multiply that by the potential impact if it were to reoccur (consequence) The overall risk grading for the event will be determined by plotting: consequence multiplied by likelihood = risk grading. Refer to Impact table here:

	Consequence				
Likelihood of recurrence	Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain (Expected to occur daily)	○	○	○	○	○
Likely (Expected to occur weekly)	○	○	○	○	○
Possible (Expected to occur monthly)	○	○	○	○	○
Unlikely (Expected to occur annually)	○	○	○	○	○
Rare (NOT expected to occur for years)	○	○	○	○	○

Grade: [redacted]

Action taken on review

Enter here any actions you have taken as a result of the incident occurring; e.g. communicating with staff / update care plan / review risk assessment (corrective and preventative action)

Action Plan Required?

A formal action plan is required for all Moderate to Catstrophic incidents. If you tick yes an "Action plan" section will appear below. Use this to create your action plan.

Action Plan

No actions.

Lessons learned

Lessons learned

If you think there are any lessons from an incident which could be shared with other teams please record here. If not please type "none".

Date investigation completed (dd/MM/yyyy)

Was any person involved in the incident? No

Was any equipment involved in the incident? No

Notepad

Communication

Medication details

Falls Information
Please Quality Assure all information as part of your investigation

Pressure Ulcers

Equipment details

Documents added

People Affected

Employees

Other Contacts

Datix

Carly Connolly

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details
ID & Status

Incident Reference ID	121877
Submitted time (hh:mm)	21:16

Incident IR1 details

Notification email ID number	Personal information
Incident date (dd/MM/yyyy)	28/07/2020
Time (hh:mm)	17:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	No
Does this incident involve a Staff Member?	Yes
Description Enter facts, not opinions. Do not enter names of people	Follow-Up CT scan performed on 17/12/19, reported on 11th January 2020. Reported 'Possible sclerotic metastasis in L1 vertebral body'. Result not actioned. Patient contacted with result 28/7/20 and further assessment requested
Action taken Enter action taken at the time of the incident	Patient Contacted Further imaging and blood tests organized
Learning Initial	Need to assess if further results are unactioned with significant or potentially significant findings.
Reported (dd/MM/yyyy)	28/07/2020
Reporter's full name	[redacted]
Reporter's SHSCT Email Address	[redacted]
Opened date (dd/MM/yyyy)	03/08/2020
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	[redacted]

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Thorndale Unit
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery

Staff initially notified upon submission

Management of Incident

Reasons for Rejection - History

Linked records

Coding

Datix Common Classification System (CCS)

Category	Diagnosis, failed or delayed
Sub Category	Cancer - Dx failed or delayed
Detail	Failure to act on adverse test results or images

Datix CCS2

Type	Patient Incidents
Category	Diagnostic Processes/Procedures
Sub-Category	Monitoring/On-going Assessment of Patient Status
Detail	Failure/insufficient response to significant change in patient status
Is this a Haemovigilance /Blood Transfusion or Labs-related Incident?	No
Is this an incident relating to confidentiality? This may include inappropriate access / disclosure, loss or theft of records etc	No

SAI / RIDDOR / NIAIC?
Click here To Help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

SAI?

Click To help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

Is this Incident RIDDOR reportable?

Below are the 5 categories which qualify a RIDDOR Reportable Incident (click on blue links for further definition):
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3. An incident connected with the Trust where an employee, or self-employed person working on Trust premises, suffers an "over 3 day injury (being incapacitated to do their normal duties for more than three consecutive days (not counting the day of the accident but including weekends and rest days). Incapacitation means that the member of staff is absent or unable to do their normal work e.g. placed on lighter duties which are not part of their normal work)
4. Dangerous Occurence attributable to the work of the Trust
5. A doctor has notified you in writing that a Trust employee suffers from a reportable work-related disease

Is this a NIAIC Incident

NIAIC (Northern Ireland Adverse Incident Centre) incidents relate to medical devices. If a medical device is involved in an incident consider the list below to identify if the incident is NIAIC reportable;
- design or manufacturing problems
- inadequate servicing and maintenance
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice

Investigation

Investigator [redacted]

Date started (dd/MM/yyyy) [redacted]

Actual Impact/Harm: Moderate

This has been populated by the reporter. To be quality assured by the investigating manager.

Risk grading

Click here
When the incident has a Severity (actualimpact/harm, grading of insignificant to moderate, you need to plot on the matrix oppositethe Potential Impact/harm. Deciding what are the chances of the incidenthappening againunder similar circumstances. (Likelihod) and multiply that by the potential impact if it were to reoccur (consequence) The overall risk grading for the event will be determined by plotting: consequence multiplied by likelihood = risk grading. Refer to Impact table here:

	Consequence				
Likelihood of recurrence	Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain (Expected to occur daily)	O	O	O	O	O
Likely (Expected to occur weekly)	O	O	O	O	O
Possible (Expected to occur monthly)	O	O	O	O	O
Unlikely (Expected to occur annually)	O	O	O	O	O
Rare (NOT expected to occur for years)	O	O	O	O	O

Grade:

Action taken on review

Enter here any actions you have taken as a result of the incident occurring; e.g. communicating with staff / update care plan / review risk assessment (corrective and preventative action)

Action Plan Required?

A formal action plan is required for all Moderate to Catstrophic incidents. If you tick yes an "Action plan" section will appear below. Use this to create your action plan.

Action Plan

No actions.

Lessons learned

Notepad

Communication

Medication details

Falls Information
Please Quality Assure all information as part of your investigation

Pressure Ulcers

Equipment details

Documents added

People Affected

Employees

Other Contacts

Datix

Carly Connolly

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details
ID & Status

Incident Reference ID	128057
Submitted time (hh:mm)	06:25

Incident IR1 details

Notification email ID number	Personal Information
Incident date (dd/MM/yyyy)	20/08/2019
Time (hh:mm)	12:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	No
Does this incident involve a Staff Member?	Yes
Description Enter facts, not opinions. Do not enter names of people	Diagnosed with high grade prostate cancer July 2019. MDM outcome '...commence an LHRHa, arrange a CT Chest and bone scan and for subsequent MDM review.' Seen in OP 20/08/19, commenced on 50mg bicalutamide, Radiological investigations requested on 4/10/19 (6.5 weeks after OP attendance), no subsequent MDM review. Admitted with local progression January 2020 requiring transurethral resection and ureteric stent / nephrostomy. During inpatient admission it was not recognized that he had not been started on an LHRHa and he subsequently started standard treatment for his locally advanced prostate cancer (Degeralex) February 2020.
Action taken Enter action taken at the time of the incident	Personal Information had been started on appropriate treatment at the time this was identified.
Learning Initial	Non standard treatment started for prostate cancer, at variance with MDM recommendation
Reported (dd/MM/yyyy)	12/11/2020
Reporter's full name	[redacted]
Reporter's SHSCT Email Address	[redacted]
Opened date (dd/MM/yyyy)	12/11/2020
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	[redacted]

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Urology Clinic
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery

Staff initially notified upon submission

Management of Incident

Reasons for Rejection - History

No records to display.

Linked records

No Linked Records.

Coding

Datix Common Classification System (CCS)

Category	Treatment, procedure
Sub Category	Male genital organs
Detail	Treatment / procedure - failed

Datix CCS2

Type	Patient Incidents
Category	Therapeutic Processes/Procedures- (except medications/fluids/blood/plasma products administration)
Sub-Category	Monitoring/On-going Assessment of Patient Status
Detail	Failure/insufficient recognition of significant change in patient status
Is this a Haemovigilance /Blood Transfusion or Labs-related Incident?	No
Is this an Incident relating to confidentiality? This may include inappropriate access / disclosure, loss or theft of records etc	No

SAI / RIDDOR / NIAIC?
Click here To Help you determine whether or not an Incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

SAI? Click To help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.	Yes
Is this incident RIDDOR reportable? Below are the 5 categories which qualify a RIDDOR Reportable incident (click on blue links for further definition): 1. Employee or self-employed person working on Trust premises is killed or suffers a major injury 2. A member of the public on Trust premises is killed or taken to hospital 3. An incident connected with the Trust where an employee, or self-employed person working on Trust premises, suffers an "over 3 day injury (being incapacitated to do their normal duties for more than three consecutive days (not counting the day of the accident but including weekends and rest days). Incapacitation means that the member of staff is absent or unable to do their normal work e.g. placed on lighter duties which are not part of their normal work) 4. Dangerous Occurence attributable to the work of the Trust 5. A doctor has notified you in writing that a Trust employee suffers from a reportable work-related disease	No
Is this a NIAIC Incident NIAIC (Northern Ireland Adverse Incident Centre) incidents relate to medical devices. If a medical device is involved in an incident consider the list below to identify if the incident is NIAIC reportable; - design or manufacturing problems - inadequate servicing and maintenance - inappropriate local modifications - unsuitable storage and use conditions - selection of the incorrect device for the purpose - inappropriate management procedures - poor user instructions or training (which may result in incorrect user practice	No

Investigation

Investigator	[redacted]
Date started (dd/MM/yyyy)	
Actual Impact/Harm This has been populated by the reporter. To be quality assured by the investigating manager.	Major [redacted]

Risk grading

Click here
When the incident has a Severity (actualimpact/harm, grading of insignificant to moderate, you need to plot on the matrix oppositethe Potential Impact/harm. Deciding what are the chances of the incidenthappening againunder similar circumstances. (Likelihod) and multiply that by the potential impact if it were to reoccur (consequence) The overall risk grading for the event will be determined by plotting: consequence multiplied by likelihood = risk grading. Refer to impact table here:

Likelihood of recurrence	Consequence: Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain (Expected to occur daily)	○	○	○	○	○
Likely (Expected to occur weekly)	○	○	○	○	○
Possible (Expected to occur monthly)	○	○	○	○	○
Unlikely (Expected to occur annually)	○	○	○	◉	○
Rare (NOT expected to occur for years)	○	○	○	○	○

Grade: High Risk

Action taken on review Enter here any actions you have taken as a result of the incident occurring; e.g. communicating with staff / update care plan / review risk assessment (corrective and preventative action)	
Action Plan Required? A formal action plan is required for all Moderate to Catstrophic incidents. If you tick yes an "Action plan" section will appear below. Use this to create your action plan.	

