nothing further to update until this was completed.

Stephen noted this would be presented in a spreadsheet but as the team had not met yet, there would be nothing to report at UAG meeting the following day.

Structured Clinical Record Review (SCRR) - Stephen advised that up to 39 patients would be considered under SCRR process. This would start once remote access had been set up for the medical staff outside NI and this should happen within the next few days.

Templates have been agreed but Stephen noted the family involvement was required for the process. The Family Liaison Officer has also been assigned to this team. Currently there is only 1 subject matter expert involved and acknowledged that more would be required.

Martina noted the majority of the 39 patients identified had come through the review backlog process and Mark would highlight any patients to be reviewed by SCRR. Stephen noted there were approx. 70 potential SAIs and this was likely to increase.

Maria added that findings to date showed that potentially 20% of AOB's practice resulted in harm with over 50% receiving sub-optimal care.

The need for the potential involvement of PCC was highlighted and discussed and Melanie noted the complexities of Urology SAI process compared to other previous inquiries.

Caroline advised of the informal meeting with PCC earlier today and noted that Johny Turnbull, PCC had agreed to develop a paper for discussion at the meeting on 20th May. It is hoped this will be circulated prior to the meeting. The role of PCC in this process was also discussed and it was noted that their involvement in Urology Inquiry would be based on experience with previous inquires.

Private Practice - Stephen advised that AOB had confirmed that letters had gone out to Phase 1 cohort of patients. AOB has now been asked to send a letter out to all private patients. The Trust advised that there had been no calls to the information line from this cohort of patients.
Paul questioned if the Trust could confirm that the letter had actually been sent out. Stephen noted the Trust couldn't confirm this but noted it would be in AOB's best interest to adhere. The potential of more patients being identified was highlighted and the cost implications associated with this.

Maria noted a failsafe would be patients coming via GPs. Helen advised that she had not been made aware of any issues coming from GPs to date.

Stephen noted that he would follow up with RQIA to ensure that the Trust has done all they can. Maria also highlighted GMC involvement and noted that AOB was due to

	appear at a GMC panel in June.	
4	**Updated UAG Report**	
	Martina confirmed the draft UAG report for the meeting on 14th May had been forwarded to Paul. The report includes updates on 9 SAIs, GMC, Private Patients, Internal Audit and the way forward.	
5	**Internal Audit**	
	Melanie noted the report was in the final draft stage and there would be a number of recommendations coming from this report.	
6	**Update on PCC Meeting**	
	Previously covered under Item 3.	
7	**AOB**	
	Litigation - Maria referred to her conversation with the Chair of the SAI process and advised that they had planned to meet with DLS in regards to concerns that some families would proceed to litigation. Maria clarified that litigation can move forward prior to the commencement of the Public Inquiry. IPT update - Melanie advised that an updated version of the IPT was being considered and that when costed this would be shared with Paul and Caroline. Helen O'Neill, Trust Director of Finance has also shared this with Tracy McCaig, HSCB Director of Finance. Regional SAI Recommendations - Paul asked when the SAI report with regional recommendations would be submitted. The Trust highlighted that some of the recommendations from 2016 SAIs have never been progressed and questioned how this should be dealt with. Paul requested Caroline to follow this up with Rodney Morton and Lisa McWilliams. Stephen advised that he and Patricia Kingsnorth had met with Anne Kane and Denise Boulter regarding the regional recommendations but that did not imply that they were being implemented. Paul agreed to discuss this further at the next meeting.	**Caroline to follow up implementation of regional SAI recommendations with R Morton/L McWilliams** **Sylvia to b/f for discussions at next meeting.**
8	**Date of Next Meeting**	
	The date of the next meeting will be Thursday **27th May 2021 at 3.30pm** - Martina to open via zoom.	
9	**Action Log**	
	• **Stephen** to forward Lookback Guidance documents to Caroline and follow up outside group meetings • **Paul/Caroline** to discuss the issue of Regional Waiting Lists with L McWilliams/UAG • **Caroline** to follow up implementation of regional SAI recommendations with R Morton/L McWilliams • **Sylvia** b/f regional SAI recommendations for agenda/discussions at next meeting	

Patients under the care of Mr O'Brien and currently in process of being reviewed
10 May 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)	750 (Result Review)	CNS/ Professor Sethia	786	Professor Sethia	July 2021	No	Update from last report: **89 records reviewed**
	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**

	Patient Group	Number of Episodes/Patients in Group	Reviewed to date	Reviewed by	Remaining to be reviewed	Reviewed by	Provisional date	Quality Assured	Comment
	Post MDM Patients	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**
	Review Backlog	511 Patients	86 (Virtual Clinics)	M Haynes	425	M Haynes/T Glackin	March 2022	No	Update from last report: **16 patients reviewed**
	Information Line	155 Patients	10(reviewed at clinic)	M Haynes	144	Prof Sethia	Sept 2021	No	Update from last report: **2 patients reviewed**
	Patients prescribed Bicalutamide	933 Patients	747 (Record Review, 26 Face to Face Reviews)	M Haynes	186	M Haynes	March 2022	No	Update from last report: **No change**
	Patients on Inpatient Waiting List for TURP	143 patients	0	TBA	143	Clinical Team	Dec 2021	No	Update from last report: **No change**
	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

Southern Health and Social Care Trust

Health and Social Care Board

Southern Urology Co-Ordination Group Minutes

Thursday 27th May 2021, 3.30pm

Via Zoom

	Item	Actions
1		
	In Attendance Paul Cavanagh (Chair) — Melanie McClements Maria O'Kane — Stephen Wallace Jane McKimm — Heather Trouton Ronan Carroll — Caroline Cullen **Apologies** Damian Gormley Mark Haynes Brid Farrell Helen Rogers Sylvia Irwin Martina Corrigan	
2	**Actions from Previous Meeting**	
	• **Welcome & Apologies** - Paul welcomed everyone to the meeting and apologies were noted. • **Minutes of Previous Meeting** - The minutes of the meeting held on 13th May were agreed. ➢ **Matters Arising from Meeting 13th May -** It was agreed that the matters arising and actions would be taken as part of the agenda.	
3	**Update from UAG**	
	Paul discussed how the UAG meeting had focussed on the issue of private patients. Stephen provided an update having had a recent conversation with Michael O'Neill	

	with regards to applying the understanding of "sole practitioner" status as defined by 2003 Act (RQIA) it was felt that it would be of benefit if the DoH could give direction to RQIA, although it was recognised that the status was not legal advice as such. Maria discussed other examples that she had read about of systems in place elsewhere for patients who had been treated outside a Trust's area and systems for providing feedback to GPs as an alternative to the current default of whistle blowing. Paul asked Maria to share some further information on alternative and proven systems for consideration at a future meeting. Next UAG meeting is scheduled for 18th June and Paul reminded the Trust that he needed an updated report together with the analysis report on activity undertaken to date beforehand. It was agreed that Caroline should be copied into the email.	**Maria to provide further information on alternative & proven systems for consideration**
4	**Update from Trust**	
	As Martina was on annual leave there wasn't an updated activity report. Melanie and Maria spoke at length about the difficulties of coping with the increased pressures within core demand and capacity, the process of regional prioritisation to available theatre capacity, as well as having the additional pressures of trying to facilitate the additional clinics required as part of the look back exercise. The Trust described the 4 options which had been looked at: 1. Seeking assistance from other Trusts – no offers 2. Stop taking new referrals and divert elsewhere 3. Repatriate those on the list back to their Trust of residence 4. Regionalise the urology waiting list It was suggested that the Trust has a discussion with other Trusts about repatriation and as a course of action elevate to a Chief Executive to Chief Executive meeting.	
5	**SAI Recommendations**	
	Caroline reported that she had spoken with Denise Boulter who confirmed that that HSCB/PHA had agreed to defer their report until the out workings of other groups/public inquiry were made known. Denise also advised that she intended to ask the Trust if the report could be shared with NICaN. The Trust confirmed at the meeting the report had already been shared with NICaN and that they were content that the MDM issue was being addressed by Paul's SMT paper. It was agreed that it was positive to know that the recommendations from the overarching report were being actioned. Caroline referred to a point which had been raised in the previous meeting about the lack of implementation of the 2016 SAI report relating to the NG12 NICE guidance. As an action Paul had asked Caroline to investigate. Caroline reported that she had written to Lisa McWilliams and Rodney Morton as the HSCB/PHA lead Directors for SAIs. They are currently reviewing the files and will	**Caroline to follow up implementation of regional SAI recommendations with R Morton/L**

	respond formally. SAI Action Plan - Stephen confirmed that the SAIs were not signed off as yet as some families have not responded. The first internal meeting happened on the 26th and the group discussed the formulation of an action plan. The group spoke with Dermot Hughes about concentrating on the 11 recommendations in the overarching report. The thinking is that the Trust will issue a letter of apology for the delay in closing the SAI process off and will commit to 3 monthly updates - they see this as a short term task and finish group. The Trust highlighted the current pressures on the family liaison post holder and their concerns of a capacity issue when an increase in numbers of involved patients/families materialises. Paul asked that both the action plan and the letter of apology are brought to the next UAG meeting.	**McWilliams**
6	**Internal Audit**	
	Melanie noted the report was in the final draft stage and there would be a number of recommendations coming from this report however the report was not yet ready to be shared.	
7	**Update on PCC Meeting**	
	Paul provided an update from the meeting held on 20th May between the DOH/HSCB/SHSCT and PCC. It was noted by Patricia Kingsnorth that a family had approached her regarding setting up a support group however, she was aware that other families did not want to go public with their involvement. The PCC felt that this was potentially an area in which they could become involved. The SCRR versus the SAI process was highlighted and discussed at the meeting. Patricia advised that the Trust was developing a leaflet and requested that the PCC review the leaflet from a patient perspective. Patricia was to share the draft with Vivian/PCC. The potential role of local charities was highlighted and how these organisations could offer support. In conclusion, Vivian agreed to consider all the issues highlighted in the two meetings and discuss with her team how best the PCC could bring value to the process.	
8	**AOB**	
	• **Policy and Guidance for Look Back Policy** - Stephen discussed the papers which he had shared with the group and noted that the guidance was not yet finalised. It was felt that there was a pragmatic approach required to the significant implications of potentially issuing 4000+ letters to patients of AOB.	.

	The process had the potential to raise an expectation that they would be reviewed but with very limited ability to actually follow up given all the current limitations expressed earlier in the meeting. It was suggested that an option appraisal should be developed and discussed at the next meeting with a view to sharing with the UAG on the 18th June.	
9	**Date of Next Meeting**	
	The date of the next meeting will be Thursday **10th June 2021 at 3.30pm** - Martina to open via zoom.	
10	**Action Log**	
	• **Maria** to provide further information on alternative & proven systems for consideration • **Caroline** to follow up implementation of regional SAI recommendations with R Morton/L McWilliams	

Southern Health and Social Care Trust

Health and Social Care Board

Southern Urology Co-Ordination Group Minutes

Thursday 10th June 2021, 3.30pm

Via Zoom

		Actions
1		
	In Attendance Paul Cavanagh (Chair) — Melanie McClements Maria O'Kane — Stephen Wallace Martina Corrigan — Caroline Cullen Jane McKimm — Sylvia Irwin Ronan Carroll Helen Rogers **Apologies** Damian Gormley Mark Haynes Brid Farrell Heather Trouton	
2	**Actions from Previous Meeting**	
	• **Welcome & Apologies** - Paul welcomed everyone to the meeting and apologies were noted. • **Minutes of Previous Meeting** - The minutes of the meeting held on 27th May were agreed. • **Matters Arising from Meeting 27th May** ➢ Implementation of Regional Recommendations from 2016 SAIs - Caroline advised that she had followed this up with R Morton & L McWilliams, HSCB and she expected to have a reply by the following day. ➢ Trust Draft Action Plan - Stephen noted the draft Action Plan would be shared with the group prior to the UAG meeting on Friday 18th June. He noted that patient apology letters had been drafted and the template for these would also be shared prior to UAG meeting on 18th June.	**Stephen to share Trust draft action plan & template patient letter prior to UAG 18th June**

	Due to the fact there would be no Co-ordination Group meeting scheduled before the next UAG meeting, Paul suggested that any issues should be taken offline.	
3	**Trust Update**	
	Patient Record Scoping Exercise - Martina provided the following update for the meeting. ➢ Summary of Activity Martina gave an overview of the attached table:  SHSCTSummOfPatsAOB-(7Jun21).docx Martina noted that had been little additional activity as Mr Haynes had been consultant of the week and that he and Professor Sethia had been on leave over this period. ➢ Royal College of Surgeons - Process to commence 28th June and the Patient Review form will be used as part of the RCS process. ➢ Radiology Patients - Professor Sethia is expected to have completed the review of Radiology patients by 30th June. The Trust has secured the services of a second consultant for the Urology Review. Dr John Kelleher who is hoping to commence reviewing patients within the next few weeks. Martina noted that in the absence of further additional capacity the expected outturn would continue to be slow. The issue of reporting patient episodes compared to number of patients was discussed and Paul requested the Summary of Patients report total line be amended to reflect total patient numbers as opposed to patient episodes, currently reported. ➢ Irish News Report 7th June - Jane gave an update on the latest media article and noted that the information had more than likely come from someone with detailed knowledge within the organisation. There had been no subsequent calls or e-mails received by the Trust following this news report. Jane also noted the DoH had been alerted to the publishing of the article but she advised the Trust had no contact from DoH regarding this. A general statement had been released following the news story noting it would be inappropriate to make any further comment in light of the forthcoming Public Inquiry.	**Martina to amend summary of patients' report** **Paul to discuss with DoH Policy colleagues and if necessary report back to Trust**

	Paul agreed to contact DoH Policy colleagues and if necessary he would report back to Trust colleagues. Melanie added that in preparation for the story breaking in the Irish News, the Trust had contacted all the families from this current investigation and also relating back to 2015 SAIs. She noted that all the families contacted had been extremely grateful for the update provided by the Trust at the onset. It was also noted that the 9th family still required more time to consider their report and the Trust wanted to accommodate this. ➢ Private Patients - Stephen advised that he had discussions with Michael O'Neill regarding RQIA powers and also the potential for GDPR to be bypassed. Stephen confirmed that he is also due to meet with RQIA and he would have more information for the UAG meeting on 18th June. Stephen noted that AOB's solicitor had confirmed that letters had gone out to his approx. 200 private patients and the Trust had requested confirmation of the period covered by these letters.	
4	**Updated UAG Report**	
	The Trust agreed to forward a copy of the UAG report dated 18th June to HSCB colleagues by Wednesday 16th June.	**Martina to forward UAG update to Paul by Wednesday 16th June**
5	**Internal Audit**	
	Melanie advised the draft report was currently with her for comment and she would provide an update to Paul once she had reviewed the report. Paul noted the matter would be discussed at UAG and should be included in UAG update for 18th June meeting.	**Melanie to provide update to Paul once she has reviewed Internal Audit report**
6	**Policy & Guidance for implementation of Lookback Review Process - Option Appraisal to be discussed**	
	Caroline confirmed that she had met with Martina and Stephen on Monday 7th June. Stephen gave an update to the group. He noted this process would require 2 separate groups, an oversight and an operational group and questioned if it would be appropriate for the co-ordination group could take on the role of the oversight group. If this was agreed, the Terms of Reference for the co-ordination group would need updated to reflect this. Stephen noted he was content with the Policy Document; however the Guidance Document was more challenging. He highlighted the issue of candour and added the decision on this would rest with the Minster of Health/DoH. He also highlighted the issue of multiple conditions being addressed in a single specification.	

	Stephen noted that Stages 2 & 3, highlighted above were ongoing, but Stage 4 would be much further down the line. He also highlighted the importance of being able to assure the Public Inquiry that the Trust did not deviate from the guidance. The 3 main issues for the Trust are whether to continue to notify by exception or send out thousands of letters to potential affected patients, or to notify only those patients with a high risk of potential harm. Paul acknowledged Stephen's overview of the policy and guidance documents. Paul suggested the Trust could compare current performance with the policy and guidance documents as a means of measuring performance. It was also noted the SCR review of 2015 patients may be helpful. Stephen also noted the issue of alignment of processes and the prioritisation of cases, e.g. cancer, etc. It was agreed an update would be included in the Trust UAG update for the meeting on 18th June. Paul also highlighted the implications of this for HSCB colleagues and he agreed to discuss further internally.	
7	**AOB**	
	Nothing further discussed.	
8	**Date of Next Meeting**	
	The date of the next meeting will be Thursday **24th June at 3.30pm** - Martina to open via zoom.	
9	**Action Log**	
	• **Stephen** to share Trust draft action plan & template patient letter prior to UAG 18th June • **Paul** to discuss Irish News article 7th June with DoH Policy colleagues and if necessary report back to Trust • **Martina** to amend Summary of Patients' report to include Total Patient Numbers, (not episodes) • **Martina** to forward UAG update to Paul by Wednesday 16th June • **Melanie** to provide update to Paul once she has reviewed Internal Audit report	

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**

	Patient Group	Number of Episodes/Patients in Group	Reviewed to date	Reviewed by	Remaining to be reviewed	Reviewed by	Provisional date	Quality Assured	Comment
	Post MDM Patients	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**
	Review Backlog	511 Patients	111 (Virtual Clinics)	M Haynes	400	M Haynes/T Glackin	March 2022	No	Update from last report: **9 patients reviewed**
	Information Line	155 Patients	10(reviewed at clinic)	M Haynes	145	Prof Sethia	Sept 2021	No	Update from last report: **No Change**
	Patients prescribed Bicalutamide	933 Patients	747 (Record Review, 26 Face to Face Reviews)	M Haynes	186	M Haynes	March 2022	No	Update from last report: **No change**
	Patients on Inpatient Waiting List for TURP	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

Southern Health and Social Care Trust

Health and Social Care Board

Southern Urology Co-Ordination Group Minutes

Thursday 24th June 2021, 3.30pm

Via Zoom

	Item	Actions
1		
	In Attendance Paul Cavanagh (Chair) Caroline Cullen Martina Corrigan Sylvia Irwin Heather Trouton Ronan Carroll Damian Gormley Mark Haynes **Apologies** Maria O'Kane Stephen Wallace Helen Rogers Brid Farrell Melanie McClements Jane McKimm	
2	**Actions from Previous Meeting**	
	• **Welcome & Apologies** - Paul welcomed everyone to the meeting and apologies were noted. • **Minutes of Previous Meeting** - The minutes of the meeting held on 10th June were agreed. • **Matters Arising from Meeting 10th June** Caroline confirmed that all the outstanding Matters Arising would be covered in the main agenda.	
3	**Trust Update**	
	Patient Record Scoping Exercise - Martina provided the following update for the meeting.	

- Summary of Activity

Martina gave an overview of the attached table:

SHSCTSummOfPatsAOB-(21Jun21).docx

- Radiology Patients - Professor Sethia is expected to have completed the review of Radiology patients by 31st July.
- Backlog Review Saturday Clinics - Martina confirmed that Mark had held a further clinic last Saturday, 19th June.
- Independent Sector Service Specification - This is being prepared by the Trust for the provision of Urology outpatient reviews from Independent Sector providers (1000 cases, initially all from Mr O'Brien's lists) to support the Urology Team in seeing the patients identified as needing reviewed. Martina noted the Trust is currently seeking legal advice from DLS regarding the use of the Patient Review Form. She highlighted discussions with BHSCT regarding the form used by them, (3 questions), as part of the Neurology Review process.

  Paul highlighted discussions at the last UAG meeting around the timeline and the Trust decision to start lookback from January 2019. He noted this first phase of the review would have to be completed before the Trust could commence any further look back, prior to January 2019.

  He noted that the RCS review would focus on lookback for 100 charts of patients seen in 2015 and highlighted the need for an Outcomes Report similar to one developed as part of the Neurology Review.

  Paul acknowledged the work completed by the Trust to date, but recognised that the Trust had some way to go in order to complete the review of the first cohort of patients.

  Heather noted the Trust had asked BSO to run a report in order to ascertain how many additional patients would be involved if the process had to go back prior to 2019. This report would detail numbers involved for each year, e.g. 2018, 2017 etc.

