ACUTE DIRECTORATE

Data provided by Corporate Office from the Datix Incident Management System to the Weekly Governance De-Brief (Thursday mornings - 9am – 10am)

1. **Status of SAI's -** Summary of the status of SAI's between 22.02.2021 - 28.02.2021

Any reports received after Friday will not be reflected in the numbers below until the following week

More than 26 weeks	Less than 26 weeks	Within Timescales	Level 3	Total
2	13	4	10*	29

*9 of the level 3 cases are the Urology SAI's

2. **SAI Notification**

Datix ID	Incident Date	Date reported to HSCB	SAI Description
Personal Information	26/02/2021	02/03/2021	Patient transferred from DHH to CAH for renal biopsy. Patient bled post procedurally into the renal tract requiring extensive resuscitation. The patient subsequently improved and the plan changed resulting in the patient being transferred without an allegedly agreed specialty bed to go to. Patient was transferred to urology ward post procedure and experienced an acute deterioration. He was subsequently taken to theatre to be intubated and ventilated. Patient remains in critical care unit in RVH. Relates to interface incident HSCB Ref: Personal Information
Personal Information	11/02/2021	02/03/2021	On 11 February 2021 the patient assaulted another patient on the ward. Security and police were immediately contacted to attend. Once medically fit the patient was transferred to Personal Information redacted by the USI .

3. **NIPSO**

- Irrelevant redacted by Accepted for investigation, Chief Executive apology letter issued to complainant.

4. **Interface Incident**

Received BHSCT Ref Personal Information: 2 Swabs lost for child in Blossom – Update –no record of the first swab. The second swab was taken, but was not requested for a rapid Cepheid by patient flow and so was processed by seegene. This result was available– however the report is against a patient record without a HCN and so is not available on NIECR. The HCN record in LABS brings up 'Infant XX, this should have been merged.

5. Issues escalated by Corporate or Directorate office at meeting

Complaint Received 25/02/2021 Personal Information –Patient attended ED Oct 2020 and had CXR which advised further CT. This was not done and patient represented in Dec 2020. CT carried out and detected lung mass.. To be brought forward to next week for update

Datix ID	Incident Date	Description
Personal Information redacted by the USI	22/02/21	CAH Trauma Ward - IV hydrocortisone reducing dose regime prescribed in 'Once only' medications section on back of Kardex by Anaesthetist. 4 doses missed by 3 different staff nurses. Head of Service is investigating the omission of critical medications.
Personal Information redacted by the USI	23/12/20	DHH ED - Personal Information old Anterior STEMI who had a significant delay in transferring from ED DHH to RVH cath lab due to delay in NIAS, review suggested a datix to enable an interface response from NIAS, Intertrust incident to be submitted NIAS
Personal Information redacted by the USI	27/02/21	DHH ED - Found white tub with foetal products presentED and and Lab HOS are investigating. Products later identified and given to family.
Personal Information redacted by the USI	24/02/21	**Recovery CAH - Patient out of theatre @ 1850hrs following Subtotal Colectomy.** 1930hrs became unresponsive after rolling and skin check, breathing became shallow and tachy 111bpm- sign of Local anesthetic systemic toxicity **Anaesthetic Head of Service .**
Personal Information redacted by the USI	24/10/20	patient attended ED 10/2020. CXR completed and discharged homeCXR report advised urgent CT Chest and follow up. This was not done and patient represented in Dec 2020 and malignant mass detected after CT.Update to be provided 11/03/2021

MENTAL HEALTH AND DISABILITY DIRECTORATE

Data provided by Corporate Office from the Datix Incident Management System to the Weekly Governance De-Brief (Thursday mornings - 9am – 10am)

6. Status of SAI's

Summary of the status of SAI's between 22.02.2021 - 28.02.2021

Any reports received after Friday will not be reflected in the numbers below until the following week

More than 26 weeks	Less than 26 weeks	Within Timescales	Level 3 – No timescale	Total
17	22*	3	2	44

***Await approval from HSCB re De-escalation request for SAI** Personal Information redacted by **and** Personal Information redacted by

7. Issues escalated by Corporate or Directorate office at meeting

22nd March Meeting set up to discuss EGR's at St Andrews Hospital who has provided care to SHSCT patients in the recent past-(UK based centre which has had recent poor performance against CQC standards.)

CHILDREN AND YOUNG PEOPLE SERVICES DIRECTORATE

Data provided by Corporate Office from the Datix Incident Management System to the Weekly Governance De-Brief (Thursday mornings - 9am – 10am)

8. Status of SAI's

Summary of the status of SAI's between 22.02.2021 - 28.02.2021

Any reports received after Friday will not be reflected in the numbers below until the following week

Less than 26 weeks	More than 26 weeks	Within Timescales	On Hold	Total
5	3	2	1	11

The CYPS Governance Team is in regular contact re: the 1 SAIs which are currently on hold.

9. Issues escalated by Corporate or Directorate office TBC at meeting

OLDER PEOPLE AND PRIMARY CARE SERVICES DIRECTORATE

Data provided by Corporate Office from the Datix Incident Management System to the Weekly Governance De-Brief (Thursday mornings - 9am – 10am)

10. Status of SAI's

Summary of the status of SAI's between 22.02.2021 - 28.02.2021

Any reports received after Friday will not be reflected in the numbers below until the following week

More Than 26 weeks	Within Timescale	Less Than 26 Weeks	Total
2*	0	2	4

*1 SAI's is currently with Safeguarding and 1 is currently in disciplinary process

11. Issues escalated by Corporate or Directorate office TBC at meeting

Early Alert to be raised for incident in Care Home in relation to the incorrect family being contacted in relation to a dying patient.. . Member of staff involved was put on special measures and has since left the NH. Numerous apologies have been provided to family which have been accepted.

LITIGATION

12. New Clinical negligence

There were no new clinical negligence claims received: 22/02/2021 – 26/02/2021

13. Clinical Negligence Claims Listed for Hearing in January 2021

Ref	Directorate	Division	Incident type	Incident date	Claim date	Opened date	Description
Personal Information redacted by the USI	ACUTE	SEC	Failure to diagnose/delay in diagnosis	01/09/2013	25/04/2014	16/05/2014	Listed 22/03/2021 for 3 days. Alleged delay in diagnosis resulting in the patient having a bowel removed.

14. Vaginal Mesh Cases

The Trust has 17 open cases where the allegations relate to vaginal mesh.

Stage	Number of Mesh Cases
Letter of Claim	**1**
Discovery	**4**
Investigation	**8**
Proceedings Issued	**3**
Trial date Set	**1**

A trial date of 17th May 2021 has been set for one of the cases. This is the first case regionally to reach a trial date. DLS advices are that there is some vulnerability in this case. Updates will be provided as the case progresses.

15. Urology Cases

Due to the announcement by the Minister for Health that a public inquiry is to be carried out in relation to the work of a Urology Consultant who was employed the Trust it is anticipated that there will be an increase in related medico-legal requests and litigation cases. To date no new medico-legal requests have been received which specifically refer to this matter. 1 litigation claim has been received which may be linked to this matter.

16. Coroner's Inquiries and Inquests

There were no new Coroners Inquiries received 22/02/2021 – 26/02/2021

There are currently no Full Inquest Hearings listed for hearing in March 2021

The following preliminary Inquest Hearings are scheduled in March 2021

Ref	Directorate	Division	Incident type	Incident date	Claim date	Opened date	Description
INQ	MHD	MHS	Self Harm	Personal Information redacted by the USI	30/07/2019	30/07/2019	**Preliminary Hearing - 08/03/2021 @ 1pm** Person died of suicide by hanging
INQS Personal Information	CYP	SOCIAL	Self Harm	Personal Information redacted by the USI	04/07/2019	04/07/2019	**PH 04.03.2021** The deceased known to the Trust's Gateway
INQ Personal Informati	ACUTE	SEC	Unexpected death	Personal Information redacted by the USI	30/04/2017	02/05/2017	***Proposed hearing date 19-23 April 2021*** **** Preliminary Hearing 03/03/2021**** The Coroner directed a post mortem in this case and the preliminary finding is multi-organ ailure, probable peritonitis and intra-abdominal haemorrhage following laparoscopic cholecystectomy.
Personal Information redacted by the USI	MHD	MHS	Unexpected death	Personal Information redacted by the USI	08/02/2018	08/02/2018	***** Preliminary Hearing Thursday 18th March 2021 at 10.00***** .*The deceased attended ED CAH via He was referred for psychiatric review in ED and was seen by Home Treatment Crisis Response who carried out a medical health assessment in the Clinical Decision Unit a management plan was put in place and he was discharged. Pt deceased the next day by suspected suicide
Personal Information redacted by the USI	ACUTE	MUC	Fail/ Delay Treatment	Personal Information redacted by the USI	11/05/2018	11/05/2018	*** PH on 03 March 2021 @ 1.15pm *** The deceased was Personal Information old and was admitted to CAH Via Ambulance with imaging consistent with as left hemispheric strokeDelay in diagnoses
Personal Information redacted by the USI	ACUTE	SEC	Unexpected death	Personal Information redacted by the USI	09/01/2019	09/01/2019	Preliminary findings, 1A: Small Bowell Perforation, 1B:Strangulated Hernia II: Diabetes Mellitus II; Hypertension; Chronic Obstructive Airways Disease;Congestive Heart Failure.

17. Number of Subject Access Requests exceeding timeframe for completion.

The Medico-Legal Team are unable to comply with the General Data Protection Regulations (GDPR) 2018 in respect of responding to Subject Access Requests within the statutory time-frames. This had been due to the sheer volume of requests (which had increased by approx. 1000 per year) and a lack of staffing to cope with the demand. The Governance Committee have been advised of the ongoing back-log; it has been brought to the attention of the Trust's SIRO and placed on the HROD Risk Register. An application was made to the Strategic Investment Committee for additional funding for staff. This was considered by the Strategic Investment Committee on 27th July 2020, and approval was provided in principle. Finance are now seeking to identify a recurring funding stream for these posts.

There is currently a back-log 243 requests that are in excess of 90 days across the following areas:-

Directorate	Acute Services	MH&D	C&YP	OPPC	TOTAL
Number of Outstanding Requests	177	36	23	7	243
New requests opened 22/02/2021 – 26/02/2021	33	2	2	0	37

The back-log has increased slightly from the previous week, the week-end days are included in counting towards the 90+days and therefore impacts on the work carried out during the week. As outlined previously, the reasons for back-log include (in addition to the staffing and volume issues) - difficulties accessing notes and records, and issues relating to redaction and consent to release.

MEDICATION INCIDENTS

18. Medication Incidents between 22.02.2021 - 28.02.2021

Medication Incidents between 22.02.2021 - 28.02.2021	
Personal Information	Staff witnessed halving lorazepam tablet and putting one half in the medication dispensing pot and the other half in her pocket.
Personal Information	It appears that a New Vaccinator while under supervision this morning drew up 2 doses of air instead of vaccine. It appears The vaccinator administered air to the 2 patients. The 2 patients have been identified and advised. Additional doses provided. Vaccinator placed under clinical supervision
Personal Information	Resus Patient, GCS 7, unclear history, seizures. Pre intubation check by consultant, Desat during intubation. Following intubation noted that C-Circuit attached to Medical Air, not O2 supply. Medical air flow-meter has flap covering Christmas tree nozzle and was functioning. Await clarification of incident 11/03/2021

SAFEGUARDING

19. Link to SharePoint site regarding RQIA Notifications/Alerts

Current Adult Protection Investigations where there are interfaces with other processes					
	SAI	Complaint	Coroner	Litigation	Potential High Profile
MHD	2				3
OPPC	1	1	1		
Acute		2			

20. 2 Ongoing SAI in MHD where adult protection investigation was undertaken

1 ongoing complaint in OPPC where adult protection investigation has been closed. Meeting with family arranged for February.

2 adult protection investigations in Acute where there has also been a complaint. Closed

3 adult protection investigations ongoing in Acute related to pressure care.

Personal Information redacted by the USI Care Home – care and governance issues are ongoing and individual adult protection investigation is ongoing (timeline for completion 3-4 months). SHSCT are writing to RQIA to address the concerns that have been raised. Pre contract meeting has been held within the Trust before the meeting is held with Personal Information redacted by the USI Care Home

1 Ongoing Adult Protection Case

INFORMATION GOVERNANCE

21. Number of Subject Access Requests exceeding timeframe for completion.

Directorate	ACUTE	OPPC	MHD	CYPS	FINANCE	P&R	HROD	CX
Number of outstanding Requests	9	-	11	19	-	-	1	-

These relate to Subject Access Requests which have not been completed within the legislative timescale (legal timeframe 30 days or 90 days for complex requests). These delays are in relation to the demands on Services to carry out redactions of these notes etc. In some cases there are requests which were made in 2019 and have not been progressed. In the last three months we have received three different complaints from the ICO in relation to the time taken to respond to requests.

22. Data Breaches reported to the ICO

Directorate	ACUTE	OPPC	MH&D	CYPS	FINANCE	P&R	HROD	CX
Breaches	-	-	-	-	-	-	1	-

There has been one data breaches reported to the ICO in this period. This is in relation to lost records; the Trust is awaiting a response from the Information Commissioners office. There has been one complaint received from the ICO in this period in relation to the time taken by the Trust to respond to a Subject Access Request and failure to explain redaction of notes.

NEW STANDARDS AND GUIDELINES RECEIVED AND ASSURANCES DUE OR SUBMITTED

23. Responses Due and Sent.

Title of Correspondence	Full Implementation Date for S&G	Directorates applicability
OPS and AS - Care Home Admission and Initial Review	Response Due 18/09/2020 – Working group meeting arranged for Friday 29th January HSCB requesting response on Action 2	OPPC
Care of Women Presenting with Post-Menopausal Bleeding	HSCB requesting response on Action 3	Acute OPPC
Process to be Followed When Preparing Syringes for Final Administration of the Pfizer Biontech Vaccine	Response Due 04/03/2021- Response sent 03/03/21	Acute, CYPS
Reissued Thrombolysis	Response Due 03/03/2021 - Extension requested	Acute,
Accessing Supported Accommodation	Response Due 03/03/2021 - Response sent 03/03/21	CYPS, MHD,
Emergency Management of Hyperkalaemia	Response Due 03/03/2021 - Response sent 03/03/21	Acute, OPPC
Delayed Diagnosis of Diabetic Ketoacidosis and Type 1 Diabetes in Children - Linked to previously issued letter SQR-SAI-2019-051	Response Due 03/03/2021 - Response sent 03/03/21	Acute, OPPC, CYPS

Maternity and Screening Revised Supersedes letter of 17 June 2020	Response Due 03/03/2021 - Response sent 03/03/21	Acute,
Planned Colonoscopy	Response Due 03/03/2021 Extension requested	Acute,
Risk of Serious Harm or Death from Choking on Foods	Response Due 03/03/2021 - Response sent 03/03/21	Acute, OPPC, CYPS
Revised Letter Unplanned Re-Attenders to the Emergency Department	Response Due 03/03/2021 – Response sent 03/03/21	Acute, CYPS
Safe Storage of Epidurals and Checking Processes for the Administration of Controlled Drug Infusions	Response Due 03/03/2021 - Response sent 03/03/21	Acute

24. Work Ongoing

- Safe use of Valproate in women of childbearing potential (HSC (SQSD)19/17 and HSS(MD) 8/2018)
  The planned meeting on 25/01/2021 has been cancelled due to COVID-19 surge pressures but the chair of the group, Dr Catherine Coyle (PHA) plans to have email discussions with the regional working group members in order to progress some of the ongoing work plan actions. Dr McKnight will share by email the SHSCT proposal for using an NIECR alert in the hope a regional consensus will be agreed.
- Care of women presenting with post-menopausal bleeding – On 15/01/2021 the HSCB responded to the SHSCT query regarding recommendation 3 – this has been sent on to the Clinical Directors and AD for IMWH for review – awaiting response to confirm if the clarity provided by the HSCB is suffice.

25. Safe storage of epidurals and checking processes for the administration of Controlled Drugs Infusions - The MDT (led by Dr Merjavy) have reviewed the alert recommendations but have a few queries in relation to auditing the Trust's current systems in processes. Whilst an audit is planned and underway to audit safe storage of epidurals under the requirements for managers, the MDT would appreciate guidance on how the staff checking responsibilities, as outlined under requirements under current guidance, can be practically undertaken.

26. S&G Received

Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	NICE Assurance 3 month	Full Implementation Date for S&G
Use of Plastic Bags on Mental Health In-Patient Wards	24/02/2021	LL-SAI-2018-033 (MH)	Safety and Quality Learning Letter	n/a	**18/03/2021**
UPDATE Advice for Carers and Young Carers during Covid-19 Pandemic	22/02/2021	n/a	COVID	n/a	n/a
UPDATE COVID-19 Therapeutic Alert Interleukin-6 Inhibitors (Tocilizumab or Sarilumab) for Hospitalised Patients with Covid-19 Pneumonia (Adults)	19/02/2021	HSS(MD) 21/2021	CMO Letter	n/a	Actions Required
COVID-19 Vaccines Weekly Publication of Yellow Card Safety Data	19/02/2021	HSS(MD) 20/21	CMO Letter	n/a	n/a
DoH Restraint and Seclusion Policy Definitions	18/02/2021	n/a	DOH Correspondence	n/a	**05/03/2021**

27. Regional PIVFAIT Audits

CAH	5/5 = 100%
DHH	1 / 2 =50% (non-compliant for indicators 1 (Patient identification), 2 (Glucose Monitoring), 4 (Cumulative input and output totalling and fluid balance) & 8 (Electrolyte monitoring) No action plan received.
ACUTE	1 case identified from last week - now excluded as aged 16yrs

Outstanding cases to review –6 cases, all ATICS - Sr Sherry. Await returns from CAH & DHH ED , Trauma.

AOB

28. PPE Incidents – There is currently not enough information provided within the Datix incidents to provide sufficient detail in relation to PPE.


PPE Report.xlsx


PPE Report by Coding.xlsx

29. NIPSO enquiry received 02/03/2021 re administration of vaccine complaint, information from HROD with NIPSO, awaiting decision.

Attendees: Nicole O'Neill, Caroline Doyle, Connie Connolly, Caroline Beattie, Catherine Weaver, Tony Black, Marita Magennis, Rebecca Murray, Dr O'Kane, Claire McNally, Joanne Bell, Deborah Hanlon, Patricia Kingsnorth, Jilly Redpath, Damian Gormley, Lauren Weir

Apologies: Lynne Hainey, Aaron Byrne

Southern Health and Social Care Trust

Chief Executive – Medical Director
1-1 Meeting
8th March 2021

	Item	Attachment
1	**Urology Update** • SAI Choreography regarding release of reports, CX agreement required • MDM Meetings –Focus on providing assurance around all cancer MDMs priority - Independent Review Process – RCPath contacted, meeting to discuss potential engagement • Irrelevant redacted by the USI [redacted]	Cancer Quality Surveillance Full policy
2	**Medical Leadership Proposal** • Potential for tabling tomorrow (Tuesday) pending discussions with staff (details from Pat McCaffrey on CD posts and Damian Scullion on patient safety lead posts)	Medical Leadership Implementation Fram DMD JD Template 25.02.2021.docx Job Description - AMD - Primary Care (I Medical Lead for Coroner Services.doc Medical Lead for Litigation Services.do
3	**Appraisal, Revalidation and Annual Management Reviews for Doctors** • Update on the discussion with UHB – potential for Annual Management Reviews to complement A&R processes. Proposal to be develop regarding implementation of the new model.	MNOTES - 15 12 2020 11 30am UHB A
4	**Individual Performance Review** • Shane to discuss what will be required for IPR re Medical Director	FW IPR's.msg
5	**Hyponatraemia** • Hyponatraemia 8B being advertised this week as secondment. • Recommendation stocktake event is scheduled for the first week of April.	
6	**Kings Fund Proposal** • Final spec to be agreed to return to the Kings Fund • Meeting with Nigel Edwards from Nuffield taking place next week • Also have attached Lord Rose report on NHS Leadership	Lord_Rose_NHS_Report_acc.pdf Southern Health and Social Care Trust NI F

7	**MLA Queries Complaints** • Currently the Trust has a 10 day response time set. This is from Mairead McAlindens time to improve MLA relationships. The rest of the regional Trusts have a 20 day response time Volumes now make this challenging (30 received in a single day alone) can this be realigned with the region – comms to be issued regarding this	
8	**Independent Medical Examiner** • Agreement from the DoH that the SHSCT will be next in line to have access to the regional medical examiner pilot. • This was due to go live in mid-January for the SHSCT however was postponed due to Surge 3. Final date for commencement to be confirmed.	 RE Indepdendent Medical Examiner.msg
9	**Colorectal Surgery** • Wasn't sure re this one re GMcA	
10	**Obs and Gynae** • Never Event - Retained Swab • Whistleblowing Update • Development of Dashboard	
11	**Cervical Cytology Service** • Proposal paper • Contact made to PHA re funding	 Cervical Cytology Service Position pape
12	**CSCG Staffing Proposal Update** • Two posts are commencing recruitment this month – 8a Patient Safety and 7 Patient Safety Strategy Lead • Personal information redacted by USI is due to continue until July. Personal information has indicated she is willing to come back for 2-3 days a week. Can this be funded • Phase 2 of CSCG Proposal to be approved (attached) • 80% of posts in CSCG are acting or temporary, need to steady structure • Proposal for the bringing CSCG under corporate leadership in development	 Phase Plan.docx
13	**Unscheduled Care Centre Governance** • Clinical Governance for the UCC will sit with ED DMD post – proposal to be finalized.	
14	**Morbidity and Mortality (including COVID-19 deaths)** • Proposal to develop a separate mini M&M to support COVID inpatient mortality reviews, both nosicomial and community deaths. Meeting planned to be held weekly to clear backlog. • Part of strategy will serve to potential reform M&M meetings as Patient Safety meetings with learning from mortality an input along with other safety data	

15	**Patient Advice and Liaison Service** Meeting with Heather has been held to potentially redevelop the PaLS service. Meeting next week to decide potential form of service.	Patient Experience Officer- band 4 JD- Ja 2962039_PALSOfficerJD.doc
16	**Structured Judgement Review** • SJR Training is due to take place on the 18th and 25th March. 20 Trust doctors in total will be trained, the training model is designed for cascade training. • Regarding applicability to Urology -the Trust is engaging an additional independent consultant urology expert with experience in SJR methodology to support.	
17	**Weekly Governance Report** • David Gilpin has commenced in 2PA role to support SAIs	Weekly Governance Report 22.02.21 - 28

Patients under the care of Mr O'Brien and currently in process of being reviewed
15 April 2021

	Patient Group	Number of Episodes/Patients in Group	Reviewed to date	Reviewed by	Remaining to be reviewed	Reviewed by	Provisional date	Quality Assured	Comment
Administrative Review Only	***Elective Cohort***	*352 Patients*	*352 (Administrative Review)*	*M Corrigan*	*0*	*Needs Clinical Review*	*N/A*	*No*	***All** are part of the 2309 patients required reviewed between Jan 2019 – Jun 2020.* ***Review to date only considered administrative processes***
	Emergency Patients (Stents)	*160 Patients*	*160 (Administrative Review)*	*M Corrigan*	*0*	*Needs Clinical Review*	*N/A*	*No*	***All** are part of the 2309 patients requiring reviewed between Jan 2019 – Jun 2020* ***Review to date only considered administrative processes***
	Radiology Results	1025 Patients (1536 Episodes)	511 (Result Review)	CNS	1025	Professor Sethia	May 2021	No	
	Pathology Results	150 Patients (168 Episodes)	168 (Result Review)	M Haynes/D Mitchell	0	N/A	N/A	Yes	
	Oncology Reviews (IS)	236 Patients	200 (Face to Face ISP)	P Keane	36	M Haynes	May 2021	No	
	Post MDM	187 Patients (271	271	Prof Sethia	52 (need	M Haynes	May 2021	No	

	Patients	Episodes)	(SME Record Review)		second opinion)				
	Review Backlog	511 Patients (509 Episodes)	40 (Virtual Clinics)	M Haynes	471	M Haynes/T Glackin	June 2021	No	
	Information Line	154 Patients	6 (reviewed at clinic)	M Haynes	148	Prof Sethia	June 2021	No	
	Patients prescribed Bicalutamide	933 Patients	747 (Record Review, 26 Face to Face Reviews)	M Haynes	186	M Haynes	May 2021	No	
	Patients on Inpatient Waiting List for TURP	143 patients	0	TBA	143	Clinical Team	June 2021	No	
	Total	**4321**	**2455**		**1918**				

- Note there were a total of 2309 patients that have been identified as being under Mr O'Brien's care from January 2019- June 2020, and a number of the above have been identified as being in this cohort of patients with multi episodes, more work is being done to identify how many of these are not included in the above groups with first look at this it may appear to be in and around another 1000 patients in this group that are not included in the above

To all concerned,

We would like to advise the Trust, the Board and the Department that we are not satisfied with the findings within the report as we feel it does not capture a complete and true representation of the care that our father, Patient 9, our mothers' husband of 49 years, received from the Health and Care system since May 2019.

Furthermore, we feel that we have been put under undue pressure to respond to this report. The first zoom call we had with the Trust, on 19th February 2021, was within days/weeks of being advised of Patient 9, our father's terminal diagnosis. During that call, we were advised we would have 2 weeks to respond to the initial report. This time should have been focused on providing better end of life care to our husband/ father to enable Patient 9, our father to be as comfortable as possible so that he/we could enjoy whatever time he had left with his family. The second call, on 21st April 2021, was within weeks of the premature death of Patient 9, our father. During this call we were asked to respond as quickly as possible. We also noted a level of impatience during the call, quoting "yours is only 1 of 9 cases". At present, having lost Patient 9, our father, less than one month ago, we are still grieving and we are again being put under strain to respond within an unrealistic time frame. This report does not consider the impact that this grief has had on our mother or on us together as a family.

We are unclear as to what the Trusts expectations are in respect of a response from us. On both calls we acknowledged that O'Brien was at the centre of Patient 9 /Dad's misdiagnosis however the report clearly states that its aim is to carry out a systematic multi-disciplinary review of the process used in the diagnosis, multidisciplinary team decision-making and subsequent follow up and treatment provided for each patient. Therefore, on each occasion we spoke with the Trust we have expressed our concerns on the care Patient 9 received from the whole HSC system including the Doctors, nurses, the GP, practice surgery receptionist, surgery in house pharmacist, the MDM team and any other Healthcare professional that interacted with our father.

We have pointed out on more than one occasion that the misdiagnosis was the start of the failings experienced by Patient 9, our father but the subsequent follow up treatment was appalling and made a difficult situation even more challenging and frustrating for my father, mother and our entire family. These failings have led to our father and mother being robbed of their twilight years together and throughout the final year of Patient 9, our fathers, life being subjected to severe pain and suffering from the mistreatment of the whole NHS. Given that we were put into this situation by the trust we would have expected above and beyond care to ensure what time Patient 9, Dad had left would be as comfortable as possible but unfortunately, we did not receive this either. We had to witness our former, strong, and proud father struggle, get weaker and become embarrassed by the situation in was left in. Our Father, a very social man began to refuse calls and visits from family and friends because he did not want anyone to see or hear him the way he was.

Within the report it states that Patient 9 /Dad met the 31-day target however we feel that this is completely inaccurate and misleading. There was a delay of 15 months on Dad receiving the correct diagnosis, therefore we would dispute any targets being met in these circumstances.

Within the report it states Doctor 1 reviewed Patient 9 / Dad on the 2nd July and documented suspected cancer and the treatment he recommended to Patient 9 /Dads GP however this was to be deferred until review in September. As we now know this review never took place, another failure, however we would like to know why it was deferred initially and why the GP never followed up on this.