Action Plan

No actions.

Lessons learned

Lessons learned If you think there are any lessons from an incident which could be shared with other teams please record here. If not please type "none".	
Date investigation completed (dd/MM/yyyy)	
Was any person involved in the incident?	No
Was any equipment involved in the incident?	No

Notepad

Communication

Medication details

Falls Information
Please Quality Assure all information as part of your investigation

Pressure Ulcers

Equipment details

Documents added

People Affected

Employees

Other Contacts

Datix

Carly Connolly

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details
ID & Status

Incident Reference ID	127251
Submitted time (hh:mm)	14:51

Incident IR1 details

Notification email ID number	Personal Information
Incident date (dd/MM/yyyy)	25/07/2019
Time (hh:mm)	17:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	No
Does this incident involve a Staff Member?	No
Description Enter facts, not opinions. Do not enter names of people	Patient diagnosed with a slow growing testicular cancer (Seminoma) had delayed referral to oncology and therefore delay in commencing chemotherapy.
Action taken Enter action taken at the time of the incident	Patient seen and treatment plan made
Learning Initial	Oncology referral should be made straight after MDM
Reported (dd/MM/yyyy)	29/10/2020
Reporter's full name	[redacted]
Reporter's SHSCT Email Address	[redacted]
Opened date (dd/MM/yyyy)	29/10/2020
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	[redacted]

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Urology Clinic
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery

Staff initially notified upon submission

Management of Incident

Reasons for Rejection - History

No records to display.

Linked records

No Linked Records.

Coding

Datix Common Classification System (CCS)

Category	
Sub Category	
Detail	

Datix CCS2

Type	
Category	
Sub-Category	
Detail	
Is this a Haemovigilance /Blood Transfusion or Labs-related Incident?	No
Is this an incident relating to confidentiality? This may include inappropriate access / disclosure, loss or theft of records etc	No

SAI / RIDDOR / NIAIC?
Click here To Help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

SAI?

Click To help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here

Is this incident RIDDOR reportable?

Below are the 5 categories which qualify a RIDDOR Reportable Incident (click on blue links for further definition):
1. Employee or self-employed person working on Trust premises is killed or suffers a major injury
2. A member of the public on Trust premises is killed or taken to hospital
3. An incident connected with the Trust where an employee, or self-employed person working on Trust premises, suffers an "over 3 day injury (being incapacitated to do their normal duties for more than three consecutive days (not counting the day of the accident but including weekends and rest days). Incapacitation means that the member of staff is absent or unable to do their normal work e.g. placed on lighter duties which are not part of their normal work)
4. Dangerous Occurence attributable to the work of the Trust
5. A doctor has notified you in writing that a Trust employee suffers from a reportable work-related disease

Is this a NIAIC Incident

NIAIC (Northern Ireland Adverse Incident Centre) incidents relate to medical devices. If a medical device is involved in an incident consider the list below to identify if the incident is NIAIC reportable;
- design or manufacturing problems
- inadequate servicing and maintenance
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice

[redacted]

Investigation

Investigator

Date started (dd/MM/yyyy) [redacted]

Actual Impact/Harm: Moderate

This has been populated by the reporter. To be quality assured by the investigating manager.

Risk grading

Click here
When the incident has a Severity (actualimpact/harm, grading of insignificant to moderate, you need to plot on the matrix oppositethe Potential impact/harm. Deciding what are the chances of the incidenthappening againunder similar circumstances. (Likelihod) and multiply that by the potential impact if it were to reoccur (consequence) The overall risk grading for the event will be determined by plotting: consequence multiplied by likelihood = risk grading. Refer to impact table here:

	Consequence				
Likelihood of recurrence	Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain (Expected to occur daily)	O	O	O	O	O
Likely (Expected to occur weekly)	O	O	O	O	O
Possible (Expected to occur monthly)	O	O	O	O	O
Unlikely (Expected to occur annually)	O	O	O	O	O
Rare (NOT expected to occur for years)	O	O	O	O	O

Grade:

Action taken on review

Enter here any actions you have taken as a result of the incident occurring; e.g. communicating with staff / update care plan / review risk assessment (corrective and preventative action)

Action Plan Required?

A formal action plan is required for all Moderate to Catstrophic incidents. If you tick yes an "Action plan" section will appear below. Use this to create your action plan.

Action Plan

No actions.

Lessons learned

Notepad

Communication

Medication details

Falls Information
Please Quality Assure all information as part of your investigation

Pressure Ulcers

Equipment details

Documents added

People Affected

Employees

No Employees

Other Contacts

No Other Contacts

Enter here any actions you have taken as a result of the incident occurring; e.g. communicating with staff / update care plan / review risk assessment (corrective and preventative action)	
Action Plan Required? A formal action plan is required for all Moderate to Catstrophic incidents. If you tick yes an "Action plan" section will appear below. Use this to create your action plan.	
Action Plan **No actions.**	
Lessons learned	
Notepad	
Communication	
Medication details	
Falls Information Please Quality Assure all information as part of your investigation	
Pressure Ulcers	
Equipment details	
Documents added	
People Affected	
Employees	
Other Contacts **No Other Contacts**	

Datix

Carly Connolly

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details
ID & Status

Incident Reference ID	125819
Submitted time (hh:mm)	09:33

Incident IR1 details

Notification email ID number	Personal Information
Incident date (dd/MM/yyyy)	06/10/2020
Time (hh:mm)	09:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	No
Does this incident involve a Staff Member?	Yes
Description Enter facts, not opinions. Do not enter names of people	Commenced on low dose (subtherapeutic) dose of bicalutamide for prostate cancer. subsequently increased to full dose of bicalutamide but in the setting of localized disease not licensed and outside of guidelines. No documentary evidence of discussion of radical treatment for prostate cancer (as per MDM recommendation). Concerns; 1) full discussion of MDM treatment recommendations not held with patient. 2) Patient commenced on sub-therapeutic dose of treatment and concern this low dose long term may have an adverse impact on disease outcome. 3) Patient commenced on bicalutamide monotherapy for localised prostate cancer which is outside of guidance and recognized as being less effective than standard treatment (and no indication for primary hormone treatment alone in the context of localized prostate cancer in a man fit for radical treatment).
Action taken Enter action taken at the time of the incident	Patient reviewed in clinic, treatment plan of surveillance agreed. Patient aware of concerns re previous treatment.
Learning Initial	MDM has been communicated with re bicalutamide monotherapy so if further patients are identified on this treatment it can be changed if required.
Reported (dd/MM/yyyy)	06/10/2020
Reporter's full name	[redacted]
Reporter's SHSCT Email Address	[redacted]
Opened date (dd/MM/yyyy)	06/10/2020
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	[redacted]

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Thorndale Unit
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	Outpatients
Speciality / Team	Outpatients

Staff initially notified upon submission

Management of Incident

Reasons for Rejection - History

No records to display.

Linked records

No Linked Records.

Coding

Datix Common Classification System (CCS)

Category	
Sub Category	
Detail	

Datix CCS2

Type	
Category	
Sub-Category	
Detail	
Is this a Haemovigilance /Blood Transfusion or Labs-related Incident?	No
Is this an incident relating to confidentiality? This may include inappropriate access / disclosure, loss or theft of records etc	No

SAI / RIDDOR / NIAIC?
Click here To Help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

SAI?

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4. Dangerous Occurence attributable to the work of the Trust
5. A doctor has notified you in writing that a Trust employee suffers from a reportable work-related disease

Is this a NIAIC Incident

NIAIC (Northern Ireland Adverse Incident Centre) incidents relate to medical devices. If a medical device is involved in an incident consider the list below to identify if the incident is NIAIC reportable;
- design or manufacturing problems
- inadequate servicing and maintenance
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice

[redacted]

Investigation

Investigator

Date started (dd/MM/yyyy)

Actual Impact/Harm

This has been populated by the reporter. To be quality assured by the investigating manager.