  Paul noted the challenges to be faced and additional resources required in

	order for the Trust to complete this task. Mark discussed the Trust's logic in deciding the timeframe of the first phase and noted this was to make the process manageable and also consider issues such as how to identify affected patients and highlight any trends. Paul noted the importance of the ability to have a clear understanding of numbers, i.e. how many patients seen/to be seen and what clinical judgement concerns have been highlighted as part of the process, as this would determine the need for further lookback prior to 2019. Heather highlighted additional areas of investigation already commenced by the Trust, e.g. TURPS, MDMs. She advised that patient charts would be sent to RCS this week and the sample would cover all examples of patient pathways. Heather noted that the number of new issues being highlighted was beginning to reduce and this was a positive sign.	
4	**Updated UAG Report**	
	Nothing further to be discussed.	
5	**Trust Draft SAI Action Plan**	
	Heather advised that an internal Trust meeting involving clinical and management teams had taken place earlier today. Ronan gave an update on how this would be progressed and noted that there would be a separate task and finish group set up to deal with each individual recommendation. The recommendations with the shortest timeframe would be dealt with first. Heather added that although the process would start with Urology, it would be extended across all tumour sites. It was agreed that a final draft would be submitted to Paul by the end of July. Paul noted that the proposal paper had been reviewed by SMT and approved. He referred to the Trust separate process which would run in parallel with the HSCB process. The HSCB MDM process would initially focus on the 5 main cancer areas and involve all Trusts, whereas the Trust process would be internal. It was noted that Cara Anderson, HSCB will be the lead in this process and will be the point of contact for Trusts. Claire Quinn will be the Trust representative.	**Trust to submit final draft SAI Action Plan to Paul by 31st July**
6	**Trust IPT**	
	Heather referred to the Public Inquiry work and noted that the 3 main areas to be focused on by the Public Inquiry would be:-	

	(i) The Clinical Lookback exercise for all of the patients identified as needing reviewed and this would look at all areas including, admin, IT, Clinical and independent reviewers. (ii) Governance systems and processes (iii) What improvements have been made in relation to SAI recommendations. Heather questioned if the IPT would cover all 3 areas listed above and if the Trust would be open to challenge if additional posts to support the Inquiry are put in place. She also highlighted the need for internal/external approval for spending associated with such posts. Paul stressed that there was no funding source available to fund the IPT and the Trust would have to fund any additional costs internally. He recommended that Board/Trust Directors of Finance have separate discussions regarding this. Paul noted that although there was no available funding source for the IPT, there may be a possibility of securing non-recurring additionality funding for any additional costs associated with the Inquiry. Paul advised Heather to raise the matter further with Michael O'Neill, DoH. He noted that as the Chair of the Inquiry is not yet in place, it may be months before the Inquiry would commence. Paul agreed to discuss the matter again with Tracy McCaig, Director of Finance, HSCB. Heather noted that any investment would feed improvement in services across the region, and not just Southern Trust. She added that although the funding stream may be internal, the Trust would be required to give an appropriate level of assurance of authority and approval. It was further agreed that a short meeting with Michael O'Neill, DoH would be of use. Caroline to organise.	**Paul to discuss funding of IPT with T McCaig, Director of Finance, HSCB** **Caroline to organise meeting with M O'Neill, DoH to discuss IPT**
7	**Revised Terms of Reference for Co-ordination Group**	
	Caroline noted that the draft Lookback Policy & Guidance document had recommended the formation of an operational group and an oversight group. At the last meeting it had been suggested that the HSCB/Trust Co-ordination group could take on the role of oversight group. Caroline agreed to discuss this further with Stephen and bring forward for discussion at the next meeting on 22nd July.	**Sylvia to b/f for discussion at next meeting 22nd July**
8	**AOB**	
	➢ <u>Fermanagh Patients</u> - Martina confirmed that an e-mail regarding this matter had been sent by Aldrina Magwood, Director of Performance & Reform, SHSCT to Teresa Molloy, Director of Performance & Improvement, WHSCT. A response is awaited. ➢ <u>IS Tender</u> - Martina confirmed that whilst this was still in train, there were	**Trust to provide**

	legal aspects associated with entering into a DAC arrangement that needed to be confirmed. Update to be provided at the next meeting.	**update at next meeting 22nd July**
9	**Date of Next Meeting**	
	It was agreed that the next meeting will take place on **Thursday 22nd July at 3.30pm** - Martina to open via zoom. Paul noted that although the next UAG meeting would not take place until the end of August, the group would continue to meet, albeit on a less regular basis over the summer. Heather noted the Trust would provide a UAG update at the end of July, as requested at the meeting on 18th June. -	**UAG update to be forwarded to Paul by 31st July**
10	**Action Log**	
	➢ **Trust** to submit final draft SAI Action Plan to Paul by 31st July ➢ **Paul** to discuss funding of IPT with T McCaig, Director of Finance, HSCB ➢ **Caroline** to organise meeting with M O'Neill, DoH to discuss IPT ➢ **Sylvia** to b/f for discussion at next meeting 22nd July ➢ **Trust** to provide update at next meeting 22nd July ➢ **UAG** update to be forwarded to Paul by 31st July	

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

	Patient Group	Number of 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	400	Professor Sethia	625	Professor Sethia	July 2021	No	Update from last report: **No change**
	Pathology Results	150 Patients	150 (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**

	Patient Group	Number of Patients in Group	Reviewed to date	Reviewed by	Remaining to be reviewed	Reviewed by	Provisional date	Quality Assured	Comment
	Post MDM Patients	187 Patients	187 (SME Record Review)	Prof Sethia	52 (need second opinion)	M Haynes	July 2021	No	Update from last report: **No Change**
	Review Backlog	511 Patients	130 (Virtual Clinics)	M Haynes	381	M Haynes/T Glackin	March 2022	No	Update from last report: **10 patients reviewed**
	Information Line	156 Patients	11(reviewed at clinic)	M Haynes	145	M Haynes/ Prof Sethia	Sept 2021	No	Update from last report: **1 patient reviewed**
	Patients prescribed Bicalutamide	933 Patients	747 (Record Review, 26 Face to Face Reviews)	M Haynes	186	M Haynes	March 2022	No	Update from last report: **No change**
	Patients on Inpatient Waiting List for TURP	143 patients	0	TBA	143	Clinical Team	Dec 2021	No	Update from last report: **No change**
	Total	**3853**	**2337**		**1568**				

Southern Health and Social Care Trust

Health and Social Care Board

Southern Urology Co-Ordination Group Minutes

Monday 23rd August 2021, 3.00pm

Via Zoom

	Item	Actions
1		
	In Attendance Paul Cavanagh (Chair) Caroline Cullen Martina Corrigan Sylvia Irwin Heather Trouton Ronan Carroll Stephen Wallace Mark Haynes Melanie McClements Jane McKimm **Apologies** Maria O'Kane Helen Rogers Damian Gormley	
2	**Actions from Previous Meeting**	
	• **Welcome & Apologies** - Paul welcomed everyone to the meeting and apologies were noted. • **Matters Arising from Meeting 30th July** Caroline confirmed that all the outstanding Matters Arising would be covered in the main agenda.	
3	**Trust Update**	
	Paul noted the purpose of this meeting was a catch up on progress made from the last meeting and in order to be able to provide an update to the next UAG meeting. Heather confirmed the Trust will provide an updated Trust report at the end of August and this will be forwarded to Paul no later than **Thursday 2nd September**.	**Trust to forward UAG update to Paul no later than Thursday 2nd September**

	Heather advised the Trust were experiencing issues in regards to availability of clinicians over the summer period, due to leave commitments. She noted that the Trust has identified a number of areas that now require additional staff to start moving forward areas in the preparation for the Inquiry and are in the process of preparing to recruit new posts. These posts and rationale for them have been shared with the Trust's SMT, who have approved to start recruitment. When the final costs are completed this will be shared with HSCB. Heather noted that at a meeting with HSCB, DoH and Trust members on Monday 28 June 2021, it was clarified that the money set aside for the Public Inquiry is not for the Trust but for the DoH aspect of the Inquiry. There is therefore no funding set aside in respect of the costs that will be incurred by the Trust. <u>Terms of Reference</u> - Heather noted that the Terms of Reference are due at the end of the month. Paul asked Caroline to set up a meeting with DoH and Trust colleagues to discuss further. <u>Review of Patients prior to 2019</u> - Heather advised that the review of patients prior to the initial review timeframe would be processed one year at a time. The Trust have now reviewed AOB's patients for the year 2018 and 615 additional patients have been identified. The issue of extra capacity to review these additional 615 patients was highlighted. Heather also noted issues around the availability of information from BSO regarding the period prior to 2018. <u>SAI Recommendations</u> - Heather advised that a steering group has been set up to implement the recommendations from SAIs and this is being led by Ronan and Martina. <u>Private Patient Records</u> - Stephen advised that the Trust has prepared correspondence to Mr O'Brien referencing a GDPR legislation clause which allows access to private patient records on a lawful basis. The Trust has agreed a formal letter with the DoH to this effect and will be issuing to Mr O'Brien's solicitor for action. However, Stephen noted that DLS were not in agreement with the letter being sent due to the issue of the Trust acting as an agent on behalf of DoH. Stephen noted that as in the Neurology review process, RQIA may be the appropriate channel to seek these records and this can be directed via DoH. Paul questioned if it would be more appropriate for the Trust to request the records as they would be best placed to use them. Stephen advised that DLS was not happy with this approach due to the issue of statutory instruments. Heather agreed to highlight the issue in the updated report for UAG. <u>Update on AOB's Private Patients</u> - Heather noted that communication from AOB's solicitor had confirmed that letters had been sent out to 253 private patients.	**Caroline to organise meeting to discuss Terms of Reference with DoH and Trust colleagues**

Patient Involvement - Following a letter of apology from the Trust to the families involved in the SAIs, 2 families have responded and are keen to work with the Trust on implementing the learning from these reports. The Trust is meeting with both families on 1 September to gauge what their expectations of their involvement.

Trust Audit of MDMs - Heather reported that the baseline assessment is now complete and recommendations have been forwarded to the Chair of the MDMs.

Paul questioned if this was linking in with the work undertaken by his regional team (NICaN), led by Cara Anderson and he requested that the Trust share any findings with the Regional team.

Melanie noted that she was a member of NICaN group and she confirmed that the Trust baseline audit had been shared with NICaN. To date 9 audits had been completed by the Trust across different tumour sites.

Martina acknowledged the high quality of work undertaken by her Trust colleagues in carrying out these audits, which have been mapped back to the SAI recommendations. She noted that this was a work in progress.

Update on Patient Reviews to date - Martina provided the following update for the meeting.

- Radiology Patients - Professor Sethia has completed the review of Radiology patients and 247 patients have been identified as having received sub-optimal care. These records are currently with Mr Haynes to decide what further action is required. Martina added that any urgent patients requiring review have already been actioned.
- 615 Patients Identified as part of Year 2018 Review - These patients will now be reviewed by Professor Sethia and anyone identified as urgent will be reviewed by the Urology Team straight away.
- Independent Sector Service Specification - It was noted that this is proving problematic in that the ISP are having difficulty in securing consultants to carry out this piece of work. The Trust have been exploring another option of working with a Limited Liability Partnership Group (LLP) from Manchester to see if they will come over at weekends to review these patients in the Trust's premises. These discussions are at the initial stages.

  Caroline highlighted the issue of governance and enquired if the use of 3FiveTwo Healthcare as a Provider was an option. The Trust advised it was easier managed if the Trust work through Kingsbridge. A meeting has been arranged with DLS on 10th September.

  Heather noted as previously discussed, the main issue of concern was clinical

	capacity and without this the process could not proceed. Paul acknowledged the Trust's position regarding clinical capacity and noted the importance of documenting their efforts to resolve this matter. <u>Outcomes Report</u> - Paul referred to the need for an Outcomes Report and acknowledged that although this would be challenging for the Trust, it was necessary to ensure that outcomes were recorded in a similar manner to the Neurology Review undertaken by BHSCT. He highlighted the importance of identifying the separate cohorts reviewed and including each cohort as a section in the Outcomes Report. In regard to the completion of the review of Cohort 1 patients in March 2022, Paul questioned whether the Trust would be able to review the 618, (Year 2018) patients before this cohort had been finalised. Martina noted the possibility of breaking the first cohort of patients into smaller sub-sections, e.g. Radiology, Oncology, as these sections have now been completed. Heather agreed to discuss the format of the report further with Martina and Caroline. <u>IPT for Public Inquiry</u> - Martina confirmed the IPT has now been transferred onto the correct template and is currently with Trust Finance for costing. <u>Repatriation of WHSCT patients</u> - Martina confirmed this process is ongoing and WHSCT are happy to accept these patients once the validation process has been completed. Martina confirmed the Trust did not require additional monies to cover the validation costs and agreed to keep Caroline updated on progress.	**Heather, Martina & Caroline to meet to discuss format of Outcomes Report**
4	**AOB**	
	Nothing further to be discussed.	
5	**Date of Next Meeting**	
	To be confirmed, (either 2nd or 16th September)	
6	**Action Log**	
	➢ **Trust to forward UAG update to Paul no later than Thursday 2nd September** ➢ **Caroline to arrange meeting to discuss Terms of Reference with DoH/Trust** ➢ **Heather, Martina & Caroline to meet to discuss format of Outcomes Report**	

Southern Health and Social Care Trust

Health and Social Care Board

Southern Urology Co-Ordination Group Minutes

Thursday 2nd September 2021, 3.30pm

Via Zoom

	Item	Actions
1		
	In Attendance Paul Cavanagh (Chair) Melanie McClements Martina Corrigan Jane McKimm Heather Trouton Ronan Carroll Maria O'Kane Sylvia Irwin Mark Haynes **Apologies** Caroline Cullen Helen Rogers Stephen Wallace	
2	**Actions from Previous Meeting**	
	• **Welcome & Apologies** - Paul welcomed everyone to the meeting and apologies were noted. • **Matters Arising from Meeting 23rd August** Paul confirmed that all the outstanding Matters Arising would be covered in the main agenda.	
3	**Trust Update**	
	Paul request that the latest UAG update and patient numbers report be forwarded to him no later than lunchtime the following day. SAI Recommendations - Melanie advised that all families had now responded to the SAI reports and this had now been finalised. She noted that the 9th family had commented on the level of care received in certain areas such as community care packages. These comments have been passed on to Mr D Hughes, Chair of the panel.	**Trust to forward UAG update reports to Paul by 3rd September** **Martina to share SAI recommendations report with Paul**

	Martina agreed to share the SAI recommendations report with Paul. The timeline for updates on implementation of the recommendations to the families are • First Update by 30th September 2021 • Second Update by 14th January 2022 • Third Update by 22nd July 2022 <u>Patient Involvement</u> - It was also noted that 2 of the patient/family reps to be involved in the Task and Finish Group had met with Trust staff on 1st September and this had been a very positive meeting. The main concerns raised by the patient/family reps was (i) the desire to prevent something like this happening in the future and (ii) their involvement in working with the Trust on putting structures in place to prevent this from happening to other patients/families. Martina also advised that Dr Tariq will chair the monthly Service User meetings. Martina noted that Service User Task and Finish group is for Urology only but they will be kept updated from the overarching group (all tumour sites) and this urology specific group will feed into the overarching group. <u>General Medical Council (GMC)</u> - Maria confirmed that the GMC had now reviewed 8 of the 9 SAIs and these will be included in the formal investigation into AOB's practice. The Trust has informed the patients/families and has shared patient case notes with the GMC. Martina advised that the weekly face to face meetings for additional patients will resume in September. <u>Private Practice</u> - The Trust has prepared correspondence to Mr O'Brien referencing a GDPR legislation clause that may allow access to private patient records on a lawful basis. A response has not yet been received. <u>Role of RQIA in Urology Inquiry</u> - Maria referred to the Neurology Review, BHSCT and noted that responsibility for this had been taken over by RQIA and she suggested that this should also be the process followed for Urology Inquiry, SHSCT. Maria noted the Trust was currently involved in discussions around access to patient records, Quality Assurance and involvement in the lookback exercise. Paul noted that during his involvement in Neurology Review he had no experience of RQIA involvement, although he acknowledged this may have happened prior to his involvement, (Cohort 1 Neurology). Paul agreed to seek clarification regarding RQIA involvement. Maria also noted that in regards to Neurology review, BHSCT had undertaken a formal lookback process and if this was the case with Urology, the Trust would be expected to notify in excess of approx. 10,000 patients that their notes are to be reviewed.	**Paul to seek clarification regarding RQIA involvement In Urology Review** **Paul to clarify if Urology Review to operate as a**

	Paul agreed to clarify for the Trust if this will be a lookback or a recall process. Paul noted that the Private Patient cohort would also have to be considered. Summary of Patients under care of AOB - 31st August update Martina provided the following update:- ➢ Additional Calls received to Urology Helpline - Martina confirmed the Trust had received 1 additional call to the helpline since the last update. The total number of calls is now 157. ➢ Weekly telephone/face to face/virtual clinics - It was noted the Trust continue to assess patients from Mr O'Brien's review list and a patient review form is completed for each review undertaken. ➢ Radiology Patients - Martina advised the review of Radiology patients is now completed and this has identified 276 patients with issues needing further review. However, it was noted that quite a number of these 276 records were highlighting issues with capacity. Martina noted that she would assist Mark in undertaking a further review of these patients highlighted by Professor Sethia. Independent Sector (IS) Process - Martina advised that the Trust is continuing to progress this, although progress has been slow. However, she is having weekly meetings with the ISP provider who is working with Manchester LLP on seeing if they will undertake this piece of work and she has shared samples of the patient review form and the detail that is required for these forms. Structured Clinical Record Review - The Trust advised that the total patients being considered under SCRR is currently 61 patients. The Trust has contacted the British Association of Urology Surgeons (BAUS) to seek additional Subject Matter Expertise (SME) to help conduct these reviews. BAUS has identified six subject matter experts and the Trust is in the process of engaging the team to commence work. A quality assurance process will be required to support this.	**lookback or recall process**
4	**Outcomes Report**	
	Paul highlighted that in addition to the lookback/recall process, the Trust would have to consider the need for an Outcomes Report to be completed. Paul added that this would need further discussion at UAG meeting on 6th September in connection with the issue of whether the process would be a lookback or recall. Heather referred to the meeting she and Martina had with Caroline last Friday regarding the format of the Outcomes report and noted this had been very helpful. She noted the history of the patient had not been looked at, but the current patient status, in light of the 3 questions on the Patient Referral Form. Heather added that if the process to be undertaken was a recall process, then this	

	would be most favourable for the Trust. This would be a separate process to the Public Inquiry. Heather also noted the Neurology review of the 3rd Cohort had been completed and had been undertaken as a recall. Mark noted that all patients reviewed to date had been reviewed under both processes; lookback and recall. Paul noted the Trust would not be able to continue both processes, given the estimated number of patients involved. Mark gave an example of a patient with incontinence issues being recalled and who was found now to be managed appropriately. However he noted that only a lookback exercise would have highlighted the historical issues associated with the patient. Maria acknowledged that she shared Mark's concerns. Paul acknowledged his limited understanding of clinical matters and the limited comparisons between the Neurology and Urology processes. Paul noted the Trust would have to make a decision on what the first cohort of patients would be classified as. He noted in regards to the Neurology cohorts, the date the patient was last seen was used to define the respective cohorts. Paul also advised that in regards to Neurology Outcomes report, the data was provided by BHSCT but the report was compiled by HSCB. Heather highlighted the time taken to produce the Neurology Cohort 2 report, approx. 3 years. Paul noted this was exceptional due to Covid-19. In conclusion, it was agreed clarity was required as to whether the process would be lookback or recall, what the role of clinicians would be and whether a 9 or 3 question template was appropriate.	
5	**Minister's Statement/Terms of Reference for Public Inquiry**	
	The Ministerial statement was discussed and Heather noted the Terms of Reference were as expected. It was also confirmed that the inclusion of FAQs would not be appropriate. Paul highlighted the importance of ensuring that staff will be adequately supported throughout the process, as would be critical to the process going forward. Heather noted the alert notification had only been received one hour prior to the public announcement; however the Trust had managed to alert staff and families in preparation for the announcement at 12 noon. Martina noted that Mr Pengelly had agreed to meet with staff, if this was felt to be necessary.	
6	**AOB**	

	Nothing further to be discussed.	
7	**Date of Next Meeting**	
	The date of the next meeting will be **Thursday 16th September, 3.30pm**.	
8	**Action Log**	
	➢ **Trust** to forward UAG update reports to Paul by 3rd September ➢ **Martina** to share SAI recommendations report with Paul ➢ **Paul** to seek clarification regarding RQIA involvement In Urology Review ➢ **Paul** to clarify if Urology Review to operate as a lookback or recall process	

Southern Health and Social Care Trust

Health and Social Care Board

Southern Urology Co-Ordination Group Minutes

Thursday 16th September 2021, 3.30pm

Via Zoom

	Item	Actions
1		
	In Attendance Paul Cavanagh (Chair) — Melanie McClements Martina Corrigan — Jane McKimm Heather Trouton — Ronan Carroll Damian Gormley — Stephen Wallace Caroline Cullen — Sylvia Irwin **Apologies** Maria O'Kane Helen Rogers Mark Haynes Brid Farrell	
2	**Actions from Previous Meeting**	
	• **Welcome & Apologies** - Paul welcomed everyone to the meeting and apologies were noted. • **Matters Arising from Meeting 2nd September** Paul confirmed that all the outstanding Matters Arising would be covered in the main agenda.	
3	**Minister's Statement 31st August**	
	Nothing further to be discussed.	
4	**Terms of Reference - Public Inquiry**	
	Nothing further to be discussed.	