The primary duty of all Doctors, Nurses and Healthcare professionals is for the care and safety of patients. Whatever their role they must raise and act on concerns about patient safety. However, we have seen countless failures by several healthcare professionals that first promised to do no harm; The Urology Peer Review 2017 indicated that all patients should have access to a Specialist Nurse. This was not the case and was known to be so however no mandatory audits were put in place, no investigations were opened; The Multi-Disciplinary Team recommendations were ignored however there was no accountability or requirement to follow these recommendations. Again, this practise was known but again no measures were put in place to eradicate these failings. We were also made aware the Mr O'Brien's working style, solo, was widely known within the HSC. However, this was not addressed, concerns were not raised by colleagues and no investigations were initiated by management. It is claimed within the report that management were unaware of these failures which we find unacceptable.

It should also be mentioned about the adverse impact this has had on our mother's health. Our mother has ignored her own health during this, as all her energy was used struggling to get Dad the care that he needed and deserved.

There is much more that we would like included within the report however the timeframe that we have been afforded does not allow for this. The calls we have had with the Trust and the Department have seemed to be centred on the Trusts agenda and have been of little benefit to Patient 9 / Dad or our family however we will continue to work with you on this process to ensure that no other HSC patient receives the same care that Patient 9, our father received.

Yours Sincerely,

Patient's Daughter and family.

Regional Guidance for Implementing a Lookback Review Process

Final Draft

Contents

Regional Guidance for the Implementing of a Lookback Review Process

1.0 Introduction

A Lookback Review Process is implemented as a matter of urgency where a number of people have been exposed/potentially exposed to a specific hazard in order to identify if any of those exposed have been harmed, and to identify the necessary steps to ameliorate the harm (e.g. repeat diagnostic test/ investigation/ referral to relevant clinical service etc.).[1]

This Regional Guidance, along with the accompanying policy document, has been drafted in order to standardise and update the approach taken to Lookback Reviews by the HSC in Northern Ireland. It replaces HSS (SQSD) 18/2007, issued by the Office of the Chief Medical Officer on 8 March 2007.

A Lookback Review is a process consisting of four stages; immediate action including a preliminary investigation and risk assessment to establish the extent, nature and complexity of the issue(s); the identification of the service user cohort through a service review or audit of records to identify those potentially affected; the recall of affected service users; and finally closing and evaluating the Lookback Review Process and the provision of a report including any recommendations for improvement (see summary diagram of Lookback Review Process (Diagram 1) and Lookback Review Process Checklist Appendix 5).

The triggering event or circumstances under which a Lookback Review would be considered include; faulty or contaminated equipment, missed/delayed/incorrect diagnosis relating to diagnostic services, failure of safety critical services or processes, competence issues with a practitioner(s) or identification of a practitioner with a transmissible infection or underlying health problem that may impact on performance (see also Policy on the Implementation of a Lookback Review Policy Section 1 for a more comprehensive list).[2]

[1] Health Service Executive (HSE) 'Guideline for the implementation of a Look-back Review Process in the HSE'. HSC National Incident Management and Learning Team, 2015. Section 7.1 Page 10.
[2] See also 'Policy for the Implementation of a Lookback Review Process' Section 1 Page 3.

The existence of a hazard exposing a number of people to a risk of harm is not always immediately apparent. The triggering event may have been raised as a concern by a service users and/or their family/carers or it may have been highlighted by a service review/audit or it may have come to light as a result of a concern expressed by a colleague or through a Serious Adverse Incident (SAI) Review or Thematic Review undertaken by the Regulation and Quality Improvement Authority. The triggering event will alert the Health and Social Care (HSC) organisation that a number of people may have been exposed to a hazard and the need to instigate a Lookback Review Process should be immediately considered.

1.1 What does a Lookback Review Process involve?

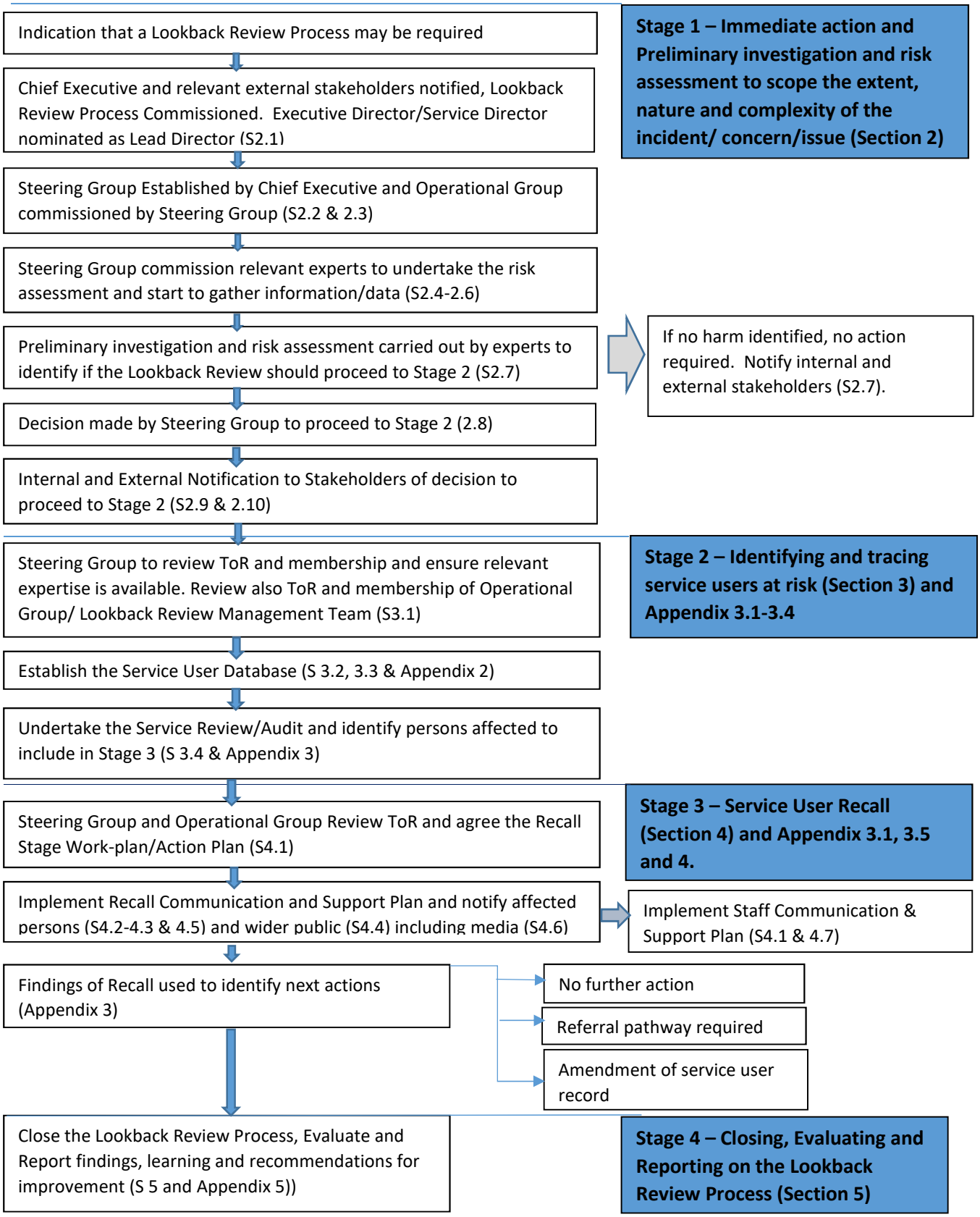
The Lookback Review Process involves:

- Identifying, tracing, communicating, and providing appropriate ongoing advice to, and/or management of, the group of service users who have been exposed or potentially exposed to a hazard and who may have been harmed, or are at risk of future harm or loss;
- Notification internally to Trust Board and to appropriate external stakeholders (see Sections 2.1, 2.9 and 2.10);
- Notification to the wider public as and when required. While openness and candour are guiding principles in a Lookback, it is essential that communication occurs at a time when clear messages can be conveyed whilst ensuring that the ‘at risk’ population has been identified and communicated with before the wider public is alerted. Relevant healthcare professionals including General Practitioners should also be identified and communicated with in advance of any public statements. This is essential to maintain public confidence and prevent unnecessary anxiety and to ensure that services can be focused on the correct group of people (See Section 4 below).

The following diagram (Diagram 1) provides a summary of each stage of the Lookback Review Process and may be used in conjunction with the Lookback Review Process Checklist (see Appendix 5). The Process, as laid out below is a step by step guide. It is important, however, that the primary focus should remain on harm and risk of harm to service users. Therefore, there will be occasions where it is

clear from the outset that a Lookback Review will be necessary and where the organisation effectively runs more than one of these stages consequently.

Diagram 1 Flowchart - Summary of Stages in a Lookback Review Process



1.3 Governance Arrangements

The HSC organisation should ensure that the Lookback Review Process is managed in line with extant Governance and Assurance Framework arrangements.[3] The Steering Group (Section 2.2) should be seen as a 'task and finish' group within the HSC organisation's Governance/Assurance Framework structure reporting to Trust Board through the Senior Management Team/ Executive Team of Trust Board. The Steering Group should commission an Operational Group or Lookback Review Management Team to take forward the operational aspects of the Review Process (unless the Lookback Review is anything other than limited in terms of nature, extent and complexity).

When scoping the nature, extent and complexity of the Lookback Review Process (Section 2.6 – 2.7) the Steering Group should evaluate and escalate the risk in line with the organisation's Risk Management Strategy. This will ensure that the risk(s) identified will be included in either the organisation's Board Assurance Framework, Corporate Risk Register or Directorate Risk Register and managed in line with the Risk Management Strategy.

The Lookback Review Process should be outlined in the mid-year Assurance and/or annual Governance Statement as required. The annual Governance Statement is the means by which the Accounting Officer provides a comprehensive explanation on the HSC organisations' approach to governance, risk management and internal control arrangements and how they operate in practice.[4] The Statement provides a medium for the Accounting Officer to highlight significant control issues which have been identified during the reporting period and those previously reported control issues which are continuing within the organisation.

1.4 Other Related Incident Management Processes including Investigations

As stated previously, Lookback Reviews are carried out in order to identify if any of those exposed to a hazard have been harmed, and to identify the necessary steps to take care of those harmed. The incident giving rise to the Lookback Review Process or issues identified as a result of the process may require review as a Serious

[3] DoH '*An Assurance Framework: a Practical Guide for Boards of DoH Arm's Length Bodies*.' April 2009.
[4] Department of Finance ' *Managing Public Money NI (MPMNI)*' AS.1

Adverse incident (SAI).[5] This will require a parallel (though interlinked) review which should be undertaken in line with Health and Social Care Board guidance [6] to identify key causal and contributory factors relating to the triggering event (see Sections 2.10 and Section 5). In some circumstances, a Lookback Review Process may have been prompted by a preceding SAI review.

The circumstances leading to a decision to implement a Lookback Review may require the HSC organisation to notify other statutory agencies such as the Coroners Service for Northern Ireland and/or the Police Service for Northern Ireland (PSNI). The reporting of the Lookback Review as an SAI to the Health and Social Care Board (HSCB) will work in conjunction with, and in some circumstances inform, the reporting requirements of other statutory agencies and external bodies. In that regard, all existing local or national reporting arrangements, where there are statutory or mandatory reporting obligations, will continue to operate in tandem with this Regional Guidance.

A Memorandum of Understanding (MoU) has been agreed between the Department of Health (DoH, on behalf of the Health and Social Care Service (HSCS), the Police Service of Northern Ireland (PSNI), the Northern Ireland Courts and Tribunals Service (Coroners Service for NI) and the Health and Safety Executive for Northern Ireland (HSENI).[7] The MoU applies to people receiving care and treatment from HSC in Northern Ireland. The principles and practices promoted in the MoU apply to other locations, where health and social care is provided e.g. it could be applied when considering an incident in a family doctor or dental practice, or for a person receiving private health or social care provided by the HSCS.

A Lookback Review Process may raise issues of professional competence/conduct. HSC organisations will then be required to instigate performance management, capability and disciplinary reviews or investigations in line with their internal Human Resource policies, procedures and relevant professional regulatory guidance for

[5] Health and Social Services Board (HSCB) 'Procedure for the Reporting and Follow-up of Serious Adverse Incidents'. November 2016 Version 1.1.
[6] *Ibid.*
[7] DoH *'A Memorandum of Understanding' developed to improve appropriate information sharing and co-ordination when joint or simultaneous investigations/reviews are required into a serious incident'.* HSS (MD) 06/2006, February 2006.

example Maintaining High Professional Standards (MHPS).[8] These processes should run as a parallel process to the Lookback Review, although relevant information from one process may inform the other. In such circumstances, confidentiality in respect of the member of staff must be taken into consideration.

[8] DoH 'Maintaining High Professional Standards in the Modern HPSS'. HSS (TC8) 6/2005. November 2005.

2.0 Stage 1 – Immediate Action, Preliminary Investigation and Risk Assessment

Immediate action should be taken to ensure the safety and wellbeing of the service users.

2.1 Notification of the need to consider a Lookback Review Process

The Director of the service involved should be notified immediately that a hazard or potential hazard has been identified which may require the organisation to consider implementing a Lookback Review Process. The Director will report the issue(s) internally through the Chief Executive to the Board of Directors in line with the organisation's risk escalation processes. The relevant Director will also need to consider if the hazard might affect other HSC Organisations or private/ independent providers.

It is recognised that at this early stage there may be limited information available to the HSC organisation until information and intelligence is gathered and the risk assessment is undertaken (see Sections 2.6 and 2.7), however, in line with extant guidance, the Director should notify the DoH of the emerging issues by way of an Early Alert (see also Section 2.9).[9] The Early Alert should make clear, if the information is available, the details of other organisations/services potentially involved in NI or in other jurisdictions, the timeframe during which the issue may have been relevant and the potential volumes of services users who may be affected. The Director should also consider if the findings, given the potentially limited information could be considered as an SAI at this time (see Section 2.10). [10] If in doubt, the extant SAI guidance provides the opportunity for the organisation to declare the matter as an SAI, which can then be 'de-escalated' later.[11] The HSC Organisation will also have to consider possible notification of the event(s) to the Coroners Service for NI and/or the PSNI (see Section 1.4).

[9]Department of Health 'Early Alert System' HSC (SQSD) 5/19.
[10] HSCB 'Procedure for the Reporting and Follow up of Serious Adverse Incidents. November 2016.
[11] *Ibid.,* Section 7.6 Page 21

It is also important to advise the organisation's Head of Communications/Communications Manager at an early stage so that a communication plan including media responses can be prepared in advance.

2.2 Establish Steering Group

A Steering Group should be convened as soon as possible after the disclosure of the issue of concern to develop an action plan and oversee its implementation. Depending on the extent, nature and complexity of the triggering event the Steering Group should be chaired by either the relevant Service Director or in some circumstances it may be chaired by the relevant Executive Director/Professional Lead.

If other investigation processes are in place (e.g. Capability/Performance Management Reviews) these should run as parallel processes, however, information from the other investigative processes, taking into account confidentiality and the information governance requirements that will apply to these parallel processes, may be used to inform the decision making of the Steering Group.

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

2.3 Composition of the Steering Group

The composition of the Steering Group will be dependent on the service involved and the nature and extent of the Lookback Review Process. The Steering Group should not normally involve personnel who may have been directly involved in the event/hazard that triggered the Lookback Review Process.

Depending again on the extent and nature of the Lookback Review the HSC organisation should consider the following as core members; a Non-Executive Director, the Director of service/speciality concerned, relevant professional Executive Director(s), Risk and Governance representative, Head of Communications, Information Technology manager, Medical Records manager and senior service representatives with expertise (including clinical and/or social care) in the services/

processes which are the subject of the Review Process, a PHA representative and an HSCB representative (in the case where the Lookback Review has been identified as an SAI, the role on the Steering Group will be clearly identified to ensure that the independence of the PHA/HSCB is not jeopardised).

The organisation may also wish to consider a member of a relevant service user representative/advocacy group is included as a member of the Steering Group.[12] In these instances, a confidentiality agreement must be signed by the service user representative. The representative should not have access to service user identifiable data. Such an agreement should be proportionate and reflect the need of the organisation to protect the information of individuals and to ensure that information disseminated is accurate, proportionate and timely and that support mechanisms are in place for service users and staff.

The Steering Group should also commission an Operational Group or Lookback Review Management team which should report to and support the Steering Group in taking forward the operational aspects of the action plan e.g. establishing the service user database (Section 3.2) and supporting the Recall Stage (Section 4).

2.4 Role of the Steering Group

Within 24-48 hours from being established the Steering Group should decide on the immediate response which includes;

- Methodology to determine the size/magnitude, complexity and nature of the risk/harm to service users/carers in order to plan an appropriate Lookback Review Process e.g. risk assessment (see Section 2.7 below);
- Determine if the Lookback Review Process is limited to one HSC organisation or if the process will involve a number of HSC organisations as well as the independent sector and organisations in other jurisdictions;
- Determine the extent of notifications to the DoH, HSCB and PHA that is required, if these notifications have not already been initiated (see Section 2.1 above and Sections 2.9 and 2.10);

[12] The Patient and Client Council (PCC) is responsible for delivering and/or providing access to advocacy and support services as specified by the DoH and HSCB guidance in supporting families through a 'hub and spoke' model of service delivery working with providers of advocacy services. Other independent services may be accessed as required through the PCC, including the development of a network of available advisory services.

- Address and manage notification internally through the Senior Management Team/Executive Team to the Board of Directors;
- Agree on the formation of an expert advisory sub group comprising experts in the area of concern, relevant clinicians, and department or directorate heads to undertake the risk assessment and service review or audit . Consideration should be given as to whether or not that expertise should come from outside the organisation;
- Agree on a service user communications plan. Communication with the service user/family is a priority and the organisation should be proactive in managing the manner and timing in which affected service users receive relevant information (see Section 4.2).
- Agree on a communication plan/liaison plan for other HSC organisations or independent/private providers which might be affected.
- Agree on a media/communications management plan if required, that aims to be proactive in disclosure to the general public and considers responses to media enquiries (see Section 4.6).[13]

2.5 Steering Group Terms of Reference and Action Planning

The Steering Group should develop and approve Terms of Reference and establish a Lookback Review Action Plan for Stage 1 of the Process. Both the Terms of Reference and action plan should be reviewed and revised as and when the Process proceeds to the next stages.

The action plan should include as a minimum; the management of immediate safety issues, identify those who may have been exposed to harm, care for those who may have been harmed/affected, actions to prevent further occurrences of harm, a communication plan, contingency planning for business continuity of the service and plans for potential service user follow-up.

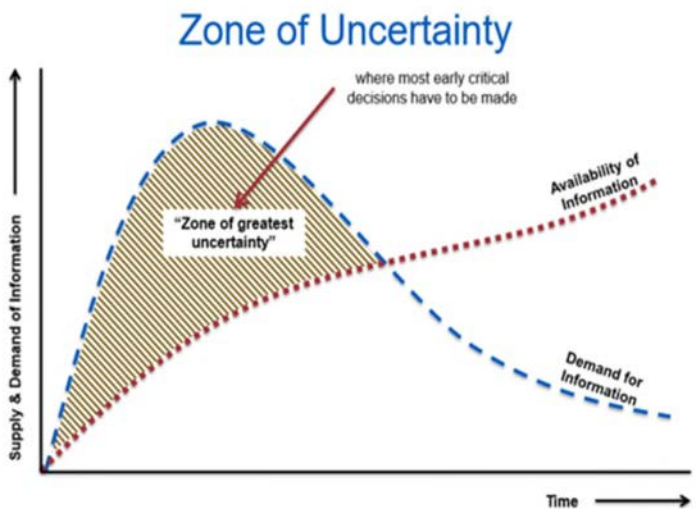
[13] New South Wales 'Lookback Policy Directive', Clinical Excellence Commission Safety & Quality, System Performance & Service Delivery, September 2007. Section 4 Page 5.

2.6 Gathering Information and Intelligence to Scope the Extent, Complexity and Nature of Harm

Key decisions have to be made at this early stage of the process when minimal information may be available to the Steering Group. Decision making should be based on a joint understanding of risk (see below) and shared situation awareness.[14] Situation awareness is having a common understanding of the circumstances, immediate consequences and implications of the triggering event along with an appreciation of the available capabilities and the priorities of the response.[15]

It is important that internal and external stakeholders are aware that the Steering Group may be required to make decisions during a time of uncertainty (or zone of uncertainty) about the level of risk or harm to service users (see Figure 1 below).[16] Depending on the extent, nature and complexity of the Lookback Review Process it can be difficult for the Steering Group to predict when it has gathered the optimum level of information to make decisions such as the decision to announce the Service User Recall stage.

Figure 1 Zone of Uncertainty

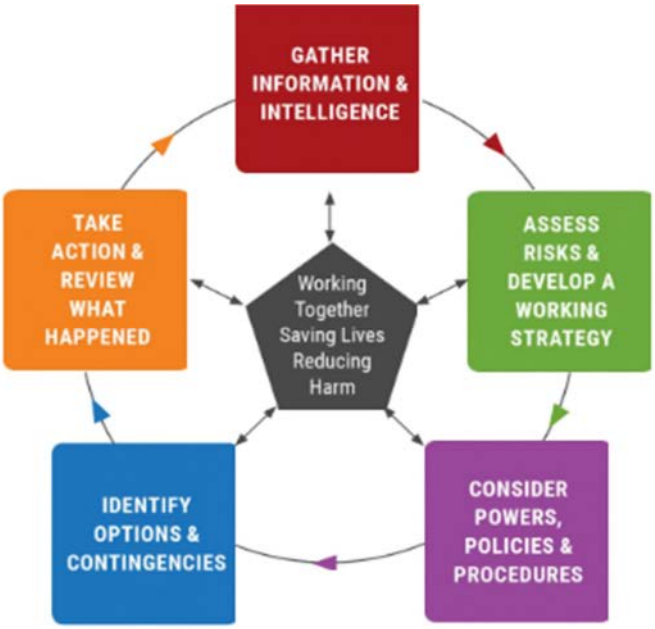


At the early stage, as above when limited information is available upon which the Steering Group will be required to make crucial decisions then a Decision Making Model, widely used amongst the emergency services as a tool, could be considered.

[14] Joint Emergency Services Interoperability Principles (JESIP) ' www.jesip.org.uk
[15] *Ibid*.
[16] *Ibid*

Tools to aid decision making include for example the Joint Decision Making (JDM) Model (Figure 2)[17] which helps bring together the available information, reconcile objectives and make effective decisions.

Figure 2 Joint –Decision Making Model



Further information and use of the JDM are available via the Joint Emergency Services Interoperability Principles (JESIP).[18]

All decisions should be recorded/logged, justified, seen to be reasonable and proportionate to the information available at the time. Therefore the Steering Group will require the services of an experienced minute-taker or 'loggist'[19] to ensure an accurate record of actions and decisions is maintained at each stage of the process.

[17] Joint-Decision Making Model @ www.jesip.org.uk/joint-descision-model
[18] *Ibid*.
[19] A term used in Major Incident Planning a loggist is the person who is responsible for capturing, through decision logs, the decision making process that might be used in any legal proceedings following an incident ' www.epcresilience.com

2.7 Risk Assessment [20]

As indicated above, the first stage in the process is to undertake a risk assessment to determine whether the scope, size/magnitude, complexity and nature of harm arising from the triggering event should progress to the next stage(s) i.e. a service user lookback and potential service user recall. In order to do this, the Steering Group should commission relevant experts to undertake this risk assessment. As above (Section 2.3), the relevant experts may include but are not exclusive to: people with the clinical or social care expertise in the services/ processes which are the subject of the Lookback Review Process, Risk and Governance Managers, and a Public Health Specialist. This will be determined by the Steering Group on a case by case basis.

A decision to undertake the completed Lookback Review Process has significant implications for service users, providers and resources. The risk assessment, therefore, should provide a thorough assessment of the chance of harm and the seriousness of that potential harm. It must be conducted in a manner that balances the need to identify and address all cases where there might be safety concerns on the one hand, with the need not to cause any unnecessary concern to service users or to the public on the other.[21]

The risk assessment should look at:

- If the Lookback Review Process is limited to one HSC organisation or if the process will involve a number of HSC organisations including the independent sector;
- The potential extent of the issue and the level of exposure to the hazard;
- Evidence of harm that has occurred;
- The likelihood of future harm occurring;
- The potential and actual (if relevant) outcomes of the issue e.g. missed diagnosis/ missed return appointments for follow up etc;
- The potential impact of the issue;
- The potential cohort of service users affected (including service users of other HSC and non-HSC Organisations);

[20] HSE. *Op.Cit* Section 7.6 Preliminary Risk Assessment Page 115-16.
[21] *Ibid*. Appendix 1

- The potential impact on other service users (not in the 'at risk' cohort) e.g. potential delays in treatment and diagnosis;
- The manner in which harm would be ameliorated (e.g. repeat investigation/ onward referral for treatment).

The HSC Regional Risk Matrix and Impact Table may be used as guidance to evaluate the risk.[22] A template for undertaking a preliminary risk assessment is included in Appendix 1 of this Guidance.[23]

The Steering Group will use the information obtained from this assessment to decide if the Process should continue to the Service User Lookback and Recall stages (see Section 2.8). If there is no harm or risk to service users, the Lookback Review Process can be closed. The Steering Group will inform the relevant internal and external stakeholders. It is advised that the Early Alert is updated to indicate that the process has been closed, outlining clear reasons for the decision. The HSC organisation should consider the incident as a 'near miss' and undertake a systems analysis to establish contributory factors, learning and recommendations.

2.8 Decision to proceed to Stage 2 Service User Lookback and Stage 3 Service User Recall

The decision to proceed to the Service User Lookback and Recall stages is a difficult and complex one and should not be taken lightly. As above, the decision should only be considered in circumstances where it is indicated following careful risk assessment, which may necessitate external peer review and advice from senior decision-makers and/or others with knowledge and experience in the specialty in which the Process is being considered and with advice from those who have experience in conducting a Lookback Review Process (see Section 2.7 Risk Assessment).[24] The decision should also include consideration of the impact on other service users (i.e. not the 'at risk' cohort) for potential delays in diagnosis and treatment.

Lookback Reviews by their nature are often high-volume, involve high-complexity and high-cost (including opportunity cost which diverts time and resources from

[22] HSCB. *Op.cit*. Appendix 16.
[23] HSE. *Op.cit*. Preliminary Risk Assessment Stage pages 15 to 16 and Appendix 1.
[24] *Loc.cit*.

ongoing care.) As described above, they involve a number of stages and logistical challenges.

If a decision is taken to proceed to the Service User Lookback and Recall stages then the Chair of the Steering Group must inform the Chief Executive and Board of Directors and notify the relevant external bodies. The Early Alert should be updated (Section 2.9). If the Process has not already been reported as an SAI then the Steering Group should review the SAI criteria and take appropriate action (see Section 2.10).

The Steering Group should continue to consider any safety concerns that may arise at any stage of the Review Process which may need prompt action. Concerns may include the following:

- Taking preventative action such as the removal of the hazard [25];
- Consideration of the benefits and risks of suspending or transferring the service under review;
- Management of staff member(s)/service whose caseload is under review in line with Professional/Regulatory Guidance/HR/Occupational Health policy and procedure;
- Clinical and social care management of service users/ staff identified by the preliminary review and suspected of being adversely affected;
- Providing support to service users and staff involved.

The Steering Group should ensure that business continuity plans are considered and implemented, where necessary, including providing for additional health and social care demands which may arise as a consequence of the Lookback Review. The HSC organisation is responsible for securing service capacity and for ensuring that the necessary resources are allocated to conduct all the stages of the Review Process and subsequent follow-up processes. If the resources required exceed what is available then this should be escalated to the organisation's Board and if necessary to the Health and Social Care Board.

The Steering Group should be prepared for the fact that when a full Lookback Review Process is being considered this information can often become publicly known at the

[25] If the hazard is associated with a medical device then the HSC organisation should report this in line with Norther Ireland Adverse Incident Centre (NIAIC) adverse incident reporting – guidance and forms. October 2018 ' www.health-ni.gov.uk.

planning stage and should have a contingency plan in place for notification of affected persons and the wider public if this should occur.