Moderate

Risk grading

Click here
When the incident has a Severity (actualimpact/harm, grading of insignificant to moderate, you need to plot on the matrix oppositethe Potential impact/harm. Deciding what are the chances of the incidenthappening againunder similar circumstances. (Likelihood) and multiply that by the potential impact if it were to reoccur (consequence) The overall risk grading for the event will be determined by plotting: consequence multiplied by likelihood = risk grading. Refer to impact table here:

Likelihood of recurrence	Consequence: Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain (Expected to occur daily)	O	O	O	O	O
Likely (Expected to occur weekly)	O	O	O	O	O
Possible (Expected to occur monthly)	O	O	O	O	O
Unlikely (Expected to occur annually)	O	O	O	O	O
Rare (NOT expected to occur for years)	O	O	O	O	O

Grade:

Action taken on review

Enter here any actions you have taken as a result of the incident occurring; e.g. communicating with staff / update care plan / review risk assessment (corrective and preventative action)

Action Plan Required?

A formal action plan is required for all Moderate to Catstrophic incidents. If you tick yes an "Action plan" section will appear below. Use this to create your action plan.

Action Plan

No actions.

Lessons learned

Notepad

Communication

Medication details

Stage

Prescriber Name

Medication error

Medication involved

If multiple medications involved enter the primary medication affecting the incident, and record the others in the description	
Correct medication	
Form administered	
Correct form	
Dose and strength involved	
Correct dose	
Route involved	
Correct route	

Falls Information [+]
Please Quality Assure all information as part of your investigation

Pressure Ulcers [-]

Was this incident in respect of a Pressure Ulcer?	No

Equipment details [+]

Documents added [+]

People Affected [+]

Employees [-]

No Employees

Other Contacts [-]

No Other Contacts

Datix

Carly Connolly

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details
ID & Status

Incident Reference ID	124328
Submitted time (hh:mm)	11:41

Incident IR1 details

Notification email ID number	Personal information redacted by the USI
Incident date (dd/MM/yyyy)	03/09/2020
Time (hh:mm)	15:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	No
Does this incident involve a Staff Member?	Yes
Description Enter facts, not opinions. Do not enter names of people	CT renal report of 13/11/2019 unsigned on NIECR. No record of action taken recorded in NIECR. Case identified at urology MDM of 3/9/2020 following review of backlog undertaken by Mr F Locum Consultant Urologist
Action taken Enter action taken at the time of the incident	Mr G consultant urologist has booked up to date staging and will see patient with results. CNS contacted patients NOK. Letter sent to patient and GP.
Learning Initial	NIECR sign off not used, this would have acted as a prompt to action. Tracking of suspected cancer case failed in this instance. I do not know what communication (email/written/verbal) was made in respect of this outstanding CT result. I do not know if this CT was entered on the DARO report?
Reported (dd/MM/yyyy)	10/09/2020
Reporter's full name	[redacted]
Reporter's SHSCT Email Address	[redacted]
Opened date (dd/MM/yyyy)	11/09/2020
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person affected details have been entered for this incident.	[redacted]

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Urology Clinic
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery

Staff initially notified upon submission

Management of Incident

Reasons for Rejection - History

No records to display.

Linked records

No Linked Records.

Coding

Datix Common Classification System (CCS)

Category	Diagnosis, failed or delayed
Sub Category	Cancer - Dx failed or delayed
Detail	Failure to act on adverse test results or images

Datix CCS2

Type	Patient Incidents
Category	Diagnostic Processes/Procedures
Sub-Category	Diagnostic Conclusions
Detail	Delayed diagnosis
Is this a Haemovigilance /Blood Transfusion or Labs-related Incident?	No
Is this an incident relating to confidentiality? This may include inappropriate access / disclosure, loss or theft of records etc	No

SAI / RIDDOR / NIAIC?
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SAI?

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Is this Incident RIDDOR reportable?

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2. A member of the public on Trust premises is killed or taken to hospital
3. An incident connected with the Trust where an employee, or self-employed person working on Trust premises, suffers an "over 3 day injury (being incapacitated to do their normal duties for more than three consecutive days (not counting the day of the accident but including weekends and rest days). Incapacitation means that the member of staff is absent or unable to do their normal work e.g. placed on lighter duties which are not part of their normal work)
4. Dangerous Occurence attributable to the work of the Trust
5. A doctor has notified you in writing that a Trust employee suffers from a reportable work-related disease

Is this a NIAIC Incident

NIAIC (Northern Ireland Adverse Incident Centre) incidents relate to medical devices. If a medical device is involved in an incident consider the list below to identify if the incident is NIAIC reportable;
- design or manufacturing problems
- inadequate servicing and maintenance
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice

[redacted]

Investigation

Investigator [redacted]

Date started (dd/MM/yyyy)

Actual Impact/Harm: Moderate

This has been populated by the reporter. To be quality assured by the investigating manager.

Risk grading

Click here
When the incident has a Severity (actualimpact/harm, grading of insignificant to moderate, you need to plot on the matrix oppositethe Potential Impact/harm. Deciding what are the chances of the incidenthappening agalnunder similar circumstances. (Likelihod) and multiply that by the potential impact if it were to reoccur (consequence) The overall risk grading for the event will be determined by plotting: consequence multiplied by likelihood = risk grading. Refer to Impact table here:

	Consequence				
Likelihood of recurrence	Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain (Expected to occur daily)	○	○	○	○	○
Likely (Expected to occur weekly)	○	○	○	○	○
Possible (Expected to occur monthly)	○	○	○	○	○
Unlikely (Expected to occur annually)	○	○	○	○	○
Rare (NOT expected to occur for years)	○	○	○	○	○

Grade:

Action taken on review

Enter here any actions you have taken as a result of the incident occurring; e.g. communicating with staff / update care plan / review risk assessment (corrective and preventative action)

Action Plan Required?

A formal action plan is required for all Moderate to Catstrophic Incidents. If you tick yes an "Action plan" section will appear below. Use this to create your action plan.

Action Plan

No actions.

Lessons learned

Notepad

Communication

Medication details

Falls Information
Please Quality Assure all information as part of your investigation

Pressure Ulcers

Equipment details

Documents added

People Affected

Employees

Other Contacts

No Other Contacts

Datix

Carly Connolly

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details ID & Status	
Incident Reference ID	127254
Submitted time (hh:mm)	15:01
Incident IR1 details	
Notification email ID number	Personal information redacted by the USI
Incident date (dd/MM/yyyy)	18/04/2019
Time (hh:mm)	17:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	No
Does this incident involve a Staff Member?	No
Description Enter facts, not opinions. Do not enter names of people	Diagnosed with penile cancer, recommended by cancer MDM for CT scan of Chest, Pelvis and Abdomen to complete staging. Same delayed by 3 months.
Action taken Enter action taken at the time of the incident	Discussed at MDM and prompt Outpatient review and commencement of treatment arranged. Patient seen and treatment plan made
Learning Initial	CT Scan referral should be made at point immediately after Oncology MDM
Reported (dd/MM/yyyy)	29/10/2020
Reporter's full name	[redacted]
Reporter's SHSCT Email Address	[redacted]
Opened date (dd/MM/yyyy)	29/10/2020
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	[redacted]
Location of Incident	
Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Urology Clinic
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery
Staff initially notified upon submission	
Management of Incident	
Handler Enter the manager who is handling the review of the incident	[redacted]
Additional/dual handler If it is practice within your team for two managers to review incidents together use this field to record the second handler	
Escalate You can use this field to note the incident has been escalated to a more senior manager within your Service/Division- select the manager from this list and send an email via the Communication section to notify the manager the incident has been escalated to them.	
Date of final approval (closed date) (dd/MM/yyyy)	
Date Notification Sent to External Agency	29/10/2020
Date Terms of Reference Due	
Date SAI Report Due	31/03/2021
SAI Level (1,2 or 3)	3.00
External Agency SAI Ref No.	Personal Inform
Date SAI Report Sent to External Agency	
Date SAI Report Shared with Family/NOK	
Date HSCB/RQIA/Coroner Queries Received	
Reasons for Rejection - History	

No records to display.

Linked records

No Linked Records.

Coding

Datix Common Classification System (CCS)

Category

Sub Category

Detail

Datix CCS2

Type

Category

Sub-Category

Detail

Is this a Haemovigilance /Blood Transfusion or Labs-related Incident? **No**

Is this an incident relating to confidentiality? No

This may include inappropriate access / disclosure, loss or theft of records etc

SAI / RIDDOR / NIAIC?

Click here To Help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

SAI?