5		
	• **Risk Assessment for Implementing a Lookback Review Template** Martina gave a brief overview of the Risk Assessment which had been drafted by Ronan, Stephen and herself and provided an overview of each section of the report. She noted in particular the wording used referring to 'evidence of harm having occurred' and that a total of 67 patients have now been identified as requiring a Structured Clinical Record Review (SCRR). The issue of future harm being identified was also discussed and it was noted that although Mr AOB had now retired, this was currently an unknown entity. Paul noted that it may be worth mentioning the role of GMC in the process, at this stage, i.e. outcomes and actions, potential harm to patients and the fact that the patient review process may take quite a number of years to complete. It was also noted that an information request from the Trust had identified that there are 10,653 patients under the care of Mr A'OB since 2009 but that it should be noted that Mr A'OB had been employed by the Trust since 1992. The area of private patients was also highlighted and Paul acknowledged the action taken by the Trust to identify this cohort of patients. Paul highlighted the potential impact this process would have on other service users along with the fact that Urology Services within the Trust were already under immense pressure. Martina noted the level of risk was currently 'extreme' and this could be made worse if there was a decision made review further back than the current cohort of 18 months. The age range of patients highlighted was from 3 to 90+ years and Paul noted his surprise at the age range of patients to be reviewed. Paul highlighted the question of potential outcomes and the areas of concern highlighted by the Trust in the risk assessment report. Heather noted this had already been covered in Section 1 of the report, but she agreed to restate again in Section 2 for ease of reference. Paul noted the final section of the report, 'Recommendations to Steering Group regarding Stage 2 Lookback Review' referred to the recommendations of the Steering Group. He questioned if this was the correct group to be referenced here. Heather noted the Steering Group includes representatives from, HSCB, PHA and it was her understanding that this Urology Co-ordination Group would take the role of the Steering Group reflected in the template. Heather also noted that a response was required from the Royal College of	**Martina** to revise wording to 'number of years' **Trust** to restate potential outcomes in Section 2 of the risk assessment report

	Surgeons, (RCS), before a determination on the period of the Lookback was confirmed. Paul acknowledged that it was necessary to determine the period to be covered by the lookback, in order to have an agreed timeframe moving forward. He also added that if further SAIs or equivalent were identified going forward, this may take the Inquiry into a further cohort of patients and would be decided upon by this group. It was agreed that this should be discussed further at the next UAG meeting due to take place in October. Heather noted the lookback process should initially consider the first cohort of patients and once the outcome of this is known, the decision could be made with regards to a further lookback period. Melanie and Damian noted their agreement to this proposal. Heather agreed to revise the draft taking into account the comments noted and forward the revised draft to Paul for Brid's comments. Paul thanked the Trust for this draft risk assessment and suggested that amendments should be completed within 2 weeks and forwarded to him. Paul noted that although Brid was currently unable to attend the meetings due to other work commitments, she still had an active role in the group and he agreed to seek her opinion regarding this proposal and provide feedback to the group. Heather discussed that by following the Lookback Policy that the first cohort of lookback patients, (approx. 2,346 patients) needed to be contacted. Paul acknowledged the concerns of the Trust in progressing this, specifically around the area of causing patients undue/unnecessary distress. Damian noted the cohort would be broken down by their condition, as this approach had been previously agreed. Paul suggested that it may be in the Trust's interest to run some publicity around this, prior to sending out individual patient letters. Paul requested that Caroline is included in further discussions on amendments to the draft document. • **<u>Summary of Patients under care of AOB</u>** - no further update • **<u>UAG Update</u>** - no further update	**Trust** to forward revised template to Paul for Brid's comments by 30th September **Paul** to seek Brid's comments on Trust draft Risk Template following receipt of revised draft **Caroline** To be involved in further discussions on Risk Template going forward
6	**Outcomes Report**	
	Paul noted that Richard Pengelly, Permanent Secretary, DoH, had requested an update on the Trust's Outcomes Report. Paul enquired if it would be based on the first cohort of patients, (approx. 2,346). Heather confirmed that the Royal College of Surgeons (RCS) had now looked at the agreed 100 records from 2015 to try and determine if there is a need to review patients prior to 2015 and the Trust awaited their report (due in approximately 10 weeks).	
7	**AOB**	

	Nothing further to be discussed.	
8	**Date of Next Meeting**	
	The date of the next meeting will be **Thursday 30th September, 3.30pm**.	
9	**Action Log**	
	➢ **Martina** - to revise wording to 'number of years' ➢ **Trust** - to restate potential outcomes in Section 2 of the risk assessment report ➢ **Trust** - To forward revised template to Paul for Brid's comments by 30th September ➢ **Paul** - To seek Brid's comments on Trust draft Risk Template following receipt of revised draft ➢ **Caroline** - To be involved in further discussions on Risk Template going forward	

Southern Health and Social Care Trust

Health and Social Care Board

Southern Urology Co-Ordination Group Minutes

Thursday 30th September 2021, 3.30pm

Via Zoom

	Item	Actions
1		
	In Attendance Paul Cavanagh (Chair) Maria O'Kane Martina Corrigan Stephen Wallace Heather Trouton Sylvia Irwin Melanie McClements Caroline Cullen **Apologies** Jane McKimm Helen Rogers Brid Farrell Ronan Carroll	
2	**Actions from Previous Meeting**	
	• **Welcome & Apologies** - Paul welcomed everyone to the meeting and apologies were noted. • **Matters Arising from Meeting 16th September** Paul confirmed that all the outstanding Matters Arising would be covered in the main agenda.	
3	**Trust Update**	
	• **<u>Summary of Patients under the care of AOB</u>** Heather advised that her main focus in future would be on the Public Inquiry as opposed to the Lookback Exercise but this would be discussed in more detail under AOB.	

	Martina advised that the UAG paper was near completion and she would forward to Paul as soon as possible. Martina confirmed that all 9 SAIs had been finalised and shared with the Public Inquiry Team. Following the Chief Executive's brief to the families in July, the first update to the families would be forwarded today. The update is related to the Task & Finish Group associated with the SAI recommendations. The report includes information on the 2 meetings that have taken place to date, and notes that a 3rd meeting is planned for 11th October. The membership and Terms of Reference for the group has been agreed. Martina confirmed the group has also completed a baseline audit on MDTs. Paul requested that this information is included in the UAG update along with a copy of the generic patient letter. Caroline advised that the UAG planned for 25th October had been postponed, but it was agreed that the UAG update would be made available as soon as possible. Patient Involvement - Martina noted there was nothing further to report but a meeting was planned for Thursday 7th October. Of the 2 representatives, Martina noted that 1 was the daughter of a patient and the second representative was a patient. The patient has been approached to sit on the Regional Cancer Group, (CRG), which is more specific to Urology. Martina noted that the patient was happy to take on this role. GMC - Martina confirmed GMC have also received all the 9 SAI reports and these will be considered as part of the ongoing investigations into Mr AOB's practice. The patient notes have also been shared with the GMC. Summary of Activity - 1 additional call to the helpline. Martina also advised that some patients had been in contact with the Trust with a view to be able to tell their own story. Of the 2 patients to date, 1 patient want to share their negative experience and 1 patient wants to share their positive experience. Martina advised the Trust was deciding on the best way to take this forward. Paul requested this information is shared with Paula Ferguson, DoH. Clinics - Martina advised that no further clinics had been held since the last meeting, however, she noted that she was meeting once a week with Mark Haynes to go through all the patients who require a 2nd opinion. This table will also be included in the UAG report. Private Practice - The Trust have met with RQIA and DoH on 28th September to discuss how to obtain Private Patient records. A revised correspondence is to be developed, involving Trust, RQIA and DoH. Stephen provided more details on the discussions that had taken place at the meeting. This is currently being progressed	**Martina to forward UAG paper to Paul as soon as possible** **Martina to share 3 patient requests received about sharing their experiences, with P Ferguson, DoH**

by DoH.

Additional Support to see more Patients - Martina advised that the Trust is still in discussions with the Independent Sector (IS) and Directorate of Legal Services (DLS) regarding securing additional support. She noted this has not been straightforward due to issues around indemnity from Trust to Private Sector and the difference in views around indemnity in NI and England. Paul noted that DLS should be able to provide the necessary support for the Trust but if HSCB can help in any way, the Trust should contact Dermot McAteer.

Caroline noted that conversations she had with Lesley Leeman earlier confirmed the complexities around securing additional help via IS.

Melanie questioned what the next plan, from a Commissioning perspective would be, if the Trust was unable to secure additional IS help. Paul confirmed the only other option would be to escalate the matter to UAG/DoH.

Repatriation to WHSCT - Martina confirmed that the re-validation process had been completed and she would follow this up with Caroline on how best to transfer these patients. She added that the majority of patients to be repatriated still wanted to be seen. Paul acknowledged that the numbers affected by the repatriation process were relatively small but noted this would help in some small way.

Structured Clinical Record Review - Martina confirmed that 76 patients had now been identified from the review of the patients undertaken to date. The Trust has contacted BAUS to seek additional help and 8 more Consultant Urologists have been identified. Martina confirmed she had met one of the Subject Matter Experts along with Stephen and Damian last Friday and she was hopeful that the Structured Clinical Record Reviews would commence shortly.

Internal Audit - Martina confirmed the Trust had started to work through the recommendations and will be discussed further at a meeting due to take place on 14th October at the Trust's Finance Committee.

- **Risk Assessment for Implementing a Lookback Review Template**

Heather advised that the document had been revised to reflect the changes requested at the last meeting. Martina also advised that the age range had now changed from 0-96 years to 3-96 years of age.

Heather also noted that the main changes had been in the final box, 'Recommendations to the Steering Group'.

Martina noted that the first cohort of patients, (January 2019 to June 2020 - Point 1), who had no issue with their care should now be sent a letter to reassure them

that their care was appropriate. This is approx. 1,000 patients. A further 76 patients from this cohort had issues identified with their care and a separate letter will need to go to these patients. Martina also noted that a decision needs to be made as to the best way to inform these patients of the issues associated with their care and further discussion has to happen regarding this.

It is anticipated that a further 300 patients will have to have their records reviewed by the end of October.

Martina discussed that the Trust recommended that that the remaining approx. 1,200 patients should not be contacted until there is a plan in place to review them, i.e. IS additional support. This is in order to avoid unnecessary stress to the patients. The timescale for this review is yet to be agreed but once this is known, the Trust will be able to write out to these 1,200 patients.

Martina also confirmed the Trust is awaiting feedback Royal College of Surgeons as this will recommend how far back the next cohort needs to include and also if it will include all patients, or just patients with specific conditions that there are issues with.

In regards to Point 1, 'Cohort 1 Patients', Stephen noted that NHSCT had made the decision regarding the review of its Radiology patients, that if a patient had died and there were no concerns regarding the level of care, the family would not receive a letter, as there would be no added value in informing them of this outcome.

Paul questioned if there were any issues in terms of duty of candour. Maria noted that although the Trust would wish to be open and honest with the families, this would have to be weighed up with any potential harm. Maria noted that currently the Trust did not have the mechanism in place to deal with this.

Paul suggested that a phrase should be written into the risk template to reflect this and this was agreed by Maria.

Paul acknowledged that the template had yet to be shared with DoH colleagues. He also noted that in writing out to 1,200 patients the issue may attract further media attention. It was agreed that before this happens, the Trust should notify the Minister for Health and DoH colleagues.

Heather advised the Trust had met internally last week, along with the Chief Executive and she noted the concerns internally around contacting 1,200 patients. She stated that this goes back to the duty of candour and that the Trust was mindful of the impact of informing patients by letter; however it was felt that more harm would be caused by not informing patients and their families of what was happening.

	Paul acknowledged the Trust's difficult position and noted he would be guided by the Trust. He added that this seemed a reasonable approach but acknowledged this would need further discussion/agreement with DoH colleagues. It was agreed that once revised to take account of today's discussions, the draft document could be shared with DoH colleagues. Paul noted the communications issues associated with this were considerable and an offline discussion may be required with DoH colleagues. Melanie raised the issue of deceased patients and noted that a letter may give them some assurance, even though the family member had passed away. In general it was agreed this could be helpful but the letter would have to be worded differently. Maria agreed the Trust would discuss further on how to address this. Melanie agreed that a separate line would be included in the risk template to reflect this.	**Trust to amend Risk Template to reflect changes discussed and revised document to be shared with DoH colleagues**
4	**RQIA Involvement in Inquiry Process**	
	Caroline referred to an e-mail she had received from Emer Hopkins, RQIA which stated that in respect of Neurology Review, RQIA had been represented on DoH Oversight Group, co-ordinating all the work-strands, but they had not been represented on any of the local groups at Trust or HSCB level. In respect of Neurology Review undertaken by BHSCT, RQIA had undertaken the following roles:- 1. A Review of Governance in the Independent Sector 2. A review of Governance in high Volume specialist in the BHSCT 3. A Review of Records of deceased patients of Doctor Watt. Heather noted this had been a significant input from RQIA in the early stages of Neurology Inquiry. Stephen noted that Emer had referred to the SCRR and she acknowledged that the Trust appeared to have things in hand; however Stephen noted that external scrutiny was important for the Trust but the way forward was not agreed. Paul questioned was there a specific task the Trust felt could be undertaken by RQIA that he could ask them to consider. Heather acknowledged it was more the importance of the expert outside independent validation role that was felt to be necessary. Paul agreed to liaise with RQIA/DoH further, if the Trust felt this was necessary. Maria noted that RQIA were open to being helpful with the inquiry but it was exploring what their role could be. Maria agreed the Trust would put some parameters around this and discuss further with RQIA. To be discussed further at future meetings	

	Paul noted that progress had been made in regards to identifying the first cohort of patients in the Outcomes Report. He added that it would likely be Spring 2022 before the Outcomes Report for Cohort 1 would be completed and this would be shaped by the Risk Assessment Template document. Paul requested Caroline to draft a short paper to be presented to the next UAG as to what the Outcomes Report will look like and share with Trust colleagues for comments prior to the next UAG.	**Caroline to draft short paper on proposed format of Outcomes Report & share with Trust prior to next UAG**
6	**UAG Prep**	
	Nothing further to discuss.	
7	**AOB**	
	<u>Urology Group Structures Going Forward</u> Heather updated on the separate roles of the Urology Inquiry process and the Lookback Exercise, although she acknowledged that they are undoubtedly linked. She noted that she had looked at clarifying the roles and responsibilities associated with both areas and shared her findings with the group. Heather shared the Lookback Guidance document and noted proposed structures within the Trust. All groups would report ultimately to Trust Board via SMT from the Lookback Steering Group, (recommended in the Lookback Guidance). This Steering Group would be chaired by Melanie McClements, Director of Acute Services, who would take responsibility for the clinical aspect of the Review. The key members of the Steering Group would be a non-executive director, relevant professional directors, risk & governance rep, Head of Communications, IT Manager, Medical Records Manager, senior Urology Personnel and PHA/HSCB representatives. Heather questioned if this current working group could effectively become the Lookback Steering Group, if it was expanded out to include others mentioned above that are not already involved. Paul noted that he felt it should be kept simpler by standing this group down in favour of the new Lookback Steering Group as required within the guidance. Paul suggested that this should be agreed with DoH colleagues before any changes were implemented. He also noted that DoH were supportive of his role as Chair of the current group, although he had no personal preference that the meetings should be chaired by him. Heather suggested that both groups could meet separately going forward, but Paul noted that he felt to operate 2 groups would be unmanageable. Paul acknowledged that the Lookback Policy did not reference the current co-ordination group's role, which had been based on Neurology Inquiry guidance.	

	The Lookback Management Team would report to the Lookback Steering Group and would be co-chaired by Ronan Carroll and Mark Haynes. This group would have responsibility for the day to day management of the Lookback exercise. The key members of this group are still to be agreed. Heather noted her intentions were not intended to influence the role of this current group but to consider the separate roles associated with the Lookback Exercise and the Public inquiry. Heather added that her role would be responsibility for the Public Inquiry aspect and she would Chair this group. She also noted that similar guidance to the Lookback Guidance was not available to clarify the Public Inquiry aspect of the work, but she had grouped it into 3 sub-sections. Heather also noted that it was unclear what role HSCB/PHA colleagues would have in the Inquiry aspect. Paul noted that in his opinion HSCB/PHA colleagues did not have a specific role in the Public Inquiry, although each organisation has separate corporate responsibilities to fulfill. Heather noted that going forward future Lookback Steering Group meetings would have to include Ronan and Melanie as key Trust representatives. Paul asked Heather to share her proposals with HSCB/PHA colleagues and he would share with DoH colleagues for comments.	**Heather to share Trust proposal for Urology Group Structure going forward**
8	**Date of Next Meeting**	
	The date of the next meeting will be **Thursday 14th October, 3.30pm**.	
9	**Action Log**	
	➢ **Martina -** To forward UAG paper to Paul as soon as possible ➢ **Martina** - To share 2 patient requests received about sharing their experiences, with P Ferguson, DoH ➢ **Trust** - To amend Risk Template to reflect changes discussed and revised document to be shared with DoH colleagues ➢ **Caroline** - To draft short paper on proposed format of Outcomes Report & share with Trust prior to next UAG ➢ **Heather** - To share Trust proposal for Urology Group Structure going forward	

Southern Health and Social Care Trust

Health and Social Care Board

Urology HSCB and Trust Group Minutes

Thursday 12 November 2020, 15:30

Via Zoom

	Item	Actions
1	**In Attendance** Paul Cavanagh (Chair) Mark Haynes Melanie McClements Jane McKimm Stephen Wallace Caroline Cullen Martina Corrigan Sylvia Irwin Maria O'Kane **Apologies** Brid Farrell Margaret O'Brien Ronan Carroll Helen Rogers Damian Gormley	
2	**Actions from Previous Meeting** • Co-ordination Group Terms of Reference Paul asked that a draft terms of reference be tabled at the next meeting for agreement – **Caroline/Martina** to link and coordinate.	**Caroline/Martina to draft Terms of Reference**
	Update and Actions from Urology Assurance Group – 6 November 2020	
3	• Independent Review - Paul discussed the Departmental suggestion that the best process might be to undertake an Independent Review and it was agreed within the group that this appeared to be the right way to go. • Private Patients - It was recognized that the review process should look at all patients. The GMC has requested that the Trust identify private patients for appropriate review – the group discussed how this could be achieved for private patients. • Ministerial Statement - The Ministerial statement is expected to be made next Tuesday 17th November and it is anticipated that the consultant in question will be named by the Minister. The potential for families of deceased patients coming to light was also discussed. Family liaison is also an issue for the Trust.	

Serious Adverse Incident (SAI) Reviews		
4	**SAIs Terms of Reference and Update** The Trust confirmed that the 9th SAI notification has now been submitted to Brid. It was noted that a 3 month turnaround would be a very tight deadline for 9 individual SAI reports plus one overarching SAI report to be completed. Melanie noted that the Trust agreed to have all reports finalised within a 4 month timeframe, with a completion date no later than 31 January 2021. Paul acknowledged the volume of work required and thanked the Trust for this assurance. The HSCB to approve Terms of Reference for 9 SAI's plus the overarching TOR. It was noted that the Trust Governance Lead had met with 3 of the families this week and 2 of the families had requested emotional and psychological support.	**Trust to complete 10 SAI reports by 31 January 2021.** **Caroline to follow up SAI Terms of Reference with Brid.**
Trust response update		
5	See activity paper attached. SHSCTUpdate-DOHUrologyAssurGroup-Mt **Caroline** and **Martina** to provide further updates to the team in advance of the weekly meetings. It was agreed the update paper submitted to Assurance Board meetings would suffice.	**Caroline and Martina to provide weekly updates in advance of future meetings**
Communications and Support Plan		
6	• Trust information line, Family Liaison and Counselling Melanie confirmed the information line was up and running and working appropriately. Governance Department would be the point of contact for counselling and Family Liaison. The services of Inspire Counselling would also be drafted in and the Trust are currently drafting up a contract with Inspire. Martina noted that a specific e-mail address has also been set up and initially all e-mails will be vetted by her personally. Jane noted that she was in regular contact with HSCB Public Relations and she would meet with him next Monday 16th November, following Friday's meeting with Urology Assurance Group. **Jane** agreed to brief HSCB PR lead as it is anticipated that some queries may come via HSCB. Jane noted that a specific webpage would also be set up on the Trust's website.	**Jane to brief Philip HSCB PR Lead**
Resource Bid (IPT)		
7	Martina advised the first draft of the IPT would be ready early next week. She noted the IPT was based on the worst case scenario and included costs to cover all clinical support, clinical teams and supporting staff to deal with contact handling. The Trust will continue to try and protect existing services. **Caroline/Martina** to liaise and identify all supporting costs to be included in the	**Caroline/Martina to liaise re IPT costs**

	IPT. Maria provided an update on a meeting had taken place with the Trust's solicitor. The timeframe of the completion of the review was discussed and it was noted that this could take up to approximately 5 years to complete. The question around statutory functions and what the Trust's role in this would be was also discussed. Paul noted that private patients and Republic of Ireland (RoI) patients would also have to be followed up by the Trust. Melanie queried if GPs could be a route for dealing with private patients. Paul noted in his opinion GPs would push responsibility of private patients back to the Trust. Maria advised the GMC has advised the Consultant A to refrain from seeing any further private patients. Mark suggested that a letter should be sent to GPs asking them to contact the Trust if they had any concerns regarding any specific patients. **Paul** agreed to discuss RoI patients at tomorrow's Urology Assurance Group meeting. It was noted that the Trust first point of contact for all patients, whether NHS or private would be the information line. The process for dealing with private patients was discussed further and it was agreed that this would need further clarification at the Urology Assurance Group meeting tomorrow. **Caroline** to seek Helen Rogers' views on this matter and report back to Paul.	**Paul to discuss RoI patients at UAG meeting Friday 13th November** **Caroline to discuss the process for private/RoI patients with Helen Rogers and advise Paul**
Any Other Business		
8	**None raised**	
Date of Next Meeting		
9	**Via Zoom – 19th November 2020 15:30**	**Martina to send out link**

Terms of Reference for the Southern Urology Oversight Steering Group - Final Version (26th January 2022)

The revised terms of reference set out below replace the "modus operandi" of the local urology coordination group by replacing the terms of reference as agreed on 19th November 2020 in order to reflect and adopt the Policy and Guidance for implementing a lookback review process

Note: *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 that 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.

The Southern Urology Oversight Steering Group will provide oversight in respect of patients identified as previously being under the care of Consultant A. The Group will also be responsible for providing the DOH with assurance regarding the rigour of approach pursued by the Southern Trust and the timeliness of patient review.