2.9 Early Alert Notification [26]

The established communications protocol between the Department and HSC organisations emphasises the principles of 'no surprises', and an integrated approach to communications. Accordingly, HSC organisations should notify the Department promptly (within 48 hours of the event in question) of any event which has occurred within the services provided or commissioned by their organisation, or relating to Family Practitioner Services. Events should meet one or more of the following criteria;

1. *Urgent regional action may be required by the Department, for example, where a risk has been identified which could potentially impact on the wider HSC service or systems;*
2. *The HSC organisation is going to contact a number of patients or clients about harm or possible harm that has occurred as a result of the care they received. Typically, this does not include contacting an individual patient or client unless one of the other criteria is also met;*
3. *The HSC organisation is going to issue a press release about harm or potential harm to patients or clients. This may relate to an individual patient or client;*
4. *The event may attract media attention;*
5. *The Police Service of Northern Ireland (PSNI) is involved in the investigation of a death or serious harm that has occurred in the HSC Service, where there are concerns that a HSC service or practice issue (whether by omission or commission) may have contributed to or caused the death of a patient or client. This does <u>not</u> include any deaths routinely referred to the Coroner, <u>unless</u>:*
   - *i. there has been an event which has caused harm to a patient or client and which has given rise to the Coroner's investigation; or*
   - *ii. evidence comes to light during the Coroner's investigation or inquest which suggests possible harm was caused to a patient or client as a result of the treatment or care they received; or*
   - *iii. the Coroner's inquest is likely to attract media interest.*
6. *The following should always be notified:*

[26] Department of Health 'Early Alert System' HSC (SQSD) 5/19.

i. *the death of, or significant harm to, a child, and abuse or neglect are known or suspected to be a factor;*
ii. *the death of, or significant harm to, a Looked After Child, a child on the Child Protection Register or a young person in receipt of leaving and after care services;*
iii. *allegations that a child accommodated in a children's home has committed a serious offence; and*
iv. *any serious complaint about a children's home or persons working there.*

7. *There has been an immediate suspension of staff due to harm to patient/client or a serious breach of statutory duties has occurred.*

The next steps will be agreed during the initial contact/telephone call and appropriate follow-up action taken by the relevant parties. In **all** cases, however, the reporting organisation must arrange for the content of the initial contact to be recorded on the updated pro forma attached at Annex C, and forwarded, within 24 hours of notification of the event, to the Department at earlyalert@health-ni.gov.uk and the HSC Board at earlyalert@hscni.net.

The Early Alert must provide a succinct description which clearly outlines the key issues and the circumstances of the event. Information contained within the brief is to include:

- urgency;
- determining who has been affected and how - physical and/or psychological harm, or no known harm;
- process for determining risks;
- need for Department participation/involvement/oversight.

2.10 SAI Notification and Investigation

In some circumstances an SAI review may have triggered the Lookback Review Process (Section 1). However, often the Lookback Review will be triggered by a concern that has been raised by a service user or their family/carers or a member of staff. The Steering Group should consider at an early stage if the findings of the Lookback Review meets any of the criteria for reporting the concerns as an SAI (see also Section 7.2.1). The criteria for reporting an SAI are defined within the HSCB

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

[27] HSCB Loc. Cit Section 4

3.0 Stage 2 Identifying and tracing service users at risk

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

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

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

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

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

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

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

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

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

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

3.2 Establish the Service User Database

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

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

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

The database may already exist on one of the organisations Information Technology (IT) systems. In some circumstances (for example service users who have not been reviewed for a period of time), it may be necessary to check the service user details with the General Register Office for NI to identify if any of these service users have since deceased.[29] Information Technology staff are essential members of the sub

[29] General Register Office for Northern Ireland @ www.gov.uk.

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

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

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

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

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

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

[30] HSE. *Op.Cit.* Section 7.7.4, page 18.
[31] Ibid. Section 7.7.3 Page 17
[32] EU Data Protection Regulation (GDPR) 25 May 2018 @ https://eugdpr.org
[33] Data Protection Act 2018 @ www.legislation.gov.uk .
[34] DoH 'Code of Practice for protecting the confidentiality of service user information' 31 January 2012 @ www.health,n-i.gov.uk

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

3.4 Undertaking the Audit

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

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

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

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

The service user database will be used to document the service users/ staff who are included and excluded following each stage of the Lookback Review Process (see Section 3.2 above). In general, it will be used to track persons affected and to record actions, interventions and outcomes.

[35]HSE. *Op.cit*. Section 7.7.3.

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

4.0 Stage 3 Service User Recall

4.1 Planning the Recall

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

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

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

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

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

Ideally, a liaison person/team should be appointed to oversee the seamless conduct of each attendance a service user has as part of the Recall stage, whether they are

clinic appointments or repeat tests/x-rays etc. Responsibilities would include; providing a point of contact, follow-up of DNAs , quality assurance of the Process (correct letter to correct person) and checking that the service user affected are referred into the 'system' for subsequent follow-up.[36]

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

4.2 Service User Communication and Support

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

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

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

- access to professional interpreters as required;
- a designated point of contact for service users, their families and/or carers;

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

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

Communication and support of families should include:

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

4.3 Service User Notification by Letter

Depending on the extent of the Lookback Review Process notification may be by a letter sent to the service users affected by the issue. As above, the timing of service user notification must be carefully choreographed with any public announcement made by the organisation. If the Process has affected small numbers of service users organisations may wish to consider alternative forms of direct communication e.g. telephone calls in first instance which should be supplemented by a follow-up letter containing the pertinent information. A sample of letters has been provided in Appendix 3 for reference/guidance.

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

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

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

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

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

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

4.4 Public Announcement of the Recall Stage

The Steering Group will determine the timing of the Public Announcement of the Recall Stage of the Lookback Review Process. Communications management throughout the Lookback Review Process should be guided by the principles of ‘Being Open’[37] balanced with the need to provide reassurance and avoid unnecessary concern.

Recall Stage will be announced to the public by the relevant HSC organisation lead Director in line with the Communication Plan (Section 4.2 and 4.6). As stated in

[37] DoH ‘Saying sorry – when things go wrong’. January 2020.

Section 4.3, it is vital that the Steering Group strive to ensure that the Lookback Review Process is not publicly announced until all of the persons affected have been notified and a clear public message can be given regarding the extent of the cohort and those that are not affected. This is not always possible, as breaches of confidentiality may occur and therefore the Communication Plan should be prepared for this eventuality at all times.

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

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

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

4.5 Setting up a Service User Helpline/ Information Line

Once it has been agreed that the Lookback Review process is to be publicly announced HSC organisations need to have in place a system to deal with potentially large numbers of enquiries from service users, their families and the general public. It is recommended that site-specific helplines are considered for persons affected and a more general information line for the wider public. Consideration should also be given to providing information on the Trust's website for example Frequently Asked Questions (FAQs) and responses. Planning at this stage is vital to ensure that public confidence in the service is not further eroded. Guidance on setting up a service user helpline/information line are contained in Appendix 4.

[38] HSE *Op Cit* Page 20

4.6 Communication with the Media

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

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

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

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

Media statements in relation to the issue, should be accurate and not add to the anxiety of the service users and their families/carers. Media statements should not be released prior to notification of the Lookback Review Process (see Sections 4.3 and 4.4). In the circumstances where a media statement is released it should state that a Lookback Review Process is being carried out, and immediately limit the area of concern to time period, region and service area within which the Process is being conducted. It should detail the numbers of persons affected being included in the

[39] *Ibid.* Section 7.11.2 Page 26

recall stage of the process and the expected timeframe for the completion of the recall stage, if known.[40]

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

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

4.7 Staff Communication and Support

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Glossary

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

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

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

Appendices

Template for Risk Assessment

Appendix 1

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

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

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

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

Please tick one:

Extreme	
High	
Medium	
Low	

Additional Details:

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

Details of Immediate Action Required

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

Details of personnel who undertook the Risk Assessment:

Name	Title

Date of Risk Assessment :

Establishing the Service User Database – Core Dataset Appendix 2

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

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

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

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

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

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

Appendix 3

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

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

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

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

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

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

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

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

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

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

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

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

The Proforma will be completed by the Service Review Team.

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

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

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

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

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

Conducting Further Assessment (Clinical)

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

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

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

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

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

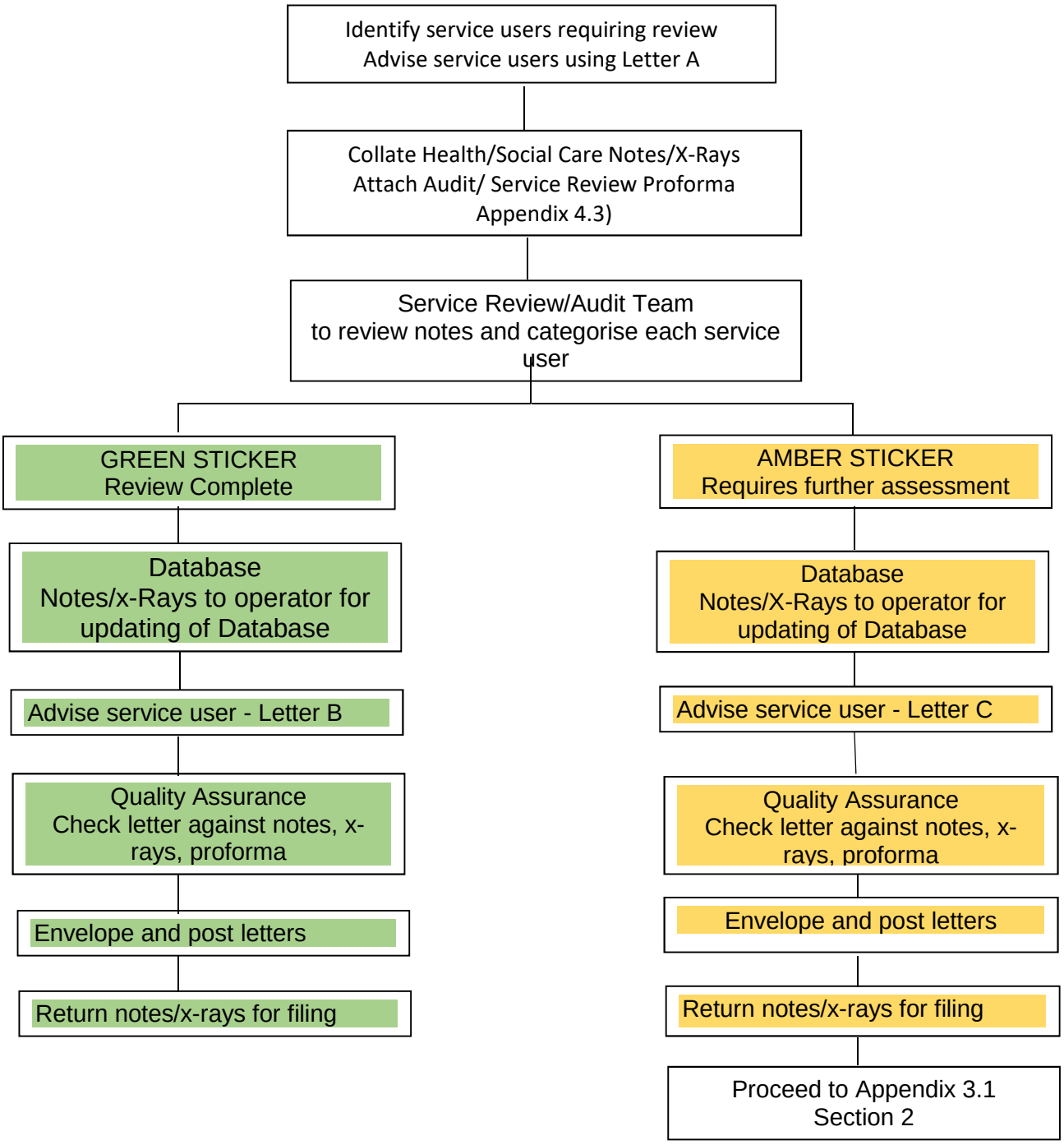
The service user database needs to be updated after completion of this proforma.

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

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

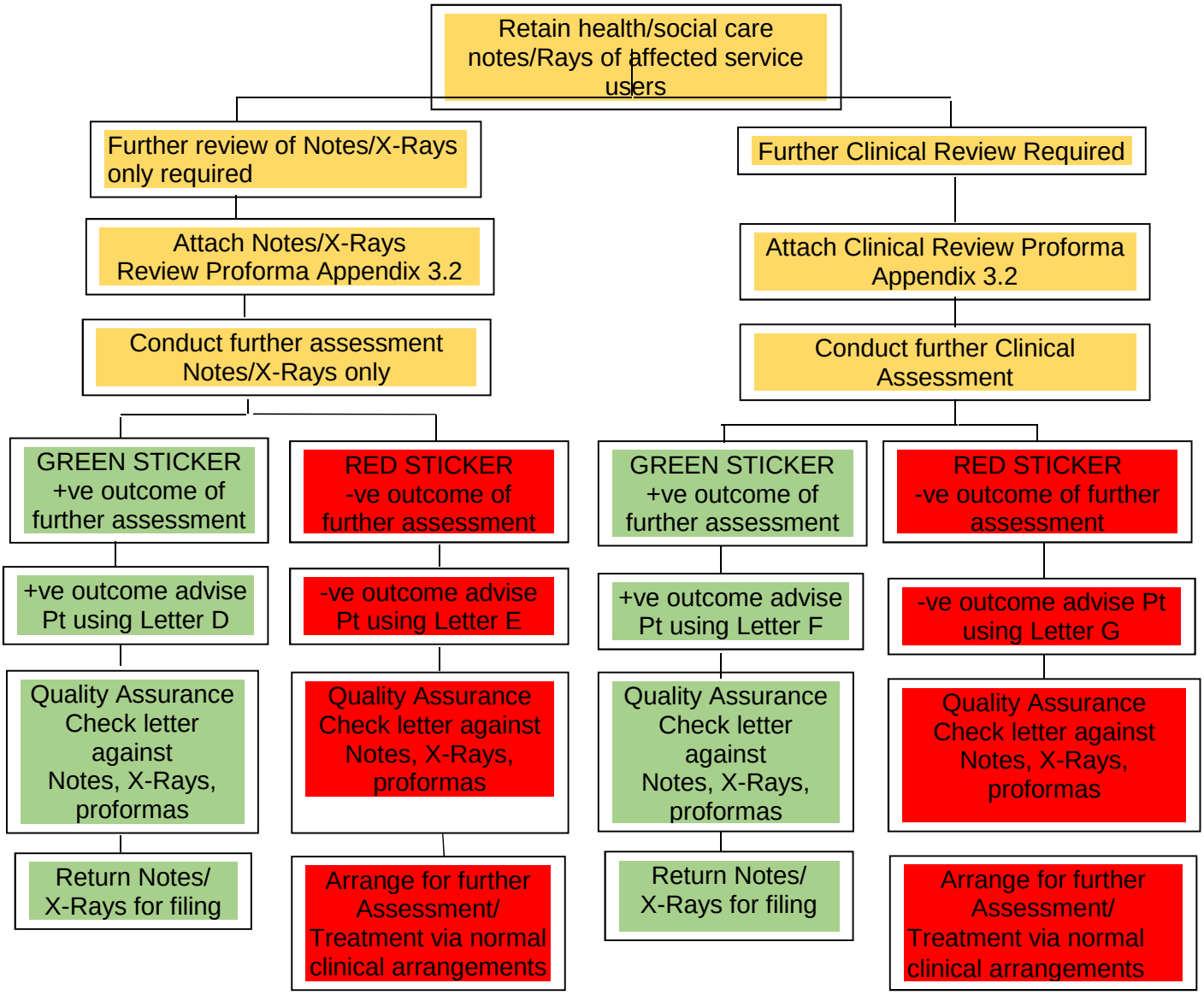
- If it has a **green** sticker attached: file into service user notes.
- If it has a **red** sticker attached: return service user notes and pro forma to admin support for processing within normal clinical arrangements.

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



Appendix 3.1 (Section 2)

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



Appendix 3.2 Service Review Proforma

SERVICE USER DETAILS (ATTACH LABEL)

CASENOTES REVIEWED ☐

X-RAYS REVIEWED ☐

OTHER MEDICAL DIAGNOSTIC/DATA REVIEWED ☐

(Give details)

DATE OF APPOINTMENT/SCAN/EXAMINATION REVIEWED ☐

REVIEWER 1

Signature & date

REVIEWER 2

Signature & date

GREEN STICKER – REVIEW COMPLETE

AMBER STICKER – FURTHER FOLLOW UP REQUIRED

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

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

LETTER SENT ☐ **(Signature & date)**

Appendix 3.3 NOTES/X RAY REVIEW PROFORMA

SERVICE USER DETAILS (ATTACH LABEL)

ADDITIONAL INFORMATION

CASENOTES REVIEWED ☐

X-RAYS/SCANS REVIEWED ☐

OTHER MEDICAL DIAGNOSTIC/DATA REVIEWED ☐

ADDITIONAL TESTS/SCANS/X-RAYS REQUIRED ☐

CLINICAL REVIEW REQUIRED ☐

REVIEWER 1

Signature & date

REVIEWER 2

Signature & date

GREEN STICKER – REVIEW COMPLETED

RED STICKER – FURTHER FOLLOW UP REQUIRED

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

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

LETTER SENT ☐ **(Signature & date)**

Appendix 3.4 CLINICAL REVIEW PROFORMA

DETAILS (ATTACH LABEL)

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

OTHER MEDICAL DIAGNOSTIC/DATA REVIEWED
(Give details)

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

CONSULTANTS SIGNATURE: _____DATE:_____

GREEN STICKER – REVIEW COMPLETED

AMBER STICKER – FOLLOW UP REQUIRED
PROCESS INTO NORMAL CLINICAL ARRANGEMENTS

RED STICKER - FOLLOW UP REQUIRED
REQUIRED URGENT REFERRAL

DATABASE UPDATED ☐ (Signature & date) _____

ADMIN QA CHECK ☐ (Signature & date) _____

LETTER SENT ☐ (Signature & date) _____

Appendix 3.5 DRAFT LETTERS

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

The following are provided for suggested content only.

LETTER A: Advising of a Lookback Review Process

LETTER B: No further follow up required

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

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

LETTER D: Positive outcome of further assessment – Notes only

LETTER E: Negative outcome of further assessment –Notes only

LETTER F: Positive outcome of further assessment – Clinical

LETTER G: Negative outcome of further assessment – Clinical

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

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

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear < Title>

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

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

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

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

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

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

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

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

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

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER B: No further follow up required

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

<Title of Lookback Review Process>

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

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

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

Yours faithfully

(Chief Executive/Director of HSC Organisation)

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

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

<Title of Lookback Review Process>

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

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

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

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

Yours faithfully

(Chief Executive/Director of HSC Organisation)

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

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

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

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

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

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

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

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

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

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER D: Positive outcome of further assessment – Notes only

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

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

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

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

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

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

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

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER E: Negative outcome of further assessment – Notes only

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

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

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

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

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

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

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

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER F: Positive outcome of further assessment – Clinical

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

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

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

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

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

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

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

Yours faithfully

(Chief Executive/Director of HSC Organisation)

LETTER G: Negative outcome of further assessment – Clinical

Healthcare Reference Number

Confidential Addressee Only

DD Month Year

Dear <*Title*>

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

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

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

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

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

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

Yours faithfully

(Chief Executive/Director of HSC Trust)

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

Service user name & address

Dear <*Doctor Name*>

<Title of Lookback Review Process>

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

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

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

Yours Faithfully

(Chief Executive/Director of HSC Organisation)

Appendix 4 Setting up a Service User Helpline or Information Line

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

The following points should be considered by the Steering Group:

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

Identification of Venue for Helpline/Information Line

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

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

Briefing Paper for Helpline Staff

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

Production of Algorithms

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

Production of Key Messages

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

Production of Proforma

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

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

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

Production of Rotas

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

Staff Briefing

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

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

Appendix 5 Lookback Review Process Guideline – Process Checklist Template

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

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

Policy for Implementing a Lookback Review Process

Final draft

Contents

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

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

Lookback Review Policy

1.0 Introduction

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

A Lookback Review is a process consisting of four stages;

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

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

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

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

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

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

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

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

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

2.0 Purpose

The purpose of this policy and regional guidance is to ensure a consistent, coordinated and timely approach for the notification and management of

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

potentially/affected service users carried out in line with the principles of openness and candour, [4] [5] [6] whilst taking account of the requirements of service user confidentiality and Data Protection. [7] [8]

3.0 Objectives

The objectives of this policy are to:

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

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

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

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

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

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

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

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

4.0 Scope

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

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

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

5.0 Roles and Responsibilities

5.1 The Chief Executive is responsible for:

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

- Reporting the rationale for the implementation of a Lookback Review Process to the DoH, HSCB and PHA as appropriate and as per extant guidance; [10] [11]
- Ensuring that the Lookback Review process is conducted with openness and transparency; and
- Providing service users, families and/or carers with a meaningful apology, where appropriate;
- Communicating the findings of the Lookback Review Process to the HSC organisation's Board and to the DoH, HSCB and PHA as appropriate and as per extant guidance. [12] [13]

5.2 The Oversight Group/Steering Group is responsible for:

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

[10] DoH. (SQSD) 5/19. *Op.cit.*
[11] HSCB. November 2016. *Op.cit.*
[12] DoH. *Op.cit.*
[13] HSCB *Op.cit*
[14] DoH. HSCB. *Loc. Cit.*

- Ensuring that the impact on ‘business as usual’ for all service users is assessed and reported on;
- Ensuring that service managers implement contingency plans for service continuity where necessary, including providing for additional health care demands which may arise as a consequence of the Lookback Review Process, this should include service users not included in the ‘at risk’ cohort who also may be affected by the impact on services as a result of the Lookback Review Process;
- Ensuring that arrangements are in place to provide support to both service users and staff e.g. counselling and welfare services;
- Ensuring that service managers allocate the necessary resources to implement the Lookback Review Process and to meet associated demands;
- Ensuring communication at the appropriate time and implementation of recommended actions arising from the Lookback Review Process.

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

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

5.4 The HSC Organisation Board of Directors is responsible for:

- Ensuring appropriate oversight of the Lookback Review and that this is reflected within the organisation's system of governance e.g. risk register;
- Satisfying itself that the Lookback Review Process is being undertaken in line with extant policy;
- Satisfying itself that the Lookback Review Process has been appropriately resourced in terms of funding, people with relevant expertise, access to expert advice and support, IT and any other infrastructure required;
- Satisfying itself that the impact of the Lookback review process on 'Business as Usual' is assessed, monitored and reported on with mitigating measures in place where possible;
- Satisfy itself that required actions identified by the Lookback Review Process are implemented;
- Providing challenge, management advice/guidance and support to the Lookback Review Commissioning Director and the Lookback Review Steering Group as required.

5.5 The Public Health Agency is responsible for;

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

5.6 The Health and Social Care Board is responsible for;

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

- Monitoring compliance with the HSCB ‘Procedure for the Reporting and Follow-up of Serious Adverse Incidents’;
- Assisting with the dissemination of learning from the Lookback Review Process.

5.7 The Department of Health is responsible for;

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

6.0 Legislative and Regional Guidelines

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

Southern Health and Social Care Trust

Quality Care - for you, with you

Our ref:

Date: 27th April 2021

Seán Holland
Deputy Secretary, Social Services Policy Group/ Chief Social Work Officer
Department of Health
Castle Buildings
Belfast

Dear Seán

MENTAL CAPACITY ACT (NI) 2016 LEGISLATION

On the 12th November 2020 you wrote formally to each of the regional Health and Social Care Trusts requesting an extension of the implementation period for the Mental Capacity Act (2016) and the protection from liability. The extension to the implementation period was made based on the recognition of pressures faced by Health and Social Care Trusts relating to the COVID-19 pandemic. The original date for the criminal offence of unlawful detention was due to commence 2nd December 2020, the extended implementation period revised this date until 31st May 2021.

In January 2021, all Trusts wrote to you to alert to the continuing impact of the COVID-19 pandemic on regional Health and Social Care Trusts' ability to comply with the Mental Capacity Act (NI) 2016 legislation.

Commented [A1]: Was this individual or collective response

Each of the Health and Social Care Trusts has endeavoured to meet this deadline by engaging a range of options which have included offering additional hours and shifts and identifying additional staff to conduct this work. Specifically, to mitigate the impact of COVID-19, each regional Trust initiated a local contingency action plan to support the completion legacy cases which requires a Deprivation of Liberty Safeguards (DoLS) assessment. However despite these concerted efforts, prioritisation of critical

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

service needs did not allow for these tasks to be completed within the designated timescales.

It is important to recognise the legislative changes associated with the introduction of the Mental Health Act (2016) are comparable both in scope and scale to those introduced by the Children's Order (1995) which introduced important legislation for protection of children including those relating to emergency protection. It is of note the introduction of this previous legislation was accompanied by a range of training and organisational supports to ensure that health and social care organisations met their legal requirements. In particular there was no attempt to introduce individual criminal offences for non-compliance with the statutory framework.

The section below sets out the challenges faced by the Trusts in meeting the 31st May 2021 implementation deadline.

Absence of a Code of Practice
It is of concern given the significant implications of the legislation for service users and staff that a designated code of practice to complement the legislation has not been developed. A code of practice that would provide detailed practical guidance on how to comply with both organisational and individual legal obligations we believe is essential for successful implementation.

Engagement of General Practitioners (GPs)
While there are particular implications for work in respect of legacy cases, the continued absence of involvement from GP colleagues presents additional challenges to the longer-term work requirements. The Trusts are of the view that renewed efforts to enable GP meaningful engagement, particularly in relation to community cases where their extensive and developed patient knowledge brings particular value, would be very beneficial. It is noted that with the ongoing requirement for COVID-19 centres and the regional vaccination programme, significant GP input will be difficult to obtain in the short term.

Trust Medical and Non- Medical Staffing Capacity
The implementation of the Act places a heavy reliance on medical staff. Each of the Trusts has made significant efforts to ensure the availability of key medical personnel to support this work. However recruiting all staff with the requisite skills and

experience has proven challenging despite the introduction of numerous and varied recruitment strategies.

DoLS Documentation
The process for completing DoLS documentation is detailed and is more extensive than the provision of a clinical summary by the attending practitioner. This has led to Attorney General's office not accepting documentation that is deemed not to have met a 'gold standard', which has resulted in delays in process. Delays are also occurring regarding the requirement to complete Rule 6 Statements for Review Tribunals and 1st and 2nd extensions are being prioritised to avoid DoLS lapsing. This is reducing teams' capacity to progress new and legacy DoLS.

Department of Legal Services (DLS) Advice
Trusts have collectively sought legal advice on the impact of the Act given the likelihood that all Trusts will be non-compliant by the time of the current deadline.
DLS have considered the legislation which has the potential for making numerous deprivations of liberty where Trusts and individual staff are acting in the best interests of individuals to keep them safe will become criminal offences. DLS have noted that the new offences of unlawful detention will be unique to Northern Ireland and that no such similar offences currently exist in England and Wales, Scotland or the Republic of Ireland.

COVID-19 Related Challenges
COVID-19 pressures have significantly impacted on the Trust's ability to meet the deadline. This includes Surge 3 which particularly impacted access to facilities and to key nursing staff. Also Trusts have been unable to redeploy staff in sufficient numbers to undertake work relating to the implementation of the Act.

Despite these challenges each Trust is continuing to operationalise, manage and monitor contingency plans to meet the requirements of the Act in full.

As referenced in your 12th November 2020 correspondence we remain cognisant of the importance of deprivation of liberty safeguards and the role they play to protect some of the most vulnerable people in our community and to ensure that people's autonomy is protected.

As a result of the continuing impact of the COVID-19 pandemic on the delivery of Trust services we are formally asking as a collective group for the Department of Health to provide a further extension of this implementation phase to allow for the full operational delivery of the requirements of the Act and consider additional supports as set out above to ensure its successful implementation.

As Chief Executives we believe that providing a further extension on the implementation period and delaying the commencement of the criminal offence of unlawful detention will continue to provide a lower risk and safer option for service users and staff moving forward.