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4. Dangerous Occurence attributable to the work of the Trust
5. A doctor has notified you in writing that a Trust employee suffers from a reportable work-related disease

[redacted]

Is this a NIAIC Incident

NIAIC (Northern Ireland Adverse Incident Centre) incidents relate to medical devices. If a medical device is involved in an incident consider the list below to identify if the incident is NIAIC reportable;
- design or manufacturing problems
- inadequate servicing and maintenance
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice

[redacted]

Investigation

Investigator

Date started (dd/MM/yyyy)

Actual Impact/Harm **Moderate**

This has been populated by the reporter. To be quality assured by the investigating manager.

Risk grading

Click here
When the incident has a Severity (actualimpact/harm, grading of insignificant to moderate, you need to plot on the matrix oppositethe Potential impact/harm. Deciding what are the chances of the incidenthappening againunder similar circumstances. (Likelihood) and multiply that by the potential impact if it were to reoccur (consequence) The overall risk grading for the event will be determined by plotting: consequence multiplied by likelihood = risk grading. Refer to impact table here:

	Consequence				
Likelihood of recurrence	Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain (Expected to occur daily)	O	O	O	O	O
Likely (Expected to occur weekly)	O	O	O	O	O
Possible (Expected to occur monthly)	O	O	O	O	O
Unlikely (Expected to occur annually)	O	O	O	O	O
Rare (NOT expected to occur for years)	O	O	O	O	O

Grade:

Action taken on review

Datix

Carly Connolly

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details
ID & Status

Incident Reference ID	123988
Submitted time (hh:mm)	14:48

Incident IR1 details

Notification email ID number	Personal information redacted by the USI
Incident date (dd/MM/yyyy)	10/08/2020
Time (hh:mm)	10:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	No
Does this incident involve a Staff Member?	Yes
Description Enter facts, not opinions. Do not enter names of people	Patient underwent TURP on 29/1/20. Pathology reported incidental prostate cancer. No follow-up or action from pathology result until brought to my attention. Outpatient review arranged on 11/8/20.
Action taken Enter action taken at the time of the incident	Patient reviewed in clinic. Apology for delay in providing diagnosis and follow-up. further assessment arranged
Learning Initial	Concern regarding risk of further unactioned results escalated
Reported (dd/MM/yyyy)	04/09/2020
Reporter's full name	[redacted]
Reporter's SHSCT Email Address	[redacted]
Opened date (dd/MM/yyyy)	09/09/2020
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	[redacted]

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Urology Clinic
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery

Staff initially notified upon submission

Management of Incident

Reasons for Rejection - History

No records to display.

Linked records

No Linked Records.

Coding

Datix Common Classification System (CCS)

Category	Diagnosis, failed or delayed
Sub Category	Cancer - Dx failed or delayed
Detail	Failure to act on adverse test results or images

Datix CCS2

Type	Patient Incidents
Category	Diagnostic Processes/Procedures
Sub-Category	Diagnostic Conclusions
Detail	Delayed diagnosis
Is this a Haemovigilance /Blood Transfusion or Labs-related Incident?	No
Is this an incident relating to confidentiality? This may include inappropriate access / disclosure, loss or theft of records etc	No

SAI / RIDDOR / NIAIC?

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SAI?

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- design or manufacturing problems
- inadequate servicing and maintenance
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice

[redacted]

Investigation

Investigator [redacted]

Date started (dd/MM/yyyy) [redacted]

Actual Impact/Harm: Moderate

This has been populated by the reporter. To be quality assured by the investigating manager.

Risk grading

Click here
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	Consequence				
Likelihood of recurrence	Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain (Expected to occur daily)	○	○	○	○	○
Likely (Expected to occur weekly)	○	○	○	○	○
Possible (Expected to occur monthly)	○	○	○	○	○
Unlikely (Expected to occur annually)	○	○	○	○	○
Rare (NOT expected to occur for years)	○	○	○	○	○
	Grade:				

Action taken on review

Enter here any actions you have taken as a result of the incident occurring; e.g. communicating with staff / update care plan / review risk assessment (corrective and preventative action)

Action Plan Required?

A formal action plan is required for all Moderate to Catstrophic incidents. If you tick yes an "Action plan" section will appear below. Use this to create your action plan.

Action Plan

No actions.

Lessons learned

Notepad

Communication

Recipients

Message

Message history

Date/Time	Sender	Recipient	Body of Message
No messages			

Medication details

Falls Information
Please Quality Assure all information as part of your investigation

Pressure Ulcers

Was this incident in respect of a Pressure Ulcer?	No

Equipment details

Documents added

Created	Type	Description	ID
09/12/2020	Form	ToR and Membership	78134
27/10/2020		Amended Notification to HSCB 27.10.2020	76312
23/09/2020		Notification to HSCB 23.9.2020	74992

People Affected

Employees

No Employees

Other Contacts

No Other Contacts

Stinson, Emma M

From: June Turkington [redacted]
Sent: 10 February 2021 14:13
To: Wallace, Stephen
Cc: Kingsnorth, Patricia
Subject: legal advice to the Trust/SAI panel - privileged - RE: Timeline

"This email is covered by the disclaimer found at the end of the message."

Stephen, Patricia,

I would be grateful if you could pass this email on to Dermot.

Following our zoom meeting this afternoon, I have now had an opportunity to consider the entirety of the timeline and the associated documents. As far as I understand it, the main outstanding issue at this stage is the correspondence from Tughans dated 22nd January. This has not yet been formally responded to on behalf of the SAI panel. However, much if not all of the information and documents sought have already been provided to Tughans.

Generally, I believe that all the information requested by Tughans to date is relevant to the issues in the SAI and it could not be said that any of the requests have been unreasonable. I think most, if not all, of their points regarding the time-scale for Mr O'Brien's responses are also well made, particularly bearing in mind the 2 recent bereavements of close family members which he has suffered. Full and clear answers to the queries should be provided.

In referring to documents and information requested from the Trust in the summer and autumn time, I think this relates to previous requests for the same information which has only recently been provided to Tughans. They are not seeking other or additional documents. There are no remaining requests which should be re-directed to the Trust. Rather, I think these previous requests are mentioned simply to explain that Mr O'Brien via Tughans has been seeking this information and these documents for some time, that he acted reasonably in this regard and delay in this regard can't be laid at this door.

At this stage, I think the Trust needs to start from the point where it has addressed all the questions – this may be the point when the formal response to Tughans is provided. Taking this as a starting point, the Trust then needs to add on a reasonable period of time thereafter to allow Mr O'B to review all the relevant records etc, obtain advice and formulate his response on the 9 cases. Trying to determine what is a reasonable time to do this is something of a judgment call, but I would suggest a period of at least 4 weeks certainly does not seem excessive.

I trust these thoughts are clear. Happy to discuss further if that would be helpful.

Regards

June

June Turkington
Assistant Chief Legal Adviser
Directorate of Legal Services
Direct Line – [redacted]
Mobile no - [redacted]

From: Wallace, Stephen [redacted]
Sent: 10 February 2021 11:40
To: June Turkington
Cc: patricia kingsnorth (SHSCT)
Subject: FW: Timeline

June,

Please see below and attached re today's meeting with Patricia and Dermot

Thanks
Stephen

From: Kingsnorth, Patricia
Sent: 10 February 2021 11:27
To: Wallace, Stephen
Cc: Dermot Hughes [redacted]; OKane, Maria
Subject: Timeline

Stephen
We are meeting with June at 1pm today. Please see attached timeline with the embedded communication to Tughans' also Dermot has provided a response to some of the questions asked.
Can you share these documents with June prior to the meeting today.

Many thanks
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
[redacted]

Response from Dr Hughes to Tughans Solicitors (marked in red)

In order for me to obtain instructions with a view to replying to your letter of 11 January 2021 (sent by email on the 12th) I will need additional information and time to obtain instructions.

The following request for documentation and/or information arises from the documentation you have provided entitled "Level 3 Serious Adverse Incident Review Urology Services".

Please provide the following:-

1. The Datix Forms referred to on the front page. I note there appear to be eight Datix Forms yet nine cases. Is there an additional Datix Form missing?
   9 datix forms have been shared on 8 Feb 2021
2. The Terms of Reference are said to be "proposed draft Terms of Reference". Can you please confirm the Terms of Reference are still in draft or have they been finalised? Clearly, we need to be working from a finalised Terms of Reference. If they have not been finalised when will that occur?
   Approved TOR were finalised on 12 December have been shared on 8.2.2021

3. I note the Terms of Reference may be amended "pending engagement with all affected patients and families". Has that engagement now occurred if not when will it occur?
   Family engagement took place between the 9, 11 November and 16 November. TOR were discussed with them and agreed.

Has any consideration been given to engagement with Mr O'Brien in relation to the Terms of Reference and, in particular, to seek his views in relation to the system within which he was working? For example, I note the Consultant Urologist (from information publicly on the internet) on the Review Team, Mr Hugh Gilbert, appears to have worked only England. It is important he considers Mr O'Brien's practice in the context of the service he was working in at SHSCT. The Terms of Reference are open to interpretation. Can you please clarify your interpretation of the Terms of Reference and the extent to which the service within which Mr O'Brien was working is considered by you to be within the terms?