Specifically the Group will be 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 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);

- Developing the scope for each element of the Lookback Review Process;

- Overseeing operational management of all aspects of the Lookback Review Process;

- Developing a Lookback Review Action/ Work Plan which outlines the methodologies to be implemented in relation to the Audit and the Recall stages of the Lookback Review Process;

- Ensuring that arrangements are in place to capture and report information on the outcome of the Lookback Review Process;

- Ensuring that the impact on 'business as usual' for all service users is assessed and reported on;

- Ensuring that service managers implement contingency plans for service continuity where necessary, including providing for additional health care demands which may arise as a consequence of the Lookback Review 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;

- Discussing and securing additional resources from Commissioners and ensuring 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.

The Group will be chaired by the Interim Director of Planning & Commissioning, HSCB

Membership will include:

- Director of Acute Services, Southern Trust (Deputy Chair)
- Medical Director, Southern Trust
- Programme Director of Public Inquiry, Southern Trust
- Assistant Director for Public Inquiry and Trust Liaison, Southern Trust
- Assistant Director of Surgery and Elective Care, Southern Trust
- Assistant Director of Systems Assurance, Southern Trust
- Deputy Medical Director, Southern Trust
- Associate Medical Director of Service Improvement for Urology, Southern Trust
- Head of Communications, Southern Trust
- Head of Service Clinical Assurance, Southern Trust

- Head of Service for Urology, Southern Trust
- Consultant Public Health, PHA
- Integrated Care Rep, HSCB
- Senior Commissioning Manager, HSCB
- Chair of any subgroups established by the group (as and when)
- Representative for Patient and Client Council (as and when)
- Business support, HSCB

Meetings will initially be held fortnightly and this will be reviewed on a regular basis.

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Progress Report on Level 3 Urology Services Serious Adverse Incidents

Southern Health and Social Care Trust

Introduction

This paper provides an update on the Level 3 Serious Adverse Incident (SAI) reviews that are being carried out regarding the treatment and care provided by Trust Consultant Urologist who is no longer employed by Health and Social Care Services in Northern Ireland.

SAI Process

In total the quality of care for nine patients who were under the care of Doctor 1 have been identified as meeting the threshold as requiring a SAI review. To ensure a robust and expedient process is conducted to identify learning themes and areas for improvement for all cases is carried out, the Health and Social Care Board (HSCB) and Public Health Agency (PHA) agreed that nine separate SAI's should be conducted supplemented by an overarching SAI report complete with themed recommendations.

The HSCB and PHA agreed that given the similarities between the cases identified and to ensure consistency of approach a single SAI chairperson and nominated panel should conduct each of the SAI's concurrently.

Case Summaries

The table below provides an overview of each of the nine patients identified as part of the SAI review cohort, the table includes details of their clinical summary and current status.

Patient details	Clinical summary	Current status
Patient 9	In May 2019 Patient 9 had an assessment which indicated he had a malignant prostate. Patient 9 was commenced on androgen deprivation therapy (ADT). Reviewed in July 2019 in outpatients and planned for repeat PSA and further review. Patient lost to review and attended Emergency Department in May 2020. Rectal mass	Alive - Palliative

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	investigated and diagnosed as locally advanced prostate cancer.	
Patient 1	Patient 1 was diagnosed with locally advanced prostate cancer in August 2019. An MDT discussion on 31 October 2019 recommended androgen deprivation therapy (ADT) and external beam radiation therapy (EBRT). Patient 1 was not referred for ERBT and his hormone treatment was not as per guidance. Patient commenced bicalutamide. In March 2020 Patient 1's PSA was rising and when restaged in June 2020 Patient 1 had developed metastatic disease.	Deceased
Patient 4	Diagnosed with high grade prostate cancer July 2019. MDM outcome '...commence androgen deprivation therapy (LHRHa), arrange a CT Chest and bone scan and for subsequent MDM review.' MDM recommendations not followed. Patient commenced on bicalutamide. Patient now deceased.	Deceased
Patient 3	Diagnosed with penile cancer, recommended by cancer MDM for CT scan of Chest, Pelvis and Abdomen to complete staging. Patient managed locally by MDT and delay to refer to tertiary centre in Western Trust. Penile Cancers should be managed by specialist team as per NICE guidelines.	Palliative
Patient 5	Patient 5 had a right radical nephrectomy March 2019.He had a follow up CT scan of chest abdomen and pelvis performed on 17 December 2019. The indication for this was restaging of current renal cell carcinoma. The CT scan report noted possible sclerotic metastasis in L1 vertebral body. Result was not actioned. Patient contacted with result on 28 July 2020 and further assessment required diagnosed with prostate cancer.	Alive

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	Delay in diagnosis due to delay in actioning the CT scan result.	
Patient 2	Patient diagnosed with a slow growing testicular cancer (Seminoma) had delayed referral to oncology and therefore delay in commencing chemotherapy.	Alive
Patient 7	Patient has had a small renal mass since 2017 which was under surveillance by Urology. On the 13 November 2019 the patient had a follow up CT renal scan. The report identified an enhancing lesion which had increased slightly in size. There was a delay in the follow up process for cancer care management.	Alive
Patient 8	Patient underwent transurethral resection of prostate (TURP) on 29 January 2020. Pathology reported incidental prostate cancer. There was a delay in the follow up process for cancer care management.	Alive
Patient 6	Patient diagnosed with prostate cancer Gleason 7. MDM 08/08/19- Significant Lower urinary tract symptoms but declined investigations. On maximum androgen blockade - No onward oncology referral was made.	Alive

Identification of Panel Chair

As per Level 3 SAI requirements the Trust has commissioned an external review panel to ensure independence and a robust investigation. HSCB, PHA and patients / families have been informed of the panel membership and have communicated their agreement. The below table provides details of each member.

Panel Member	Role
Dr Dermot Hughes	**External independent Chair**: Former Medical Director Western Health and Social Care Trust. Former Chair of the Northern Ireland Cancer Network (NICAN)

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Mr Hugh Gilbert	Expert External Consultant Clinical Urologist - Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick	Head of Clinical Cancer Services (SHSCT)
Ms Patricia Thompson	Clinical Nurse Specialist (SHSCT)
Mrs Patricia Kingsnorth	Acting Acute Clinical Governance Coordinator To provide facilitation

Terms of Reference

A full term of reference for the reviews can be found in Appendix 1. The terms of reference have been shared and discussed with each of the patients / families and agreed by the HSCB/PHA.

Family Engagement

Trust engagement with families has commenced and is ongoing, key points are below:

- All families have received an initial phone call to advise of the SAI process. Some of the families were made aware of the SAI process previously directly by the clinical team.
- The Chair of the SAI team and the Clinical Governance Coordinator and personally met with all families (with the exception of one who didn't want to meet with the team or be involved in family engagement, however discussions have taken place with his family and the patient wants to wait the outcome of the review).
- The families have been advised about the process, shared terms of reference and told their stories.
- Support in the form of counselling has been provided to those families who wished to avail of the support.

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- For those who didn't want to avail of support, they have contact numbers to the clinical governance coordinator who will update them.

Support for Families (Family Liaison)

The Trust is in the process of recruitment of a Family Liaison Officer. The role of this staff member will be to support families through the SAI process including after the report is completed. An appointment is expected to be made at the beginning of January 2021, a full role description is provided in Appendix 2.

Documentation

All requested documentation that has been requested by the panel has been provided:

- Patient Medical Notes have been reviewed and timelines generated for each of the nine patients and shared with the review team.
- The review team have been provided with the appropriate clinical guidelines and protocols.
- NICAN Urology cancer clinical guidelines (2016)
- The Urology MDT Operational Policy
- SHSCT Urology MDT annual report
- NICE: Suspected cancer recognition and referral: site or type of cancer
- Self-Assessment Peer Review document 2017/ 2019
- Leadership and management for all doctors (GMC)

Staff Interviews

The review team are in the process of interviewing relevant staff members and aim for completion in early January. To date interviews have been carried out with the following staff:

- Trust MDM chairperson

Further interviews are scheduled for January 2021 including:

- Lead for Cancer Services

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- AMD for Urology Services
- Doctor 1

Doctor 1 has been sent a letter from the panel chairperson offering for him to contribute to the process, a response is awaited. The panel have agreed that if a response is not received by 24th December 2020 written questions will be provided to Doctor 1 via his legal team for consideration and response.

Any Early Findings

- To date early learning has identified potential concerns regarding the prescribing of anti-androgen therapy (Bicalutamide) at low dose, sub therapeutic levels. A review of Bicalutamide prescribing has been undertaken and where required patients whose medication has required review has commenced.
- Concerns regarding non adherence to regionally agreed pathways
- Concerns regarding non adherence to MDM decisions
- Concerns regarding isolated working with non-use of specialist nurses uniquely resulting in unsupported patient experience
- Concerns regarding non re-referral to MDM when patients deteriorated resulting in non-access of appropriate services

Timescales

The SAI is currently on target for completion end of January.

- A draft copy of the report will be sent to relevant staff for factual accuracy check a response period is normally two weeks for staff to comment.
- Families will be provided with a draft copy of the reports for comments. A period of 3 weeks will be given to families to respond to the report and meet with the chair of the panel to discuss the findings and ask for amendments.
- A draft copy of the report will be shared with the HSCB at the same time as the families pending family engagement. Once comments are received and report finalised the completed report will be submitted to the HSCB.

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A Gantt chart featuring key milestones is provided below.

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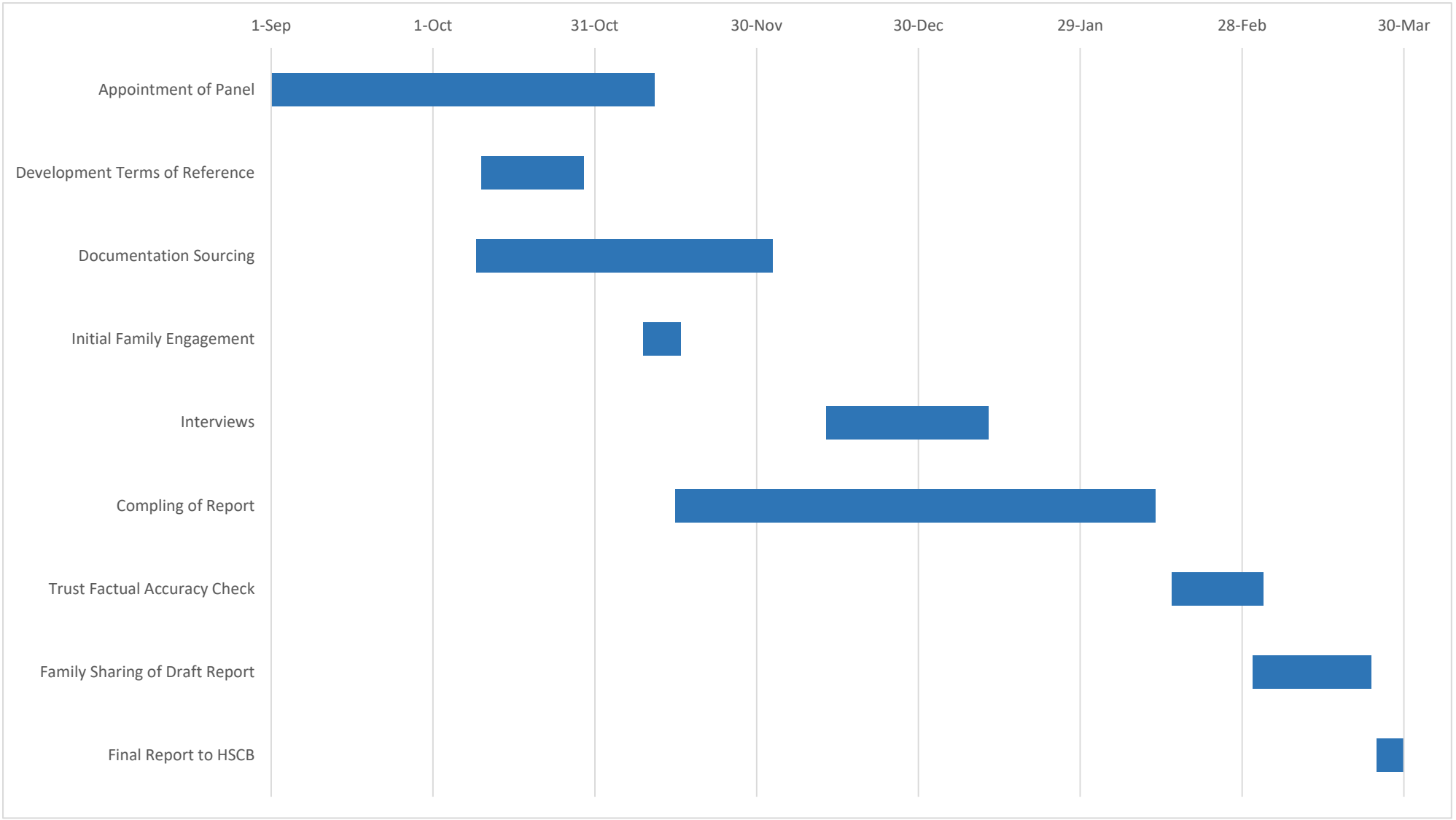

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Appendix 1 – Terms of Reference

Introduction

The core values of the Southern Health and Social Care Services (Northern Ireland) are of openness, honesty, respect and compassion. In keeping with these values, the Director of Acute Service has commissioned a level 3 SAI review to address the issues referenced above. The draft terms of reference may be amended pending engagement with all affected patients and families.

Purpose of Review

The purpose of the review is to consider the quality of treatment and the care provided by Doctor 1 and to understand if actual or potential harm occurred. The review findings will be used to promote learning, to understand system wide strengths and weaknesses and to improve the quality and safety of care and treatment provided.

Scope of Review

As part of an internal review of patients under the care of Doctor 1, a number of patients have been identified as possibly been exposed to increased or unnecessary risk.

Review Team

The proposed review team is as follows:

Chairperson / Lead Reviewer	Dr Dermot Hughes
Independent Consultant Urologist	Mr Hugh Gilbert
Cancer Services Lead	Mrs Fiona Reddick
Clinical Nurse Specialist	Ms Patricia Thompson
Clinical Governance Facilitator	Mrs Patricia Kingsnorth

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Review Aims and Objectives

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high quality care.
- Examine any areas of good practice and opportunities for sharing learning from the incidents.

Review Team Access Arrangements

Through the Review Commissioner, the Review Team will:

- Be afforded the assistance of all relevant staff and other relevant personnel.
- Have access to all relevant files and records (subject to any necessary consent/data protection requirements, where necessary).

Should immediate safety concerns arise, the Lead Reviewer will convey the details of these concerns to the Director of Acute Services / Trust Board (known as Review Commissioner) as soon as possible.

Review Methodology

The review will follow a review methodology as per the Regional Serious Adverse Incident Framework (2016) and will be cognisant of the rights of all involved to

privacy and confidentiality and will follow fair procedures. The review will commence in October 2020 and will be expected to last for a period of 4 months approximately, provided unforeseen circumstances do not arise. Following completion of the review, an anonymised draft report will be prepared by the review team outlining the chronology, findings and recommendations. All who participated in the review will have an opportunity to provide input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Reviewer will ensure that the Review Team apply Trust quality assurance processes to ensure compliance of the review process with regional guidance prior to delivery of the final report to the Review Commissioner. The Review Commissioner will seek assurance that the quality assurance process has been completed.

Recommendations and Implementation

The report, when finalised, will be presented to the Review Commissioner. The Review Commissioner is responsible for ensuring that the local managers responsible for the service where the incident occurred will implement the recommendations of the review report. The Review Commissioner is responsible for communicating regionally applicable recommendations to the relevant services for wider implementation.

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Appendix 2 – Service User Liaison Officer

JOB TITLE	Acute Service User Liaison Officer
BAND	7
DIRECTORATE	Medical Directorate
INITIAL LOCATION	Trustwide

JOB SUMMARY

The post holder will have responsibility for management of the proactive liaison service for service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety. The post holder will be the key central point of contact between the affected service users, relatives[1] and carers and will ensure they remain fully supported, including pastoral and tangible supports where required, throughout and following any Trust review processes.

The post holder will ensure the Trust maintains a responsive liaison service for patients, relatives, carers at all times. This will include liaising with internal Trust services and external agencies to ensure that appropriate supports are provided to service users and families who may require access.

KEY RESULT AREAS

1. Provide a central point of contact for service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety. The contact may be in person, by telephone, e-mail or written correspondence.

[1] *The definition of family includes any person(s) who may be affected as a result of a healthcare related incident regardless of their personal connection to the services provided*

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2. Facilitate meetings with service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety. This will include dealing with situations which are highly emotive and challenging where information may be of a sensitive and complex clinical nature.

3. Where necessary, advise and support service users to access alternative sources of information, including advocacy services, other healthcare organisations, or voluntary sector services suited to their needs.

4. Keep service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety continuously informed of Trust review processes and expected timescales for completion.

5. In cases where service users, families or carers require on-going help and support to regarding their contact with a serious adverse incident of complaint, chair liaison meetings between Trust staff and service users, families or carers to discuss any concerns they have.

6. With the consent of service users, families or carers, provide links to Trust services, General Practitioner services or external counselling agencies.

7. Lead on communication with service users, families or carers when sharing sensitive and complex information and with input from clinical subject matter experts the factors that led to adverse events affected them.

8. With operational directorate teams, make objective analysis and assessment of concerns that may be complex and/or sensitive, make judgements and through liaison with chair / reviewer to ensure the appropriate level of reviews are carried out and if required, facilitate negotiations with all concerned to find solutions.

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9. With operational directorate teams, communicate the outcome of any review to individuals in response to concerns or feedback raised, either verbally and/or in writing.

10. Keep accurate and contemporaneous records of all communications with service users, relatives and carers including outcomes and actions and input data onto the Datix system.

11. Work collaboratively with directorates to monitor the progress of action plans as a result of concerns and patient feedback and ensure that lessons are learned and share with affected service users, relatives and carers.

12. Work closely with directorates to embed a culture which views adverse events, complaints, concerns and patient feedback as opportunities for learning and support services to ensure adequately supported and empowered to deal with complaints quickly, effectively and objectively at local level

13. Represent the Trust at regional meetings and forums including the patient and client council regional working group

14. Lead and manage multidisciplinary service improvement projects designed to create improved systems and processes for the identification and dissemination of learning from adverse events and complaints

15. Provide guidance to the Chief Executive, operational directors, senior managers and clinicians on the management of communications with patients, relatives and carers.

16. Using evidence based approaches, design and deliver specialist training for clinical staff to support them when communicating with patients, families and carers.

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17. Lead on the local development of guidance in respect of service user, relative and carer engagement processes by leading on the assessment, interpretation and implementation of national and regional guidance and policies.

18. Lead and oversee an ongoing review of organisational engagement processes with regard to patients, relatives and carers and lead on the development of appropriate levels of staff, public and service user consultations.

19. Lead on the development of quality metrics and targets based on national and regional policies and provide action plan and monitoring information to the Medical Director.

20. Have input in the governance agenda by highlighting patient safety issues raised through concerns, complaints and patient feedback to the AD Clinical and Social Care Governance

21. Assist the AD Clinical and Social Care Governance and Head of Patient Safety Data and improvement analysing trends and themes arising from concerns/complaints or feedback and assist in the production of reports to Care Groups and departments

22. Work to undertake surveys, audits and other projects relevant to the department

23. Ensure that members of the public know how to raise concerns and complaints and that any barriers preventing this are addressed

24. Provide assistance to the AD Clinical and Social Care Governance collating and presenting data in preparation for external audits

25. To contribute to Trust-wide training on customer services including; staff supporting service users; relatives and carers; frontline resolution of concerns and complaints, in order to ensure that staff are supported and enabled to meet patients' needs in practice

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26. Responsible for maintaining own professional development and to be aware of current practices and developments within the Trust and the Health and Social Care in order to fulfil the role effectively

SUBMISSION TO CHIEF EXECUTIVE

FROM: Paul Cavanagh, interim Director of Commissioning

DATE: **June 2021**

TO: **SMT/CEx**

ISSUE:	Update following receipt of SAI overarching report - SHSCT Urology Lessons learned and implications for all cancer pathway MDMs in each Trust
TIMING:	**Urgent**
PRESENTATIONAL ISSUES	Should the Director identify that there may be presentational issues the submission must be cleared by Comms Team prior to submission
FOI IMPLICATIONS	There are possible FOI implications as the SAI overarching report was causal to SHSCT Urology Public Inquiry
FINANCIAL IMPLICATIONS	There are no current financial implications
LEGISLATION/POLICY IMPLICATIONS	Consideration/Approval to be given to update the MDM policy guidance issued in 2010
EQUALITY/HUMAN RIGHTS/RURAL NEEDS IMPLICATIONS	Not applicable
RECOMMENDATION:	• To note the attached briefing that sets out the concerns which have been raised as a consequence of having received the SAI overarching report (referred to as the 10th SAI) relating to the 9 SAIs from SHSCT, Urology • To approve a task and finish group be established to design an assessment tool that Trusts will be asked to complete in order to undertake a review of all cancer related MDM structures and operating practices

Introduction/Background

The Health Minister gave an Oral Assembly Statement on the Urology Services in the Southern Trust, on 24 November 2020, outlining his serious concerns about the clinical practice of Urology consultant, Mr Aidan O'Brien and the requirement for a statutory public inquiry.