Yours sincerely

Southern Health and Social Care Trust

Nosocomial COVID-19 Deaths Mortality Review Process

Version 1

Date: 23rd March 2021

Southern Health and Social Care Trust

Background

1. COVID-19 has been extensively documented as a particularly potent and virulent nosocomial infection that can spread easily in health care settings in part due to the increased susceptibility to infection among patients with co-morbidities and those who are immunocompromised.

2. As a result of the COVID-19 pandemic the Trust has experienced to date (23rd March 2021) 392 patient deaths where COVID-19 was recorded on either Part 1 or 2 of their death certificate.

3. As part a key element of Patient Safety, the Trust operates a Morbidity and Mortality review process that as part of its function reviews and quality assures the care we provided to our patients who die while resident under our care.

4. Given the scale and spread of COVID-19 and the subsequent number of deaths that record COVID-19 as a factor the Trust has developed a stratified review approach that utilises the Public Health Agency algorithm for assigning probability of COVID-19 resulting from nosocomial source, the Royal College of Physicians Structured Judgement Review and the regional Serious Adverse Incident review processes.

Mechanism of Review

The stages of the review process are as follows, a flow chart of actions is attached below

Identification of Patients with COVID-19 as a Cause of Death

5. Patients with COVID-19 recorded on their death certificate are held in electronic form by the MDO Patient Safety team. The Trust COVID-19 'App' allows for the automatic identification of patients according to the Public Health Agency definitions of Indeterminate, Probable and Define hospital onset of COVID-19.

Southern Health and Social Care Trust

Information Collation

6. The Post Infection Review form will be initially pre-populated with patient information from electronic records by the MDO support team (Medical Technicians). The IPC team will review the content of the forms for completeness.
7. A Structured Judgement Review will be conducted by one of the Trust trained Medical reviewers, pending the outcome score a second, verification will be required if concerns in care are identified by the first reviewer.

Serious Adverse Incident Process

8. For those cases where the Structured Judgement review outcome indicates potential issues with care, the case will be considered for adverse incident screening and if required enter in to the Serious Adverse Incident review process.

Sharing of Learning from Nosocomial COVID-19 Mortality Reviews

9. Where learning has been identified from either post infection review, Structured Judgement Review or Serious Adverse Incident process this will be shared with Trust Morbidity and Mortality meetings and via other relevant Trust shared learning mechanisms.

Mortality Sign Off by M&M Chairs

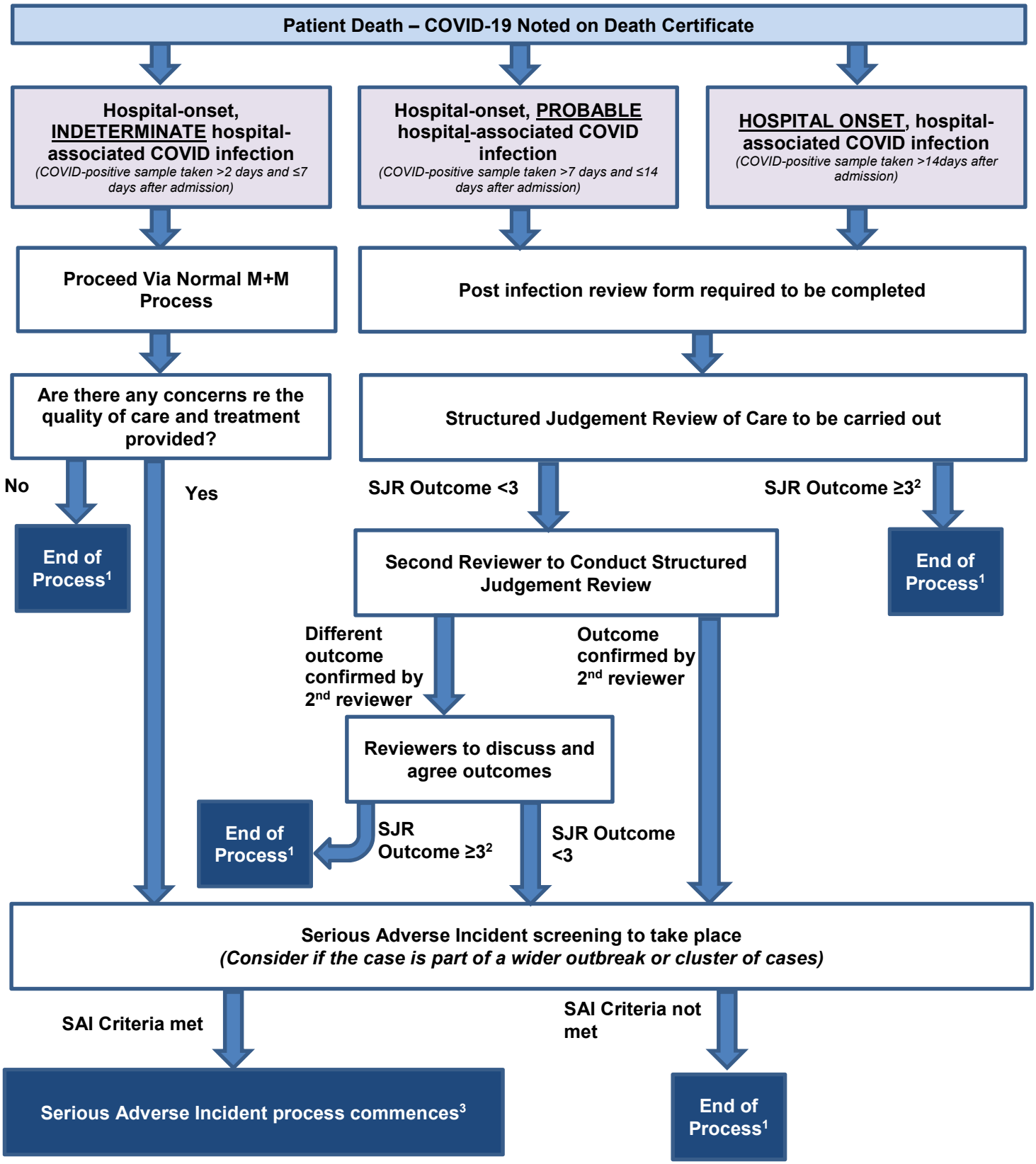
10. M&M Chairs will be asked to suspend full sign off of cases either found to be a result of probable or define nosocomial transmission pending completion of the Nosocomial mortality review process.

Timescales for Delivery

11. It is anticipated that based on the number of cases requiring review this process will take approximately 3 months to complete.

Southern Health and Social Care Trust

Appendix 1 - Nosocomial COVID-19 Deaths Mortality Review Process



[1]A Generic theme analysis will be conducted for all cases. Any relevant learning shared including via M+M. This will include areas of good practice and any assessment of problems identified.
[2] If there are there any concerns re the quality of care and treatment provided consideration should still given as to whether this reaches the threshold for an SAI?
[3]Any relevant learning shared including via M+M.

Received from Maria O'Kane on 02/09/22. Annotated by Urology Services Inquiry

Southern Health and Social Care Trust

Appendix 2 – Post Infection Review Form

Addressograph	**Confidential** (When completed) **COVID-19 MORTALITY Information (SHSCT)**

Name		**Gender**	**F/M**
HSC			
D.O.B		**AGE**	
Address			
Consultant			
Speciality			
GP			
Hospital of 1st Admission			
ED Admission	**Yes/ No**		
Planned Admission	**Yes/ No**		

DIAGNOSIS

Presenting complaint	

Patient outcome (at point of completing this form) tick appropriate

Fatal		**Non-Fatal**	

Frailty Score (if known)

Charlson co-morbidity score	

CURRENT ADMISSION

Southern Health and Social Care Trust

Date of Admission	
Date of death	
No of days between death/ discharge and admission	

If admitted from a long term care facility, name of facility	
Was the facility known to have a COVID-19 outbreak at that time?	

PREVIOUS ADMISSION within 14 days prior to positive test: **YES/NO**
If YES, please give detail test

Place (please note location if known)	Date of Admission	Date of Discharge	Length of stay

MOVEMENT OF PATIENT DURING CURRENT ADMISSION Ward(s): Please list all the wards and bed moves with dates where the patient have been during this admission (including bed spaces)

Hospital and Ward	Bed location (BAY and BED NO)	Single room YES/ NO	Dates	Duration of stay

Total number of bed moves during episode, EXCLUDING ED:	**0**

Southern Health and Social Care Trust

How long after covid positive test was patient isolated? (hours)	0

RISK FACTORS

Older age ≥ 70 years			
Cardiovascular Disease			
Chronic Respiratory Disease			
Renal Disease			
Diabetes			
Hypertension			
Cancer			
Chemotherapy or immunosuppressive agents and/or steroid			
Obesity: BMI: ≥ 30			
Smoker			
BAEM			
Other			

TESTING

Covid Type Result: Circle as appropriate	Group 1	Group 2	Other

	Yes	No	N/A

Southern Health and Social Care Trust

Was a repeat of negative screen completed within 5-7 days?			
Repeat PCR Test prior to discharge to Care Home (if relevant)			

EXPOSURE HISTORY *before* patient's positive test within 14 days of positive COVID test

Hospital setting

	Yes	No	Not available
Patient admitted via Respiratory ED			
Please note time spent in ED if appropriate			
Did patient have any contacts in previous 14 days prior to positive test with a patient who subsequently tested positive?			

COVID 19 INFORMATION OF DEATH CERTIFICATE

Death Certificate information:	
Place of Death: Please tick out as appropriate	☐ Hospital ☐ in the community within 28 days
Part 1a	
Part 1b	
Part 1c	
Part 2	

Communication with Patient	YES/ NO
Communication with Patient's relative	YES/ NO

Southern Health and Social Care Trust

M&M Summary Attached (if appropriate)	Yes

Additional Information and Comments

Root Cause Analysis

Root Cause Analysis			
Contributory Factors		Tick relevant boxes	
1. Communications and team working		6. Policy and protocol	
2. Training, skills and knowledge includes use of appropriate PPE		7. Care pathway: includes failure of appropriate testing	
3. Workload and staffing resources		8. Patient-derived risk factors	
4. Environmental conditions; includes cleaning		9. Treatment-derived risk factors	
5. Equipment and utilisable resources: includes re-use of equipment		10. Failure of isolation	
		11. Visitor factors (e.g. potentially contaminated items brought in by family members).	

Issues identified (provide and explanation of the contributory factors – enter under corresponding section number)	
1	
2	
3	
4	
5	
6	
7	
8	

Southern Health and Social Care Trust

9	
10	
11	

Southern Health and Social Care Trust

Lessons Learnt / Lapses in care

Action Plans / Changes in practice to prevent further cases

Further comments / Recommendation

Completed by			
Name: (print)		Job Title:	
Signature:		Date:	
Updated			
		Date :	

Additional information:-

Southern Health and Social Care Trust
Quality Care - for you, with you

MEDICAL REVALIDATION OVERSIGHT GROUP

TERMS OF REFERENCE (20th April 2021)

Purpose

Medical revalidation is the process by which licensed doctors demonstrate to the General Medical Council (GMC) that they are up to date and fit to practice. A cornerstone of the revalidation process is that doctors participate in annual medical appraisal. On the basis of this and other information available to the Trust Responsible Officer (RO) from local clinical governance systems and additional feedback mechanisms, the RO makes a recommendation to the GMC, normally once every five years, about the doctor's revalidation.

The purpose of the Trust Medical Revalidation Group (the Group) is to provide a forum for Trust Medical Senior Management Team members to consider and inform decision regarding medical revalidation of Trust licensed doctors.

Aim and Objectives

The aim of the Group is to ensure that decisions regarding Medical Revalidation are consistent, robust and quality assured by the relevant Trust Senior Medical Leader. To meet this aim each relevant Associate Medical Director / Divisional Medical Director for doctors under their leadership will:

- Provide assurance that opportunities for reflection, learning and development e.g. significant events and complaints have been adequately discussed and reflected on appropriately at appraisal
- Ensure there is has been a formative approach taken to the doctors appraisal process and there has been an appropriate level of engagement by the doctor
- Ensure outputs are adequate and identify if additional time is required to review a doctor's portfolio before the RO's decision prior to the revalidation recommendation date
- Assure that all summaries from all sources accurately reflect the doctor's work and if the documentation is inadequate, advise the responsible officer allowing for an informed decision to be made regarding a recommendation for revalidation

- Bring to the attention of the RO any additional information that has not been captured in other sources that require the consideration of the RO prior to making a revalidation recommendation.

Membership

Members of the group shall be made up of:

- Medical Director (Chair)
- Deputy Medical Directors
- All operational Associate Medical Directors / Divisional Medical Directors
- Assistant Director – Medical Directors Office

Others may be invited by the Chair to attend all or part of any meeting as and when appropriate and necessary.

Quorum

The quorum necessary for the meeting will be each AMD / DMD or nominated deputy for each operational area.

Members should aim to attend all meetings.

Frequency of Meetings

The Group shall meet via Zoom on a monthly basis.

Group members will receive agenda and papers confidential to their area no less than five working days in advance of the meeting.

Stinson, Emma M

From: OKane, Maria
Sent: 09 December 2020 11:01
To: Wallace, Stephen
Subject: FW: IPR's

Can we discuss???

From: Gibson, Simon
Sent: 09 December 2020 08:44
To: Reid, Trudy; OKane, Maria; Wallace, Stephen
Subject: RE: IPR's

See below

Individual Performance Review

Kind regards

Simon

Simon Gibson
Assistant Director – Medical Directors Office
Southern Health & Social Care Trust
Personal Information redacted by the USI
Personal Information redacted by the USI
Personal Information redacted by the USI (DHH)

From: Reid, Trudy
Sent: 09 December 2020 08:44
To: Gibson, Simon; OKane, Maria; Wallace, Stephen
Subject: RE: IPR's

Simon I have a mental block, what is it?
Trudy

From: Gibson, Simon
Sent: 09 December 2020 08:28
To: OKane, Maria; Wallace, Stephen; Reid, Trudy
Subject: RE: IPR's

P>S – If you don't have one, I'm sure we could all help you put one together as a baseline document

Kind regards

Simon

Simon Gibson
Assistant Director – Medical Directors Office
Southern Health & Social Care Trust

Personal Information redacted by the USI
Personal Information redacted by the USI
Personal Information redacted by the USI (DHH)

From: OKane, Maria
Sent: 09 December 2020 08:26
To: Wallace, Stephen; Reid, Trudy; Gibson, Simon
Subject: FW: IPR's

What are iprs?

From: Devlin, Shane
Sent: 08 December 2020 11:07
To: Beattie, Brian; Magwood, Aldrina; McClements, Melanie; McNeany, Barney; OKane, Maria; O'Neill, Helen; Morgan, Paul; Toal, Vivienne; Trouton, Heather
Cc: Alexander, Ruth; Campbell, Emma; Stinson, Emma M; Gilmore, Sandra; Griffin, Tracy; Mallagh-Cassells, Heather; Livingston, Laura; PADirectorofP&RSHSCT; Willis, Lisa
Subject: IPR's

Dear All

At our next 1:1 meetings we will be discussing IPR's for 2019/20 and 2020/21. Can I ask that you do two things in advance of the meeting.

1. Please review your 2019/20 IPR noting achievements (up until 31st March 2020) and forward to me.
2. Based on 2019/20 IPR produce for 2020/21 a roll forward of those items not achieved in 2019/20. I would then suggest a general statement, which I will prepare, to go into all IPR's with regards to managing the organisation through the COVID-19 pandemic

Given the year of COVID we have had, I think this is a fair approach to IPRs for 2020/21.

We will for 2021/22 have a modified approach and I will discuss this further.

Many thanks, Shane

Version 5 – 11th February 2021

Principles for the Management of Surgical Paediatric Patients up to their 16th Birthday

1) Introduction

These principles have been developed to provide clear guidance with regards to the admission and management of children and young people up to their 16th birthday with surgical presentations.

Children and young people before their 16th birthday will be admitted to the Blossom Children's and Young People's Unit, Craigavon or Daisy Children's and Young People's Ward Daisy Hill Hospital.

2) Exclusions

Young People excluded from these admission arrangements are those with specific specialist needs where they will be admitted to the specialist areas with support from Paediatric teams if requested:

- Trauma & Orthopaedics (T&O)
- Obstetrics & Gynaecology (OG)
- Emergency Department (ED)

Children and Young People up to their 16th Birthday with Diabetic Ketoacidosis (DKA) will be admitted to the CYP wards. Young adolescents 16 -18 years in DKA will be admitted to adult wards under the care of General Physicians with support and advice as requested from Paediatric Consultants; the paediatric DKA Pathway will be used in the management of these young people.

3) Purpose and Scope

a. This guidance is aligned with the following documents:

- the Royal College of Surgeons documents "Working together to improve the local delivery of the *General Surgery of Childhood - Statement of Intent (2018)*[1] and *Standards for Non Specialist Emergency Surgical Care of Children (2015)*[2]

- The recommendations from Inquiry into Hyponatraemia-related Deaths (IHRD) Clinical Workstream 4

a. The Southern Health and Social Care Trust is committed to providing safe, appropriate local surgical care to paediatric patients presenting to the Trust in both elective and non-elective settings. Each paediatric surgical patient will be in the care of a named Surgeon. Where specialist Paediatric input is required the 'Paediatrician of the Week' (and their Paediatric medical team) will be available to discuss the case and provide guidance.

b. Where Paediatric input has been sought from the 'Paediatrician of the Week' the Paediatricians name will be recorded in the child's notes. Equally, children who are under the care of a Paediatrician who require discussion or advice is the Surgical Team will have the Consultant Surgeon name recorded in the notes.

c. Paediatric patients are defined as all patients up to their 16th birthday.

d. The working practices outlined in this paper relate to children (<16yrs) admitted under the care of any surgical specialities within Southern Health and Social care trust, including to General Surgery, Urology, ENT, Trauma and Orthopaedics and Gynaecology. References in this document to surgery / surgical patients refer to children & young people under the age of 16 admitted under the care of any / all of these specialities. This excludes admissions requiring the admission to be into maternity services units'

e. The IHRD report highlighted some risks of current, established care pathways in the management of children, in particular with regards fluid management in the sick child.

f. Regional working group (clinical workstream 4) established to examine the recommendations of the O'Hara report have highlighted that some recommendations

[1] Working together to improve the local delivery of the General Surgery of Childhood, Royal College of Surgeons (2018) https://www.rcseng.ac.uk/-/media/files/rcs/library-and-publications/non-journal-publications/final_workingtogethertoimprovethelocaldeliveryofthegeneralsurgeryofchildhood_110618.pdf

[2] Standards for Non Specialist Emergency Surgical Care of Children, Royal College of Surgeons (2015) https://www.rcseng.ac.uk/-/media/files/rcs/standards-and-research/standards-and-policy/service-standards/childrens-surgery/service-standards-for-csf-final-published-101215.pdf

(e.g. recommendation 12 'Senior paediatric medical staff should hold overall patient responsibility in children's wards accommodating both medical and surgical patients) would not provide the care required by children and young people requiring surgical intervention/management'. The trust is committed to establishing working patterns and care arrangements which intend to mitigate the deficiencies in care highlighted in the findings of the O'Hara report.

1) Southern Trust recognises that current surgical training programmes in Northern Ireland provide limited exposure to surgery in childhood and in particular limited exposure to the recognition and management of the deteriorating / sick paediatric patient.

2) Southern Trust also recognises that established surgical consultants manage small numbers of children during their ongoing practice, and in particular manage very small numbers of sick children or those requiring IV fluid replacement or those with long term medical conditions (eg diabetes). In recognising this, Southern Trust recognises that surgical consultants are not able to provide adequate clinical supervision of junior surgical care of trainees in these aspects of care.

3) Southern Trust recognises that Paediatric teams have limited exposure and training in the management of surgical conditions.

4) While patients can only be admitted under the care of a single consultant, Southern Trust recognises that different individuals may provide inputs into specific aspects of a patients care. In such collaborative working, responsibilities for different aspects of a patients care are shared by the clinical teams. For example a patient with diabetes may be admitted with appendicitis and cared for during the admission by the surgical team and paediatric team. The surgical team would be responsible for the surgical aspects of care while the paediatric team would be responsible for management of the child's diabetes with the consultant surgeon as the named consultant. The Southern Trust recognises that clinicians providing input and advice on patients under the care of another clinician are responsible for this aspect of the patients care.

4) Southern Trust Inpatient / Day Case Paediatric Surgical Services

a. Paediatric surgical services are provided to children on the Craigavon Area Hospital and Daisy Hill Hospital sites (?and south Tyrone for children aged 14-16 eg T&O??).

b. Elective orthopaedic inpatient / day case treatments are only provided to children aged 14-16 in Southern Trust as per current commissioning arrangements.

c. Unscheduled care for paediatric surgical patients is provided in Daisy Hill Hospital (General Surgery and Gynaecology) and Craigavon Area Hospital (General Surgery, ENT, Urology, Gynaecology). Unscheduled orthopaedic services (Fracture services) are provided to children aged 14-16 in Craigavon Area Hospital.

d. Assessing and treating the very young presents specific surgical challenges which necessitate specialist skills. The trust guideline (Guideline Policy as to who should Operate on and Anaesthetise Children for Elective and Emergency Paediatric Surgery in Southern Health & Social Care Trust) recognises this and children under the age of 5 should be transferred for specialist care in the Royal Belfast Hospital for Sick Children (RBHSC) unless their treatment is time critical and can be safely assessed and treated by the available anaesthetic and surgical team in Southern Trust. Similarly assessing children with special educational needs can on occasion present specific diagnostic challenges which may necessitate a skill set outside of those possessed by the available Southern Trust surgical team.

e. Unscheduled care provided to children in Southern Trust includes the management of;

i. Minor injuries (DHH and CAH)

ii. Appendicectomy (DHH and CAH)

iii. Testicular torsion / acute scrotum (DHH and CAH)

iv. Abscesses (DHH and CAH)

v. Lifesaving surgery, including trauma, this includes the initial management and stabilisation of paediatric trauma patients in the Emergency Department (DHH and CAH)

vi. Outpatient only fracture services (<14) (DHH and CAH)

vii. Inpatient fracture services (14-16) (CAH)

viii. Isolated Head injuries; below the age of 5 should be managed by the paediatric teams. Children over the age of 5, with minor head injuries, can be admitted for observation under the general surgical team. However, if the mechanism of injury is significant, or the child has multiple trauma, or a CT scan indicates ANY traumatic intracranial /head pathology the child should be referred to and transferred to RBHSC.

ix. ENT conditions refer to ENT protocol

x. Gynaecology refer to Gynaecology protocol

Management of conditions outside of this scope of practice may be carried out in Southern Trust where it lies within the competencies and expertise of individual consultants. However, where the locally available team do not have the required surgical expertise to treat conditions outside of these conditions it is expected that the child will be referred to the specialist paediatric surgical team in RBHSC.

5) Principles for Unscheduled Care Of Children

a. Most children admitted acutely in Southern Trust have uncomplicated inpatient stays and can be primarily managed by the admitting surgical team.

b. Small numbers of children have a more complex inpatient stay including, requirement for intravenous fluid resuscitation /maintenance, management of long term co-existent medical conditions or show deterioration in their paediatric early warning scores.

c. Some children may be admitted surgically with ongoing symptoms but without a surgical diagnosis. Similarly children may be admitted under the paediatric team with ongoing symptoms that may be explained by a surgical diagnosis.

d. Expertise for managing some specialist paediatric surgical conditions does not exist within either the surgical or paediatric teams in Southern Trust.

e. Paediatric and Surgical teams are committed to collaborative working within a shared care principle, with the teams agreeing responsibilities in patients requiring input from both teams.

f. Surgical trainees will have undertaken their BMJ hyponatraemia module and have completed in house training on prescribing IVF in children with the paediatric team. Prescriptions for short term (<24hrs), peri-procedural maintenance IVF will be prescribed by the surgical and / or anaesthetic team and the paediatric medical team will be available for assistance to support at all times.

g. Simple prescriptions, such as those for simple analgesia (eg ibuprofen and paracetamol) and oral antibiotics require dose calculations according to the patients weight and such prescriptions can and should be safely managed by the surgical team. Any concerns regarding dose should be raised with the appropriate team. Nurses and Pharmacists have a responsibility to ensure medications are prescribed in accordance with

professional standards and concerns raised by these members of staff should also be addressed appropriately.

h. More complex prescribing including prescription of IV antibiotics and IV fluid prescriptions, except short term peri-procedural maintenance IVF (as per 'f'), should be discussed with the paediatric team by the surgical juniors and this consultation detail and outcome clearly recorded in the notes including the name of the doctor giving the advice. IV fluid prescriptions should comply with Trust's IV fluid prescribing guidelines / hyponatraemia monitoring. Any advice provided should/must be recorded in the patient's notes in accordance with good clinical practice.

i. All children admitted under the care of the surgical team with long term conditions requiring medical treatment (eg diabetes) should have daily paediatric review specifically with regards the management of these medical conditions during their inpatient stay.

j. All children (under paediatric and surgical care) receiving IV fluids are discussed at the Paediatric safety huddle/ handover. The surgical team are welcome to attend the safety huddle. All surgical patients on IVF will be discussed with the surgical team at handover safety brief by paediatric team (9:00am and 4:45pm) to enquire re any concerns.

k. Foundation doctors in surgery form part of the clinical team and will be involved in the inpatient management of surgical paediatric inpatients. When assessing paediatric surgical inpatients, all input and decision making will be supervised by more senior surgical trainees (core trainee and above). Foundation doctors in surgery should always seek assistance from a doctor who is competent in prescribing IVF (Post foundation) when prescribing IV fluids and the IVF prescription will be co-signed by the paediatric doctor who provides input at the earliest opportunity. This support is available for all surgical trainees as required.

l. For children in whom there is no surgical diagnosis and ongoing symptoms should be referred to the paediatricians for review and joint discussion on ongoing care / management including consideration of seeking a specialist paediatric surgical opinion and agreement on responsibility for ongoing inpatient care. The reverse principle applies to children under the care of the paediatric team who have symptoms which may be attributable to a surgical diagnosis ie they should be referred to the surgical teams for review and joint discussion on ongoing care / management including consideration of seeking a specialist paediatric surgical opinion and agreement on responsibility for ongoing inpatient care.

m. All children admitted under the care of the surgical team, who are deteriorating on their Paediatric early warning score should be assessed by both the surgical team and paediatric team and a joint discussion regarding ongoing management should occur.

n. Children requiring surgical treatment outside of the expertise of the local surgical team should be referred to and transferred urgently to the specialist paediatric surgeons at RBHSC, and receive appropriate resuscitation / stabilisation with the input of surgical, anaesthetic and paediatric teams as required.

o. A clear unambiguous pathway for transfer of paediatric surgical patients to Belfast needs to be established. This is appropriate when experienced surgical staff feel that the resources (technical and physical) required by the patient have been exceeded in their present location (DHH or CAH), and ongoing care requires superior resources and expertise elsewhere.

p. Any child judged to require laparotomy should be transferred to Belfast EXCEPT in cases of emergency (no other option). DHH and CAH lack the resources and expertise for post-operative management of these cases.

q. In the spirit of shared care for the child, the surgical team may require assistance from the paediatric medical team with fluid or medicine prescriptions for a child under their care if they are unavailable in theatre, to enable timely care. Similarly, if imaging results are made available to the surgical team, and show significant non surgical pathology, the paediatric medical team are expected to provide input, and take over care where appropriate, upon request By surgical team

r. Nursing staff, using professional and objective criteria eg PEWS, must contact medical teams, surgeon or paediatrician as appropriate if there are concerns with a patient's condition.

DR MARK HAYNES
ASSOCIATE MEDICAL DIRECTOR
SURGERY AND ELECTIVE CARE

DR AHMED KHAN
ASSOICATE MEDICAL DIRECTOR
CHILDREN AND YOUNG PEOPLES SERVICES

Stinson, Emma M

From: Wallace, Stephen
Sent: 05 May 2021 09:02
To: Reid, Trudy; OKane, Maria
Subject: RE: Letter re SAI Procedures

Thanks Trudy,

Further to this I doubt the Trust would have the legal authority to access the required details for a full outbreak review, access to non-Trust residents and staff would make a full review all but impossible.