It would not be part of our processes to consult any person subject to review to be involved in the generation of the Terms of reference.
The Expert Opinion to the SAI is external to Northern Ireland was provided independently by the British Association of Urological Surgeons. The review will take account of the Northern Ireland context as defined by local Northern Ireland cancer services, The Northern Ireland Cancer Network and Regional (Northern Ireland) Peer Review.

4. The review methodology is said to be "as per the Serious Adverse Incident Framework (2016)". Please provide a copy of that Framework. It is important that we are clear on the framework you are working to.
   This has been provided 4.2.2021

5. Please let me know how Mr O'Brien's confidentiality is to be preserved in this process (as referred to in the review methodology).
   The SAI process is patient focused and all professionals delivering care in the timeframe of the reviews are anonymised.

In relation to the document entitled "Questions for Mr O'Brien" please provide the following information and to ensure there is no misunderstanding and that we are working from the guidance/protocols, reviews and reports you refer to:-

(i) Please let me have a copy of the NICAN Guidance (2016) as referred to for Service User A. Please identify the particular paragraphs arising from that Guidance relevant to the issue identified in relation to Service User A.
NICAN guidelines emailed on 4.2.2021. In relation to Service User A – NICAN guidance Section 9.2

(ii) Please let me have a copy of the Peer Review and Annual Report documents in relation to allocation of Nurse Specialists as referred to in relation to Service User A (this is repeated in relation to a number of other patients).
Peer review emailed on 4.2.2021
2017 peer review submission stating increase in resource and availability of Specialist nurse to all patients.

(iii) In relation to Service User B reference is made to the "NICAN Urological Clinical Guidance Pathway". Please clarify whether this is the same Guidance as the 2016 Guidance referred to above? If not, please provide a copy of this further Guidance. In any event, please identify the paragraphs it is said were not followed.
I can confirm this is the same guidance. Section 9.2 Page 45. Prostate biopsy.

(iv) In relation to Service User B reference is made to "NICAN Regional Guidance" regarding androgen deprivation therapy." Please clarify whether this refers to the 2016 Guidance. If not, please provide a copy of any additional Guidance. In any event, please identify the specific paragraphs it is suggested were not adhered to.
Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines (March 2016) section 9.2 page 58

(v) In relation to Service User D please provide a copy of the protocol referred to in relation to prescription of ADT. Please identify the paragraphs which it is suggested were not followed in relation to that protocol.
Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines (March 2016) section 9.2 page 58.

(vi) In relation to Service User G, you refer to the patient not being referred to the MDM in accordance with "guidance". Can you please identify what

guidance this refers to and provide us with a copy of same identifying the paragraphs it is suggested were not followed?
Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines (March 2016) Section 9.4 page 84.

In relation to Service User H, can you please let me know whether you are referring to the 2016 Guidance? If not, please produce the Guidance you refer to. In any event, please identify the paragraphs it is suggested were not followed in relation to this patient.
Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines (March 2016) Section 9.3 page 69

I note the purpose of the review is to "consider the quality of treatment of the care provided by "Doctor 1 and understand if actual or potential harm occurred". As the review team are considering that Mr O'Brien should be allowed to address that issue, should he wish. Mr O'Brien had the opportunity of carrying out a preliminary review of the records, received by us in hard copy by post on the 14th of January, prior to his recent bereavement. From that review the following records have not been included, to enable Mr O'Brien to make observations on this crucial issue:-

1. Service User A: All information available on NIECR from 22 June 2020 until death in August 2020

2. Service User B: All information available on NIECR from 01 August 2020 to date

3. Service User C: All information available on NIECR from 12 August 2020 to date

4. Service User D: All information available on NIECR from 14 May 2020 until death in July 2020

5. Service User E: All information available on NIECR from 25 September 2019 to date

6. Service User F: All information available on NIECR from 02 October 2020 to date

7. Service User G: All information available on NIECR from 27 November 2020 to date

8. Service User H: All information available on NIECR from 25 February 2020 to date

9. Service User I: All information available on NIECR from 29 January 2020 to date

All relevant documents were previously sent in the notes packs. All NIECR records sent and received 9.2.2021.

In your letter of 11 January 2021 you requested Mr O'Brien to provide comments in relation to nine separate cases by 29 January 2021. With respect, this is not a reasonable timescale. Your request for information needs to be set in the following context:-

1 .Mr O'Brien was written to by the Trust on 11 July 2020 with a document entitled "Summary of Concerns". I replied on his behalf to the Trust on 16 July 2020 noting Mr O'Brien could not comment on concerns without the data upon which the document was based. Between then and 14h of January 2021 the only documentation which has been provided to Mr O'Brien by the Trust were partial copies of the records for Service Users A and B.

2. By 16 October 2020 the Review Team was appointed according to the document "Level 3 Serious Adverse Incident Review Urology Services".

3. The Trust wrote, via its legal representatives, to me, on 25 October 2020. Within that correspondence they provided a "Summary table Serious Adverse Incidents (SAI) confirmed to date". The table included reference to altogether nine patients. As far as we can ascertain those patients are the same patients that you have written in relation to (although notably the matters you request to be addressed differ from the "elements of concern" identified within that correspondence). No underlying documents, such as records were provided with that correspondence.

4. On 29 October 2020 I requested information in relation to the SAI processes, including Terms of Reference, SAI notification forms and whether Mr O'Brien would be asked for any comments and when those would be expected. I also requested details of what information would be disclosed to him. I noted how Mr O'Brien was entitled to see all documentary evidence any concerns were based upon in order for him to be in a position to obtain advice and respond.

5. The first questions that have been put to Mr O'Brien by the Team were received on 12 January 2021. I appreciate there will have been a considerable amount of documentation for the team to consider, and that had to occur in the context of the pandemic.

6. Copies of records were delivered to my office on 14 January 2021 which had to be paginated and copied before being forwarded on to Mr O'Brien. He therefore received the records very recently, just prior to his recent bereavement.

From the above you will note I have been making efforts on behalf of Mr O'Brien to obtain details of the matters under consideration and copies of relevant documentation for a substantial period of time. Whilst I appreciate the desire to move on with the SAIs, that must be done in a fair manner cognisant to the rights of all parties (as the terms of reference stipulate). That will include a reasonable period of time for Mr O'Brien to provide any comments, following receipt of adequate information upon which he can seek advice.

For Mr O'Brien to understand the issues you request him to address we will need:-

1. Responses to the above requests for further information and documentation. – sent via email 4.2.2021 and post as requested.

2. Adequate time for Mr O'Brien to consider the various records and obtain advice thereon. That is particularly challenging given the current pandemic. Instructions will have to be taken remotely in relation to several cases.

3. Even if the pandemic was not current, two weeks would be an inadequate timescale in which to consider voluminous records on several cases, consult, obtain instructions thereon, provide advice and draft and approve responses. This is an important matter for the patients, their families and also for my client, Mr O'Brien. Sufficient time should be allowed for Mr O'Brien to provide his comments.

Stinson, Emma M

From: Andrew Anthony [redacted]
Sent: 19 February 2021 16:06
To: Kingsnorth, Patricia
Subject: RE: Confidential response [TS-Live.FID694915]

Dear Ms Kingsnorth,

Thanks for your email, I did receive your below email.

Mr O'Brien is working through the voluminous documentation provided. The only manageable way to deal with this is on a case by case basis. We are progressing well with comments on Service Users A and B. I am on leave for the early part of next week. I hope to have comments to you on these two cases by the end of next week or at the latest early the following week. Perhaps you would be good enough to update Dr Hughes.

Would it be possible for you to forward to me the IR 1's upon which the Datix reports were based?

Kind regards,

Andrew

ANDREW ANTHONY
Partner
[redacted]
T: [redacted]
M
D:

Tughans / Marlborough House, 30 Victoria Street, Belfast BT1 3GG

From: Kingsnorth, Patricia [redacted]
Sent: 19 February 2021 10:39
To: Andrew Anthony [redacted]
Subject: FW: Confidential response

Dear Mr Anthony
Please can you confirm if you received my email sent on 10th February as I didn't receive an acknowledgement.
If not please see attached response.
Kind regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
[redacted]

From: Kingsnorth, Patricia
Sent: 10 February 2021 20:21
To: Personal Information redacted by the USI
Subject: Confidential

Dear Mr Anthony

Please see correspondence from Dr Hughes in response to your questions which have been highlighted in red.
Kind regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
Personal Information redacted by the USI

King, Dawn

From: Kingsnorth, Patricia [redacted]
Sent: 11 December 2020 12:56
To: Andrew.Anthony [redacted]
Subject: your Client
Attachments: Letter to Mr O' Brien inviting to participate in SAI_.doc

Dear Mr Anthony

I have been asked to forward this letter to your client Mr Aidan O'Brien from the external Chair of the Urology SAI review.
I understand Mr O'Brien has suffered a recent bereavement and appreciate you will know the appropriate timing of this letter.