(Source of full extract: https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-min-statement-241120.pdf)

As there were potential patient safety concerns identified, an initial lookback exercise in relation to the consultant's work was conducted, to ascertain if there were other areas of potential concern.

This initial lookback, which considered cases over a 18 month period of the consultant's work in the Southern Trust (from 1st January 2019 - 30th June 2020), concentrated on whether patients had a stent inserted during a particular procedure and if this stent had been removed within the clinically recommended timeframe. The initial lookback identified concerns with 46 cases within a total of 147 patients who had the particular procedure and were listed as being under the care of the Consultant during the period addressed by the initial lookback exercise.

The Trust also established a Review Group to assess the further findings of the initial lookback exercise and to explore the potential need for a further lookback exercise in the context of the concerns emerging.

In consultation with the Royal College of Surgeons, the Review Group has looked at the timeframe from 1 January 2019 until 30 June 2020 and during this time there were a total of 2,327 patients under the care of AOB. The Review Group identified the most vulnerable group of urology patients within this cohort and has concentrated on these patients initially. There are areas of concern relating to elective and emergency activity; radiology, pathology and cytology results; patients whose cases were considered in Multidisciplinary Team Meetings; oncology and in relation to the safe prescribing of an anti-androgen drug, outside of established NICE guidance in the management of prostate cancer.

Across those areas, to date 1,159 patients' records have initially been reviewed and 271 patients or families have been contacted by the Trust and their work continues across those areas of concern. Further details of the various review strands are appended in the above link.

So far 9 cases have been identified that meet the threshold for a Serious Adverse Incident (SAI) review and all 9 patients and/or their families have been contacted by the Trust to inform them of the position in relation to their respective cases.

A further 6 cases are currently being reviewed in more detail to establish if those patients have come to harm.

The overarching report (referred to as the 10th SAI) has been drafted and shared with all concerned. It was felt appropriate, given the enormity of the situation and impending Statutory Public Inquiry (to be chaired by QC Christine Smith) that it be shared with SMT.

2. **The aims and objectives of the SAI review were to:**

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients/families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high quality care.

- Examine any areas of good practice and opportunities for sharing learning from the incidents.
- To share the report with the Director of Acute Services/Medical Director of SHSCT/ HSCB/ Patients and families involved/ Staff involved.

3**. Lessons Learned**

- The SAI review of the 9 cases identified a number of areas which required lessons to be learned from. This paper focusses on one specific and pressing aspect which is that Cancer Care given by Dr 1 did not follow agreed MDM (multi-disciplinary meeting) recommendations nor follow regional or national best practice guidance. It was found that care was given without other input from Cancer Specialist Nurses, Oncology and Palliative Care. It was found to be inappropriate, did not meet patient need and was the antithesis of quality multidisciplinary cancer care.

- The review reinforced that we must ensure that all patients receive appropriately supported high quality cancer care irrespective of the professional delivering care.

- The review reinforced that we must ensure that all cancer care is multidisciplinary and centred on patient's physical and emotional need.

- The review reinforced that processes should be in place to provide assurances to patients and public that care meets these requirements.

- The review reinforced that the role of the Multidisciplinary Meeting Chair is defined by a Job Description with specific reference to Governance, Safe Care and Quality Care. That it should be resourced to provide this needed oversight.

4. Required action

In total there were 134 findings listed and11 recommendations within the report of which there are 3 issues which require immediate action for the SHSCT

(1) The Southern Health and Social Care Trust must provide high quality urological cancer care for all patients.

a) ***This will be achieved by***: Urology cancer care must be delivered through a co-operative multi-disciplinary team, which collectively and inter-dependently ensures the support of all patients and their families through, diagnosis, treatment planning and completion and survivorship

b) ***Assurance:*** must be demonstrated by comprehensive pathway audit for all patients care and experience. This should externally benchmarked within a year by Cancer Peer Review/External Service Review by Royal College

(2) All patients receiving care from the SHSCT Urology Cancer Services should be appropriately supported and informed about their cancer care. This should meet the standards set out in Regional and National Guidance and meet the expectation of Cancer Peer Review

a) This will be achieved by: Ensuring all patients receive multidisciplinary, easily accessible information about the diagnosis and treatment pathway. This should be verbally, and supported by documentation. Patients should understand all treatment options recommended by the MDM and be in a position to give fully informed consent.

b) Assurance: Comprehensive Cancer Pathway Audit and Patient experience

(3) The SHSCT must promote and encourage a culture that allows all staff to raise concerns openly and safely

a) ***This will be achieved by*:** Ensuring a culture primarily focused on patient safety and respect for the opinions of all members. The SHSCT must take action if it thinks that patient safety, dignity or comfort is or may be compromised. Issues raised must be included in the Clinical Cancer Services oversight fortnightly agenda. There must be action on issues escalated.

b) Assurance - Numbers of issues raised through Cancer Services, Datix Incidents identified, numbers of issues resolved, and numbers of issues outstanding.

There are 8 further recommendations which require action to be taken within 3 months for the SHSCT and these are listed in appendix 1

Considerations for the HSCB/PHA

Accepting that there will be a range of recommendations which are not yet fully agreed it is my view that, without hesitation, consideration should be given as to how best to apply the known learning regarding MDMs from the SHSCT Urology SAI overarching report regionally, across all cancer MDMs. The HSCB/PHA needs to ensure that there is a consistency of approach across Northern Ireland which is safe and meets the standards set out in Regional and National Guidance and meets the expectation of Cancer Peer Review. **It is essential that Trusts/HSCB/PHA are assured that at all times cancer patients receive high quality, timely care and support throughout the cancer pathway.**

While cancer peer review is a useful quality assurance tool, alongside other measures such as clinical appraisal and audit, it is not designed to identify or address individual performance issues. While the behaviour of individuals is difficult to legislate for, these SAIs suggest a need to look beyond peer review measures to understand the processes that exist around the MDM, ensuring that all patients are appropriately discussed and the advice of the MDM acted upon.

It is proposed that a task and finish group is established to design a regional MDM assessment tool that looks in detail at the processes and resources that underpin effective MDM functioning. The review of the baseline data will then enable us to identify areas of variation together with examples of good practice and will allow the development of regional recommendations/procedures that support effective MDM functioning and clinical governance. It is proposed that the work will be led by the Cancer Commissioning Team, supported by NICaN, and will report back via SMT.

There are 45 MDT across the region. Given the significant pressures in the system it is proposed that MDMs are reviewed in two phases:

- **Phase 1** - Tool to be undertaken for the "big five" tumour sites of breast, lung, gynaecology, colorectal and urology plus haematology (total 27 MDTs) over the Summer with initial report produced in September.
- **Phase 2** – Remainder of .specialist MDTs (n=18) will be completed and reported on by November 2021

The assessment tool

The self-assessment tool, which will draw on best practice guidance, will consider issues such as:

- the processes for listing patients for discussion at MDM;
- the process for referral, discussion at MDM and completion of CAPP's;
- the process for communicating the outcome to GPs;
- the process for communication of the outcome to patients;
- the process for making decisions outside of MDM;
- process for ensuring patients are referred to the CNS / have an identified key worker;
- adequacy of tracking support;
- how the role of MDM chair is operationalised and supported;
- the process for follow up of patients to ensure that first definitive treatment has commenced in line with MDM advice.
- the process to inform Consultants about MDT working and assessment of competence;
- use of protocolised registration of patients; and
- processes to ensure discussion of relapse/refractory disease.

Where possible Trusts will encourage MDT chairs to lead the review, undertaking peer review of MDTs within their Trust area. Where capacity does not allow, the tool will be completed by the Cancer Manager or Service Improvement lead on behalf of the MDT.

Fundamentally we know there are significant issues with the data infrastructure within cancer services which make undertaking routine clinical audit challenging. This issue is being progressed under the auspices of the Cancer Strategy but is likely to be something that is highlighted as an area of development by this process. The process is also likely to highlight challenges with tracking resource. While there is significant investment planned in year (13WTE trackers), further resource is required, particularly in the context of the impact of COVID on cancer pathways. This additional resource has been reflected in the Cancer Recovery Plan.

The recommendations to SMT represent the need for an enhanced level of assurance. They are in response to findings from nine patients where Dr 1 did not adhere to agreed recommendations, varied from best practice guidance and did not involve other specialists appropriately in care. They are to address what was asked of the Review by the families involved - "that this does not happen again."

Risks

Failure to review processes with a view to strengthening governance arrangements around MDMs creates a risk that similar SAIs might occur in the future

Recommendation to SMT

- To note Appendix 1 which sets out the recommendations and actions required which have been raised as a consequence of having received the SAI overarching report relating to the 9 SAIs from SHSCT and have provided justification for the Health Minister to instigate a full Independent Inquiry into care provided by the identified SHSCT Urology Consultant .

- To agree that a small task and finish working group be convened in June to develop a regional MDM self-assessment tool which will be issued to the Trusts for completion for 27 MDTs during July and August with an initial report to come

to SMT in September; the remaining MDMs will be reviewed and reported on by November 2021.

Name of Director - Mr Paul Cavanagh

Ext no.

Copied to:
As relevant e.g. Press Officer/Other Directors/ADs

Appendix 1 - Recommendations and Action Planning

1.0 RECOMMENDATIONS AND ACTION PLANNING

The recommendations represent an enhanced level of assurance. They are in response to findings from nine patients where Dr 1 did not adhere to agreed recommendations, varied from best practice guidance and did not involve other specialist appropriately in care. They are to address what was asked of the Review by families - "that this does not happen again".

Recommendation 1

The Southern Health and Social Care Trust must provide high quality urological cancer care for all patients.

This will be achieved by - Urology Cancer Care delivered through a co-operative multi-disciplinary team, which collectively and inter-dependently ensures the support of all patients and their families through, diagnosis, treatment planning and completion and survivorship.

Timescale - Immediate

Assurance - Comprehensive Pathway audit of all patients care and experience. This should be externally benchmarked within a year by Cancer Peer Review / External Service Review by Royal College.

Recommendation 2

All patients receiving care from the SHSCT Urology Cancer Services should be appropriately supported and informed about their cancer care. This should meet the standards set out in Regional and National Guidance and meet the expectation of Cancer Peer Review.

This will be achieved by - Ensuring all patients receive multidisciplinary, easily accessible information about the diagnosis and treatment pathway. This should be verbally and supported by documentation. Patients should understand all treatment options recommended by the MDM and be in a position to give fully informed consent.

Timescale - Immediate

Assurance - Comprehensive Cancer Pathway Audit and Patient experience.

Recommendation 3

The SHSCT must promote and encourage a culture that allows all staff to raise concerns openly and safely.

This will be achieved by - Ensuring a culture primarily focused on patient safety and respect for the opinions of all members. The SHSCT must take action if it thinks that patient safety, dignity or comfort is or may be compromised. Issues raised must be included in the Clinical

1.0 RECOMMENDATIONS AND ACTION PLANNING
Cancer Services oversight fortnightly agenda. There must be action on issues escalated.
Timescale – Immediate
Assurance - Numbers of issues raised through Cancer Services, Datix Incidents identified, numbers of issues resolved, and numbers of issues outstanding.
Recommendation 4
The Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals.
This will be achieved by - All MDMs being quorate with professionals having appropriate time in job plans. This is not solely related to first diagnosis and treatment targets. Re-discussion of patients, as disease progresses is essential to facilitate best multidisciplinary decisions and onward referral (e.g. Oncology, Palliative care, Community Services).
Timescale - 3 months
Assurance - Quorate meetings, sufficient radiology input to facilitate pre MDM QA of images - Cancer Patient pathway Audit - Audit of Recurrent MDM discussion - Onward referral audit of patients to Oncology/Palliative Care etc.
Recommendation 5
The Southern Health and Social Care Trust must ensure that MDM meetings are resourced to provide appropriate tracking of patients and to confirm agreed recommendations / actions are completed.
This will be achieved by - Appropriate resourcing of the MDM tracking team to encompass a new role comprising whole pathway tracking, pathway audit and pathway assurance. This should be supported by fail-safe mechanisms from laboratory services and Clinical Nurse Specialists as Key Workers. A report should be generated weekly and made available to the MDT. The role should reflect the enhanced need for ongoing audit/assurance. It is essential that current limited clinical resource is focused on patient care.
Timescale - 3 months
Assurance - Comprehensive Cancer care Pathway audit - Exception Reporting and escalation
Recommendation 6
The Southern Health and Social Care Trust must ensure that there is an appropriate Governance Structure supporting cancer care based on patient need, patient experience and

1.0 RECOMMENDATIONS AND ACTION PLANNING

patient outcomes.

This will be achieved by - Developing a proactive governance structure based on comprehensive ongoing Quality Assurance Audits of care pathways and patient experience for all. It should be proactive and supported by adequate resources. This should have an exception reporting process with discussion and potential escalation of deficits. It must be multidisciplinary to reflect the nature of cancer and work with other directorates.

Timescale - 3 months

Assurance - Cancer Pathway Audit outcomes with exception discussion and escalation. Data should be declared externally to Cancer Peer Review.

Recommendation 7

The role of the Chair of the MDT should be described in a Job Description, funded appropriately and have an enhanced role in Multidisciplinary Care Governance.

Timescale - 3 months

Recommendation 8

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, and Improving Outcome Guidance).

This will be achieved by - Ensuring the multi-disciplinary team meeting is the primary forum in which the relative merits of all appropriate treatment options for the management of their disease can be discussed. As such, a clinician should either defer to the opinion of his/her peers or justify any variation through the patient's documented informed consent.

Timescale - Immediate

Assurance - Variance from accepted Care Guidelines and MDM recommendations should form part of Cancer Pathway audit. Exception reporting and escalation would only apply to cases without appropriate peer discussion.

Recommendation 9

The roles of the Clinical Lead Cancer Services and Associate Medical Director Cancer Services should be reviewed. The SHSCT must consider how these roles can redress Governance and Quality Assurance deficits identified within the report.

1.0 RECOMMENDATIONS AND ACTION PLANNING
Timescale - 3 months **Recommendation 10** ***The families working as 'Experts by experience' have agreed to support the implementation of recommendations and will receive updates on the assurances at 3, 6 and 12 month intervals This recommendation will be agreed following discussion with families*** **Recommendation 11** ***The Southern Health and Social Care Trust should consider if assurance mechanisms detailed above, should be applied to patients or a subset of patients retrospectively.***

UROLOGY ASSURANCE GROUP

Urology Lookback Outcomes Report

In order to respond to the identified 9 SAIs, it was agreed that the Trust needed to be able to fully answer fundamental underpinning questions for each patient being reviewed with regards to the clinical practice of Consultant A:

1. Is the present diagnosis reasonable?
2. Are the current medications prescribed appropriate?
3. Is a secure clinical management plan currently in place?
4. Were appropriate and complete investigations carried out for all relevant conditions?
5. Were the medications prescribed appropriate?
6. Were the diagnosis/diagnoses reasonable?
7. Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc.)?
8. On balance, did the patient suffer any harm or detriment as a result of any of the above questions?

In order to do so, the Trust has agreed to undertake a risk stratified phased lookback exercise, in line with the process adopted with the Neurology Review.

A clinical process audit was undertaken to identify and review patients who had been under the care of Consultant A for the period January 2019 to June 2020. There were 2,346 patients identified with an age range of 3yrs to 96yrs who are referred to as the **cohort**.

Cohort patients who have been reviewed or who have had their record reviewed and have no issue with their care will be sent a letter as per the Lookback Guidance to reassure them that their care has been reviewed and that they are on the correct management plan. This equates to 1,000 patients. A detailed monthly monitoring report on progress achieved is forwarded to UAG to reflect status

As part of the ongoing process, the Trust will also write to those patients that have been identified as part of the Structured Clinical Review (69 identified as meeting criteria for an SAI as of 30 September) and advise them that the Trust are reviewing their care and will advise them of the outcome from this review.

It is anticipated that a further 300 patients will have their records reviewed by end of October 2021 and when completed the Trust will write to these patients

For the remaining patients approximately 1,200 patients, it is recommended that, due to current capacity within the Urology Service, these patients should not be contacted until there is a plan in place to review them (currently working with the Independent Sector as a solution) as it is felt that this will avoid unnecessary stress

and anxiety for the patients. Timescale for this review is still to be worked through as dependent on Limited Liability Partnership (LLP) and IS capacity.

It is intended that an outcomes report will be completed for the Cohort by May 2022

Paul Cavanagh

29 October 2021

Sarah McClatchey

From: Caroline Cullen
Sent: 14 October 2022 15:05
To: Merrisa McGeary; Sarah McClatchey
Subject: FW: Structured Clinical Record Review - needs a file number

FYI

Senior Commissioning Manager
Strategic Planning and Performance Group (SPPG)
Tel: Personal Information redacted by the USI
Mob: Personal Information redacted by the USI
Email: Personal Information redacted by the USI

From: Brid Farrell <Personal Information redacted by the USI t>
Sent: 18 February 2021 16:59
To: Sylvia Irwin <Personal Information redacted by the USI >; Paul Cavanagh <Personal Information redacted by the USI >; Helen Rogers <H Personal Information redacted by the USI >; 'Maria.okane Personal Information redacted by the USI ' <Maria.okane Personal Information redacted by the USI >; 'Corrigan, Martina (Personal Information redacted by the USI)' <Personal Information redacted by the USI >; damian gormley (SHSCT) <Personal Information redacted by the USI >; 'Haynes, Mark' <Personal Information redacted by the USI >; 'Carroll, Ronan' <Personal Information redacted by the USI >; 'stephen.wallace Personal Information redacted by the USI <Personal Information redacted by the USI >; 'Jane.mckimm Personal Information redacted by the USI ' <Jane.mckimm Personal Information redacted by the USI >; Melanie Mcclements (SHSCT) <Personal Information redacted by the USI >
Cc: Caroline Cullen <Personal Information redacted by the USI >; Martine Mateer <Personal Information redacted by the USI >
Subject: Structured Clinical Record Review

Colleagues

Thank you for the opportunity to comment on the SCCR. The SCCR is based on the mortality tool developed by RCP (Structured Judgement review) modified to assess potential suboptimal care along different parts of the care pathway. It includes case selection criteria (same as SAIs), timescales, user engagement, identification of regional learning. A proforma has (is being) been developed for in patients and out patients but was not included in the paper.

Overall the approach seems to be fit for purpose and worth testing on 1 or 2 cases before finalisation

Dr Brid Farrell
Assistant Director of Service Development, Safety and Quality
Public Health Agency
Personal Information redacted by the USI
Personal Information redacted by the USI

From: Sylvia Irwin
Sent: 18 February 2021 11:55

To: Paul Cavanagh; Brid Farrell; Helen Rogers; 'Maria.okane[redacted]'; 'Corrigan, Martina ([redacted])'; damian gormley (SHSCT); 'Haynes, Mark'; 'Carroll, Ronan'; 'stephen.wallace[redacted]'; 'Jane.mckimm[redacted]'; Melanie Mcclements (SHSCT)
Cc: Caroline Cullen; Martine Mateer
Subject: Urology HSCB-SHSCT Co-Ordination Group Meeting Thursday 18th February
Importance: High

Good morning everyone

Please find attached documents for this afternoon's HSCB/SHSCT Urology meeting at 3.30pm:-

(i) Agenda - 18th February.
(ii) Draft Notes of the meeting held on 11th February.
(iii) Terms of Reference Clinical Records Review (Invited)
(iv) Urology Patient Review Form
(v) Draft Proposal for Structured Clinical Records Review

Regards

Sylvia

Business Support Manager
Commissioning
SLCG
Tower Hill
Armagh
BT61 9DR

E-mail: [redacted]
Office number: [redacted]
Mobile: [redacted]

(Monday to Thursday)

Due to Covid 19 I am primarily working from home

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Reference: HSC (SQSD) 6/21

Date of Issue: 16 July 2021

REGIONAL LOOKBACK REVIEW POLICY

For Action:
Chief Executives HSC Trusts
Chief Executive HSCB
Chief Executive PHA
Chief Executive RQIA
Chief Executive, NIMDTA
Chief Executive, NIPEC

For Information:
Distribution as listed at the end of this circular.

Superseded documents
HSS (SQSD) 18/07 Conducting Patient Service Reviews/Lookback Exercises

Implementation
1st September 2021

DoH Safety and Quality Circulars including Patient Safety Alerts can be accessed on: https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

Dear colleagues

SUMMARY

The purpose of this circular is to advise you of the Department's updated policy (**Annex 1**) and regional guidance (**Annex 2**) for implementing a Lookback Review. Process. It replaces HSS (SQSD) 18/07, issued by the Office of the Chief Medical Officer on 8 March 2007.

ACTION

Chief Executives of HSC Trusts should:

- Disseminate this circular to all relevant Trust staff for immediate implementation of the updated policy and guidance.

Chief Executives, HSCB and PHA should:

- Disseminate this circular to all relevant HSCB/PHA staff for immediate implementation

Chief Executive, NIMDTA and NIPEC should:

- Disseminate this circular to doctors and dentists in training in all relevant specialities for information.

Chief Executive, RQIA should:

- Disseminate this circular to all relevant staff and all relevant independent sector providers for immediate implementation.

BACKGROUND

Lookback Reviews are undertaken frequently in the health and social care system and there have been a number of recent high-profile examples. They are undertaken as a matter of urgency whenever 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 also to identify the necessary steps to ameliorate the harm (e.g. repeat diagnostic test/ investigation/ referral to relevant clinical service etc.)