A much more pragmatic and sensible approach would be for the PHA to develop a pandemic outbreak review template (potential SJR based) for completion by the PHA and care home collectively. Its not a dissimilar solution to what we are doing for COVID mortality

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From: Reid, Trudy
Sent: 04 May 2021 23:13
To: OKane, Maria; Wallace, Stephen
Subject: RE: Letter re SAI Procedures

Maria reviewing the guidance, I don't think it's as straight forward as 'overseeing the SAI in line with the regional SAI procedure' the here are some of the elements I thing guide us . The guidance would not have been written in the context of a pandemic where the PHA have responsibility for the management of COVID outbreaks as noted in the Draft Regional Infection Prevention and Control Framework for Northern Ireland. The HSC Trusts have been asked to provide IPC input/support to the homes, however, it is my understanding the PHA still get regular/daily updates from homes, give advice and formally close the outbreaks).
Some of the sections of note are
3.3 In*cidents that occur within the Independent /Community and Voluntary Sectors (ICVS) SAIs that occur within ICVS, where the service has been commissioned/funded by a HSC organisation must be reported. For example: service users placed/funded by HSC Trusts in independent sector accommodation, including private hospital, nursing or residential care homes, supported housing, day care facilities or availing of HSC funded voluntary/community services. These SAIs must be* ***reported and reviewed by the HSC organisation who has****: - referred the service user (this includes Extra Contractual Referrals) to the ICVS; or, if this cannot be determined; - the HSC organisation who holds the contract with the IVCS. HSC organisations that refer service users to ICVS should ensure all contracts, held with ICVS, include adequate arrangements for the reporting of adverse incidents in order to ensure SAIs are routinely identified. All relevant events occurring within ICVS which fall within the relevant notification arrangements under legislation should continue to be notified to RQIA….*

3.6 Reporting of SAIs to RQIA- ***RQIA have a statutory obligation to investigate some incidents that are also reported under the SAI procedure****. In order to* ***avoid duplication of incident notification and review****, RQIA will work in conjunction with the HSCB/PHA with regard to the review of certain categories of SAI. In this regard the following SAIs should be notified to RQIA at the same time of notification to the HSCB: -*

- *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 (whether statutory or independent) for a service that has been commissioned/funded by a HSC organisation.*

It is acknowledged these incidents should already have been reported to RQIA as a 'notifiable event' by the statutory or independent organisation where the incident has occurred (in line with relevant reporting regulations). This notification will alert RQIA that the incident is also being reviewed as a SAI by the HSC organisation who commissioned the service. –
The HSCB/PHA Designated Review Officer (DRO) will lead and co-ordinate the SAI management, and follow up, with the reporting organisation; however for these SAIs this will be carried out in conjunction with RQIA professionals. A separate administrative protocol between the HSCB and RQIA can be accessed at Appendix 15.

Can also be considered under MOU as it could be applied when considering an incident in a family doctor or dental practice, or for a person receiving private health or social care provided by the HSCS.

Level 2 RCA reviews may involve two or more organisations. In these instances, it is important a lead organisation is identified but also that all organisations contribute to, and approve the final review report (Refer to Appendix 13 Guidance on joint reviews/investigations)…..

Appendix 13 notes
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.***

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.*

Happy to discuss

Regards,

Trudy

From: OKane, Maria
Sent: 01 May 2021 19:13
To: Reid, Trudy; Wallace, Stephen
Subject: FW: Letter re SAI Procedures
Importance: High

What does this mean exactly?

From: Reid, Trudy
Sent: 30 April 2021 22:21
To: OKane, Maria; Wallace, Stephen; Gormley, Damian; Diamond, Aisling; Doyle, Caroline; Beattie, Brian; Devlin, Shane
Subject: FW: Letter re SAI Procedures
Importance: High

Dear all please see attached letter received today from Rodney Morton and Brendan Whittle in relation to lead responsibility for SAI's in care homes.

Regards,
Trudy

Trudy Reid

Interim Assistant Director Corporate Clinical & Social Care Governance and Infection Prevention & Control
Craigavon Area Hospital
SHSCT
Mobile Personal Information redacted by the USI

From: OHara, Annette
Sent: 30 April 2021 11:10
To: Reid, Trudy; Wellwood, Gemma; Hedderwick, Sara; Boulos, Angel; McKeating, Cara; Donnelly, Claire Mary; Lewis, Kevin; Kelly, Kate; Rennie, Elizabeth; Lynch, Dymphna; Clarke, Colin; McClughan, Naomi; Soye, Barbara
Subject: FW: Letter re SAI Procedures
Importance: High

FYI

Kind regards
Annette

From: Hannah Gamble [mailto Personal Information redacted by the USI]
Sent: 30 April 2021 10:44
To: Bob Brown (WHSCT); Beattie, Brian; Gillian Traub (BHSCT); Nicki Patterson (SEHSCT); Roy Hamill (NHSCT); Brenda Creaney (BHSCT); Catherine McDonnell; Lynne Charlton; OKane, Maria; Nicki Patterson (SEHSCT); Suzanne Pullins (NHSCT); sinead.okane Personal Information redacted by the USI ; Adverse Incidents North (HSCB); 'caroline.doyle Personal Information redacted by the USI '; Corporate.Governance; 'martine.mcnallly Personal Information redacted by the USI ; 'SeriousAdverse.Incidents Personal Information redacted by the USI '; 'therese.brown Personal Information redacted by the USI '; 'adverse.incidents Personal Information redacted by the USI '; 'claire.cairns Personal Information redacted by the USI ; 'SeriousAdverseIncident Personal Information redacted by the USI '
Cc: Rodney Morton; Ruth Lockhart; Brendan Whittle; Margaret Blakley; Denise Boulter; Caroline McGeary; serious incidents; OHara, Annette; Caroline McGeary; Claire Fitzsimons; Clare Robertson; McDonagh, Denise; Emily Roberts; Fiona Hughes; Gillian Clarke; Grace Doherty; Hannah Gamble; Isobel.king Personal information redacted by USI Janeen McKeown; Jean Gilmour; Jonathan Montgomery; Karen Scarlett; Karen Devenney (BHSCT); Maxine Gibson; Naomi Baldwin (NHSCT); Pauline McMullan; Philip Boyle; Rodney Morton; Ruth Donaldson; Ruth Finn; Ruth Robb; Shaunagh Small; Siobhan Donald; Thomas Hughes; Wendy Cross
Subject: Letter re SAI Procedures
Importance: High

Dear all

Please see attached letter from Rodney Morton, Executive Director of Nursing, Midwifery and Allied Health Professionals PHA and Brendan Whittle, Director of Social Care and Children & Executive Director of Social Work HSCB in relation to SAI Procedures.

Many thanks

Hannah

Hannah Gamble
Project Manager for Infection, Prevention and Control Cell

Public Health Agency | Nursing and AHP Directorate |
12- 22 Linenhall Street | Belfast | BT2 8BS |
M: Personal Information redacted by the USI

E: Personal Information redacted by the USI | Web: www.publichealth.hscni.net |

Public Health Agency

Via email

Office of the Director of Nursing,
Midwifery and Allied Health
Professionals
Public Health Agency
4th Floor South
12-22 Linenhall Street
BELFAST
BT2 8BS

Tel: Personal Information redacted by the USI
Website: www.publichealth.hscni.net
Email: Personal Information redacted by the USI

30th April 2021

Dear Colleagues

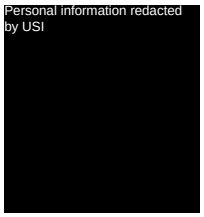
Serious Adverse Incident (SAI) Procedure

We are writing to you following a query raised at the Regional Infection, Prevention and Control Cell on Wednesday 21st April 2021 seeking clarity with regards to who has lead responsibility for SAI related outbreaks in Care Homes, in light of the PHA Health Protection role in supporting Care Homes during an outbreak.

We can confirm that, as with any other Serious Adverse Incidents (SAI's) occurring within a Care Home, the commissioning Trust retains responsibility for overseeing the SAI in line with the regional SAI Procedure. (http://www.hscboard.hscni.net/download/PUBLICATIONS/policies-protocols-and-guidelines/Procedure-for-the-reporting-and-follow-up-of-SAIs-2016.pdf)

The HSCB Governance Team and PHA Safety and Quality Nursing Teams can provide guidance with regarding the SAI procedure if required. For any queries please email serious.incidents@hscni.net and your query will be disseminated to the relevant team/person.

Yours sincerely



Mr Rodney Morton
Executive Director of Nursing, Midwifery and Allied Health Professionals
PHA

Mr Brendan Whittle
Director of Social Care & Children & Executive Director of Social Work
HSCB

DOI: 10.1111/j.1744-4667.2011.00081.x
The Obstetrician & Gynaecologist
http://onlinetog.org
2012;14:50–53

Views and counterviews

What have maternity networks ever done for us?

Simon Jenkinson FRCOG

Consultant Obstetrician and Gynaecologist; and Lead Clinician, Staffordshire, Shropshire and Black Country Maternity Network, Department of Obstetrics and Gynaecology, Royal Wolverhampton Hospitals NHS Trust, New Cross Hospital, Wednesfield Road, Wolverhampton WV10 0QP, UK
Correspondence: Simon Jenkinson. Email: Personal information redacted by USI

Key content
- Maternity networks are the key to the future of successful maternity services.
- Funding issues are putting their future at risk.

Learning objectives
- To be aware of the range of maternity networks that exist/have existed.
- To be aware of the outputs of maternity networks.
- To recognise the potential of maternity networks and their importance to the future of maternity services.

Ethical issues
- How can we ensure that maternity services meet the demands of women and families?

Keywords care pathways / Department of Health / European Working Time Directive / funding / neonatal services

Please cite this paper as: Jenkinson S. What have maternity networks ever done for us? *The Obstetrician & Gynaecologist* 2012;14:50–53.

Introduction

The question, 'What have maternity networks ever done for us?' anticipates an impressive list of effective contributions to the world of obstetrics attributable to managed, collaborative working. While maternity networks are a feasible solution to the challenges faced by present and future maternity services, their full potential has not yet been realised. An expectation that maternity services will naturally join forces across localities without commissioning input or regional strategic planning has discouraged their use and limited the extent of their work. High-quality, collaborative maternity services need commissioned, managed maternity networks to ensure that women receive the right treatment in the right place at the right time.

How did we get here?

The UK model of maternity care has undergone significant change over the last 20 years. While individual hospitals have in the past provided all the care needed by women throughout pregnancy and by their newborn babies, maternity units are now differentiated by the level of care they are able to provide and women are transferred accordingly.

The report of the Department of Health expert group into the provision of neonatal services in 2003[1] made two main recommendations:

- Care should be provided across managed clinical newborn networks.
- Within each network units should have a level of care designation ranging from routine care up to neonatal intensive care (level 3 units). When extreme prematurity is anticipated, mothers should be transferred, with their babies in utero if possible, to an appropriate unit within the network.

This new model is supported by evidence suggesting a significant improvement in outcome for preterm infants transferred in utero to larger centres focusing on low-volume, high-technology care.[2–4] At the same time, advances in fetal and maternal medicine have been concentrated in larger units or perinatal centres. Smaller units often refer maternity cases to these centres for diagnostic or therapeutic services.

Minimum training standards and shorter, more structured training times[5] have been introduced for doctors in training, together with a reduction in working hours (the New deal[6]/European Working Time Directive). These changes have meant that some smaller units which have relied in the past on long working hours and extensive service provision from a small junior doctor establishment have had to scale down or cease obstetric services altogether.

All this has led to a need for more collaboration between units over wide geographical areas and there are implications for staffing, skill mix and training for individual maternity units collaborating within such a network of units.

What are we trying to achieve?

In 2004 the National Service Framework for Children, Young People and Maternity Services[7] set out a vision for maternity networks as linked groups of professionals working together to ensure equitable provision of high-quality, clinically effective care.

> Knowing which path to follow, and who is responsible for providing what, will help to reduce clinical variation, eliminate duplication of services, maintain quality of care and adherence to clinical or other guidelines and give professionals agreed control over the care of the delivery process.

In 2007, in the *Maternity Matters* report[8] it was stated that women and families should be offered a choice of antenatal care and type and place of birth, depending on their circumstances (Figure 1).

> Development of maternity, neonatal and perinatal mental health networks will ensure that all women and their babies have equitable access to the whole range of more specialist services where necessary and can be readily transferred via ambulance should any possible complications or emergencies arise.

In 2007, the Royal College of Obstetricians and Gynaecologists, in conjunction with the Royal College of Midwives, the Royal College of Anaesthetists and the Royal College of Paediatrics and Child Health, published *Safer Childbirth*,[9] an updated set of standards for obstetric care. This fresh look at the organisation of care in labour introduced minimum staffing levels for consultant and middle grades on labour wards and made recommendations that would make it difficult in the future for smaller units to continue to provide a full range of services safely. Maternity networks were presented as key in helping maternity services to achieve these standards.

A maternity network, which includes births at home, in midwifery units and in obstetric units, should have a common governance structure, including robust systems and clear guidelines for monitoring the safety, quality and performance of the maternity services and transfer arrangements within the network should problems arise.[9]

How did maternity networks begin?

Maternity services were faced with government objectives of greater clinical effectiveness, improved quality and increased choice for women and families, plus a demand for higher standards in maternity care, and presented with local alliances of maternity health professionals as the solution. Thus, maternity networks were developed. Without the support of a strategic framework, however, their development has been somewhat restricted. There is no single maternity network model, but somewhat isolated groups of collaborating clinicians with objectives derived from sometimes limited local perspectives, with little opportunity to share their successes on a national stage. Maternity networks were developed in a variety of circumstances but, in many cases, are now struggling for survival.

What do maternity networks do?

The nhsnetworks website (see Websites) lists 22 networks with an interest in maternity care. In some cases, this interest has a specialist focus. Fetal medicine research, smoking cessation, maternity risk management, midwifery standards and HIV in pregnancy are among those topics that have networks devoted to them. Twelve of those listed are networks of local maternity services aimed at facilitating collaborative solutions to the challenges of modern day maternity care.

The common themes of work for all of these local networks are:

- obstetric collaboration with neonatal services
- common agreement on care pathways
- shared learning and training.

The Staffordshire, Shropshire and Black Country (SSBC) Maternity Network sits within the SSBC Newborn Network. It covers one-third of the West Midlands, a large region with the highest perinatal mortality rates in the UK. Across the six units that constitute the SSBC Network there are approximately 26 000 births annually. The network was proposed in 2005 following a series of stakeholder consultation events. In 2006, European Working Time Directive money funded a project team which was given the task of scoping the impact of the European Working Time Directive and facilitating the development of clinical care pathways across local maternity services. The project team established working groups which focused on in utero transfer protocol and the patient experience, workforce planning and collaborative work on clinical guidelines and audit.

How are they funded?

Unlike their neonatal counterparts, maternity networks are funded in a somewhat ad hoc way. Newborn networks were established following recommendations from the Department of Health's 2003 National Strategy for Improvement. As the way forward for neonatal care, they were allocated funding through specialist commissioning using national resources. The national recognition that maternity networks are a vital part of perinatal service planning has never been accompanied by allocated resources. When available, funding has, therefore, happened locally, from a variety of sources with a range of interests. There is no standard model of maternity networks and no guarantee that any of the existing networks will continue.

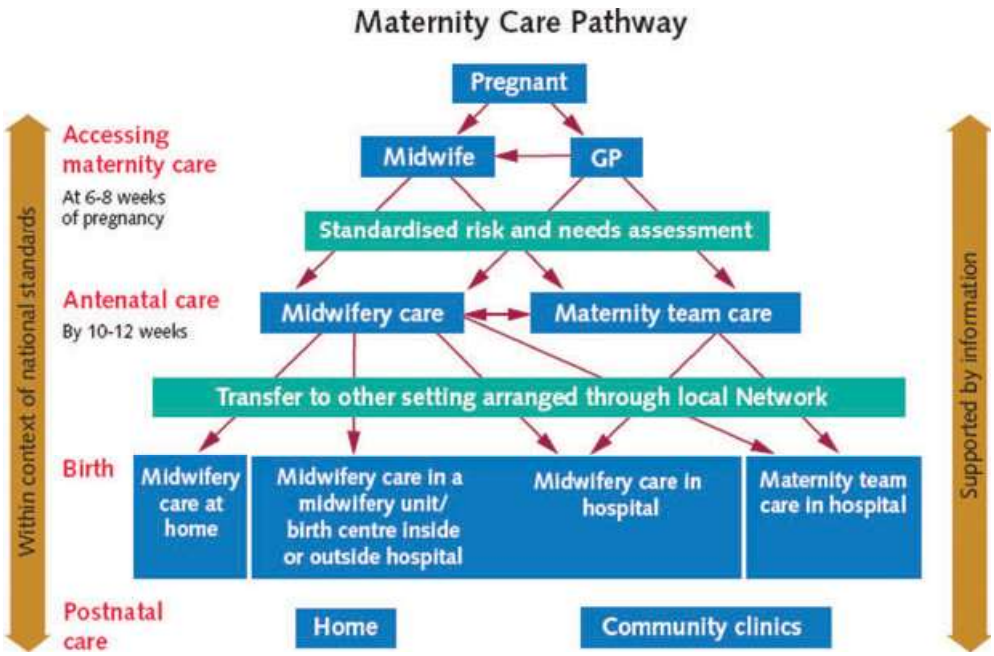


Figure 1. Maternity care pathway. Reproduced from *Maternity Matters: Choice, Access and Continuity of Care in a Safe Service*.[8] ©Crown copyright (reproduced under the Open Government Licence)

Since 2007, the SSBC Maternity Network has been funded through the SSBC Newborn Network. This has been a temporary arrangement which has enabled the development of the already established network. Future funding, however, is uncertain.

How should they be funded?

The concept of a managed clinical network implies a funded clinical network established to meet local maternity needs. This needs to be a locally commissioned service with a service level agreement setting out the expected outcomes and collaborative activities in alignment with the strategic planning of the local strategic health authority. *Maternity Matters*[8] advocates a responsibility to develop high-quality maternity services. The role of primary care trusts (PCTs) is to 'commission high-quality, equitable, integrated maternity services as part of local networks according to local need'.[8] It falls to strategic health authorities to 'provide strategic leadership to assist PCTs in the development of the local vision for local maternity services, the development of networks and of user involvement'.[8]

What could they do?

Managed clinical care entails the provision of all maternity services within a network area according to a locally agreed care pathway. In the Staffordshire, Shropshire and Black Country area, for example, this could mean, perhaps, there being one network for directing or managing the care pathways of 26 000 women. A maternity network would be designed according to the needs of the local population. This would, typically, include a number of small units providing local care to most women, with one or two larger units for high-risk cases. Maternity services would be planned according to clear care pathways, ensuring the capability and capacity for high-quality care. Such collaborative work opens up a range of possibilities for workforce planning and solutions to the training of junior doctors. There is also a clear potential for comprehensive data collection and collaborative audit.

Websites

nhsnetworks [www.networks.nhs.uk]

SSBC Maternity Network [www.networks.nhs.uk/nhs-networks/staffordshire-shropshire-and-black-country]

References

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6 Department of Health. *Junior Doctors: the New Deal*. London: Her Majesty's Stationery Office; 1991.

7 Department of Health. *National Service Framework for Children, Young People and Maternity Services: Maternity services*. London: DoH; 2004.

8 Department of Health. *Maternity Matters: Choice, Access and Continuity of Care in a Safe Service*. London: DoH; 2007 [www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_074199.pdf].

9 Royal College of Anaesthetists, Royal College of Midwives, Royal College of Obstetricians and Gynaecologists, Royal College of Paediatrics and Child Health. *Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour*. London: RCOG Press; 2007 [www.rcog.org.uk/files/rcog-corp/uploaded-files/WPRSaferChildbirthReport2007.pdf].

Cervical Cytology Service – Position paper - Feb 2021

Background

The Trust's Cervical Cytology Service is delivered through Craigavon Area Hospital (CAH) Cellular Pathology Laboratory. The service typically supports primary screening for 24,000 smears per year. 6000 of these smears also require further verification by a senior Biomedical Scientists (BMS) in the lab.

In the last three years, the service required additional sessions to keep up with demand, supported by waiting list funding from Health & Social Care Board. In recent months the service has lost three WTE BMS to other Trusts and backlogs are now accruing. In addition to the imbalance between service demand and capacity, additional NI Cervical Cancer Audit Framework requirements have been introduced which are putting additional pressure on the service.The current position is not sustainable and this position paper sets out a proposed more viable way forward for the service in the context of Pathology modernisation.

Pathology Modernisation

The Pathology Modernisation program is progressing through the regional Pathology Network chaired by Jennifer Welsh (Chief Executive – Northern Trust). It is recognised that in future there will be some changes to how laboratory services are delivered across Northern Ireland as a region. Whilst most cellular pathology services will remain unchanged and continue to be delivered on their current locations, a small number of service areas will be delivered by either one or two laboratories. Cervical Cytology Screening is one of those service areas.

Primary HPV testing will eventually replace Cervical Cytology screening as a primary screening tool and this policy change will consequently mean a smaller number of locations are needed to deliver the future service. The Southern Trust Laboratory Team accepts that change is inevitable and that Cervical Cytology will not be delivered here in the future. Therefore we are seeking to proactively manage this change whilst supporting staff through the process and focusing on a robust and sustainable SHSCT Cellular Pathology service model.

Target areas for CAH Cellular Pathology service development include:

- Support and expand Radiology in Rapid Onsite Evaluation Diagnostics.
- Increase capacity in biopsy reporting for elective and unscheduled care.
- Digital Pathology and Advanced Roles for Biomedical Scientists to support Consultant workforce shortages.
- Develop and deliver training programme for advanced BMS roles.

Primary HPV Testing

NI is the only region of the UK not to have rolled out primary HPV testing within cervical screening. Primary HPV testing is more sensitive than cytology which means it is less likely to miss pre-cancer compared to cytology. Cytology is a suboptimal test relative to what is available and a policy decision to move to primary HPV testing has been awaited in the region for several years.

As we deliver the screening programme by cytology rather than HPV testing, Quality Assuring the service is difficult as no national benchmarking will be available in the future. There is added risk at present and until a policy decision is made to introduce primary HPV testing this risk continues. To mitigate this risk co-testing could be considered and adopted (where all smears have both cytology and HPV testing done) however, the PHA does not currently support this move. Co-testing would mean little change to patient pathways as the colposcopy referral rate in SHSCT is high already. There would be a small additional financial cost of a HPV test.

Demand and Capacity

There is currently insufficient capacity available in the cellular pathology service to meet demand. Despite a significant amount of additional screening having been done, backlogs can accrue thus introducing clinical risk. The current staffing model for Cervical Screening is as follows:

Table 1:

Staffing	Sessions / WTE	Role
Consultant Sessions	3	Consultant Pathologist reporting / MDT
Band 8A BMS	0.5	CSPL
Band 7 BMS	2.5	Primary screening and checking
Band 7 BMS	0.5	Primary screening

This current staffing model in **Table 1** provides capacity for 12000 smears to be screened and reported by the Cervical Cytology Service at SHSCT. The demand currently however is, based on 2019 cervical cytology workload, around 24,000. The additional numbers were supported at financial risk through overtime.

The current deficit in capacity is resulting in backlogs and delays in reporting resulting in reduced turnaround times. Currently the training of cervical screeners is paused and recruitment of staff to support our service here is not an option. As a short to medium term solution, through the regional cellular pathology escalation process, it is proposed that 12,000 cervical cytology specimens are sent to Cellular Pathology in the WHSCT for primary screening and reporting through an SLA / contract. This proposal will ensure the safe delivery of the Cervical Cytology Service at the proposed reduction of the current workload. The WHSCT are agreeable to this proposal.

Cervical Cancer Audit Review

New Framework

The Northern Ireland Framework for the Audit of Invasive Cervical Cancers and Disclosure of Findings was published in 2019 and applies to all new cervical cancer diagnoses from the start of 2019 onwards.

This requires the Trust to carry out a review of the cervical screening history in all women diagnosed with cervical cancer. This involves a review of any previous screening test (cervical cytology), diagnostic test (biopsy) and any clinical treatment or management (colposcopy).

In most cases there is either no adverse review finding or minor review findings within the limitations of screening, classified as Category 1 and 2 outcomes respectively. In all these cases the patient is written to and advised that the audit review is complete and the outcome disclosed to patients where they require this, including invitations to meet with the Trust to discuss if necessary.

However, sometimes a more serious error is found (Category 3 outcome) and if such an error is found it is usually within the screening test, where a patient has received a false negative result – this is when the test result says you don't have a condition, but you actually do.

In the specific circumstances of this audit review of cervical cancer patients we will identify some women who were previously told they had a negative or normal smear test when in fact pre-cancer changes were present. These changes could have been treated and prevented cancer from developing.

The Framework asks for a specific standard to be applied when defining the audit outcome – *'Did staff carrying out the screening or diagnostic test do so to a standard that most staff could be expected to achieve?'* Applying this means for the Southern Trust around 3 women per year diagnosed with cervical cancer will have a previous false negative result. These are then required to be investigated as a SAI.

Every year in which cytology has been used as the primary screening test will have this outcome. Since it usually takes around 10 years for cervical cancer to develop the Trust will have to continue to undertake this audit until at least 2030 adding an additional year for each year that passes where HPV is not introduced to replace cytology as the primary test.

SHSCT New Framework outcomes 2019 and 2020

The Trust has completed the new framework approach for the 2019 patient cohort. There are three category 3 outcomes for 2019 and these are being investigated as Level I SAI. The review team has been established and the process to engage with patients has begun. This new framework approach has a significant additional administrative time commitment, acknowledged in other Trusts also, which is unfunded. So far there are no Category 3 outcomes for 2020.

Cervical Cancer patients 2009 – 2018

Prior to the Framework above Trusts had been asked to carry out a review of the cervical screening history in all women diagnosed with cervical cancer. The Medical Director of the Public Health Agency wrote to Trust Chief Executives to ask that this be done for all cases diagnosed from 2009 onwards and that the NHS cervical Screening Programme guidance (*'Disclosure of Audit results in Cancer Screening, Advice on Best Practice')* was to be followed. In 2014 a laboratory specific protocol was introduced but largely resulted in little change to the audit review.

Whilst this audit review has been done in the Southern Trust 2009 – 2018 but there is no evidence of patients having been told it was happening and subsequently very few instances of disclosure of outcomes.

This issue has been put to the Directorate of Legal Services (DLS) as questions below:

Questions to DLS

1. Considering the *'Disclosure of Audit results in Cancer Screening, Advice on Best Practice'* guidance drawn to the attention of Trusts in 2009:

Between 2009 and 2014 did the Trust have a duty of care or any obligation to patients in respect of this audit of invasive cervical cancers?

(a) To ensure patients knew the audit was being undertaken *and*

(b) To disclose the results of audit reviews for those who asked to know the outcome?

2. Considering the *'NI Protocol'* Trusts was asked to follow in December 2014:

From then onwards did the Trust have a duty of care or any obligation to patients in respect of this audit of invasive cervical cancers?

(a) To ensure patients knew the audit was being undertaken *and*

(b) To disclose the results of audit reviews for those who asked to know the outcome?

3. Does the Trust have a duty of care or obligation to now retrospectively disclose the results of all audit reviews were a patient consents to know the outcome?

Response from DLS:

The Trust owes a duty to the patients from 2009 onwards to advise that an audit of their screenings has taken place and disclose same where the patient consents.

Governance and Patient Safety

The current service model for cellular pathology is not sustainable and will inevitably change as the pathology modernisation work progresses. The new NI Cervical Cancer Audit Framework will add pressure to the team, which they are not currently able to deliver. It is in this context that now is the time to change the service model – committing to cellular pathology activity that is deliverable and safe, as well as refocussing on the development of different parts of the service in the context of the pathology modernisation programme.

In conclusion

We need a sustainable service model for Cellular Pathology which takes cognisance of regional pathology modernisation and focuses on the parts of the service that will be delivered from SHSCT Cellular Pathology Laboratory.