I will await your response.

Kind regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
[redacted]

11 December 2020 **Our Ref:**

Private & Confidential

Dear Aidan

As you may be aware, I am the External Chair of the SAI processes into 9 patients who were previously under your care.

As part of the normal SAI process we have been carrying out interviews with all relevant members of staff who have been involved in these patients' care.
The interviews are based on the patient's journey and are aimed at identifying learning and making recommendations for future care. We are seeking to complete the staff interviews before Christmas in order to keep the timeframes of the review.

We would be keen to have your input into this process and would like to agree an appropriate time (in person/ zoom/ telephone).

Yours sincerely

Dermot

Dr Dermot Hughes
Chair of the SAI Panel

Dr Dermot F C Hughes MB BCH BAO FRCPath Dip Med Ed

Southern Health and Social Care Trust

Incident Oversight Group

Tuesday 10th November 2020, 4:30pm

Via Zoom

AGENDA

	Item	Attachments
1	Apologies	
2	Minutes	MINUTES - Incident Group 03.11.2020 DF
4	DoH Oversight Meeting Update (30th October 2020)	
5	Trust Board Update Paper 12th November 2020	Trust Board Update - Urology Oversight Gr
	Professional Governance	
6	**GMC Discussions** - Request for information	Mr O'Brien.msg
7	Administration Review Update	
8	Mileage Claims	
	Serious Adverse Incident (SAI) Reviews	
9	Process for Managing SAI's going forward	
10	Original SAI's – Deceased Service User Family Contact	
11	Initial Feedback from SAI Chair - MDM Processes - Oncology Attendance MDM	
12	Family Liaison Role	
	Management of Patient Reviews	
13	Update on Radiology Review	
14	IPT for Review Process	
15	Additional Subject Matter Expertise / Consultant Reviews	CV 2020.doc
16	Bicalutamide Patient Review	Clinical And Social Care Audit Registrati
17	Engagement of ISP to undertake waiting list work	
18	Telephone Support Service / Patient Triage Update	
	Communications	
19	Ministerial Update Statement 10th November 2020	
20	Media / Assembly Questions	FAQs urology 02112020.docx
	Any Other Business	
21	Any Other Business	
	Date of Next Meeting	

22	Via Zoom – 10th November 2020	

Southern Health and Social Care Trust

Urology Oversight Group Minutes

Tuesday 3rd November 2020, 4:30pm

Via Zoom

	Item	Actions
1	**In Attendance** Stephen Wallace — Melanie McClements Martina Corrigan — Mark Haynes Damian Gormley — Jane McKimm Siobhan Hynds — Ronan Carroll Vivienne Toal — Maria O'Kane Patricia Kingsnorth	
2	**Apologies** None	
3	**Review of Action Log** Group agreed	
4	**DoH Oversight Meeting Update (30th October 2020)** Melanie updated on the DoH assurance meeting that took place on the 30th October. Meeting will be 2 weekly; this was chaired this week by Jackie Johnson. The Trust was commended on good work to date and progress. Group felt the Thursday meeting should continue to meet with current membership and will inform the DoH assurance group. The group felt the SAI process was not the best process moving forward. The focus of this incident is not the best process going forward. DoH / PHA to come back with a decision. The group felt external views on the process would be crucial. The group asked if there was any opportunities to act earlier in the summer by the Trust. Group discussed private practice and the challenges surrounding this. Dr O'Kane referenced MDM issues that were faced. It has been confirmed that the Minister will be making a statement to the assembly on the 10th November 2020. The group also required to consider family liaison roles. This is including psychology support. The status of impact to date included services that were stood down to conduct the review. The Trust has been asked to develop an IPT to state impact of incident. David Gordon felt we are moving towards a wider recall. Question was asked regarding who will front the media communications. Mark Haynes referenced the clinical review process suggested at the meeting and how that will interface with the current work ongoing and what outputs. The group discussed what are reasonable timescales for conducting processes such as triage, Mark Haynes stated these should be discussed with the external experts in the first instance to ascertain what is reasonable and what delay is reasonable.	**Martina / Stephen to contact Bernie Owens to form Trust oversight team** **Thursday meeting to discuss clinical review process** **Mark Haynes to discuss reasonable triage and administration response times with external experts**
	Professional Governance	
4	**Response from Tughans re Trust Letter** Vivienne Toal discussed the letter received from Tughans. The letter largely forms a request for information. Stephen and Vivienne to draft a response to the Tughans response. Jane McKimm asked has the solicitors contacted the DoH directly, group unsure.	**Stephen and Vivienne to draft a response**
5	**GMC Discussions** Dr O'Kane referred to the attached correspondence. Dr O'Kane has advised that the GMC have been asked explicitly to consider interim orders.	20201013_LtrGENERAL MEDICAL COUNCI

	Dr O'Kane explained that a conversation was had with Dr Fitzpatrick, NHS Resolutions to update on the case progression. Dr Fitzpatrick advised that NHS Resolutions would end at this stage. Dr O'Kane also advised that the chair and legal team of the Neurology Inquiry had been contacted to discuss potential early learning from the neurology review that can be incorporated into strengthening our assurance processes.	
6	**Administration Review Update** Martina Corrigan advised a meeting to review the administration review will be meeting tomorrow to progress. Melanie McClements asked for a summary document to be brought back for next week, with a plan for the final report to be issued on GMC. Mark Haynes referenced the work required regarding MDM processes and the importance of improving these. Dr O'Kane stated that she would be happy to endorse any improved processes for MDM that could be created. Patricia Kingsnorth stated that breast care have a failsafe nurse to ensure that actions to not get dropped. Melanie McClements stated that there is potential for regional learning from SAIs to improve processes.	**Melanie McClements to present summary report next week** **Mark Haynes to identify model for MDM improvement**
7	**Mileage Claims** Vivienne stated claims have been validated and payments are being processed via payroll currently, circa 270 miles.	
	Serious Adverse Incident (SAI) Reviews	
8	**Process for Managing SAI's going forward** Melanie McClements asked what process should govern new SAI's. Dr O'Kane stated that there is a requirement from the PHA and HSCB to indicate what process should be followed going forward new SAIs. Melanie McClements asked is the 3 month timescale achievable; Patricia Kingsnorth felt this was possible. Dr O'Kane stated that if there is a move outside of process PHA need to provide written confirmation.	**Thursday meeting to discuss clinical review process**
9	**Original SAI's – Deceased Service User Family Contact** Mark Haynes stated that the decision to inform to the final family could be guided by the process to notify patients who are part of the review process, e.g. if there care had an adverse outcome they would be told, if there was not an adverse outcome they would be told.	
10	**Initial Feedback from SAI Chair** Discussed under item 6	
11	**Family Liaison Role** Melanie McClements stated that Patricia had informed that family liaison requirement was low at this stage. Patricia stated that some families will require psychological support especially those that are being spoken to about medication errors. Mark Haynes stated that each service user was required to be told of incidents face to face, Dr O'Kane suggested that a leaflet would be required to assist with sharing of information. Group discussed the potential of contracting Inspire to offer additional support for both staff and patients.	**Vivienne to follow up with Inspire re additional support**
	Management of Patient Reviews	
12	**IPT for Review Process** Mark Haynes stated the impact is difficult to quantify with lack of clinic space and disruption to services. Melanie McClements asked how many of the 2336 patients identified to date how many patients have been identified that will require review. Martina Corrigan was unsure as this work is ongoing. Mark Haynes stated that if we are	 IPT for urology required.msg **Ronan /**

	required to arrange face to face for all patients who AOB has saw this would be enormous. If these were triaged by exception, those which there are concerns regarding this is much more manageable.	**Martina to follow up with Aldrina Magwood and Carol Cassells**
13	**Additional Subject Matter Expertise / Consultant Reviews** Mark Haynes to contact Professor Sethia to arrange additional subject matter expertise.	KS CV 2020.doc
14	**Bicalutamide Patient Review** Mark Haynes has started reviewing patients on Monday. Mark Haynes confirmed that the patient identified by the spotter practice as a long term bicalutamide prescription was prescribed appropriately	Clinical And Social Care Audit Registratic
15	**Engagement of ISP to undertake waiting list work** Work continuing, 26 patients has refused as they did not wish to travel.	
16	**Telephone Support Service / Patient Triage Update** Five calls this week, 147 in total, 5 have been required to be reviewed. One required reviewed. Martina Corrigan stated that more backup will be required following the ministerial statement which potentially could increase call volume.	**Martina / Melanie to discuss before next week**
	Communications	
17	**Ministerial Update Statement 10th November 2020** Date noted by the group. Jane McKimm stated it was still unknown what the Minister will include in his statement, hopefully this will be clearer on Thursday / Friday	
18	**Media / Assembly Questions**	FAQs urology 02112020.docx
	Any Other Business	
19	**Any Other Business**	
	Date of Next Meeting	
20	**Via Zoom – 10th November 2020**	

Southern Health and Social Care Trust

Quality care – for you, with you

COMMITTEE 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
Corporate Objective:	Safe, high quality care
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

The background and current status of the ongoing review is provided below:

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 accept the adverse impact on overall survival and gynaecomastia with the aim of retaining sexual function, offer anti-androgen monotherapy*

[1] Prostate cancer: diagnosis and management. National Institute for Health and Care Excellence. NICE guideline 131. May 2019.