Following some more recent patient service reviews and patient call back exercises further learning was identified. It was decided in 2018 that the 2007 Guidance needed to be reviewed and updated to take account of this learning along with HSC organisations' Statutory Duty of Quality, their systems of governance and extant guidance on Assurance Frameworks.

This review of the previous guidance has now been completed and a new policy document (**Annex 1**) along with new regional guidance (**Annex 2**) have been prepared, with the aim of standardising and refreshing the approach taken to Lookback Reviews by the HSC in Northern Ireland.

Any enquiries about the content of this circular should be addressed to:

Safety Strategy Unit
Department of Health
Room D1.4
Castle Buildings
BELFAST
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Tel: Personal Information redacted by the USI

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Dr Lourda Geoghegan
Deputy Chief Medical Officer

Distributed for Information to:

Executive Medical Director/Director of Public Health, PHA
Director of Nursing and Allied Health Professions, PHA
Director of Performance Management & Service Improvement, HSCB
Safety and Quality Alerts Team, HSC Board
Head of Nursing & Midwifery, QUB
Head of Medical School, QUB
Director of Centre for Medical Education, QUB
Head of School of Pharmacy QUB
Head of School of Nursing, UU
Head of Pharmacy School, UU
Chief Executive, NIAS
Staff Tutor of Nursing, Open University
Director, HSCQI
NI Centre for Pharmacy Learning and Development
Clinical Education Centre
NI Royal College of Nursing
Linda Greenlees, DOH
Annemarie Bovill, DOH

Policy for Implementing a Lookback Review Process

July 2021

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.

For immediate implementation

For review July 2031

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;

[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.

- 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;
- 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 complaint, 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] [3] and Department of Health (DoH) Early Alert Guidance.[4]

[2] HSCB 'Procedure for the Reporting and Follow up of Serious Adverse Incident'. November 2016.
[3] If the hazard is associated with a medical device then the HSC organisation should report this in line with the Norther Ireland Adverse Incident Centre (NIAIC) adverse incident reporting – guidance and forms. October 2018 'www.health-ni.gov.uk.
[4] DoH 'Early Alert System' Reference HSC (SQSD) 5/19.

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, or professional regulators e.g. Nursing & Midwifery Council or General Medical Council. In that regard, all existing statutory or mandatory reporting obligations, will continue to operate in tandem with this Regional Policy.

2.0 Purpose

The purpose of this policy and regional guidance is to ensure a consistent, coordinated and timely approach for the notification and management of potentially/affected service users carried out in line with the principles of openness and candour, [5] [6] [7] whilst taking account of the requirements of service user confidentiality and Data Protection. [8] [9]

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.

[5] 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.
[6] DoH 'Being Open – Saying sorry when things go wrong'. January 2020.
[7] 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.
[8] General Data Protection Regulation ((EU) 2016/679) (UK GDPR).
[9] Data Protection Act 2018 at www.legislation.gov.uk

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;[10]

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.

[10] South Australia Health ' Lookback Review Policy Directive', Safety & Quality, System Performance & Service Delivery, July 2016. Section 1 page 4.

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; [11] [12]
- 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. [13] [14]

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 at risk and Stage 3 Service User Recall;

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

- 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);[15]
- Developing the Scope and Terms of Reference for each element of the Lookback Review Process;
- Overseeing operational management of all aspects of the Lookback Review Process;
- Developing a Lookback Review Action/ Work Plan which outlines the methodologies to be implemented in relation to the Audit and the Recall stages of the Lookback Review Process;
- Ensuring that arrangements are in place to capture and report information on the outcome of the Lookback Review Process;
- Ensuring that the impact on 'business as usual' for all service users is assessed and reported on;
- Ensuring that service managers implement contingency plans for service continuity where necessary, including providing for additional health care demands which may arise as a consequence of the Lookback Review 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.

[15] DoH. HSCB. *Loc. Cit.*

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;
- Satisfying 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;
- General Data Protection Regulation ((EU) 2016/679) (UK GDPR);
- Data Protection Act 2018;
- Department of Health 'Code of Practice for protecting the confidentiality of service user information' April 2019;
- 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.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Regional Guidance for Implementing a Lookback Review Process

July 2021

Contents

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

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).

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 pose a serious risk to a service user following procedures undertaken (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?

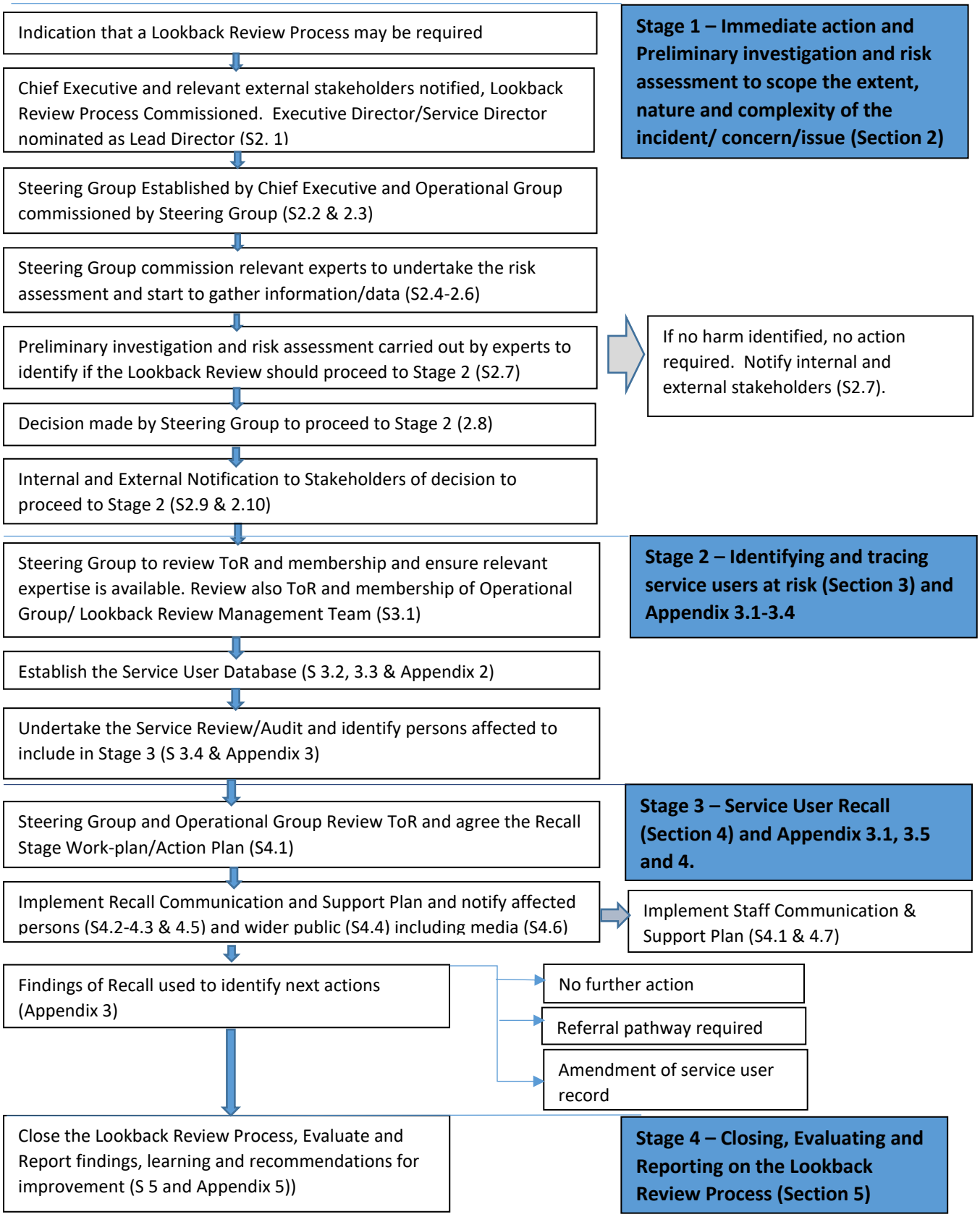
The Lookback Review Process involves:

- 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;

[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.

- 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);
- 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.

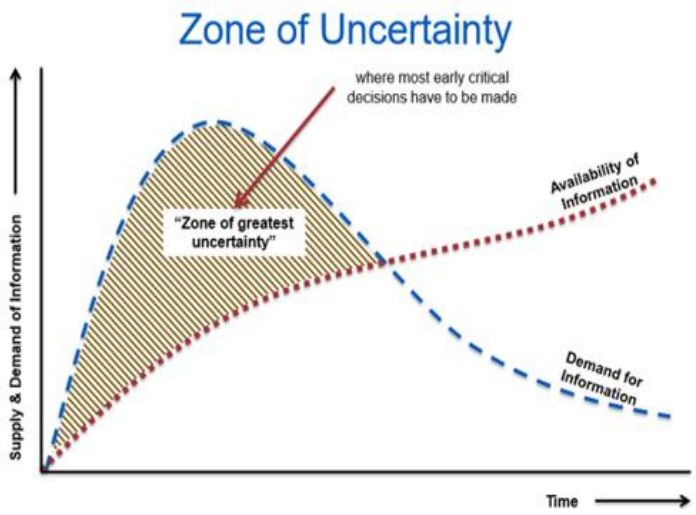
[13] New South Wales 'Lookback Policy Directive', Clinical Excellence Commission Safety & Quality, System Performance & Service Delivery, September 2007. Section 4 Page 5.

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.

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

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

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);
- The potential impact on other service users (not in the 'at risk' cohort) e.g. potential delays in treatment and diagnosis;

[21] *Ibid*. Appendix 1

- 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.

[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.

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 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*

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

ii. *evidence comes to light during the Coroner's investigation or inquest which suggests possible harm was caused to a patient or client as a result of the treatment or care they received; or*

iii. *the Coroner's inquest is likely to attract media interest.*

6. *The following should always be notified:*

i. *the death of, or significant harm to, a child, and abuse or neglect are known or suspected to be a factor;*

ii. *the death of, or significant harm to, a Looked After Child, a child on the Child Protection Register or a young person in receipt of leaving and after care services;*

iii. *allegations that a child accommodated in a children's home has committed a serious offence; and*

iv. *any serious complaint about a children's home or persons working there.*

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

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; and
- 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; and
- At the end of the Lookback Review Process to generate information on numbers of service users identified, further assessed and their outcomes.

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

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

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

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

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

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

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

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

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 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.

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[32] General Data Protection Regulation ((EU) 2016/679) (UK GDPR) @ 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' April 2019 @ www.health,n-i.gov.uk
[35] HSE. *Op.cit*. Section 7.7.3.

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.

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); and
- 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 any service user affected are referred into the 'system' for subsequent follow-up.[36]

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

4.2 Service User Communication and Support

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

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

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

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

- access to professional interpreters as required;
- a designated point of contact for service users, their families and/or carers;
- regular and ongoing information updates provided to service users and families and/or carers;
- affected service users offered a written apology by the health service organisation;
- establishment of a Helpline/Information Line/website to ask questions and to obtain information (see Section 4.5 and Appendix 4 for practical guidance); and
- 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; and
- 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; and
- 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 numbers are manageable.

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

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

4.4 Public Announcement of the Recall Stage

The Steering Group will determine the timing of the Public Announcement of the Recall Stage of the Lookback Review Process. Communications management

throughout the Lookback Review Process should be guided by the principles of 'Being Open'[37] balanced with the need to provide reassurance and avoid unnecessary concern.

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

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

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

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

4.5 Setting up a Service User Helpline/ Information Line

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

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

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 is contained in Appendix 4.

4.6 Communication with the Media

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

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

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

- nominate a spokesperson for public and media communications;
- minimise the delay in response to the public and the media;
- develop a media pack which should contain; and
    - 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

[39] *Ibid.* Section 7.11.2 Page 26

of concern to time period, region and service area within which the Process is being conducted. It should detail the numbers of persons affected being included in the recall stage of the process and the expected timeframe for the completion of the recall stage, if known.[40]

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

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

4.7 Staff Communication and Support

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

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

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

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

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

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

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

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

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

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

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

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

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

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

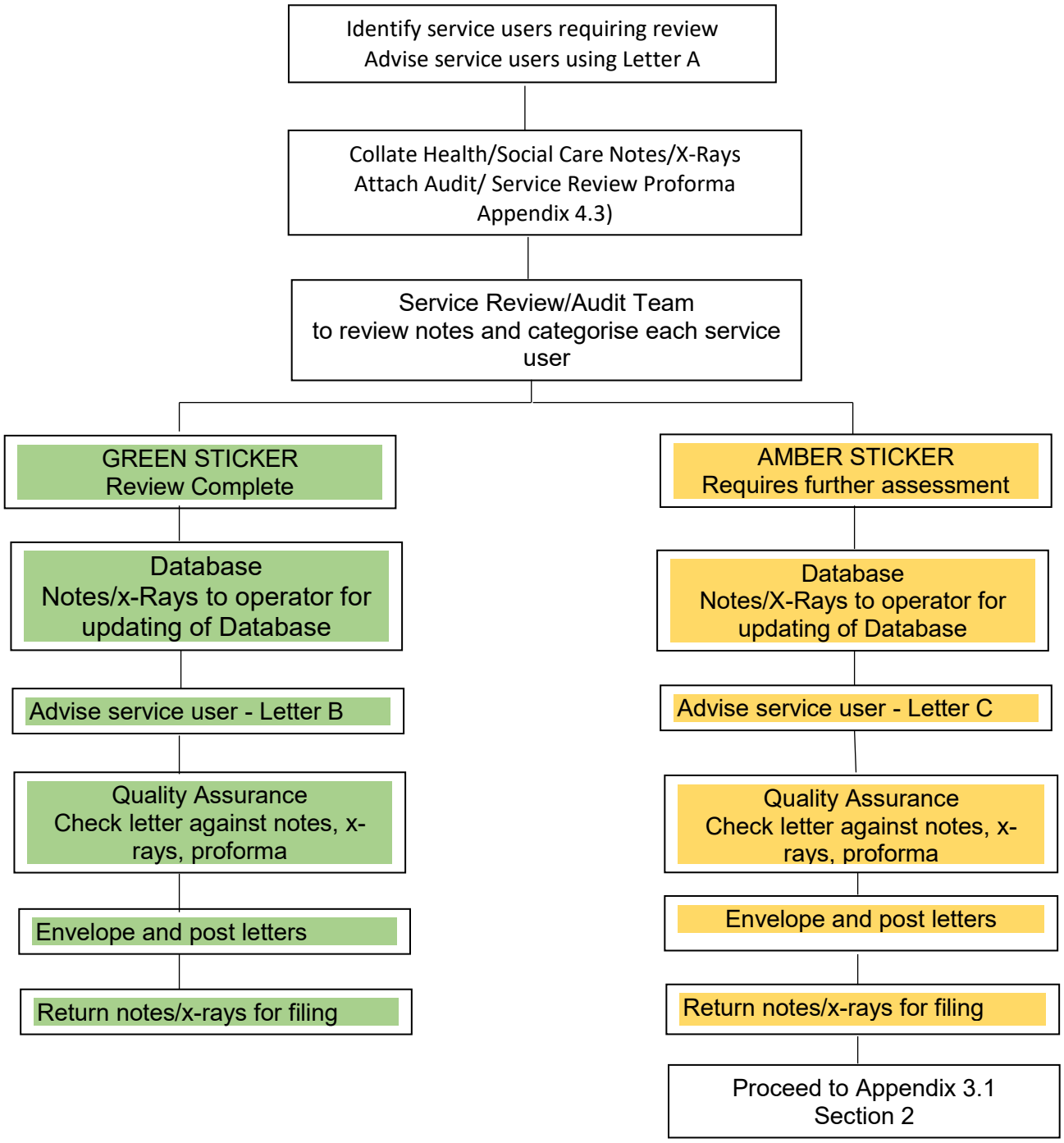
The service user database needs to be updated after completion of this proforma.

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.

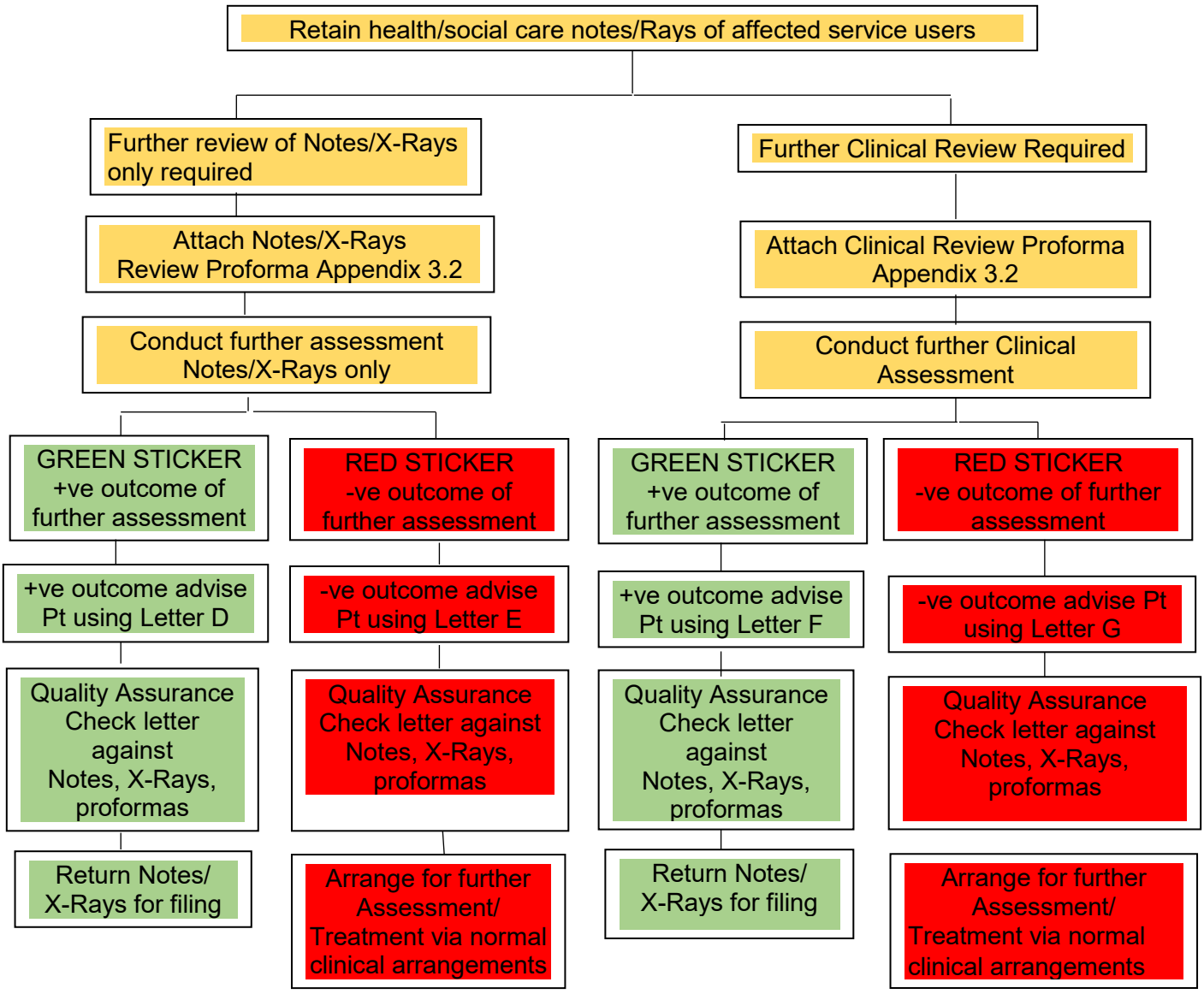
- If it has a **green** sticker attached: file into service user notes.
- If it has a **red** sticker attached: return service user notes and pro forma to admin support for processing within normal clinical arrangements.

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	OUTCOME -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			

Terms of Reference for the Southern Urology Co-ordination Group
Agreed 19th November 2020

The Southern Co-ordination Group will provide oversight of the Urology enquiry in respect of patients identified as previously being under the care of Consultant A. The Group will also be responsible for providing the DOH with assurance regarding the rigour of approach pursued by the Southern Trust and the timeliness of patient review.

Specifically the Group will:

- Coordinate and provide oversight of the operational work necessary to complete the enquiry and a review of patients affected.
- Establish subgroup(s) as deemed necessary to complete specific pieces of work.
- Work with Southern Trust to clarify their assessment of the numbers of people who may be affected.
- Work on identifying patients who Consultant A may have treated privately and review if necessary and work with DOH and HSE on ensuring these patients are considered.
- Ensure a consistent approach to the recall and review of people affected, including producing consistent aggregate summaries of the outcomes of these recalls and reviews.
- Seek assurance regarding the ongoing capacity available to ensure timely review.
- Ensure good communication on issues that need to be addressed.
- Seek assurance on the arrangements in place to maintain service continuity in the Southern Urology Service.
- Draft a report on the activity of the enquiry and the outcomes, to be submitted to the DoH for approval and subsequent publication. Provide regular assurance to DOH.
- Complete an IPT on the staffing support required to meet the needs of the patients identified during the enquiry, including support for the information line, clinical activity and activity/data gathering. To be submitted to the HSCB for approval and subsequently to the DOH.