It is acknowledged that cervical cytology as a service area will not be delivered from the SHSCT in the long term. We are seeking to proactively manage this change whilst supporting staff through the process and focusing on the development of development of other services in the context of pathology modernisation.

In the short to medium term it is proposed that the following actions are progressed to address the issues / risks highlight in this report:

- **An SLA is established with the WHSCT to support delivery of the SHSCT cervical cytology service** pending regional progress on a policy decision. Our current staffing model provides the capacity for 12000 cervical cytology specimens to be reported by the SHSCT cellular pathology laboratory. We propose sending 12000 cervical cytology specimens to the WHSCT for screening and reporting through the establishment of an SLA. This SLA would also free up time to allow us to deliver the Cervical Cancer Audit Review Framework. *The cost of this arrangement will be c£115K*. The SLA can commence on 15 March 2021.Previously this need would have been met through a combination of additionality, support from other Trusts or through high cost locums screeners, therefore this plan would be broadly in line with costs from previous years.

- Primary HPV testing is a more sensitive test and will eventually replace cervical cytology as a primary screening tool. NI is the only region of the UK not to have rolled out primary HPV testing. It will be difficult to quality assure our service as no national benchmarking will be available. We acknowledge the false negative risk of a cytology based test screening programme and that NI is currently at variance with UK and ROI. **Until a policy decision is made to introduce primary HPV testing in Northern Ireland It is proposed that we commence co-testing from 15 March 2021. The cost of this arrangement per year is estimated to be up to £100K**

- **The team are requesting that the Trust formally raises the issue of disclosure for the patients during the period 2009-2018 with the PHA** - this could equate to approximately 30 patients. The Trust should indicate to the PHA that we plan to make contact with these patients; however it would be preferable if this was coordinated regionally.

Phase	Action
Phase 1	• Patient Safety Data and Improvement Manager, Band 8a **Being Recruited** • Senior Manager Risk & Learning, Band 8b **Complete** • Datix Manager Band 6 **Being Recruited** • Patient Safety Strategy Manager, Band 7 **Being Recruited** • Project Manager Band 7 **Being Recruited**
Phase 2	• Corporate Clinical Audit Manager, Band 7 • CSCG Training Officer Band 7 • Morbidity and Mortality Manager Band 6 • Directorate Clinical audit and patient safety posts Band 5
Phase 3	• Datix Admin, Band 4 • Risk and Learning Admin Support Band 4 • Training admin Support Band 4 • Business Partner posts Band 5

Southern Health and Social Care Trust

Quality care – for you, with you

GOVERNANCE COMMITTEE COVER SHEET

Meeting Date	13th May 2021		
Agenda item	Learning from Experience Update		
Accountable Director	Dr Maria O'Kane, Medical Director		
Report Author	Name	Caroline Doyle	
	Contact details	Personal Information redacted by the USI	
This paper is presented for: **Information**			
Links to Trust Corporate Objectives	√	Promoting Safe, High Quality Care	
	☐	Supporting people to live long, healthy active lives	
	√	Improving our services	
	√	Making best use of our resources	
	☐	Being a great place to work – supporting, developing and valuing our staff	
	☐	Working in partnership	

	This report cover sheet has been prepared by the Accountable Director. *Its purpose is to provide the Trust Committee with a clear summary of the paper being presented, with the key matters for attention and the ask of the Committee.* *It details how it impacts on the people we serve.*

1. Detailed summary of paper contents:

This paper is a Clinical and Social Care Governance proposal paper to update Trust Governance Commitee on Trust Learning from Experience ongoing progress and identified challenges. This paper should be considered as supplementary to the Trust Clinical and Social Care Governance Review. The key elements that are addressed are listed below:

- Challenges of Learning from Experience
- Developing a Culture of Learning from Experience
- Pathways for Sharing Learning from Experience
- Implementing Change as A Result of Learning
- Learning from Experience Objectives 2021/22

2. Areas of improvement/achievement:

The following learning from experience objectives have been set for year 2021/22

- To reissue the Trust Safety Culture Survey first launched 2017
- To develop templates and standardised processes for identifying and sharing Organisational level learning
- To develop an accessible Organisational repository of learning allowing staff to access learning across departments and time periods
- Conduct activities to further promote a learning culture within the Trust
- To fully map the network of formal and informal learning functions and forums throughout the Trust
- To develop a 'lessons learned log' to track progress on acting on learning

3. **Areas of concern/risk/challenge:**

What should be included here:

4. Impact: Indicate if this impacts with any of the following and how:

Corporate Risk Register	Not Applicable
Board Assurance Framework	Not Applicable
Equality and Human Rights	Not Applicable

Learning from Experience Update 13th May 2021

Introduction

Purpose of Paper:

This paper is a Clinical and Social Care Governance proposal paper to update Trust Governance Committee on Trust Learning from Experience ongoing progress and identified challenges. This paper should be considered as supplementary to the Trust Clinical and Social Care Governance Review. The key elements that are addressed are listed below,

- Challenges of Learning from Experience
- Developing a Culture of Learning from Experience
- Pathways for Sharing Learning from Experience
- Implementing Change as A Result of Learning
- Learning from Experience Objectives 2021/22

1. Healthcare will never be risk free, but we can minimise these risks in order to provide high quality care for service users. Learning from experience is crucial to continually improve person-centred, safe and effective delivery of care.

2. A learning culture is promoted within the trust and any review is not intended to blame individuals but to seek the causal factors and share the lessons learned to prevent a reoccurrence of an incident or other negative event.

3. Learning from experience will contribute to the supporting the Trust health and wellbeing outcome that people who use health and social care services are safe from harm. *"The best way to reduce harm ... is to embrace wholeheartedly a culture of learning."*

4. The Trust has made a number of improvements to our processes for managing and learning from adverse events including strengthening our responses to Serious Adverse Incidents (see Trust Serious Adverse Incident Framework). However, achieving cultural change regarding learning from experience is challenging and will take time. There are increasing the opportunities to actively learn from experience and put improvements into practice.

5. The Trust recognises that learning can come from a variety of other sources and so it is useful to routinely review all types of learning to ensure that this is embedded into local practice and to prevent recurrence of events that led to the learning in the first place, these include:
    - Service User Complaints / Complaints Ombudsman Reviews
    - Morbidity and Mortality Reviews
    - Litigation Outcomes
    - Coronial Outcomes
    - Patient Safety Alerts (local, regional and national)

6. Learning can also be shared from events that have taken place in other organisations and to that end the Trust is committed to working effectively with other bodies, whether external agencies who undertake assessments and reviews or other Trusts, to learn from these experiences. Best practice can also be obtained from other organisations.

7. This Learning from Experience Framework outlines how the Trust aims to strengthen our systematic approach to learning from all types of events and ensure that this is disseminated through appropriate mechanisms.

8. To support improvement in sharing learning from experience, the Trust operates a Lessons Learned Forum, chaired by the Medical Director which will oversee the management and sharing of learning from experience (Terms of Reference Appendix 1). The Forum was rebranded as the 'Learning from Experience Forum' in 2020.

Challenges of Learning from Experience

9. The Southern Trust as with other healthcare providers has identified a variety of challenges with the management, monitoring and sharing of learning from experience. Some of the more common challenges are listed below under identified themes of capacity, stakeholder engagement, sharing learning, governance and overview and quality improvement. The term 'event' is used throughout this document to signify any potential learning event (adverse event, complaint, litigation etc)

    - Creating the capacity and capability to carry out effective event reviews
    - Providing support to those involved in an event (patients, family, carers and staff)
    - Ensuring review recommendations are translated into practical actions that lead to improvements
    - Identifying and sharing key learning points widely,
    - Working across directorate and Trust boundaries to move towards a more consistent approach.

10. Several of these challenges were identified as part of the Trust Staff Cultural Survey conducted in 2016. This is not to say that progress has not been made, but rather emphasises the complexity and long-term nature of the task to transform the culture to an open learning one. The Trust paper on Strengthening Our Response to Adverse Incidents addresses several of the areas of challenge.

Area of Challenge	Elements
Capacity	• Having capacity to undertake event reviews. Due to clinical or other commitments, event reviews can become person dependent, can result in delays and can lead to a focus on the process rather than on identifying the key learning points and improvement required. • Meeting event review timescales outlined within regional guidance can be difficult, particularly for events which are inter-organisational. • Having sufficiently trained staff in critical review and analysis, interview techniques and human factors, and maintaining review skills for those staff who only occasionally take part in adverse event reviews.
Stakeholder Engagement	• Providing meaningful and timely support to patients, family and carers. • Providing support to staff involved in adverse events; involving all staff in adverse event processes and encouraging local ownership. • Staff feeling confident to have conversations with patients, family and carers about adverse events.
Sharing Learning	• Understanding and reflecting relevant background information and situational context in thematic event reviews, review reports and learning summaries to ensure the information supports improvement. • Understanding and sharing lessons learned and promoting a systematic approach to sharing learning.
Governance and Overview	• Capacity to monitor actions arising from event reviews and ensuring actions are taken. • Capacity to evaluate if actions taken following event reviews result in changes that are improvements. • Prioritising which areas to focus on when there are a number of identified themes and issues around events. • Ensuring that external review recommendations (e.g. Inquiry into Hyponatraemia Related Deaths) are implemented in a way that builds on existing adverse event processes and does not create a system that is built around solely quantitative measurement
Consistency	• Ensuring consistency in the quality of event reviews and reports, and developing expertise in operational units to support a standardised approach. • Supporting an open culture around adverse events

11. Much regional work has taken place in recent years to foster an open learning culture, and ongoing work from the regional IHRD programme has contributed to this. However, a number of barriers to moving to an open learning culture still exist.

12. Additionally, the ever-increasing interest from the media and wider public for identifying who is to blame fuels a defensive, blame culture where individuals working within the service are afraid of being open about failures to protect their careers. It has been well reported that only by combating the blame culture in health and social care will transparency and meaningful change take place. Learning from adverse events is one contributor to changing that culture.

Developing a Culture of Learning from Experience

13. To make our care safer we are required to improve our learning about how day-to-day care is delivered, how it feels to work for frontline staff, and ways in which they need to adapt and adjust what they do to keep patients safe.

14. This means learning how care is delivered, not how we imagine it is delivered, but exactly how it is done on a day-to-day basis. It requires us to improve our learning about what is working well and what doesn't go as planned or expected.

15. Underpinning this learning is a culture which is kind, respectful and which enables people to speak out openly, and to share issues, concerns and ideas without judgement, Dekker 2013, describes this as:

    - A learning organisation is where everyone facilitates a culture that helps to continually transform and improve that organisation.
    - A learning organisation that has safety at its heart studies all aspects of care. This, in turn, uses that knowledge to help people redesign the workplace

16. To achieve this there is a growing body of evidence that demonstrates that a way forward is for organisations to embed a just and learning culture. Healthcare providers therefore, have the responsibility for role modelling the right behaviours to create and maintain a safe and supportive environment for both the patients and staff that is fair, open and able to learn.

17. To gain an insight into the Trust's safety culture in 2017 a Trustwide survey was undertaken to assess the safety culture level in the organisation. The survey provided direction on how we should target resources to further develop our safety culture.

18. In order to further support our learning agenda there is a requirement for the Trust to support and promote a culture that seeks to understand the actions and choices made by our staff before they are judged, our staff should be primarily supported to learn from them. Furthermore, they should be asked for their advice and help to design the systems that could help change things for the better.

Pathways for Sharing Learning from Experience

19. The following table lists existing reports that provide data on the trends and themes relating to incidents, complaints, litigation and clinical audit projects separately or for specific areas of the organisation.

Report Name	Frequency	Content	Receiving Group
Clinical and Social Care Governance Report	Quarterly	Trend information on complaints, adverse incidents and Serious adverse Incidents	• Trust SMT • Directorate Governance Coordinators • Trust Governance Committee
Annual Quality Report	Annual	Information on Trust quality indicators including summary lessons learned information	• Trust SMT • Directorate Governance Coordinators • Trust Board / Governance Committee
Trust Mortality Report	Quarterly	Information on both quantitative and qualitative mortality measures including analysis of trends among specific mortality indicators	• Medical and Nursing Leaders • Trust SMT • Directorate Governance Coordinators • Trust Governance Committee
Service User Experience Annual Report	Annual	Information on service user feedback and potential improvements in service provision	• Trust SMT • Directorate Governance Coordinators • Trust Governance Committee
Litigation Governance Report	Quarterly	Information on trends in litigation and coronial activity within the Trust	• Trust SMT • Directorate Governance Coordinators • Trust Governance Committee
Clinical Audit Report	Annual	Summary of implementation of clinical audit both local and national recommendation implementation	• Medical and Nursing Leaders • Trust SMT • Directorate Governance Coordinators

Annual Complaints Report	Annual	Detailed information on complaints received	• Trust SMT • Directorate Governance Coordinators • Trust Governance Committee
*Learning/Good Practice Template**	*As required*	*Key learning from events*	• *Lessons Learned Forum* • *Directorate Governance Coordinators*
*Learning Bulletins**	*As required*	*Key learning from events*	• *Lessons Learned Forum* • *Dissemination in operational and professional groups as relevant*
*Learning Log**	*Monthly*	*List of learning and actions taken*	• *Lessons Learned Forum* • *Trust SMT* • *Trust Governance Committee*

**Under development via the Trust Lessons Learned Forum*

20. The following table lists high level meetings where lessons learned are discussed and shared with relevant staff and divisional groups.

Meeting	Frequency	Content /	Attendees
Morbidity and Mortality Meetings	Monthly	Discussion of inpatients who have died / suffered a serious harm or near miss event. Meetings held at a divisional level (e.g. surgery, medicine, pediatrics etc)	• Trust Medical Staff • Other Staff Groups Invited
Nursing and Midwifery Governance Forum	Monthly	Reserved section to discuss learning / service improvements that may require cross directorate / corporate support to implement learning	• Trust Nurse and Midwifery Senior Staff
Medical Forum	Quarterly	Reserved section to discuss learning / service improvements that may require cross directorate / corporate support to implement learning	• Trust Associate Medical and Clinical Directors
Directorate Operational Governance Meetings	Monthly	Discussion of adverse incident / complaints and litigation cases that occurred within the directorate	• Directorate senior management • Directorate senior medical. Nursing and social work staff

21. It is acknowledged that the above list of meetings is non-exhaustive and local level learning will take place at various levels within each operational directorate. The information shared via each will be tailored to the specifics of the audience group.

22. The Trust Lessons Learned Forum seeks to further standardise and identify new pathways for sharing of learning from experience.

Organisational Process for Implementing Change as a Result of Learning

23. The Trust is committed to learning lessons and promoting improvements and making changes in practice using all of the information and experience available. Learning from experience is derived from three main sources as listed in the table below.

Learning Source	Details	Responsibility for Sharing
Learning from Trust level events and experiences	Analysing individual and aggregated information relating to incidents (including, Serious Incidents), complaints, litigation etc which includes identifying trends, causes and impacts	The directorate where the learning is identified are responsible for sharing the lessons; directly with other directorate governance fora where the similar services are provided and with the Trust Lessons Learned Forum
External assessments, reviews, national enquiries and recognised best practice;	Reviewing and understanding best practice standards and requirements, this includes: • Allocating responsibilities for implementation • Developing and implementing actions plans to address identified	Directorate governance forums are responsible for implementing and providing assurance on the adoption and implementation of learning from experience from external bodies.
Cross Organisational learning	Reviewing and understanding learning that may be regional or from another HSC Trust. • Liaising with regional organisations to develop action plans for implementation • Developing organisational action plans and informing directorate governance teams of learning	Trust corporate clinical and social care governance team work with directorate governance teams to share learning from experience

Department Level Learning

24. Each operational governance team is responsible for reviewing all event information relevant to their service areas and are responsible for owning issues that arise and feeding back the results of these reviews to staff.

25. A variety of systems for embedding learning are considered which include simulation-based learning, reflective practice sessions, and reviewing how changes can be made and implemented in practice. The system used for embedding individual learning is dependent on the issue that is being addressed. Each directorate has its own mechanism for disseminating and communicating learning which can be in the form of a bulletin or newsletter.

26. All department learning is captured and discussed as part of individual departmental team meetings and this in turn is fed into the governance reporting structure within individual directorates.

27. Each directorate discusses learning within its governance structure, reporting any wider issues to the appropriate Board level committee/group. These governance groups act as the link to facilitate the dissemination of learning from Trust SMT down to staff and from staff to Trust SMT.

28. Any learning which impacts on the care of service users is considered for dissemination centrally from the Corporate Clinical and Social Care Governance office.

Learning from Experience Objectives 2021/22

29. The following objectives have been set for learning from experience for f2021/22

	Objective	Purpose
1	To reissue the Trust Safety Culture Survey first launched 2017	To gauge the current level of Safety Culture within the organisation against the 2017 baseline.
2	To develop templates and standardised processes for identifying and sharing Organisational level learning	To ensure that significant Organisational level learning is captured an d shared in a consistent manner
3	To develop an accessible Organisational repository of learning allowing staff to access learning across departments and time periods	To ensure an Organisational memory of lessons learned is maintained
4	Conduct activities to further promote a learning culture within the Trust	To engage staff and leaders at a variety of levels to support the development of an

		open and learning culture (such as Being Open)
5	To fully map the network of formal and informal learning functions and forums throughout the Trust	To ensure a comprehensive map of learning functions is available to help assist learning dissemination and embedding
6	To develop a 'lessons learned log' to track progress on acting on learning	To allow the organisation to track progress on actions that were outcomes of lessons learned

Appendix 1 - Lessons Learned Forum – Terms of Reference

Learning from Experience Forum – Terms of Reference

Date: 2nd December 2020

Background

As a Trust we recognise the benefits that can be had from sharing and cascading learning from incidents and near misses, and know that if this is done effectively it can help to minimise future risk and strengthen the quality of the services we provide.

The Trust is committed to quality improvement, and will continue its strong focus on delivering high quality, safe and effective services. The Trust Learning from Experience forum will assist in the identification, sharing and appropriate risk mitigation of areas of concern by highlighting areas of learning and sharing these messages.

Purpose / Role of the Group

- To provide a formal corporate cross directorate interface for the identification and sharing lessons learned from adverse incidents, complaints, morbidity and mortality, litigation cases learning through patient experience , nursing and other quality indicators and areas of good practice for service improvements, internal to the Trust, regional and national.
    - To support the presentation and discussion of sharing learning from experience
    - To provide input to corporate level communications in the form of emails, newsletters, staff education and briefings to support the embedding of learning from experience
    - To oversee and review a learning from experience learning log to track actions
    - To identify Learning from Experience projects that have potential as Quality Improvement projects
    - To provide assurance and updates in the form of 6 monthly reports to Trust Governance Committee on the work of the forum

Membership

- Medical Director (Chair)
- Trust Operational Directors
- Non-Executive Director
- Deputy Medical Director Safety and Quality

- Associate Medical Directors (or nominees)
- Operational Assistant Directors (as nominated by Directors)
- Assistant Director Clinical and Social Care Governance
- Directorate Governance Coordinators
- Director of Pharmacy
- Executive Director of Nursing
- Assistant Director Professional Lead Social Work and Care
- Assistant Director Professional Lead Nursing Governance
- Assistant Director AHPs
- Assistant Director Quality Improvement
- Operational Assistant Directors as nominated by Directors
- Project Manager Clinical and Social Care Governance
- Governance Officer, Clinical and Social Care Governance
- Trust Simulation Lead
- Lead Medicines Governance Pharmacist
- Head of Patient Safety Data and Improvement
- Trust Litigation Manager
- Deputy Director HROD
- Trust Board Secretary

Meeting Format

- Meetings held on a quarterly basis (4 meetings per year)
- Chaired by Medical Director
- Papers will be circulated 5 working days prior to meeting date via email
- Additional members or presenters will be invited as dictated by the Forum Chair

Review

- Terms of reference for the group will be reviewed at least annually

Confidentiality

- Lessons Learned will be anonymised and confidential information removed.

Reporting

- The Forum will provide quarterly updates to the Trust Quality Improvement Steering Group
- The Forum will report twice yearly to the Trust Governance Committee

REPORT SUMMARY SHEET

Meeting: Date:	Senior Management Team 4th May 2021
Title:	Clinical and Social Care Governance Report
Lead Director:	Dr Maria O'Kane, Medical Director
Corporate Objective:	Safe, high quality care
Purpose:	Information

Overview:

Provide SMT with an Oversight of Weekly Activity in relation to Clinical & Social Care Governance

Key Issues / Risks for SMT Consideration:

- Ongoing SAIs 84
- 5 SAI Notifications being prepared for O&G
- Trust introduced weekly governance reporting in relation to Granville Care Home
- Introduction of a summary table of Adult Safeguarding Activity
- One additional Urology claim received
- Exploring the use of Student Lawyers to assist in Subject Access Requests.
- Preliminary Hearings held in the last week details can be found in section 22.

-Outcome of SMT Discussion:

Summary of Weekly Governance Activity 19.04.2021 - 25.04.2021

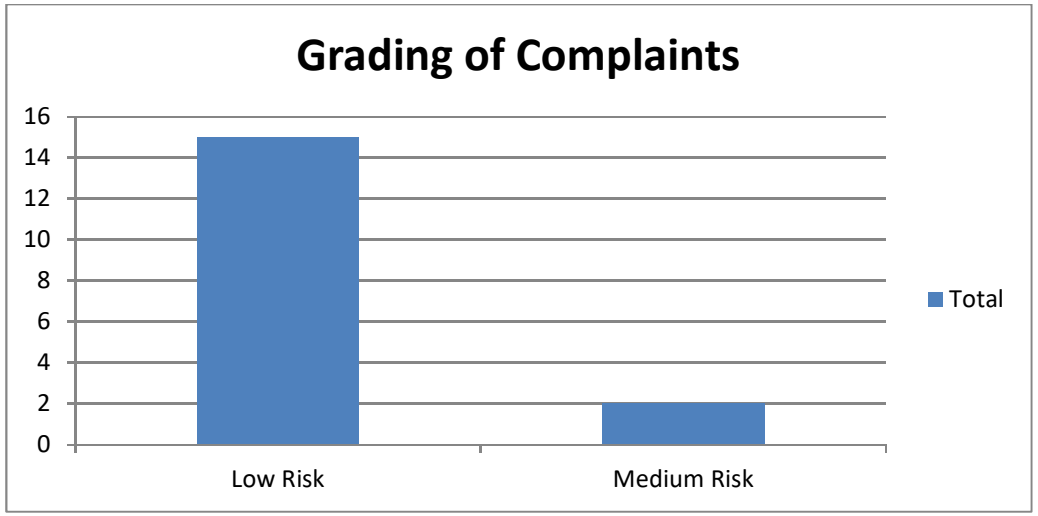
	DIRECTORATE				
	ACUTE Number	MHLD Number	CYP Number	OPPC Number	TOTAL Number
New SAI's Notification's	0	0	0	0	0
SAI Reports submitted to HSCB	0	0	0	0	0
Ongoing SAI's*	26	46	8	4	84[1]
High Risk Complaints	0	0	0	0	0
NIPSO Case Accepted for Investigation	0	0	0	0	0
NIPSO Draft/Final Reports Received	0	0	0	0	0
Early Alerts	0	0	1	2	3

*Below highlights the change in ongoing SAI figures from 83 last week to 83 this week:

Ongoing SAIs reported last week – 18/04/2021	83
Add New SAI notifications:	0
	83
Less SAI reports submitted:	0
Ongoing SAIs reported week ended 25/04/2021	83

[1] Includes one notification reported w/b 26th April 2021.

Grading of Formal Complaints Received 19.04.2021 – 25.04.2021



ACUTE DIRECTORATE

Data provided by Corporate Office from the Datix Incident Management System to the Weekly Governance De-Brief (Thursday mornings - 9am – 10am)

1. **Status of SAI's -** Summary of the status of SAI's between 19.04.2021 - 25.04.2021

Any reports received after Friday will not be reflected in the numbers below until the following week

More than 26 weeks	Less than 26 weeks	Within Timescales	Total
6	12	8	26

Discussion at meeting	Action
Another 5 SAIs will be reported in the coming week in relation to O&G.	Meeting taken place to review at 2pm 29/04/2021

2. **Catastrophic Incidents**

Datix ID	Incident Date	Description
Personal Information	27/04/2021	Readmission with Hospital Aquired Pneumonia, >6 weeks post acetabular fracture. Covid +ve during previous admission (Ramone ward).
Personal Information	Personal Information redacted by the USI	Death of patient post surgery. This incident has been screened and notes requested.

Discussion at meeting	Action
Dr Gormley confirmed that the SJR model being used for the review of Covid deaths does not replace any existing Governance arrangements.	n/a

3. **Never Events**

None

4. **Issues escalated by Corporate or Directorate office at meeting**

Discussion at meeting	Action
Incident: Personal Information **Description:** Personal Information old covid positive patient admitted to 2 north. Suicidal, had taken an overdose. Not clerked in prior to coming to ward, no 1:1 staff available and no medical plan in place. Patient then clerked in on 2 north but later had respiratory arrestand transferred to ICU.	Screening process commenced.
Incident: Personal Information **Description:** Patient attended DHH following RTC diagnosed with unstable cervical spine injury, BHSCT initially advised transfer to them in them in the morning. Ortho team in CAH refused patent. Patient admitted to general surgery.	Patricia to forward details to Dr O'Kane for sharing with the Medical Director of the BHSCT.
Incident: Personal Information Patricia escalated SAI Personal Information to Dr O'Kane, difficulties obtaining input from SET regarding plastics.	Patricia to forward details to Dr O'Kane for sharing with South Eastern Trust.

MENTAL HEALTH AND DISABILITY DIRECTORATE

Data provided by Corporate Office from the Datix Incident Management System to the Weekly Governance De-Brief (Thursday mornings - 9am – 10am)

5. Status of SAI's

Summary of the status of SAI's between 19.04.2021 - 25.04.2021

Any reports received after Friday will not be reflected in the numbers below until the following week

More than 26 weeks	Less than 26 weeks	Within Timescales	Level 3 – No timescale	Total
25	12	7	2	46

Discussion at meeting	Action
Tony confirmed there are a number of SAI reports nearly ready for submission to the HSCB. Tony raised a case within Physical Disability that will potentially require a cross directorate case review to identify learning.	Tony will link with Dr O'Kane to discuss this in more detail and resend her draft SAI reports.

6. Catastrophic Incidents

Datix ID	Incident Date	Description
Personal Information	Personal Information redacted by the USI	"The Trust were notified via the SD1 process of the suspected suicide of a service user in the community. The service user was known to Primary Mental Health Care Team"

7. Never Events

None

8. Issues escalated by Corporate or Directorate office at meeting

Discussion at meeting	Action
Tony informed the group of the Trust attending a Serious Concerns meeting with the RQIA regarding Personal Information. The Trust has started Weekly Governance reporting in relation to this with a steering group set up for 30/04/2021, there will also be a Directors oversight meeting to monitor progress of the concerns raised at the meeting.	n/a

CHILDREN AND YOUNG PEOPLE SERVICES DIRECTORATE

Data provided by Corporate Office from the Datix Incident Management System to the Weekly Governance De-Brief (Thursday mornings - 9am – 10am)

9. Status of SAI's

Summary of the status of SAI's between 19.04.2021 - 25.04.2021

Any reports received after Friday will not be reflected in the numbers below until the following week

Less than 26 weeks	More than 26 weeks	Within Timescales	Total
5	2	1	8

10. Early Alerts

Irrelevant redacted by the USI – Missing child

Discussion at meeting	Action
Marita has sought an update in relation to this Early Alert but no response received.	n/a

28/04/2021 – Overdose, will be reported on next week's paper

Discussion at meeting	Action
Dr O'Kane has arranged for Clinical staff to meet the patient to offer additional support.	n/a

11. Never Events

None

12. Issues escalated by Corporate or Directorate office at meeting.

None

OLDER PEOPLE AND PRIMARY CARE SERVICES DIRECTORATE

Data provided by Corporate Office from the Datix Incident Management System to the Weekly Governance De-Brief (Thursday mornings - 9am – 10am)

13. Status of SAI's

Summary of the status of SAI's between 19.04.2021 - 25.04.2021

Any reports received after Friday will not be reflected in the numbers below until the following week

More Than 26 weeks	Within Timescale	Less Than 26 Weeks	Total
4	0	0	4

14. Early Alert

19/04/2021 – GP OOH

23/04/2021 – GP OOH

15. Never Events

None

16. Issues escalated by Corporate or Directorate office

17. Actions from Previous Week

Discussion at meeting	Action
Misidentification of end of life patient in PNH	SAI to be raised, HSCB notification pending Update 29/04/2021 Notification pending, work progressing to ensure appropriate action has been taken.
Incident involving a care worker assaulting a patient. Care worker is to be prosecuted.	Early Alert submitted. . Update 29/04/2021 Notification pending.
Review of Covid deaths in Care Homes. Connie advised that at the Regional Governance meeting held this week, the Trust was advised there had been a letter sent to confirm if the Incident meets the criteria of SAI then an SAI is to be raised. Ambiguity remains in realton to the Governance Framework around all of these incidents.	Connie to locate this letter and forward to Dr O'Kane who will write to Rodney for clarification of the Governance Framework for Care Homes.