	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.

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 have 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.

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 – 151 (up to and including Thursday 5 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 this on 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 look into 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

VIVIENNE

Additional Subject Matter Expertise / Consultant Reviews

The Trust 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 to 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.

Witczak, Maria

From: Chris Brammall [redacted]
Sent: 04 November 2020 10:28
To: OKane, Maria; Joanne Donnelly [redacted]; David Horkin [redacted]
Subject: Mr O'Brien

Hi Dr O'Kane, I hope you are managing to keep safe and well in these uncertain times.

As you will be aware, Stephen Wallace kindly sent me copies of the relevant medical records for patients [redacted], [redacted], [redacted], [redacted] and [redacted]. Unfortunately, these were very heavily redacted before they were sent to us (to the point where it is not possible to establish Mr O'Brien's role in the patients' care). Please would you be able to supply unredacted copies of the records that were previously sent for these patients?

Please would it also be possible to obtain some further information about Service Users A&B?

- Service User A. If there is an oncology referral dated 27 January 2020 (or around this date), please would you be able to send this to me?
- Service User B, if the results of the MRI scan are available, please would you be able to send these to me?

Lastly, in your recent email exchange with Joanne Donnelly I can see that the panel expert has raised possible further concerns in regard to the prescribing of Bicalutamide. Please would you be able to send me any further information that you hold about this? If there is no further information available at the moment, please would you be able to send this to me when this becomes available?

Many thanks for your continued help here Dr O'Kane

Chris Brammall
Investigation Officer
General Medical Council
3 Hardman Street, Manchester, M3 3AW

Email: [redacted]
Website: www.gmc-uk.org
Telephone: [redacted]

Regents Place, 350 Euston Road, London NW1 3JN

The Tun, 4 Jacksons Entry, Holyrood Road, Edinburgh EH8 8AE

4th Floor, Caspian Point 2, Caspian Way, Cardiff Bay CF10 4DQ

9th Floor, Bedford House, 16-22 Bedford Street, Belfast BT2 7FD

Curriculum Vitae

Professor Krishna K Sethia

Consultant Urological Surgeon

Norfolk & Norwich NHS Trust
Colney
Norwich NR4 7UZ

1 February 2020

NAME		Krishna Kumar **SETHIA**
ADDRESS	HOME	Personal Information redacted by the USI
	WORK	Norfolk & Norwich NHS University Trust Colney Norwich NR4 7UZ
TELEPHONE	HOME MOBILE	Personal Information redacted by the USI
Email		Personal Information redacted by the USI
NATIONALITY		Personal Information redacted b
DATE OF BIRTH		Personal Information redacted by the USI
MARITAL STATUS		Personal Information redacted by the USI
GENERAL MEDICAL COUNCIL		Full Registration No Personal Information redacted by the USI
MEDICAL DEFENCE		Medical Protection Society

QUALIFICATIONS	MA (Oxford)	1986
	MBBS (London)	1979
	FRCS (England)	1984
	DM (Oxford)	1988
	FRCSEd	2006

EDUCATION

Eton College, Windsor, Berks

Exeter College, Oxford

Guys Hospital Medical School, London SE1

PRESENT APPOINTMENTS

Consultant Urologist
Norfolk & Norwich NHS Trust
Colney
Norwich NR4 7FP

Honorary Professor
University of East Anglia, Norwich

Chairman
British Journal of Urology International

PREVIOUS APPOINTMENTS

Medical Director, Norfolk & Norwich University NHS Trust (2009-2015)

Hon Treasurer, British Association of Urological Surgeons (2003-2006)

Director of Surgical Division, Norfolk & Norwich University NHS Trust (2003-2007)

Manpower Planning Officer, British Association of Urological Surgeons (2000-2006)

Member of and Examiner for the Intercollegiate Board in Urology (2000-2008)

Vice-Chairman of Specialist Advisory Committee in Urology, Royal College of Surgeons (2003-2006)

Clinical Director, Urology & Nephrology, Norfolk & Norwich University NHS Trust (1997-2002)

Member of Council, British Association of Urological Surgeons (1997-2002)

Honorary Lecturer, Institute of Urology (1996-1999)

Norwich District Ethics Committee (1994-1998)

R& D Committee, Norfolk & Norwich NHS Trust (1996-1998)

Lead Doctor in Urology, Waveney Cancer Centre (1998 -2003)

Senior Registrar in Urology, Freeman Hospital, Newcastle (1988-1990)

EXPERIENCE

1. Clinical

Having completed training posts in Oxford and Newcastle I was appointed to a Consultant Urologist post in Norwich in 1990. As well as providing a general urological service I developed special interests in urological cancers (especially bladder and prostate) and andrology and during the 1990's I developed the Norwich unit into a tertiary referral centre for both these subspecialties. I also established the superregional service for the management of patients with cancer of the penis.

Together with the specialist urological cancer nursing team for which I secured the initial funding I set up a local patient support group for men with prostate cancer and their families.

My clinical commitments inevitably decreased when I became Medical Director but since relinquishing that post in I have increased my clinical practice. I continue to develop the urological cancer services in Norwich. My current main interests are in the management of superficial bladder tumours, penile cancers and the diagnosis of prostate cancer. I continue to run the specialist andrology service for the region.

2. Hospital Management

a. Director of Surgery (2003-2007)

As Director of Surgery I was responsible for the organisation of surgical services, clinical governance in surgery and ensuring that access targets were met. My specific achievements in my 4 year tenure were;

1. Reorganisation of the theatre schedules and surgeon timetables to create 25% more operating time in the week and increased theatre utilisation to over 90%.
2. Introducing centralised pre-operative assessment for all surgical patients.
3. Building of a unit to ensure that all patients were admitted on the day of surgery rather than the night before.
4. Achieving all access targets.
5. Increasing day-case surgical rates to the best quartile in the country.
6. Achieving cost-savings to plan.

b. Medical Director (2009 to 2015)

1. Clinical Governance

In my time as Medical Director I was involved in two reorganisations of clinical governance the second of which was designed to take account of all the Francis, Keogh and Berwick reports and CQC requirements. I was chairman of the Clinical Safety and Clinical Effectiveness Sub-Boards and of meetings of all Directorate Governance Leads.

2. Quality Improvement.

Five years ago I instigated a programme of annual safety improvement projects based on IHI methodology. Over 250 clinicians were eventually involved and significant changes to practice have resulted. Projects I have led or been involved in with other Executive Directors by 2015 had achieved significant improvements including

a. No hospital-acquired MRSA bacteraemias for 3 years
b. 85% reduction in C difficile infection over 3 years
c. Significant reduction in medication prescribing errors
d. Compliance with the WHO checklist
e. Compliance with thromboprophylaxis assessment. Hospital granted exemplar status.
f. Improved Early Warning Score completion and response to triggers.
g. Declining cardiac arrest calls outside critical care
h. Central line infection rates of under 1/1000 hospital days

c. Operational

As Medical Director

a. I shared responsibility for day-to-day operational performance.
b. I led a project to enlarge and redesign the emergency areas of the NNUH. We have established a regular GP presence in the emergency department.
c. I completed a review of critical care capacity and formulated plans for an increase thereof.
d. I regularly met and represented the hospital with the local Clinical Commissioning Groups and played an active role in contract negotiations.

d. Revalidation

a. I was Responsible Officer for over 800 doctors working at the Norfolk & Norwich Hospital.
b. I was responsible for introducing the policies and processes for enhanced appraisal and, with the help of a Revalidation Lead, ensured that the Trust was prepared for medical revalidation.

e. University

a. In 2009 together with the Medical School I instigated a strategy to increase research activity in the hospital by appointing a series of clinical academics with focussed areas of interest.
b. I established a Joint Research Committee which includes doctors, nurses, allied health professionals and university staff.
c. I helped establish a joint research office with UEA for managing clinical research.
d. Together with the Dean of Health I have supervised the development of the Norwich Clinical Trials Unit and Clinical Research facilities which now have full NIHR registration.
e. I promoted joint projects involving the hospital and other Institutes on the Norwich Research Park. I was the hospital representative on the NRP Scientific Board.
f. I supported the UEA project to obtain a new Medical School Building (BCRE) including a Biorepository.
g. In 2013, I was author of and together with the CEO led the Norfolk & Norwich Hospital successful bid to host the NIHR Eastern Clinical Research Network
h. I was involved with the Norwich bid to build a new Institute for Food and Health to include clinical gastroenterology.
i. I represented the hospital on the UEA/NNUH Joint Board University/NNUH (chaired by the Vice-Chancellor and Trust CEO)

f. Other hospitals

I have actively encouraged clinical collaborations with neighbouring hospitals (Kings Lynn and James Paget). To date this has resulted in an **i**ncreasing number of consultant joint appointments. I was instigated and was involved with projects to

a. Standardise clinical guidelines between the Trusts
b. Establish joint formularies
c. Establish a single Drugs, Therapeutics and Medicines Management Committee
d. Integrate clinical teams