The Group will be chaired by Interim Director of Planning and Commissioning, HSCB

Membership will include:

- Interim Director of Planning and Commissioning- HSCB (Chair)
- Medical Director - Southern Trust
- Director of Acute Services - Southern Trust
- Assistant Director of Surgery and Elective Care - Southern Trust
- Interim Assistant Director of Clinical and Social Care Governance - Southern Trust
- Deputy Medical Director – Southern Trust
- Associate Medical Director of Surgery – Southern Trust
- Head of Communications – Southern Trust
- Head of Service for Urology – Southern Trust
- Consultant Public Health - PHA
- Integrated Care Rep - HSCB
- Senior Commissioning Manager - HSCB
- Chair of any subgroups established by the SUCG
- Representative for Patient and Client Council
- Communication leads from the HSCB and PHA will be involved in meetings at appropriate stages in the process and will be copied into relevant papers
- Business support - HSCB

Meetings will initially be held weekly and this will be reviewed on a regular basis.

serious incidents

From: Corporate.Governance <Personal Information redacted by the USI>
Sent: 22 March 2016 14:54
To: serious incidents
Subject: ENCRYPTION: SAI Notification - ID Personal Information
Attachments: SAI Notification - ID Personal Information pdf

Categories: Work in progress, SHSCT actioned, New SAI notification

Please see attached SAI Notification for appropriate action – ID Personal Information redacted by the USI

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

'You can follow us on Facebook and Twitter'

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

1. ORGANISATION: **SHSCT**	**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE Personal Information redacted by the HSI
3. HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)* **Craigavon Area Hospital**	**4.** DATE OF INCIDENT: 06/01/16
5. DEPARTMENT / WARD / LOCATION EXACT *(where incident occurred)* Urology Outpatients	
6. CONTACT PERSON: Connie Connolly	**7.** PROGRAMME OF CARE: *(refer to Guidance Notes)* Acute Services

8. DESCRIPTION OF INCIDENT:

Had a CT scan 24/6/2014 as follow-up of bowel cancer. CT showed an abnormal renal cyst with two further cysts in the right kidney.

US performed 24/7/2014 showed solid elements within the anterior lower pole cyst and recommended an MRI to further evaluate.

MRI performed 2/9/2014

Referral to Urology was not triaged on receipt. Patient 10 sent OP appointment for 6/1/2016. Patient 10 was seen in clinic on 6/1/16. The sequence of events was outlined and surgical treatment of a suspected cystic renal cancer recommended after completion of up to date staging with a further CT scan. There has been a resultant 18 month delay in OP review and recommendation of treatment for a suspected kidney cancer. The SHSCT wish to submit this incident as an SAI in order to establish any areas of learning.

DOB: Personal Information redacted by the HSI GENDER: F AGE: Personal Information redacted by the HSI years
(complete where relevant)

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING

STAGE OF CARE:	DETAIL:	ADVERSE EVENT:
Implementation of care	*Delay in monitoring*	*Test results available but inaccurate*

9. IMMEDIATE ACTION TAKEN TO PREVENT RECURRANCE:
N/A

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

The patient is undergoing treatment

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

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

serious injury to, or the unexpected/unexplained death of: - a service user - a staff member in the course of their work - a member of the public whilst visiting a HSC facility.	X

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

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

14. IS ANY <u>IMMEDIATE</u> REGIONAL ACTION RECOMMENDED: *(please select)*		NO

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

15. HAS THE SERVICE USER / FAMILY BEEN ADVISED THE INCIDENT IS BEING INVESTIGATED AS A SAI-		If NO – *The Trust intend to inform the family by letter in the first instance of this serious incident review and will advise HSCB when this has been done.*
16. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(refer to guidance notes e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HCPC etc.) please specify where relevant*		NO

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

17. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	DATE INFORMED:	OTHERS: *(please specify where relevant, including date notified)*
DHSS&PS EARLY ALERT		
HM CORONER		
INFORMATION COMMISSIONER OFFICE (ICO)		
NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)		
NORTHERN IRELAND HEALTH AND SAFETY EXECUTIVE (NIHSE)		
POLICE SERVICE FOR NORTHERN IRELAND (PSNI)		
REGULATION QUALITY IMPROVEMENT AUTHORITY (RQIA)		
SAFEGUARDING BOARD FOR NORTHERN IRELAND (SBNI)		
NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP (NIASP)		
18. LEVEL OF INVESTIGATION REQUIRED: *(please select)*		**Level 2**

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

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

19. I confirm that the designated Senior Manager and/or Chief Executive has been advised of this SAI and is content that it should be reported to the Health and Social Care Board. (*delete as appropriate*)

Report submitted by: Connie Connolly Designation: Lead Nurse for Acute Governance SHSCT

Email: Personal Information redacted by the USI Telephone: Personal Information redacted by the USI Date: 21/03/16

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

Additional information submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MMM / YYYY

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

serious incidents

From: serious incidents
Sent: 22 March 2016 15:30
To: 'Corporate.Governance'
Subject: Acknowledgement - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Attachments: NEW HSC SAI NOTIFICATION FORM February 2016.docx

This communication acknowledges receipt of the Serious Adverse Incident Notification made to the HSCB seriousincidents@hscni.net mail box and confirms that the **Southern Trust** will complete a **LEVEL 2** Root Cause Analysis (RCA) investigation relating to this SAI.

Your Reference: **SHSCT SAI** [redacted]

HSCB Reference: [redacted]

In line with the HSCB Procedure for the Reporting and Follow up of SAIs, please provide the following:

- the **Terms of Reference and Membership** of the investigation team by completing sections 2 and 3 of the HSCB RCA template and submitting directly to seriousincidents@hscni.net by no later than **19 April 2016**
- submit a copy of the **completed RCA Report** and where appropriate the associated **Action Plan** for this SAI by no later than **14 June 2016** directly to seriousincidents@hscni.net.
- **In addition the HSCB SAI Checklist should be completed and submitted along with the RCA Report.**

Please note all RCA Review Reports **must** be completed using the **newly revised HSCB template and Checklist** which were issued on 8 June 2015.

NB. Please note that this SAI was not submitted on the new HSC SAI Notification Form template. Can you please ensure that any new SAI's are completed and submitted on the new form (attached).

Regards
Roísín
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: [redacted]
T: [redacted]

From: Corporate.Governance [mailto: [redacted]]
Sent: 22 March 2016 14:54
To: serious incidents
Subject: ENCRYPTION: SAI Notification - ID [redacted]

Please see attached SAI Notification for appropriate action – ID [redacted]

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

Tel [redacted]
Email [redacted]

'You can follow us on Facebook and Twitter'

serious incidents

From: serious incidents
Sent: 22 March 2016 16:03
To: 'Corporate.Governance'
Subject: Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

In relation to the above incident, can you please clarify the Date of Birth of the Service User as on the SAI Notification Form it states the Date of Birth as [redacted] and age as [redacted] these don't match. Either the Date of Birth should be [redacted] or age needs changed to [redacted]? Can you please clarify correct Date of Birth/Age and send your response to seriousincidents@hscni.net mailbox by **return of email**?

Regards
Roísín

Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: [redacted]
T: [redacted]

From: Corporate.Governance [mailto:[redacted]]
Sent: 22 March 2016 14:54
To: serious incidents
Subject: ENCRYPTION: SAI Notification - ID 5[redacted]

Please see attached SAI Notification for appropriate action – ID [redacted]

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

Tel [redacted]
Email [redacted]

'You can follow us on Facebook and Twitter'

serious incidents

From: serious incidents
Sent: 22 March 2016 16:17
To: Paul Darragh
Cc: Carolyn Harper; Janet Little; Mary Hinds; Pat Cullen; Lynne Charlton; Mary McElroy; Oriel Brown; Michael Bloomfield; Anne Kane; Jacqui Burns; Margaret McNally; Elaine Hamilton; Mareth Campbell
Subject: DRO Assigned - Trust Ref: SHSCT SAI Personal Information HSCB Ref: S Personal Information
Attachments: SAI Notification - ID Personal Information .pdf

Paul,

You have been identified as the DRO for the above SAI. Please can you advise by email to seriousincidents@hscni.net on any immediate action you have taken or action required; the governance team will be update the Datix record for this incident accordingly.

I attach the Serious Adverse Incident Notification from the **Southern Trust** received 22 March 2016. This notification confirms that a **Level 2** Root Cause Analysis (RCA) Review will be undertaken.

This incident has been reported to the HSCB in line with the HSCB Procedure for the Reporting and Follow up of SAIs.

SHSCT SAI Reference Number: **SHSCT SAI** Personal Information

HSCB SAI Reference Number: Personal Information

PROGRAMME OF CARE: **Acute**

An acknowledgement of receipt of this notification has been forwarded to the **Southern Trust**, requesting:

- the **Terms of Reference and Membership** of the investigation team by no later than **19 April 2016** and
- a copy of the **completed RCA Report** and the HSCB **SAI Checklist** and the associated **Action Plan** for this SAI by no later than **14 June 2016.**

If you require any further information, please do not hesitate to contact me.

Regards
Roísín
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: Personal Information redacted by the USI
T: Personal Information redacted by the USI

From: Corporate.Governance [mailto: Personal Information redacted by the USI]
Sent: 22 March 2016 14:54
To: serious incidents
Subject: ENCRYPTION: SAI Notification - ID Personal Information

Please see attached SAI Notification for appropriate action Personal Information redacted by the USI

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

'You can follow us on Facebook and Twitter'

serious incidents

From: Paul Darragh
Sent: 23 March 2016 10:00
To: serious incidents
Subject: RE: DRO Assigned - Trust Ref: SHSCT SAI Personal Information HSCB Ref: Personal Information

Noted.

From: serious incidents
Sent: 22 March 2016 16:17
To: Paul Darragh
Cc: Carolyn Harper; Janet Little; Mary Hinds; Pat Cullen; Lynne Charlton; Mary McElroy; Oriel Brown; Michael Bloomfield; Anne Kane; Jacqui Burns; Margaret McNally; Elaine Hamilton; Mareth Campbell
Subject: DRO Assigned - Trust Ref: SHSCT SAI Personal Information HSCB Ref: Personal Information

Paul,

You have been identified as the DRO for the above SAI. Please can you advise by email to seriousincidents@hscni.net on any immediate action you have taken or action required; the governance team will be update the Datix record for this incident accordingly.

I attach the Serious Adverse Incident Notification from the **Southern Trust** received 22 March 2016. This notification confirms that a **Level 2** Root Cause Analysis (RCA) Review will be undertaken.

This incident has been reported to the HSCB in line with the HSCB Procedure for the Reporting and Follow up of SAIs.

SHSCT SAI Reference Number: **SHSCT SAI** Personal Information

HSCB SAI Reference Number: Personal Information

PROGRAMME OF CARE: **Acute**

An acknowledgement of receipt of this notification has been forwarded to the **Southern Trust**, requesting:

- the **Terms of Reference and Membership** of the investigation team by no later than **19 April 2016** and
- a copy of the **completed RCA Report** and the HSCB **SAI Checklist** and the associated **Action Plan** for this SAI by no later than **14 June 2016.**

If you require any further information, please do not hesitate to contact me.

Regards
Roisín
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: Personal Information redacted by the USI
T: Personal Information redacted by the USI

From: Corporate.Governance [mailto Personal Information redacted by the USI
Sent: 22 March 2016 14:54
To: serious incidents
Subject: ENCRYPTION: SAI Notification - ID Personal Information

Please see attached SAI Notification for appropriate action – ID Personal Information redacted by the

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

'You can follow us on Facebook and Twitter'

serious incidents

From: Corporate.Governance <Personal Information redacted by the USI>
Sent: 23 March 2016 12:38
To: serious incidents
Subject: ENCRYPTION: Amended SAI Notification SAI Personal Information
Attachments: Notification.doc

Please see attached amended SAI Notification to read correct DOB and age.

Many apologies

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

'You can follow us on Facebook and Twitter'

In relation to the above incident, can you please clarify the Date of Birth of the Service User as on the SAI Notification Form it states the Date of Birth as Personal Information redacted by the USI and age as Personal, these don't match. Either the Date of Birth should be Personal Information or age needs changed to Personal? Can you please clarify correct Date of Birth/Age and send your response to seriousincidents@hscni.net mailbox by **return of email**?

Regards
Roisin

Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: Personal Information redacted by the USI
T: Personal Information redacted by the USI

From: Corporate.Governance [mailto: Personal Information redacted by the USI]
Sent: 22 March 2016 14:54
To: serious incidents
Subject: ENCRYPTION: SAI Notification - ID Personal Information

Please see attached SAI Notification for appropriate action – ID Personal Information redacted by the

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

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SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

1. ORGANISATION: **SHSCT**	**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE Personal Information
3. HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)* **Craigavon Area Hospital**	**4.** DATE OF INCIDENT: 06/01/16
5. DEPARTMENT / WARD / LOCATION EXACT *(where incident occurred)* Urology Outpatients	
6. CONTACT PERSON: Connie Connolly	**7.** PROGRAMME OF CARE: *(refer to Guidance Notes)* Acute Services

8. DESCRIPTION OF INCIDENT:

Had a CT scan 24/6/2014 as follow-up of bowel cancer. CT showed an abnormal renal cyst with two further cysts in the right kidney.

US performed 24/7/2014 showed solid elements within the anterior lower pole cyst and recommended an MRI to further evaluate.

MRI performed 2/9/2014

Referral to Urology was not triaged on receipt. Patient 10 sent OP appointment for 6/1/2016. Patient 10 was seen in clinic on 6/1/16. The sequence of events was outlined and surgical treatment of a suspected cystic renal cancer recommended after completion of up to date staging with a further CT scan. There has been a resultant 18 month delay in OP review and recommendation of treatment for a suspected kidney cancer. The SHSCT wish to submit this incident as an SAI in order to establish any areas of learning**.**

DOB: Personal Information GENDER: F AGE: Personal years
(complete where relevant)

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING

STAGE OF CARE:	DETAIL:	ADVERSE EVENT:
Implementation of care	*Delay in monitoring*	*Test results available but inaccurate*

9. IMMEDIATE ACTION TAKEN TO PREVENT RECURRANCE:
N/A

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

The patient is undergoing treatment

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

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

serious injury to, or the unexpected/unexplained death of: - a service user - a staff member in the course of their work - a member of the public whilst visiting a HSC facility.	X

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

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

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

15. HAS THE SERVICE USER / FAMILY BEEN ADVISED THE INCIDENT IS BEING INVESTIGATED AS A SAI-		If NO – *The Trust intend to inform the family by letter in the first instance of this serious incident review and will advise HSCB when this has been done.*
16. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(refer to guidance notes e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HCPC etc.) please specify where relevant*		NO
if 'YES' (*full details should be submitted including the date notified*):		

17. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	DATE INFORMED:	OTHERS: *(please specify where relevant, including date notified)*
DHSS&PS EARLY ALERT		
HM CORONER		
INFORMATION COMMISSIONER OFFICE (ICO)		
NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)		
NORTHERN IRELAND HEALTH AND SAFETY EXECUTIVE (NIHSE)		
POLICE SERVICE FOR NORTHERN IRELAND (PSNI)		
REGULATION QUALITY IMPROVEMENT AUTHORITY (RQIA)		
SAFEGUARDING BOARD FOR NORTHERN IRELAND (SBNI)		
NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP (NIASP)		
18. LEVEL OF INVESTIGATION REQUIRED: *(please select)*		**Level 2**

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

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

19. I confirm that the designated Senior Manager and/or Chief Executive has been advised of this SAI and is content that it should be reported to the Health and Social Care Board. (*delete as appropriate*)

Report submitted by: Connie Connolly Designation: Lead Nurse for Acute Governance SHSCT

Email: Personal Information redacted by the USI Telephone: Personal Information redacted by the USI Date: 21/03/16

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

Additional information submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MMM / YYYY

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

serious incidents

From: Corporate.Governance <Personal Information redacted by the USI>
Sent: 05 April 2016 09:53
To: serious incidents
Subject: ENCRYPTION: TOR and Membership - ID Personal Information
Attachments: TOR Membership - ID Personal Information .pdf

Categories: Work in progress

Please see attached Terms of Reference and Membership for SAI – ID Personal Information redacted by the USI

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

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Southern Health and Social Care Trust

Quality Care - for you, with you

Root Cause Analysis report on the review of a Serious Adverse Incident

Organisation's Unique Case Identifier: [redacted]

Date of Incident/Event: 6 January 2016

HSCB Unique Case Identifier: ID[redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M Age: [redacted] yrs

Responsible Lead Officer: Mr Anthony Glackin

Designation: Consultant Urologist

Report Author: Review Team

Facilitator: Connie Connolly Lead Nurse Acute Governance

Date report signed off:

Date submitted to HSCB:

1.0 THE REVIEW TEAM

Mr Anthony Glackin Consultant Urologist SHSCT Chair
Dr David Gracey Consultant Radiologist
Mrs Katherine Robinson Booking Centre Manager
Mrs Connie Connolly Lead Nurse Acute Governance

2.0 SAI REVIEW TERMS OF REFERENCE

The terms of reference for this review will be finally approved by the Chair and review team members at the initial SAI review meeting.

Draft Terms of Reference for the Serious Adverse Incident Investigation are as follows:

- To carry out a Level 2 review into the care provided to Patient 10 within the SHSCT between the 24 June 2014 and 6 January 2016.

- To carry out this review into the care provided to Patient 10 using the National Patient Safety Agency Root Cause Analysis methodology

- To use a multidisciplinary team approach to the review

- To provide an agreed chronology based on documented evidence and staff accounts of events

- To identify the key contributory factors which may have had an influence or contributed to Patient 10's treatment and care.

- To ensure that recommendations are made in line with evidence based practice.

- To set out the findings, recommendations, actions and lessons learnt in an anonymous report

- To adhere to the principles of confidentiality throughout the review.

- To report the findings and recommendations of the review through the Director of Acute Services SHSCT, to Patient 10, family of Patient 10 and the staff associated with Patient 10's care

THIS LIST IS NOT EXHAUSTIVE

serious incidents

From: serious incidents
Sent: 05 April 2016 12:05
To: Paul Darragh
Subject: TERMS OF REFERENCE AND TEAM MEMBERSHIP - Trust Ref: SAI – ID Personal Inform HSCB Ref: Personal Inform
Attachments: TOR and Membership.pdf

Dr Darragh

Please see attached Terms of Reference and Team Membership received from the Southern Health and Social Care Trust.

Following consideration, please advise seriousincidents@hscni.net if the Terms of Reference and Membership of Review Team has been approved by 12 April 2016.

Warm regards,
Donna

Donna Britton
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

DDI: Personal Information redacted by the USI
E: Personal Information redacted by the USI

From: Corporate.Governance [mailto: Personal Information redacted by the USI]
Sent: 05 April 2016 09:53
To: serious incidents
Subject: ENCRYPTION: TOR and Membership - ID Personal Inform

Please see attached Terms of Reference and Membership for SAI – ID Personal Informati

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

Tel Personal Information redacted by the USI

Email [redacted]

'You can follow us on Facebook and Twitter'

serious incidents

From: serious incidents
Sent: 05 April 2016 15:27
To: Paul Darragh
Subject: RE: TERMS OF REFERENCE AND TEAM MEMBERSHIP - Trust Ref: SAI – ID [redacted] HSCB Ref: [redacted]
Attachments: Position Report 5.4.16.pdf

Dr Darragh

Please find position report as requested.

Regards,
Donna

From: Paul Darragh
Sent: 05 April 2016 12:56
To: serious incidents
Subject: RE: TERMS OF REFERENCE AND TEAM MEMBERSHIP - Trust Ref: SAI – ID [redacted] HSCB Ref: [redacted]

Please send a position report.

From: serious incidents
Sent: 05 April 2016 12:05
To: Paul Darragh
Subject: TERMS OF REFERENCE AND TEAM MEMBERSHIP - Trust Ref: SAI – ID [redacted] HSCB Ref: [redacted]

Dr Darragh

Please see attached Terms of Reference and Team Membership received from the Southern Health and Social Care Trust.

Following consideration, please advise seriousincidents@hscni.net if the Terms of Reference and Membership of Review Team has been approved by 12 April 2016.

Warm regards,
Donna

Donna Britton
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

DDI: [redacted]
E: [redacted]

From: Corporate.Governance [mailto Personal Information redacted by the USI]
Sent: 05 April 2016 09:53
To: serious incidents
Subject: ENCRYPTION: TOR and Membership - ID Personal Inform

Please see attached Terms of Reference and Membership for SAI – ID Personal Informati

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

'You can follow us on Facebook and Twitter'

serious incidents

From: Paul Darragh
Sent: 05 April 2016 16:43
To: serious incidents
Subject: RE: TERMS OF REFERENCE AND TEAM MEMBERSHIP - Trust Ref: SAI – ID [redacted] HSCB Ref: [redacted]

Categories: Work in progress

I would encourage the Trust to consider adding someone from outside the Trust to the Team Membership.

From: serious incidents
Sent: 05 April 2016 15:27
To: Paul Darragh
Subject: RE: TERMS OF REFERENCE AND TEAM MEMBERSHIP - Trust Ref: SAI – ID [redacted] HSCB Ref: [redacted]

Dr Darragh

Please find position report as requested.

Regards,
Donna

From: Paul Darragh
Sent: 05 April 2016 12:56
To: serious incidents
Subject: RE: TERMS OF REFERENCE AND TEAM MEMBERSHIP - Trust Ref: SAI – ID [redacted] HSCB Ref: [redacted]

Please send a position report.

From: serious incidents
Sent: 05 April 2016 12:05
To: Paul Darragh
Subject: TERMS OF REFERENCE AND TEAM MEMBERSHIP - Trust Ref: SAI – ID [redacted] HSCB Ref: [redacted]

Dr Darragh

Please see attached Terms of Reference and Team Membership received from the Southern Health and Social Care Trust.