LITIGATION

18. New Clinical negligence

New clinical negligence claims: 19.04.2021 – 23.04.2021

Ref	Directorate	Division	Incident type	Incident date	Claim date	Opened date	Description
Personal Information redacted by the USI	ACUTE	MUC	Failure / Delay in diagnosis	11/01/2016	15/04/2021	19/04/2021	It is alleged that there was a failure to diagnose a fracture to the wrist (MIU, STH)
Personal Information redacted by the USI	ACUTE	SEC	Failure / Delay in treatment	01/03/2018	15/04/2021	19/04/2021	It is alleged that there was a failure to provide appropriate treatment in Urology, CAH (case added to Section 4)
MNS	OPPC	OPS	Moving/Handling	23/09/2020	22/04/2021	22/04/2021	It is alleged that staff failure to set up moving and handling equipment correctly (in the community) resulted in a service-user's fall
MNS	OPPC	OPS	Failure / Delay in treatment	01/05/2007	19/04/2021	23/04/2021	It is alleged that there was a failure by District Nursing services to adequately assess and provide appropriate treatment for wound care.

19. Clinical Negligence Claims Listed for Hearing in May 2021

The following clinical negligence cases are listed for hearing in May 2021.

Ref	Directorate	Division	Incident type	Incident date	Claim date	Opened date	Description
Personal Information redacted by the USI	ACUTE	IMWH	Lack of Assistance/Care	08/06/2015	10/08/2015	28/05/2015	Alleged failure to provide assistance to a patient with mobility issues, resulting in a fall and injuries sustained **Trial is listed for 11 May 2021 (for 3 days)**
Personal Information redacted by the USI	ACUTE	MUC	Failure / delay in diagnosis	13/09/2010	16/02/2011	31/01/2011	Alleged failure to diagnose an ankle fracture **Trial is listed for 11 May 2021 (for 1 day)**

Personal Information redacted by the USI	ACUTE	SEC	Failure to Monitor/Failure to Treat	22/12/2012	31/03/2016	06/04/2016	Alleged failure to monitor patient following an ERCP procedure, and treat for cholangitis and sepsis **Trial is listed for 17 May 2021 (no of days still to be confirmed)**
Personal Information redacted by the USI	CYP	Corporate	Failure to Monitor/Assess	16/10/2009	01/10/2012	08/10/2012	Alleged failure of the Trust to ensure foster care placement appropriate/alleged failure to safeguard and promote welfare of the Plaintiff **Trial is listed for 23 May 2021 (3-4 days)**

Discussion at meeting	Action
Dr O'Kane asked for an additional column for the Litigation cases to identify the Trust process the incident has been through eg M&M/SAI.	Lynne to consider for future papers.

20. Vaginal Mesh Cases

The Trust has 17 open cases where the allegations relate to vaginal mesh. The case that was originally scheduled to take place in May 2021 is now rescheduled for 6 December 2021 (for 4 days).

Stage	Number of Mesh Cases
Letter of Claim	0
Discovery	5
Investigation	8
Proceedings Issued	3
Trial date Set	1

21. Urology Cases

Due to the announcement by the Minister for Health that a public inquiry is to be carried out in relation to the work of a Urology Consultant who was employed in the Trust, it is anticipated that there will be an increase in related medico-legal requests and litigation cases. There has been one further urology claim that was received (as outlined in Section 1). Whilst this Letter of Claim does not specifically refer to the Consultant in question, it has been established that there was involvement of the above Urology Consultant in this patient's care This claim has therefore been added into the figures below:-

Medico-Legal Requests	Litigation Claims
0	2 (at early stage)

Discussion at meeting	Action
In addition to the 9 SAIs submitted for Urology there are a number which are being investigated via the SJR. Patricia raised a point regarding notifiying the families of this process. Heather Trouton is leading on this piece of work with input from Melanie McClements and Dr O'Kane. The Royal College has appointed a number of External retired urologists. Subsequent updates will be notified at this meeting.	Connie to speak with Stephen regarding liaison framework for Urology. Patricia to speak with Martina Corrigan about notifying the families of SJR. Patricia and Connie to speak regarding leaflets for the families involved in SJR.

22. Coroner's Inquiries and Inquests

There were no Coroners Inquiries received 19.04.2021 – 23.04.2021

The following Inquest Hearings were heard during April 2021. There are no Inquest Hearings scheduled for May 2021

Ref	Directorate	Division	Incident type	Incident date	Opened date	Hearing Date	Description
Personal Information redacted by the USI	ACUTE	SEC	Unexpected death	Personal Information redacted by the USI	09/01/2019	16 April 2021	A post-mortem was not directed in this case. Coroner agreed cause of death 1A – small bowel perforation 1B – Strangulated hernia II - Diabetes Mellitus II; Hypertension; Chronic Obstructive Airways Disease; Congestive Heart Failure **Written findings have been received and communicated to relevant senior management.**
Personal Information	ACUTE	SEC	Unexpected death	Personal Information redacted by the USI	02/05/2017	19-23 April 2021	Coroner directed a post mortem in this case and the preliminary finding is multi-organ failure, probable peritonitis and intra-abdominal haemorrhage following laparoscopic cholecystectomy. **Currently await written findings from the Coroner's Office.**

The following preliminary Inquest Hearings are scheduled in April 2021

Ref	Directorate	Division	Incident type	Incident date	Opened date	Hearing Date	Description
INQ Personal Information	ACUTE	IMWH	Maternal Death	Personal Information redacted by the USI	09/03/2018	28/04/2021	PM Report records cause of death as post-partum haemorrhage following emergency c-section in association with lacerations of uterus, uterine atony, breech position of the foetus and premature rupture of membranes
Personal Information redacted by the USI	MHD	MHS	Self-harm	Personal Information redacted by the USI	08/02/2018	29/04/2021	The deceased died of suspected suicide on following discharge from CAH
Personal Information redacted by the USI	CYP	SOCIAL	Self-harm	Personal Information redacted by the USI	04/07/2019	29/04/2021	The deceased was known to the Trust's Gateway Service and died of suspected suicide.

Discussion at meeting	Action
MHD discussed the double Homicide incident. Litigation confirmed there is Preliminary Hearing on 22nd June.	MHD Governance to follow up on the action plan and send to Dr O'Kane. Update 15/04/2021 – Tony Black confirmed that Acute are following up with Paul Smith regarding the first Action Plan. Tony to link with Stephen Wallace to establish if the second action plan was submitted to HSCB prior to Christmas 2020.

23. Number of Subject Access Requests exceeding timeframe for completion.

The Medico-Legal Team are unable to comply with the General Data Protection Regulations (GDPR) 2018 in respect of responding to Subject Access Requests within the statutory time-frames. This had been due to the sheer volume of requests (which had increased by approx. 1000 per year) and a lack of staffing to cope with the demand. The Governance Committee have been advised of the ongoing back-log; it has been brought to the attention of the Trust's SIRO and placed on the HROD Risk Register. An application was made to the Strategic Investment Committee for additional funding for staff. This was considered by the Strategic Investment Committee on 27th July 2020. Approval has since been provided and the recruitment process is under-way. The Team however are also faced with unexpected absences in respect of current funded staff, which is impacting on the ability to deal with requests.

There is currently a back-log of 318 requests that are in excess of 90 days across the following areas:-

Directorate	Acute Services	C&YP	MH&D	OPPC	HROD	TOTAL
Number of Outstanding Requests	253	29	28	8	0	318
New requests opened 19.04.2021 – 23.04.2021	52	1	2	0	1	56

The back-log has Increased from the previous week, the week-end days are included in counting towards the 90+days and therefore impacts on the work carried out during the week. As outlined previously, the reasons for back-log include (in addition to the staffing and volume issues) - difficulties accessing notes and records, and issues relating to redaction and consent to release.

Discussion at meeting	Action
Dr O'Kane confirmed the team will need additional resource for the number of outstanding SARs and the Public Inquiry. Lynne confirmed that the numbers above don't reflect the positive activity performed by her team in relation to the completion of Medico Legal Claims. The team average 246 per month.	Dr Diamond and Lynne Hainey to discuss the possibility of using student lawyers to assist with this process.

MEDICATION INCIDENTS

24. Medication Incidents between 19.04.2021 - 25.04.2021

- Personal Information redacted by IIR – Patient on methadone attended and advised could take own supply of methadone during admission. Own supply taken for two days before transfer to ward where this was noted. No duplicate doses received.

SAFEGUARDING

25. Link to SharePoint site regarding RQIA Notifications/Alerts

http://sharepoint/pr/perfimp/scc/_layouts/15/WopiFrame.aspx?sourcedoc=/pr/perfimp/scc/RQIA%20Notifications%20and%20Alerts/Alert%20Notice%20Board.xlsx&action=default

New adult safeguarding activity week beginning 19.4.2021 – 25.04.2021 by Directorate

Adult Safeguarding Activity 19.04.2021 - 25.04.2021	Trustwide	MHD	OPPC	Acute
No of new adult safeguarding referrals	23	17	2	4
No of new adult safeguarding referrals meeting threshold for Adult Protection Gateway team	13	10	1	2
No of new referral assessed as Adult in Need of Protection (APGT)	7	6	1	0
No of new referrals managed as adult at risk of harm	7	7	0	0
No of new referrals with NFA under Adult Safeguarding	6	2	0	4
Referrals by category of allegation				
▪ Physical	9	6	0	3
▪ Psychological	4	3	1	0
▪ Sexual	7	6	0	1
▪ Financial	3	2	1	0
▪ Neglect				
▪ Institutional				

	0 0	0 0	0 0	0 0
No of open adult protection cases	177	103	59	11

3 referrals pending outcome of assessment and decision making (2 OPPC & 1 MHD)

Current Adult Protection Investigations where there are interfaces with other processes					
	SAI	**Complaint**	**Coroner**	**Litigation**	**Potential High Profile Protection Cases**
MHD	2				1
OPPC	2	1	1		
Acute		2			

2 Ongoing SAI in MHD where adult protection investigation was undertaken. 1 API ongoing.
1 SAI on hold OPPC - Ongoing Joint Protocol – awaiting PPS decision – Personal Information care Home
1 SAI OPPC – relates to JP case common assault in Personal Information care home. Proceeding to court hearing.
1 ongoing complaint in OPPC where adult protection investigation has been closed. Final meeting with medics to confirm info to close case outstanding. Coroner involved.
2 adult protection investigations in Acute where there has also been a complaint.
1 adult protection investigation ongoing in Acute related to pressure care.
Personal Information redacted by the USI Care Home – ongoing support being provided by SHSCT to address wider care and governance issues. Review due mid April. Individual adult protection JP case is ongoing. Next court date Mid May – date to be set.
1 complaint regarding Adult Protection Process – MHD case

26. Number of Subject Access Requests exceeding timeframe for completion.

Directorate	ACUTE	OPPC	MHD	CYPS	FINANCE	P&R	HROD	CX
Number of outstanding Requests	7	-	8	17	-	-	-	-

These relate to Subject Access Requests which have not been completed within the legislative timescale (legal timeframe 30 days or 90 days for complex requests). These delays are in relation to the demands on Services to carry out redactions of these notes etc. In some cases there are requests which were made in 2019 and have not been progressed.

27. Data Breaches reported to the ICO

Directorate	ACUTE	OPPC	MH&D	CYPS	FINANCE	P&R	HROD	CX
Breaches	-	-	-	-	-	-	-	-

There have been no data breaches reported to the ICO in this period. In this period one complaint (from the ICO) has been closed and we have received another complaint in relation to the time taken to respond to a SAR.

NEW STANDARDS AND GUIDELINES RECEIVED AND ASSURANCES DUE OR SUBMITTED

28. Responses Sent.

Title of Correspondence	Full Implementation Date for S&G	Directorates applicability	Assurance Response
Potential Risk of Towel Dispensers Being Used as a Ligature Point	Response sent 23/04/2021	Acute, CYPS, OPPC, MHD **SHSCT Point of Ligature MDT working group**	20210423_SHSCT

29. Responses that are due to be submitted to an external agency within the next 4 weeks (up until 1 June 2021)

Title of Correspondence	Category	Full Implementation Date for S&G	Directorates applicability	Clinical Lead
Steroid Emergency Card to Support Early Recognition and Treatment of Adrenal Crisis in Adults	Patient Safety Alert	12/05/2021	**Acute, OPPC**	**Short life MDT Working group**
Implementation of guidance on Group B Streptococcus in Pregnancy	CMO Correspondence	19/05/2021	**Acute, CYPS**	**Dr Kamath**
Assurance Required in relation to HSC (SQSD) Deterioration Due to Rapid Offload of Pleural Effusion Fluid from Chest Drains	DOH Correspondence	01/06/2021	**Acute,**	**Dr Alexander John**
Foreign Body Aspiration During Intubation, Advanced Airway Management or Ventilation	Patient Safety Alert	01/06/2021	**Acute,**	**TBC**

30. Responses that are overdue for submission

Title of Correspondence	Full Implementation Date for S&G	Directorates applicability
OPS and AS - Care Home Admission and Initial Review	18/09/2020	**OPPC, Acute, MHD**
Refusal of Treatment	15/04/2021	**Acute, OPPC**
Investigation and Management of Pulmonary Nodules	15/04/2021	**Acute,**
Incidents Relating To Significant or Unexpected Radiological Findings	15/04/2021	**Acute,**

31. Newly Issued S&G received by SHSCT from date of last Corporate Governance meeting

Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	NICE Assurance 3 month	Full Implementation Date for S&G
End of the 2020/21 Flu season and related issues	23/04/2021	HSS (MD) 31/2021	CMO Correspondence	n/a	n/a
Implementation of guidance on Group B Streptococcus in Pregnancy	23/04/2021	HSS (MD) 19/2017 HSS (MD) 29/2019	CMO Correspondence	n/a	19/05/2021
COVID-19 vaccine (Astrazeneca) and thromboembolic events with concurrent low platelet counts	20/04/2021	n/a	PHA Correspondence	n/a	n/a

32. Regional PIVFAIT Audits

CAH CYP	2 /3 = 50%. •Non-compliant for indicator 4 (Cumulative input and output totalling and fluid balance) PIFVAIT action plan 18.4.21.docx
DHH CYP	1/3 = 33%. Both cases Non-compliant for indicator 4 (Cumulative input and output totalling and fluid balance)
ACUTE	1 case this week, returns awaited- 6 from previous to be reviewed – Total = 7 to review

Discussion at meeting	Action
Joanne advised a potential theme has been identified in relation to indicator 4.	Joanne is going to review audits over the last few weeks to identify any areas for improvement and create an action plan.

33.PPE Report

Discussion at meeting	Action
Trudy informed the panel there has been a number of incident reported, whereby staff are experiencing reactions to the masks. These incidents are being reported through Datix.	n/a

AOB

Attendees: Connie Connolly, Rebecca Murray, Caroline Beattie, Joanne McConville, Lynne Hainey, Nicole O'Neill, Damian Gormley, Marita Maginness, Jillian Redpath, Patricia Kingsnorth, Christopher Warr, Caroline Doyle, Catherine Weaver, Tony Black, Aisling Diamond, Claire McNally, Deborah Hanlon, Dr O'Kane, Heather Trouton, Trudy Reid, Mark McKeever, Lauren Weir

Apologies:

Southern Health and Social Care Trust

Chief Executive – Medical Director
1-1 Meeting
5th May 2021

	Item	Attachment
1	**Urology Update SAIs** • Final SAI's have been issued to the HSCB and shared with GMC. Copies are being sent to the DoH this week. Final family who suffered a bereavement has responded requesting amendments to the report (attached, being considered by SAI chair • QIP structure for Urology and Cancer services agreed. Terms of Reference being finalised this week. • Trust is pursuing ISP support for expediting patient reviews • Additional SME obtained by the Trust to support Prof Sethia review • Additional SME obtained by the Trust to conduct SCRR	Summary of Patients under the care of AO SAI Review - Patient Family.docx
2	**Urology Public Inquiry** • Lookback Guidance – DoH have agreed this requires discussion at the UAG. DoH not opposed to Trust operating outside of this in the circumstances however will seek assurance that alternative arrangements are safe. • Stephen has met with Heather to form an oversight assurance mechanism, this will be presented next week. ***Resourcing*** • Fiona Davidson (8B) will be working 2 days per week overseeing work to deliver on the recommendations. This may increase to 4 days from June. • There will be a requirement to secure QI input for this work as an action plan develops • Meeting with NHS England Cancer Services peer review team to take place in next weeks to identify supports for external peer review	Regional Guidance for Implementing a Lc Policy for Implementing a Lookb
3	**Mental Health and Learning Disability** • Mental Capacity Act update • Update on regional MHLD challenges	DoLS Response 28.04.2021.docx
4	**Infection Prevention and Control** • Role of the DIPC – potential for this to be a nurse lead. Consideration of banding of this post	

5	**Nosocomial COVID-19 Mortality** • Process agreed and endorsed by regional group as the basis for all reviews. MDO team are currently gathering data to support this process	Nosocomial COVID-19 Deaths Mo
6	**Medical Leadership Proposal** • Original date delayed due to discussion with HR on T&Cs for the DMD posts, finalising Management Allowance and taxable implications • Identification of 3rd Deputy Medical Director post – Professional Governance / Appraisal and Revalidation	
7	**Appraisal, Revalidation and Annual Management Reviews for Doctors** • Monthly DMD Revalidation Oversight Group has been established to inform revalidation recommendations. • Update on the discussion with UHB further meeting planned for April – potential for Annual Management Reviews to complement A&R processes. Proposal to be develop regarding implementation of the new model. Meeting with UHB DMD Dr Nick Murphy to take place this week.	Medical Revalidation Oversight Group ToR
8	**Individual Performance Review** • Shane to discuss what will be required for IPR re Medical Director	FW IPR's.msg
9	**Hyponatraemia** • Paediatric / Surgery paper finalised • Hyponatraemia 8B appointed – David Calvin successful applicant. Post Commences being of May 2021 • Recommendation stocktake event took place at the start of April – successful outcome	Principles for the Management of Surgi
10	**SAIs in Care Homes** • Communication from Rodney Morton re management of outbreaks – challenges present, response to be issued	RE Letter re SAI Procedures .msg Irrelevant Letter re SAI Procedure.pdf
11	**Crowe SAI** • Update	
12	**GMC Standards – Compliance re Surgical Rota**	
13	**MDO risk register** • Meeting to update to take place	
14	**COVID-19 Level 3 SAI Update** • Outcome of Site Visit	

15	**Obs and Gynae** • Whistleblowing Update • DHH meeting Update • [redacted] Meeting 13th May 2020 • RCOG Discussion	[redacted].pdf
16	**Cervical Cytology Service** • Proposal paper • Contact made to PHA re funding	Cervical Cytology Service Position pape
17	**CSCG Staffing Proposal Update** • Two posts are commencing recruitment this month – 8a Patient Safety and 7 Patient Safety Strategy Lead • Connie retiring in July, 8B replacement post being advertised • Proposal for ringing CSCG under corporate leadership in development paused	Phase Plan.docx
18	**Unscheduled Care Centre Governance** • Clinical Governance for the UCC will sit with ED. • Meeting last Friday	
19	**NEWS2** • NEWS2 Now live from 1st May 2020	
20	**Structured Judgement Review** • SJR Training took place on the 18th and 25th March. 20 Trust doctors were trained, the training model is designed for cascade training. • John Simpson has completed his SJR review of Mental Health cases – findings to be shared with the HSCB for consideration of regional adoption.	
21	**Learning from Experience Update** • Attached	Gov Committee Lessons Learned Upd
22	**LNC Meeting 6th May 2020** • SAS Grade and Appraisal • Medical Leadership Review • Revalidation Oversight Meeting	
23	**Weekly Governance Report** • 24.04.2021 Report	Weekly Governance Report 19.04.2021 -

Southern Health and Social Care Trust

Quality Care - for you, with you

27th May 2021 Ref:

XXXXXXX
XXXXXXX
XXXXXXX
XXXXXXX

Dear XXXXXX,

RE: CARE PROVIDED TO XXXXXXXX

My name is XXXXXXXX and I am XXXXXXXXX for Southern Health and Social Care Trust. I am writing to you, to offer my apologies regarding the shortfall in care you received whilst being treated within the Southern Health and Social Care Trust.

At the Southern Health and Social Care Trust, we aim to provide a quality service to all of our patients, service users and families and we would like to acknowledge on this occasion the care delivered has fallen short of these standards.

Commented [WS1]: Is this appropriate wording

As you are aware, to determine what happened a review of your care was conducted by Dr Dermot Hughes. Dr Hughes produced a report which has been shared with you that contains lessons to be learned and recommendations for the Trust to prevent any reoccurrence. I personally want to assure you that we will be enacting this learning and recommendations promptly.

As a Trust, we are committed to being open when events such as this happen and we want to ensure as well as sharing the review findings we would like to keep you informed of the progress towards implementing the lessons learned and recommendations. To deliver on

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ
Tel: Personal information redacted by HSI Email: maria.okane Personal information redacted by HSI

this commitment we will write to update you in regular intervals of our progress ensuring you are fully informed at all stages.

- First Update by 27th August 2021
- Second Update by 26th November 2021
- Third Update by 25th February 2021

You have a right to expect the very best care every time you use our services. However, if things do go wrong, it is the role of the Trust and our staff to learn from any failings, so that we can provide answers to families and patients and improve our care now and in the future.

Commented [MR2]: Added paragraph

We will do everything we can to support you and your family during this process. In the meantime, I would like to reassure you that that we are working hard to deliver the high quality Urology Services that the people in our communities rightly deserve.

If you would like to meet or speak with me or have any questions then please contact me as follows: INSERT NUMBER/EMAIL. The Trust also has a designated Family Liaison Officer, Fiona Sloan who has been in contact with you. Fiona is independent of the service and can support you at this time.

Once again I offer my sincerest apologies to you and our assurance that we will continue to work openly and honestly to learn from this event.

Yours sincerely

_____

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ
Tel: Personal information redacted by HSI Email: maria.okane Personal information redacted by HSI

Southern Health and Social Care Trust

Quality Care - for you, with you

25th May 2021 Ref:

XXXXXXX
XXXXXXX
XXXXXXX
XXXXXXX

Dear XXXXXX,

RE: CARE PROVIDED TO XXXXXXXX

My name is XXXXXXXX and I am XXXXXXXXX for Southern Health and Social Care Trust. I am writing to you, to offer my deepest condolences, following the death of your RELATIONSHIP TO DECEASED. Please also accept my sincere apology that this happened, while XXXXXXXX was in our care. At the Southern Health and Social Care Trust, we aim to provide a quality service to all of our patients, service users and families and we would like to acknowledge on this occasion the care delivered has fallen short of these standards.

Commented [WS1]: Is this appropriate wording

As you are aware to determine what happened a review of XXXXXXX's care was conducted by Dr Dermot Hughes. Dr Hughes produced a report which has been shared with you that contains lessons to be learned and recommendations for the Trust to prevent any reoccurrence. I personally want to assure you that we will be enacting this learning and recommendations promptly.

As a Trust, we are committed to being open when events such as this happen and we want to ensure as well as sharing the review findings we would like to keep you informed of the progress towards implementing the lessons learned and recommendations. To deliver on

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You have a right to expect the very best care every time you use our services. However, if things do go wrong, it is the role of the Trust and our staff to learn from any failings, so that we can provide answers to families and patients and improve our care now and in the future.

Commented [MR2]: Added paragraph

We will do everything we can to support you and your family during this process. Please be assured that it is not our intention to intrude upon you, or your family at this difficult time, however, we would like to keep you informed.

If you would like to meet or speak with me or have any questions then please contact me as follows: INSERT NUMBER/EMAIL. The Trust also has a designated Family Liaison Officer, Fiona Sloan who has been in contact with you. Fiona is independent of the service and can support you at this time.

Once again I offer my sincerest apologies and condolences to you and our assurance that we will continue to work openly and honestly to learn from this event.

Yours sincerely

_____

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Patients under the care of Mr O'Brien and currently in process of being reviewed
7 June 2021

	Patient Group	Number of Episodes/Patients in Group	Reviewed to date	Reviewed by	Remaining to be reviewed	Reviewed by	Provisional date	Quality Assured	Comment
Administrative Review Only	***Elective Cohort***	*352 Patients*	*352 (Administrative Review)*	*M Corrigan*	*0*	*Needs Clinical Review*	*N/A*	*No*	***All** are part of the 2309 patients required reviewed between Jan 2019 – Jun 2020. **Review to date only considered administrative processes***
	Emergency Patients (Stents)	*160 Patients*	*160 (Administrative Review)*	*M Corrigan*	*0*	*Needs Clinical Review*	*N/A*	*No*	***All** are part of the 2309 patients requiring reviewed between Jan 2019 – Jun 2020 **Review to date only considered administrative processes***
	Radiology Results	1025 Patients (1536 Episodes)	911 (Result Review)	CNS/ Professor Sethia	625	Professor Sethia	July 2021	No	Update from last report: **No change**
	Pathology Results	150 Patients (168 Episodes)	168 (Result Review)	M Haynes/D Mitchell	0	N/A	N/A	Yes	Update from last report: **No change**
	Oncology Reviews (IS)	236 Patients	200 (Face to Face ISP)	P Keane	36	M Haynes	June 2021	No	Update from last report: **No change**

		187 Patients (271 Episodes)	271 (SME Record Review)	Prof Sethia	52 (need second opinion)	M Haynes	July 2021	No	Update from last report: **No Change**
		511 Patients	111 (Virtual Clinics)	M Haynes	400	M Haynes/T Glackin	March 2022	No	Update from last report: **9 patients reviewed**
		155 Patients	10(reviewed at clinic)	M Haynes	145	Prof Sethia	Sept 2021	No	Update from last report: **No Change**
		933 Patients	747 (Record Review, 26 Face to Face Reviews)	M Haynes	186	M Haynes	March 2022	No	Update from last report: **No change**
		143 patients	0	TBA	143	Clinical Team	Dec 2021	No	Update from last report: **No change**
	Total	**4465**	**2930**		**1587**				

- Note there were a total of 2309 patients that have been identified as being under Mr O'Brien's care from January 2019- June 2020, and a number of the above have been identified as being in this cohort of patients with multi episodes, more work is being done to identify how many of these are not included in the above groups with first look at this it may appear to be in and around another 1000 patients in this group that are not included in the above

Regional Guidance for Implementing a Lookback Review Process

Final Draft

Contents

Regional Guidance for the Implementing of a Lookback Review Process

1.0 Introduction

A Lookback Review Process is implemented as a matter of urgency where a number of people have been exposed/potentially exposed to a specific hazard in order to identify if any of those exposed have been harmed, and to identify the necessary steps to ameliorate the harm (e.g. repeat diagnostic test/ investigation/ referral to relevant clinical service etc.).[1]

This Regional Guidance, along with the accompanying policy document, has been drafted in order to standardise and update the approach taken to Lookback Reviews by the HSC in Northern Ireland. It replaces HSS (SQSD) 18/2007, issued by the Office of the Chief Medical Officer on 8 March 2007.