3. National Associations / Committees

i. British Association of Urological Surgeons

a. Council Member (1997-2002)
b. Manpower Planning Officer (200-2007)
c. Treasurer (2005-2008)

For the past 18 years I have contributed to the development of BAUS and British Urology. Particular achievements have been:

1. As a major contributor to the development of different types of Consultant Urologists trained to have skills matching service need.
2. Regular liaison with National Workforce Planning Groups to ensure training numbers correct.
3. Responsibility for the reorganisation of BUAS into a charitable company limited by guarantee.
4. Rewriting of the M&A's and Rules of the Association.
5. Rewriting of all protocols for Governance within the organisation.
6. Establishing the budgeting process for the Association.
7. Creating a Strategic Plan for the Association.

ii. SAC in Urology (2000-2006), Vice-Chairman (2003-2006)

Apart from the normal duties of an SAC member I have made a particular contribution in:

i. The revision of the curricula in Urology
ii. Supervision and planning of urological manpower.
iii. Review of section 14 applications to PMETB

iii Examiner for Intercollegiate Board in Urology (2000 to 2008)
Member of Intercollegiate Board in Urology (2003 -2008)
Examiner for International Urology exam (2018- present)

As a member of the Intercollegiate Board I was responsible for exam design, standard-setting and ensuring educational validity. I personally rewrote over 25% of the then clinical question bank. In 2018 I was again appointed an examiner for the joint colleges international exam in urology.

4. British Journal of Urology International (BJUI)

Having been a Trustee for 7 years I was appointed Chairman of the BJUI in 2015.

For the past 5 years I have led the development of a comprehensive educational on-line programme which will serve international CPD and CME requirements. This involves collaboration with the Urological Societies of Australia and New Zealand, Hong Kong, Canada, India, Indonesia, Malaysia, Korea and the Republic of Ireland. The education programme was launched in January 2016 and has accreditation from the Edinburgh College of Surgeons (RCSEd). It has been now used by all UK urological trainees and widely in Asia and Australasia. We are working with the GMC and urology SAC to establish it as the standard for knowledge for all trainees.

5. Teaching experience

In the 1990's I was responsible for Higher Surgical Training in Urology in Norwich. I established and ran an annual residential regional teaching course which has remained an important part of our specialist registrar programme and is consistently highly-rated by trainees. I continue to contribute to this.
For the past 60 months I have been working with the RCSEd to develop a surgical training programme for Myanmar. This is being expanded to involve all the surgical specialties in the country.

6. Research experience

Following appointment as a consultant I was PI in several clinical trials within the Urology department.
For most of my career my other research activity has involved facilitating researchers in collaborations with University departments.
I took responsibility for establishing and organising the Norwich contribution to the national 100,000 Genome project.
In the past 12 years I have been involved in supervising 3 PhD and one MD student.

8. Medicolegal

For the past 17 years I have provided medicolegal opinions. I have been instructed by solicitors for acting both for the plaintiff and the defence (current ration 30:70). I currently provide approximately 80 reports per year. I am prepared to travel anywhere in the UK to see patients. I regularly attend case conferences with barristers and I have experience of giving expert evidence in Court.

9. Other

In the past 7 years I have been invited to perform 3 major reviews of urology department's performance and organisation in the UK.
I am experienced in reviewing serious incidents which I have done both for the Royal College of Surgeons and when requested by individual Trusts.

PUBLICATIONS

Sethia K.K., Darke S.G. Long Saphenous incompetence as a cause of venous ulceration. Br J Surg (1984) 71:154-755

Sethia K.K., Berry A.R., Morrison J.D., Collin J., Murie J.A., Morris P.J. The changing pattern of lower limb amputation in peripheral vascular disease. Br J Surg (1986) 73:701-703

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Speakman M.J., Sethia K.K., Fellow G.J., Smith J.C. A study of pathogenesis, urodynamic assessment and outcome of detrusor instability associated with bladder outflow obstruction. Br J Urol (1987) 60:516-518

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Mills R.D., Sethia K.K. Reproducibility of penile arterial ultrasonography. Br J Urol (1996) 78:109

Mills R.D., Sethia K.K. Limited sub-coronal incision for insertion of semirigid penile prostheses. Br J Urol (1997) 79:802

Kirby R.S., Chapple C.R., Sethia K.K., Flannigan M., Milroy E.J.G., Abrams P. Mornign vs evening doxasosin in benign prostatic hyperplasia: efficacy and safety. Prost.Cancer (1998) 1:1630171

Mills R.D., Sethia K.K. Maximisation of the erectile response in the investigation of impotence. Int J Impot Res (1999) 11:29-32

Mitchell S.M., Sethia K.K. Hazards of aspirin withdrawal prior to transurethral prostatectomy. Br J Urol (1999) 84:101

Probert JL, Mills R, Persad RA, Sethia KK. Imaging assessment of uncomplicated bladder outflow obstruction. Int J Clin Pract. (2000) Jan-Feb;54:22-4

Szemere J.C., …Sethia K.K., Ball R.Y., Bardsley A. A surgical technique to the conservative management of urethral melanoma. Br J Plast Surg (2001) 45:361-3

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Riddick A.C.P…..Sethia K.K., Edwards D.R, Ball R.Y. Banking of fresh-frozen prostate tissue: methods, validation and use. Br J Urol (2003) 91:315

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Ann R Coll Surg Engl. (2008) Mar; 90(2):153-5.

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Bayles AC, Sethia KK. The impact of Improving Outcomes Guidance on the management and outcomes of patients with carcinoma of the penis. Ann R Coll Surg Engl (2010) 92:44-45

Chitale S, Morsey M, Swift L, Sethia K. Limited shock wave therapy vs sham treatment in men with Peyronie's disease: results of a prospective randomized controlled double-blind trial. BJU Int. (2010) 106:1352-6

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BOOKS

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Eardley I., Sethia K. Erectile Dysfunction. Mosby-Wolfe 1998

Eardley I., Sethia K. Erectile Dysfunction for General Practitioners. Mosby-Wolfe 1999

OTHER

Models and Mechanisms of Detrusor Instability - Bard Silver Medal, British Association of Urological Surgeons, 1988

The Pathophysiology of Detrusor Instability. D.M. Thesis, University of Oxford.

EDITORIAL ACTIVITY

I am a regular reviewer for the British Journal of Urology International, Current Opinions in Urology, the Journal of Clinical Urology and the Journal of Sexual Medicine.

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 .....

Priority levels for clinical audit (please see criteria overleaf)

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

Audit approval process

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.

Information Team Requests

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.

Trust's M&M and Clinical Audit team contacts

The clinical audit team can be contacted via:
Email: clinical.audit@southerntrust.hscni.net
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: *clinical.audit@southerntrust.hscni.net*

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

FAQs Urology October 2020

Why has the Southern Trust decided to look back at Urology patients?

Clinical concerns were raised regarding the work of one Consultant Urologist in June 2020 when two patients were identified has having not been listed on to the Trust Patient Administration System in a timely manner. This was alerted as a potential patient safety issue due to potential delays in treatment and prompted a wider review of the Consultant's workload to establish if there were additional service impacts.

What happened when concerns were raised?

Following the identification of clinical concerns, the Trust provided information about the Consultant's practice to the General Medical Council. In addition to this, restrictions were placed on the Consultant's practice by the Trust so they could no longer undertake clinical work and could not access patient information. The Department of Health were provided with details of the case via the 'Early Alert' mechanism.

A further review of the Consultant's workload over an 18 month period - January 2019 to June 2020 – has been on-going since June, with expert independent advice sought to inform the scope and scale of the work.

Why is the Trust only looking at cases between January 2019 and June 2020?

The Trust has agreed with the Health and Social Care Board, Public Health Agency and Department of Health to a chronological and incremental approach when reviewing the Consultants workload. In the first instance the Trust has reviewed cases in this 18 month period. The scope and scale of any further review may be extended. This will be based on our internal review of patient records and advice from the Royal College of Surgeons.

What issues have the Trust now identified?

The Trust has reviewed all of the Consultants elective and emergency activity that occurred between January 2019 and June 2020. The review has progressed to diagnostic testing conducted including radiology, pathology and cytology to ensure appropriate action has been taken on each result. Of these patients who have been reviewed, there have been **nine** cases which are now part of an independently chaired Serious Adverse Incident Review process.

The Trust has also recently identified concerns regarding medication prescribing, as a result 26 patients have been reviewed by our Urology team.d

How many patients are involved in the review process?

Were all the patients treated by the same doctor?

All the patients included in this review were under the care of the same Consultant.

Have all patients who are affected been told?