A Lookback Review is a process consisting of four stages; immediate action including a preliminary investigation and risk assessment to establish the extent, nature and complexity of the issue(s); the identification of the service user cohort through a service review or audit of records to identify those potentially affected; the recall of affected service users; and finally closing and evaluating the Lookback Review Process and the provision of a report including any recommendations for improvement (see summary diagram of Lookback Review Process (Diagram 1) and Lookback Review Process Checklist Appendix 5).

The triggering event or circumstances under which a Lookback Review would be considered include; faulty or contaminated equipment, missed/delayed/incorrect diagnosis relating to diagnostic services, failure of safety critical services or processes, competence issues with a practitioner(s) or identification of a practitioner with a transmissible infection or underlying health problem that may impact on performance (see also Policy on the Implementation of a Lookback Review Policy Section 1 for a more comprehensive list).[2]

[1] Health Service Executive (HSE) 'Guideline for the implementation of a Look-back Review Process in the HSE'. HSC National Incident Management and Learning Team, 2015. Section 7.1 Page 10.
[2] See also 'Policy for the Implementation of a Lookback Review Process' Section 1 Page 3.

The existence of a hazard exposing a number of people to a risk of harm is not always immediately apparent. The triggering event may have been raised as a concern by a service users and/or their family/carers or it may have been highlighted by a service review/audit or it may have come to light as a result of a concern expressed by a colleague or through a Serious Adverse Incident (SAI) Review or Thematic Review undertaken by the Regulation and Quality Improvement Authority. The triggering event will alert the Health and Social Care (HSC) organisation that a number of people may have been exposed to a hazard and the need to instigate a Lookback Review Process should be immediately considered.

1.1 What does a Lookback Review Process involve?

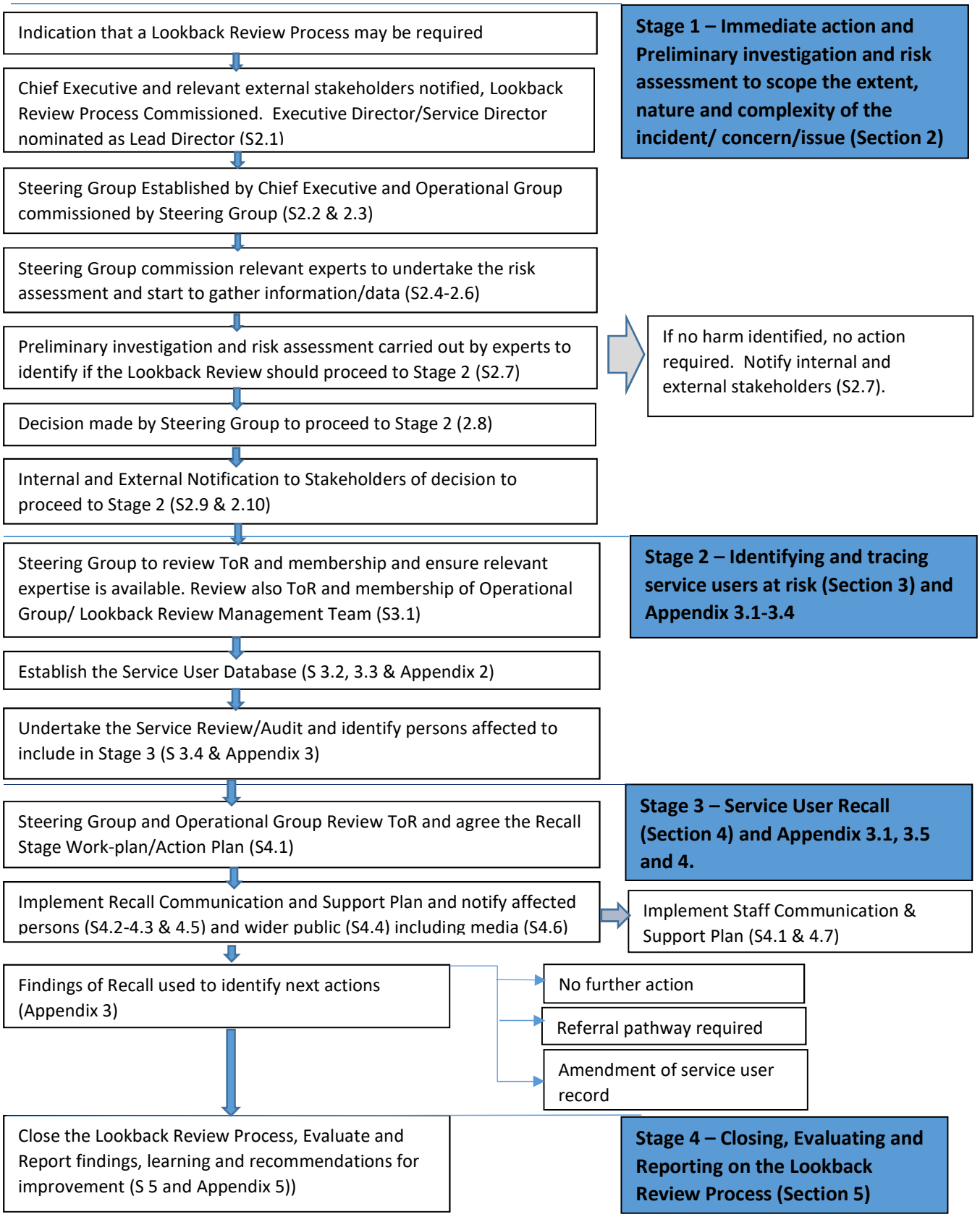
The Lookback Review Process involves:

- Identifying, tracing, communicating, and providing appropriate ongoing advice to, and/or management of, the group of service users who have been exposed or potentially exposed to a hazard and who may have been harmed, or are at risk of future harm or loss;
- Notification internally to Trust Board and to appropriate external stakeholders (see Sections 2.1, 2.9 and 2.10);
- Notification to the wider public as and when required. While openness and candour are guiding principles in a Lookback, it is essential that communication occurs at a time when clear messages can be conveyed whilst ensuring that the 'at risk' population has been identified and communicated with before the wider public is alerted. Relevant healthcare professionals including General Practitioners should also be identified and communicated with in advance of any public statements. This is essential to maintain public confidence and prevent unnecessary anxiety and to ensure that services can be focused on the correct group of people (See Section 4 below).

The following diagram (Diagram 1) provides a summary of each stage of the Lookback Review Process and may be used in conjunction with the Lookback Review Process Checklist (see Appendix 5). The Process, as laid out below is a step by step guide. It is important, however, that the primary focus should remain on harm and risk of harm to service users. Therefore, there will be occasions where it is

clear from the outset that a Lookback Review will be necessary and where the organisation effectively runs more than one of these stages consequently.

Diagram 1 Flowchart - Summary of Stages in a Lookback Review Process



1.3 Governance Arrangements

The HSC organisation should ensure that the Lookback Review Process is managed in line with extant Governance and Assurance Framework arrangements.[3] The Steering Group (Section 2.2) should be seen as a 'task and finish' group within the HSC organisation's Governance/Assurance Framework structure reporting to Trust Board through the Senior Management Team/ Executive Team of Trust Board. The Steering Group should commission an Operational Group or Lookback Review Management Team to take forward the operational aspects of the Review Process (unless the Lookback Review is anything other than limited in terms of nature, extent and complexity).

When scoping the nature, extent and complexity of the Lookback Review Process (Section 2.6 – 2.7) the Steering Group should evaluate and escalate the risk in line with the organisation's Risk Management Strategy. This will ensure that the risk(s) identified will be included in either the organisation's Board Assurance Framework, Corporate Risk Register or Directorate Risk Register and managed in line with the Risk Management Strategy.

The Lookback Review Process should be outlined in the mid-year Assurance and/or annual Governance Statement as required. The annual Governance Statement is the means by which the Accounting Officer provides a comprehensive explanation on the HSC organisations' approach to governance, risk management and internal control arrangements and how they operate in practice.[4] The Statement provides a medium for the Accounting Officer to highlight significant control issues which have been identified during the reporting period and those previously reported control issues which are continuing within the organisation.

1.4 Other Related Incident Management Processes including Investigations

As stated previously, Lookback Reviews are carried out in order to identify if any of those exposed to a hazard have been harmed, and to identify the necessary steps to take care of those harmed. The incident giving rise to the Lookback Review Process or issues identified as a result of the process may require review as a Serious

[3] DoH '*An Assurance Framework: a Practical Guide for Boards of DoH Arm's Length Bodies*.' April 2009.
[4] Department of Finance ' *Managing Public Money NI (MPMNI)*' AS.1

Adverse incident (SAI).[5] This will require a parallel (though interlinked) review which should be undertaken in line with Health and Social Care Board guidance [6] to identify key causal and contributory factors relating to the triggering event (see Sections 2.10 and Section 5). In some circumstances, a Lookback Review Process may have been prompted by a preceding SAI review.

The circumstances leading to a decision to implement a Lookback Review may require the HSC organisation to notify other statutory agencies such as the Coroners Service for Northern Ireland and/or the Police Service for Northern Ireland (PSNI). The reporting of the Lookback Review as an SAI to the Health and Social Care Board (HSCB) will work in conjunction with, and in some circumstances inform, the reporting requirements of other statutory agencies and external bodies. In that regard, all existing local or national reporting arrangements, where there are statutory or mandatory reporting obligations, will continue to operate in tandem with this Regional Guidance.

A Memorandum of Understanding (MoU) has been agreed between the Department of Health (DoH, on behalf of the Health and Social Care Service (HSCS), the Police Service of Northern Ireland (PSNI), the Northern Ireland Courts and Tribunals Service (Coroners Service for NI) and the Health and Safety Executive for Northern Ireland (HSENI).[7] The MoU applies to people receiving care and treatment from HSC in Northern Ireland. The principles and practices promoted in the MoU apply to other locations, where health and social care is provided e.g. it could be applied when considering an incident in a family doctor or dental practice, or for a person receiving private health or social care provided by the HSCS.

A Lookback Review Process may raise issues of professional competence/conduct. HSC organisations will then be required to instigate performance management, capability and disciplinary reviews or investigations in line with their internal Human Resource policies, procedures and relevant professional regulatory guidance for

[5] Health and Social Services Board (HSCB) 'Procedure for the Reporting and Follow-up of Serious Adverse Incidents'. November 2016 Version 1.1.
[6] *Ibid.*
[7] DoH *'A Memorandum of Understanding' developed to improve appropriate information sharing and co-ordination when joint or simultaneous investigations/reviews are required into a serious incident'.* HSS (MD) 06/2006, February 2006.

example Maintaining High Professional Standards (MHPS).[8] These processes should run as a parallel process to the Lookback Review, although relevant information from one process may inform the other. In such circumstances, confidentiality in respect of the member of staff must be taken into consideration.

[8] DoH 'Maintaining High Professional Standards in the Modern HPSS'. HSS (TC8) 6/2005. November 2005.

2.0 Stage 1 – Immediate Action, Preliminary Investigation and Risk Assessment

Immediate action should be taken to ensure the safety and wellbeing of the service users.

2.1 Notification of the need to consider a Lookback Review Process

The Director of the service involved should be notified immediately that a hazard or potential hazard has been identified which may require the organisation to consider implementing a Lookback Review Process. The Director will report the issue(s) internally through the Chief Executive to the Board of Directors in line with the organisation's risk escalation processes. The relevant Director will also need to consider if the hazard might affect other HSC Organisations or private/ independent providers.

It is recognised that at this early stage there may be limited information available to the HSC organisation until information and intelligence is gathered and the risk assessment is undertaken (see Sections 2.6 and 2.7), however, in line with extant guidance, the Director should notify the DoH of the emerging issues by way of an Early Alert (see also Section 2.9).[9] The Early Alert should make clear, if the information is available, the details of other organisations/services potentially involved in NI or in other jurisdictions, the timeframe during which the issue may have been relevant and the potential volumes of services users who may be affected. The Director should also consider if the findings, given the potentially limited information could be considered as an SAI at this time (see Section 2.10). [10] If in doubt, the extant SAI guidance provides the opportunity for the organisation to declare the matter as an SAI, which can then be 'de-escalated' later.[11] The HSC Organisation will also have to consider possible notification of the event(s) to the Coroners Service for NI and/or the PSNI (see Section 1.4).

[9]Department of Health 'Early Alert System' HSC (SQSD) 5/19.
[10] HSCB 'Procedure for the Reporting and Follow up of Serious Adverse Incidents. November 2016.
[11] *Ibid.,* Section 7.6 Page 21

It is also important to advise the organisation's Head of Communications/Communications Manager at an early stage so that a communication plan including media responses can be prepared in advance.

2.2 Establish Steering Group

A Steering Group should be convened as soon as possible after the disclosure of the issue of concern to develop an action plan and oversee its implementation. Depending on the extent, nature and complexity of the triggering event the Steering Group should be chaired by either the relevant Service Director or in some circumstances it may be chaired by the relevant Executive Director/Professional Lead.

If other investigation processes are in place (e.g. Capability/Performance Management Reviews) these should run as parallel processes, however, information from the other investigative processes, taking into account confidentiality and the information governance requirements that will apply to these parallel processes, may be used to inform the decision making of the Steering Group.

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

2.3 Composition of the Steering Group

The composition of the Steering Group will be dependent on the service involved and the nature and extent of the Lookback Review Process. The Steering Group should not normally involve personnel who may have been directly involved in the event/hazard that triggered the Lookback Review Process.

Depending again on the extent and nature of the Lookback Review the HSC organisation should consider the following as core members; a Non-Executive Director, the Director of service/speciality concerned, relevant professional Executive Director(s), Risk and Governance representative, Head of Communications, Information Technology manager, Medical Records manager and senior service representatives with expertise (including clinical and/or social care) in the services/

processes which are the subject of the Review Process, a PHA representative and an HSCB representative (in the case where the Lookback Review has been identified as an SAI, the role on the Steering Group will be clearly identified to ensure that the independence of the PHA/HSCB is not jeopardised).

The organisation may also wish to consider a member of a relevant service user representative/advocacy group is included as a member of the Steering Group.[12] In these instances, a confidentiality agreement must be signed by the service user representative. The representative should not have access to service user identifiable data. Such an agreement should be proportionate and reflect the need of the organisation to protect the information of individuals and to ensure that information disseminated is accurate, proportionate and timely and that support mechanisms are in place for service users and staff.

The Steering Group should also commission an Operational Group or Lookback Review Management team which should report to and support the Steering Group in taking forward the operational aspects of the action plan e.g. establishing the service user database (Section 3.2) and supporting the Recall Stage (Section 4).

2.4 Role of the Steering Group

Within 24-48 hours from being established the Steering Group should decide on the immediate response which includes;

- Methodology to determine the size/magnitude, complexity and nature of the risk/harm to service users/carers in order to plan an appropriate Lookback Review Process e.g. risk assessment (see Section 2.7 below);
- Determine if the Lookback Review Process is limited to one HSC organisation or if the process will involve a number of HSC organisations as well as the independent sector and organisations in other jurisdictions;
- Determine the extent of notifications to the DoH, HSCB and PHA that is required, if these notifications have not already been initiated (see Section 2.1 above and Sections 2.9 and 2.10);

[12] The Patient and Client Council (PCC) is responsible for delivering and/or providing access to advocacy and support services as specified by the DoH and HSCB guidance in supporting families through a 'hub and spoke' model of service delivery working with providers of advocacy services. Other independent services may be accessed as required through the PCC, including the development of a network of available advisory services.

- Address and manage notification internally through the Senior Management Team/Executive Team to the Board of Directors;
- Agree on the formation of an expert advisory sub group comprising experts in the area of concern, relevant clinicians, and department or directorate heads to undertake the risk assessment and service review or audit . Consideration should be given as to whether or not that expertise should come from outside the organisation;
- Agree on a service user communications plan. Communication with the service user/family is a priority and the organisation should be proactive in managing the manner and timing in which affected service users receive relevant information (see Section 4.2).
- Agree on a communication plan/liaison plan for other HSC organisations or independent/private providers which might be affected.
- Agree on a media/communications management plan if required, that aims to be proactive in disclosure to the general public and considers responses to media enquiries (see Section 4.6).[13]

2.5 Steering Group Terms of Reference and Action Planning

The Steering Group should develop and approve Terms of Reference and establish a Lookback Review Action Plan for Stage 1 of the Process. Both the Terms of Reference and action plan should be reviewed and revised as and when the Process proceeds to the next stages.

The action plan should include as a minimum; the management of immediate safety issues, identify those who may have been exposed to harm, care for those who may have been harmed/affected, actions to prevent further occurrences of harm, a communication plan, contingency planning for business continuity of the service and plans for potential service user follow-up.

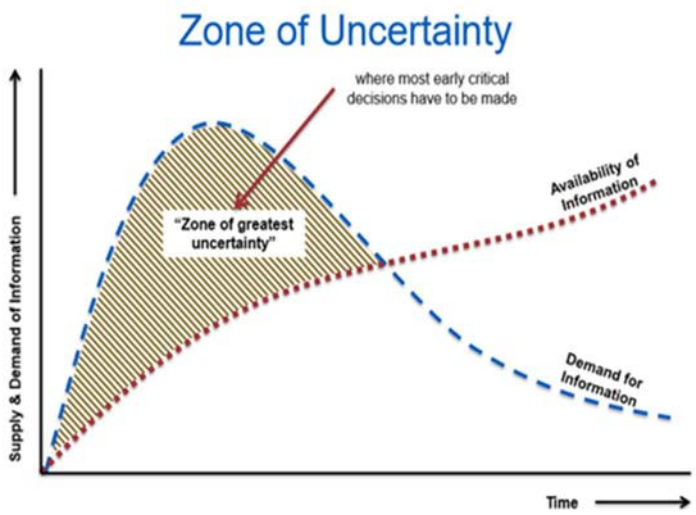
[13] New South Wales 'Lookback Policy Directive', Clinical Excellence Commission Safety & Quality, System Performance & Service Delivery, September 2007. Section 4 Page 5.

2.6 Gathering Information and Intelligence to Scope the Extent, Complexity and Nature of Harm

Key decisions have to be made at this early stage of the process when minimal information may be available to the Steering Group. Decision making should be based on a joint understanding of risk (see below) and shared situation awareness.[14] Situation awareness is having a common understanding of the circumstances, immediate consequences and implications of the triggering event along with an appreciation of the available capabilities and the priorities of the response.[15]

It is important that internal and external stakeholders are aware that the Steering Group may be required to make decisions during a time of uncertainty (or zone of uncertainty) about the level of risk or harm to service users (see Figure 1 below).[16] Depending on the extent, nature and complexity of the Lookback Review Process it can be difficult for the Steering Group to predict when it has gathered the optimum level of information to make decisions such as the decision to announce the Service User Recall stage.

Figure 1 Zone of Uncertainty



At the early stage, as above when limited information is available upon which the Steering Group will be required to make crucial decisions then a Decision Making Model, widely used amongst the emergency services as a tool, could be considered.

[14] Joint Emergency Services Interoperability Principles (JESIP) ' www.jesip.org.uk
[15] *Ibid*.
[16] *Ibid*

Tools to aid decision making include for example the Joint Decision Making (JDM) Model (Figure 2)[17] which helps bring together the available information, reconcile objectives and make effective decisions.

Figure 2 Joint –Decision Making Model

Further information and use of the JDM are available via the Joint Emergency Services Interoperability Principles (JESIP).[18]

All decisions should be recorded/logged, justified, seen to be reasonable and proportionate to the information available at the time. Therefore the Steering Group will require the services of an experienced minute-taker or 'loggist'[19] to ensure an accurate record of actions and decisions is maintained at each stage of the process.

[17] Joint-Decision Making Model @ www.jesip.org.uk/joint-descision-model
[18] *Ibid*.
[19] A term used in Major Incident Planning a loggist is the person who is responsible for capturing, through decision logs, the decision making process that might be used in any legal proceedings following an incident ' www.epcresilience.com

2.7 Risk Assessment [20]

As indicated above, the first stage in the process is to undertake a risk assessment to determine whether the scope, size/magnitude, complexity and nature of harm arising from the triggering event should progress to the next stage(s) i.e. a service user lookback and potential service user recall. In order to do this, the Steering Group should commission relevant experts to undertake this risk assessment. As above (Section 2.3), the relevant experts may include but are not exclusive to: people with the clinical or social care expertise in the services/ processes which are the subject of the Lookback Review Process, Risk and Governance Managers, and a Public Health Specialist. This will be determined by the Steering Group on a case by case basis.

A decision to undertake the completed Lookback Review Process has significant implications for service users, providers and resources. The risk assessment, therefore, should provide a thorough assessment of the chance of harm and the seriousness of that potential harm. It must be conducted in a manner that balances the need to identify and address all cases where there might be safety concerns on the one hand, with the need not to cause any unnecessary concern to service users or to the public on the other.[21]

The risk assessment should look at:

- If the Lookback Review Process is limited to one HSC organisation or if the process will involve a number of HSC organisations including the independent sector;
- The potential extent of the issue and the level of exposure to the hazard;
- Evidence of harm that has occurred;
- The likelihood of future harm occurring;
- The potential and actual (if relevant) outcomes of the issue e.g. missed diagnosis/ missed return appointments for follow up etc;
- The potential impact of the issue;
- The potential cohort of service users affected (including service users of other HSC and non-HSC Organisations);

[20] HSE. *Op.Cit* Section 7.6 Preliminary Risk Assessment Page 115-16.
[21] *Ibid*. Appendix 1

- The potential impact on other service users (not in the 'at risk' cohort) e.g. potential delays in treatment and diagnosis;
- The manner in which harm would be ameliorated (e.g. repeat investigation/ onward referral for treatment).

The HSC Regional Risk Matrix and Impact Table may be used as guidance to evaluate the risk.[22] A template for undertaking a preliminary risk assessment is included in Appendix 1 of this Guidance.[23]

The Steering Group will use the information obtained from this assessment to decide if the Process should continue to the Service User Lookback and Recall stages (see Section 2.8). If there is no harm or risk to service users, the Lookback Review Process can be closed. The Steering Group will inform the relevant internal and external stakeholders. It is advised that the Early Alert is updated to indicate that the process has been closed, outlining clear reasons for the decision. The HSC organisation should consider the incident as a 'near miss' and undertake a systems analysis to establish contributory factors, learning and recommendations.

2.8 Decision to proceed to Stage 2 Service User Lookback and Stage 3 Service User Recall

The decision to proceed to the Service User Lookback and Recall stages is a difficult and complex one and should not be taken lightly. As above, the decision should only be considered in circumstances where it is indicated following careful risk assessment, which may necessitate external peer review and advice from senior decision-makers and/or others with knowledge and experience in the specialty in which the Process is being considered and with advice from those who have experience in conducting a Lookback Review Process (see Section 2.7 Risk Assessment).[24] The decision should also include consideration of the impact on other service users (i.e. not the 'at risk' cohort) for potential delays in diagnosis and treatment.

Lookback Reviews by their nature are often high-volume, involve high-complexity and high-cost (including opportunity cost which diverts time and resources from

[22] HSCB. *Op.cit*. Appendix 16.
[23] HSE. *Op.cit*. Preliminary Risk Assessment Stage pages 15 to 16 and Appendix 1.
[24] *Loc.cit*.

ongoing care.) As described above, they involve a number of stages and logistical challenges.

If a decision is taken to proceed to the Service User Lookback and Recall stages then the Chair of the Steering Group must inform the Chief Executive and Board of Directors and notify the relevant external bodies. The Early Alert should be updated (Section 2.9). If the Process has not already been reported as an SAI then the Steering Group should review the SAI criteria and take appropriate action (see Section 2.10).

The Steering Group should continue to consider any safety concerns that may arise at any stage of the Review Process which may need prompt action. Concerns may include the following:

- Taking preventative action such as the removal of the hazard [25];
- Consideration of the benefits and risks of suspending or transferring the service under review;
- Management of staff member(s)/service whose caseload is under review in line with Professional/Regulatory Guidance/HR/Occupational Health policy and procedure;
- Clinical and social care management of service users/ staff identified by the preliminary review and suspected of being adversely affected;
- Providing support to service users and staff involved.

The Steering Group should ensure that business continuity plans are considered and implemented, where necessary, including providing for additional health and social care demands which may arise as a consequence of the Lookback Review. The HSC organisation is responsible for securing service capacity and for ensuring that the necessary resources are allocated to conduct all the stages of the Review Process and subsequent follow-up processes. If the resources required exceed what is available then this should be escalated to the organisation's Board and if necessary to the Health and Social Care Board.

The Steering Group should be prepared for the fact that when a full Lookback Review Process is being considered this information can often become publicly known at the

[25] If the hazard is associated with a medical device then the HSC organisation should report this in line with Norther Ireland Adverse Incident Centre (NIAIC) adverse incident reporting – guidance and forms. October 2018 ' www.health-ni.gov.uk.

planning stage and should have a contingency plan in place for notification of affected persons and the wider public if this should occur.

2.9 Early Alert Notification [26]

The established communications protocol between the Department and HSC organisations emphasises the principles of 'no surprises', and an integrated approach to communications. Accordingly, HSC organisations should notify the Department promptly (within 48 hours of the event in question) of any event which has occurred within the services provided or commissioned by their organisation, or relating to Family Practitioner Services. Events should meet one or more of the following criteria;

1. *Urgent regional action may be required by the Department, for example, where a risk has been identified which could potentially impact on the wider HSC service or systems;*
2. *The HSC organisation is going to contact a number of patients or clients about harm or possible harm that has occurred as a result of the care they received. Typically, this does not include contacting an individual patient or client unless one of the other criteria is also met;*
3. *The HSC organisation is going to issue a press release about harm or potential harm to patients or clients. This may relate to an individual patient or client;*
4. *The event may attract media attention;*
5. *The Police Service of Northern Ireland (PSNI) is involved in the investigation of a death or serious harm that has occurred in the HSC Service, where there are concerns that a HSC service or practice issue (whether by omission or commission) may have contributed to or caused the death of a patient or client. This does <u>not</u> include any deaths routinely referred to the Coroner, <u>unless</u>:*
   - *i. there has been an event which has caused harm to a patient or client and which has given rise to the Coroner's investigation; or*
   - *ii. evidence comes to light during the Coroner's investigation or inquest which suggests possible harm was caused to a patient or client as a result of the treatment or care they received; or*
   - *iii. the Coroner's inquest is likely to attract media interest.*
6. *The following should always be notified:*

[26] Department of Health 'Early Alert System' HSC (SQSD) 5/19.

i. *the death of, or significant harm to, a child, and abuse or neglect are known or suspected to be a factor;*
ii. *the death of, or significant harm to, a Looked After Child, a child on the Child Protection Register or a young person in receipt of leaving and after care services;*
iii. *allegations that a child accommodated in a children's home has committed a serious offence; and*
iv. *any serious complaint about a children's home or persons working there.*

7. *There has been an immediate suspension of staff due to harm to patient/client or a serious breach of statutory duties has occurred.*

The next steps will be agreed during the initial contact/telephone call and appropriate follow-up action taken by the relevant parties. In **all** cases, however, the reporting organisation must arrange for the content of the initial contact to be recorded on the updated pro forma attached at Annex C, and forwarded, within 24 hours of notification of the event, to the Department at earlyalert@health-ni.gov.uk and the HSC Board at earlyalert@hscni.net.

The Early Alert must provide a succinct description which clearly outlines the key issues and the circumstances of the event. Information contained within the brief is to include:

- urgency;
- determining who has been affected and how - physical and/or psychological harm, or no known harm;
- process for determining risks;
- need for Department participation/involvement/oversight.

2.10 SAI Notification and Investigation

In some circumstances an SAI review may have triggered the Lookback Review Process (Section 1). However, often the Lookback Review will be triggered by a concern that has been raised by a service user or their family/carers or a member of staff. The Steering Group should consider at an early stage if the findings of the Lookback Review meets any of the criteria for reporting the concerns as an SAI (see also Section 7.2.1). The criteria for reporting an SAI are defined within the HSCB