Following consideration, please advise seriousincidents@hscni.net if the Terms of Reference and Membership of Review Team has been approved by 12 April 2016.

Warm regards,
Donna

Donna Britton
Governance Support Officer

Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

DDI: Personal Information redacted by the USI
E Personal Information redacted by the USI

From: Corporate.Governance [mailto: Personal Information redacted by the USI]
Sent: 05 April 2016 09:53
To: serious incidents
Subject: ENCRYPTION: TOR and Membership - ID Personal Inform

Please see attached Terms of Reference and Membership for SAI – ID Personal Informati

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

'You can follow us on Facebook and Twitter'

serious incidents

From: serious incidents
Sent: 06 April 2016 11:45
To: 'Corporate.Governance'
Subject: TOR and Team Membership - Trust Ref: SHSCT SAI Personal Inform HSCB Ref: Personal Inform

Thank you for receipt of the Terms of Reference and Team Membership. The DRO would encourage the Trust to consider adding someone from outside the Trust to the Team Membership. Can you please amend and submit to seriousincidents@hscni.net mailbox by **13 April 2016**?

Many Thanks
Roísín

Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: Personal Information redacted by the USI
T: Personal Information redacted by the USI

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To: serious incidents
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Please see attached Terms of Reference and Membership for SAI – ID Personal Informati

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Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

'You can follow us on Facebook and Twitter'

serious incidents

From: serious incidents
Sent: 20 April 2016 11:41
To: 'Corporate.Governance ([redacted]'
Subject: DRO query - TOR and Team Membership - Trust Ref: SHSCT [redacted] HSCB Ref: [redacted]

Further to the email below, can the Trust advise if they have included someone from outside the Trust to the Membership of the Review Team as suggested by the DRO.

The DRO would appreciate a response at the earliest opportunity.

Regards.
Elaine Hyde
Governance Office
Health and Social Care Board - Southern Office
Tower Hill
Armagh BT61 9DR
Tel: [redacted]
Email: [redacted]
www.hscboard.hscni.net

From: serious incidents
Sent: 06 April 2016 11:45
To: 'Corporate.Governance'
Subject: TOR and Team Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

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Many Thanks
Roísín
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: [redacted]
T: [redacted]

From: Corporate.Governance [mailto:[redacted]]
Sent: 05 April 2016 09:53
To: serious incidents
Subject: ENCRYPTION: TOR and Membership - ID [redacted]

Please see attached Terms of Reference and Membership for SAI – ID [redacted]

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

Tel [redacted]
Email [redacted]

'You can follow us on Facebook and Twitter'

serious incidents

From: serious incidents
Sent: 10 May 2016 11:26
To: 'Corporate.Governance ([redacted])'
Subject: 2nd reminder - DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

Importance: High

Further to receipt of the Terms of Reference/Team Membership for the above incident and the subsequent query from the DRO, as noted below, can the Trust advise if they have considered the comments from the DRO in relation to including someone from outside the Trust on the Review Team

The DRO would be grateful for a response by return.

Regards.
Elaine Hyde
Governance Office
Health and Social Care Board - Southern Office
Tower Hill
Armagh BT61 9DR
Tel: [redacted]
Email: [redacted]
www.hscboard.hscni.net

From: serious incidents
Sent: 20 April 2016 11:41
To: 'Corporate.Governance ([redacted])'
Subject: DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

Further to the email below, can the Trust advise if they have included someone from outside the Trust to the Membership of the Review Team as suggested by the DRO.

The DRO would appreciate a response at the earliest opportunity.

Regards.
Elaine Hyde
Governance Office
Health and Social Care Board - Southern Office
Tower Hill
Armagh BT61 9DR
Tel: [redacted]
Email: [redacted]
www.hscboard.hscni.net

From: serious incidents
Sent: 06 April 2016 11:45
To: 'Corporate.Governance'
Subject: TOR and Team Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref:[redacted]

Thank you for receipt of the Terms of Reference and Team Membership. The DRO would encourage the Trust to consider adding someone from outside the Trust to the Team Membership. Can you please amend and submit to seriousincidents@hscni.net mailbox by **13 April 2016**?

Many Thanks
Roísín

Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: [redacted]
T: [redacted]

From: Corporate.Governance [mailto:[redacted]]
Sent: 05 April 2016 09:53
To: serious incidents
Subject: ENCRYPTION: TOR and Membership - ID [redacted]

Please see attached Terms of Reference and Membership for SAI – ID [redacted]

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

Tel [redacted]
Email [redacted]

'You can follow us on Facebook and Twitter'

serious incidents

From: serious incidents
Sent: 02 June 2016 15:52
To: Corporate.Governance ([redacted])
Subject: Final reminder - DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

Good Afternoon

I refer to the email below and would be grateful if you would provide a response in relation to the DRO comments.

Please provide an urgent response.

Warm Regards,
Donna

Donna Britton
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

DDI: [redacted]
E: [redacted]

From: serious incidents
Sent: 10 May 2016 11:26
To: 'Corporate.Governance ([redacted]
Subject: 2nd reminder - DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Importance: High

Further to receipt of the Terms of Reference/Team Membership for the above incident and the subsequent query from the DRO, as noted below, can the Trust advise if they have considered the comments from the DRO in relation to including someone from outside the Trust on the Review Team

The DRO would be grateful for a response by return.

Regards.
Elaine Hyde
Governance Office
Health and Social Care Board - Southern Office
Tower Hill
Armagh BT61 9DR

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

From: serious incidents
Sent: 20 April 2016 11:41
To: 'Corporate.Governance (Personal Information redacted by the USI)'
Subject: DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI Personal Inform HSCB Ref: Personal Inform

Further to the email below, can the Trust advise if they have included someone from outside the Trust to the Membership of the Review Team as suggested by the DRO.

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Regards.
Elaine Hyde
Governance Office
Health and Social Care Board - Southern Office
Tower Hill
Armagh BT61 9DR
Tel: Personal Information redacted by the USI
Email: Personal Information redacted by the USI
www.hscboard.hscni.net

From: serious incidents
Sent: 06 April 2016 11:45
To: 'Corporate.Governance'
Subject: TOR and Team Membership - Trust Ref: SHSCT SAI Personal Informa HSCB Ref: Personal Inform

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Many Thanks
Roísín
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: Personal Information redacted by the USI
T: Personal Information redacted by the USI

From: Corporate.Governance [mailto: Personal Information redacted by the USI]
Sent: 05 April 2016 09:53
To: serious incidents
Subject: ENCRYPTION: TOR and Membership - ID Personal Inform

Please see attached Terms of Reference and Membership for SAI – ID [redacted]

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

Tel [redacted]
Email [redacted]

'You can follow us on Facebook and Twitter'

serious incidents

From: serious incidents
Sent: 09 June 2016 16:47
To: Paul Darragh
Subject: TOR and Team Membership query - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Attachments: 20160609_TOR and Membership ID [redacted].pdf

Dear Paul

I refer to the query you raised in relation to including someone from outside the Trust on the Review Team for the above SAI.

I include the update provided by the trust for your information;

Mrs Trudy Reid contacted the DRO and had a lengthy discussion regarding adding an external to the review team. It was agreed during the conversation that the membership would stay the same at present but he did state that during the review the panel may take the opportunity to ask for an independent opinion.

Warm Regards,
Donna

Donna Britton
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

DDI: [redacted]
E: [redacted]

From: Corporate.Governance [mailto:[redacted]]
Sent: 09 June 2016 16:38
To: serious incidents
Subject: ENCRYPTION : TOR and Team Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

Further to your email below regarding the team membership of SAI ID [redacted] I can advise that Mrs Trudy Reid contacted the DRO and had a lengthy discussion regarding adding an external to the review team. It was agreed during the conversation that the membership would stay the same at present but he did state that during the review the panel may take the opportunity to ask for an independent opinion.

I have enclosed the ToR and Team Membership for your reference.

Many thanks,

Jacqueline
Jacqueline Marshall
Corporate Governance
Ground Floor, Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

☎ Personal Information redacted by the USI
Personal Information redacted by the USI

From: serious incidents [mailto: Personal Information redacted by the USI]
Sent: 02 June 2016 15:52
To: Corporate.Governance
Subject: Final reminder - DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI Personal Inform HSCB Ref: Personal Inform

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

Good Afternoon

I refer to the email below and would be grateful if you would provide a response in relation to the DRO comments.

Please provide an urgent response.

Warm Regards,
Donna

Donna Britton
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

DDI: Personal Information redacted by the USI
E: Personal Information redacted by the USI

From: serious incidents
Sent: 10 May 2016 11:26
To: 'Corporate.Governance Personal Information redacted by the USI '
Subject: 2nd reminder - DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI Personal Inform HSCB Ref: Personal Inform
Importance: High

Further to receipt of the Terms of Reference/Team Membership for the above incident and the subsequent query from the DRO, as noted below, can the Trust advise if they have considered the comments from the DRO in relation to including someone from outside the Trust on the Review Team

The DRO would be grateful for a response by return.

Regards.
Elaine Hyde
Governance Office
Health and Social Care Board - Southern Office
Tower Hill
Armagh BT61 9DR
Tel: Personal Information redacted by the USI
Email: Personal Information redacted by the USI
www.hscboard.hscni.net

From: serious incidents
Sent: 20 April 2016 11:41
To: 'Corporate.Governance (Personal Information redacted by the USI)'
Subject: DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI Personal Inform HSCB Ref: Personal Inform

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Governance Office
Health and Social Care Board - Southern Office
Tower Hill
Armagh BT61 9DR
Tel: Personal Information redacted by the USI
Email: Personal Information redacted by the USI
www.hscboard.hscni.net

From: serious incidents
Sent: 06 April 2016 11:45
To: 'Corporate.Governance'
Subject: TOR and Team Membership - Trust Ref: SHSCT SAI Personal Inform HSCB Ref: Personal Inform

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Many Thanks
Roísín
Roisin Hughes

Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: Personal Information redacted by the USI
T: Personal Information redacted by the USI

From: Corporate.Governance [mailto: Personal Information redacted by the USI]
Sent: 05 April 2016 09:53
To: serious incidents
Subject: ENCRYPTION: TOR and Membership - ID Personal Inform

Please see attached Terms of Reference and Membership for SAI – ID Personal Informati

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

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other than the intended recipient is prohibited. If you receive this in error, please contact the sender and delete the material from any computer.

Southern Health & Social Care Trust archive all Email (sent & received) for the purpose of ensuring compliance with the Trust 'IT Security Policy', Corporate Governance and to facilitate FOI requests.

Southern Health & Social Care Trust IT Department Personal Information redacted by the USI

serious incidents

From: Paul Darragh
Sent: 10 June 2016 11:53
To: serious incidents
Subject: RE: TOR and Team Membership query - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

Noted.

From: serious incidents
Sent: 09 June 2016 16:47
To: Paul Darragh
Subject: TOR and Team Membership query - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

Dear Paul

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Donna Britton
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

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E: [redacted]

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Sent: 09 June 2016 16:38
To: serious incidents
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Many thanks,

Jacqueline
Jacqueline Marshall
Corporate Governance
Ground Floor, Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

☎ Personal Information redacted by the USI
Personal Information redacted by the USI

From: serious incidents [mailto: Personal Information redacted by the USI]
Sent: 02 June 2016 15:52
To: Corporate.Governance
Subject: Final reminder - DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

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Donna

Donna Britton
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

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E: Personal Information redacted by the USI

From: serious incidents
Sent: 10 May 2016 11:26
To: 'Corporate.Governance ([redacted])'
Subject: 2nd reminder - DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Importance: High

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Regards.
Elaine Hyde
Governance Office
Health and Social Care Board - Southern Office
Tower Hill
Armagh BT61 9DR
Tel: [redacted]
Email: [redacted]
www.hscboard.hscni.net

From: serious incidents
Sent: 20 April 2016 11:41
To: 'Corporate.Governance ([redacted])'
Subject: DRO query - TOR and Team Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

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Health and Social Care Board - Southern Office
Tower Hill
Armagh BT61 9DR
Tel: [redacted]
Email: [redacted]
www.hscboard.hscni.net

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Many Thanks
Roisín

Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: Personal Information redacted by the USI
T: Personal Information redacted by the USI

From: Corporate.Governance [mailto: Personal Information redacted by the USI]
Sent: 05 April 2016 09:53
To: serious incidents
Subject: ENCRYPTION: TOR and Membership - ID Personal Inform

Please see attached Terms of Reference and Membership for SAI – ID Personal Informati

Many thanks

Mrs Sandra McLoughlin
Corporate Governance Officer
Corporate Clinical & Social Care Governance Office
SHSCT Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

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

'You can follow us on Facebook and Twitter'

Southern Health & Social Care Trust IT Department Personal Information redacted by the USI

serious incidents

From: Corporate.Governance <[redacted]>
Sent: 23 November 2016 15:20
To: serious incidents
Subject: ENCRYPTION : Amended ToR and Membership SAI ID [redacted]
Attachments: 20161123_AMENDED ToR and Membership SAI ID [redacted].pdf

Categories: Work in progress

Please see attached Amended Terms of Reference and Membership for SAI ID [redacted]

Kind Regards,

Jacqueline
Jacqueline Marshall
Corporate Governance
Ground Floor, Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

[redacted]
[redacted]

Southern Health and Social Care Trust

Quality Care - for you, with you

Root Cause Analysis report on the review of a Serious Adverse Incident

Organisation's Unique Case Identifier: Personal Information redacted by the USI

Date of Incident/Event: 6 January 2016

HSCB Unique Case Identifier: ID Personal Information redacted by the USI

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M Age: Personal Information redacted yrs

Responsible Lead Officer: Mr Anthony Glackin

Designation: Consultant Urologist

Report Author: Review Team

Facilitator: Connie Connolly Lead Nurse Acute Governance

Date report signed off:

Date submitted to HSCB:

1.0 THE REVIEW TEAM

Mr Anthony Glackin Consultant Urologist SHSCT Chair
Dr David Gracey Consultant Radiologist
Mrs Christine Rankin, Booking Centre Supervisor
Mrs Connie Connolly Lead Nurse Acute Governance

2.0 SAI REVIEW TERMS OF REFERENCE

The terms of reference for this review will be finally approved by the Chair and review team members at the initial SAI review meeting.

Draft Terms of Reference for the Serious Adverse Incident Investigation are as follows:

- To carry out a Level 2 review into the care provided to Patient 10 within the SHSCT between the 24 June 2014 and 6 January 2016.

- To carry out this review into the care provided to Patient 10 using the National Patient Safety Agency Root Cause Analysis methodology

- To use a multidisciplinary team approach to the review

- To provide an agreed chronology based on documented evidence and staff accounts of events

- To identify the key contributory factors which may have had an influence or contributed to Patient 10's treatment and care.

- To ensure that recommendations are made in line with evidence based practice.

- To set out the findings, recommendations, actions and lessons learnt in an anonymous report

- To adhere to the principles of confidentiality throughout the review.

- To report the findings and recommendations of the review through the Director of Acute Services SHSCT, to Patient 10, family of Patient 10 and the staff associated with Patient 10's care

THIS LIST IS NOT EXHAUSTIVE

serious incidents

From: serious incidents
Sent: 24 November 2016 13:56
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Attachments: AMENDED ToR and Membership ([redacted].pdf; Position Report [redacted].pdf

Joanne,

Please find attached **Amended** Terms of Reference and Team Membership received from the Southern Trust in relation to the above incident.

Following consideration, please advise seriousincidents@hscni.net if the Amended Terms of Reference and Membership of Investigation Team has been approved/not approved by **1 December 2016.** I also attach a Position Report for ease of reference.

Regards
Roisín
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: Personal Information redacted by the USI
T: Personal Information redacted by the USI

From: Corporate.Governance [mailto: Personal Information redacted by the USI
Sent: 23 November 2016 15:20
To: serious incidents
Subject: ENCRYPTION : Amended ToR and Membership SAI ID [redacted]

Please see attached Amended Terms of Reference and Membership for SAI ID [redacted]

Kind Regards,

Jacqueline
Jacqueline Marshall
Corporate Governance
Ground Floor, Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

Personal Information redacted by the USI
Personal Information redacted by the USI

Southern Health & Social Care Trust IT Department Personal Information redacted by the USI

serious incidents

From: serious incidents
Sent: 01 December 2016 16:54
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Attachments: AMENDED ToR and Membership ([redacted].pdf; Position Report [redacted].pdf

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Regards
Roisín
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

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T: [redacted]

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Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board

Tower Hill
Armagh

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From: Corporate.Governance [mailto: Personal Information redacted by the USI]
Sent: 23 November 2016 15:20
To: serious incidents
Subject: ENCRYPTION : Amended ToR and Membership SAI ID Personal Inform

Please see attached Amended Terms of Reference and Membership for SAI ID Personal Informatio

Kind Regards,

Jacqueline
Jacqueline Marshall
Corporate Governance
Ground Floor, Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

Personal Information redacted by the USI
Personal Information redacted by the USI

Roisin Hughes (Corporate Services)

From: serious incidents
Sent: 12 December 2016 16:04
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI Personal Inform HSCB Ref: Personal Inform
Attachments: AMENDED ToR and Membership Personal Informati.pdf; Position Report Personal Informatio pdf

Importance: High

Joanne,

Please see email below in relation to the above incident. The Amended Terms of Reference and Team Membership have yet to be improved. Can you please advise if these have been approved/not approved to seriousincidents@hscni.net mailbox by **return of email**?

Regards
Roisin
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: Personal Information redacted by the USI
T: Personal Information redacted by the USI

From: serious incidents
Sent: 01 December 2016 16:54
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI Personal Inform HSCB Ref: Personal Inform

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Regards
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Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

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T: Personal Information redacted by the USI

From: serious incidents
Sent: 24 November 2016 13:56
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI Personal Inform HSCB Ref: Personal Inform

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Regards
Roísín
Roisin Hughes
Governance Support Officer
Corporate Services Department
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To: serious incidents
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Please see attached Amended Terms of Reference and Membership for SAI ID Personal Informatio

Kind Regards,

Jacqueline
Jacqueline Marshall
Corporate Governance
Ground Floor, Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

Personal Information redacted by the USI
Personal Information redacted by the USI

Southern Health & Social Care Trust IT Department Personal Information redacted by the USI

serious incidents

From: serious incidents
Sent: 27 January 2017 12:16
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Attachments: AMENDED ToR and Membership ([redacted].pdf; Position Report ([redacted].pdf

Importance: High

Joanne,

Please see emails below in relation to the above incident. The Amended Terms of Reference and Team Membership have yet to be improved. Can you please advise if these have been approved/not approved to seriousincidents@hscni.net mailbox by **return of email**?

Regards
Roisin
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: [redacted]
T: [redacted]

From: serious incidents
Sent: 12 December 2016 16:04
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Importance: High

Joanne,

Please see email below in relation to the above incident. The Amended Terms of Reference and Team Membership have yet to be improved. Can you please advise if these have been approved/not approved to seriousincidents@hscni.net mailbox by **return of email**?

Regards
Roisin
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: [redacted]

T: Personal Information redacted by the USI

From: serious incidents
Sent: 01 December 2016 16:54
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI Personal Inform HSCB Ref: Personal Inform

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Tower Hill
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Please see attached Amended Terms of Reference and Membership for SAI ID Personal Informatio

Kind Regards,

Jacqueline
Jacqueline Marshall
Corporate Governance
Ground Floor, Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

Personal Information redacted by the USI
Personal Information redacted by the USI

serious incidents

From: serious incidents
Sent: 08 February 2017 14:18
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Attachments: AMENDED ToR and Membership ([redacted].pdf; Position Report [redacted].pdf

Importance: High

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Roísín
Roisin Hughes
Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: [redacted]
T: [redacted]

From: serious incidents
Sent: 27 January 2017 12:16
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Importance: High

Joanne,

Please see emails below in relation to the above incident. The Amended Terms of Reference and Team Membership have yet to be improved. Can you please advise if these have been approved/not approved to seriousincidents@hscni.net mailbox by **return of email**?

Regards
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Governance Support Officer
Corporate Services Department
Health & Social Care Board
Tower Hill
Armagh

E: [redacted]

T: Personal Information redacted by the USI

From: serious incidents
Sent: 12 December 2016 16:04
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI Personal Informa HSCB Ref: Personal Informa
Importance: High

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Armagh

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Sent: 23 November 2016 15:20
To: serious incidents
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Please see attached Amended Terms of Reference and Membership for SAI ID Personal Informa.

Kind Regards,

Jacqueline
Jacqueline Marshall
Corporate Governance
Ground Floor, Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

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serious incidents

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Attachments: AMENDED ToR and Membership ([redacted].pdf; Position Report [redacted].pdf

Importance: High

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Jacqueline
Jacqueline Marshall
Corporate Governance
Ground Floor, Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

Personal Information redacted by the USI
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serious incidents

From: serious incidents
Sent: 07 March 2017 16:45
To: Joanne McClean
Subject: Amended ToR and Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]
Attachments: AMENDED ToR and Membership [redacted].pdf; Position Report ([redacted].pdf

Importance: High

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Can you please advise if the amended Terms of Reference and Team Membership, for the above SAI, have been approved?

Many Thanks
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Kind Regards,

Jacqueline
Jacqueline Marshall
Corporate Governance
Ground Floor, Trust Headquarters
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PORTADOWN
BT63 5QQ

[redacted]
[redacted]

other than the intended recipient is prohibited. If you receive this in error, please contact the sender and delete the material from any computer.

Southern Health & Social Care Trust archive all Email (sent & received) for the purpose of ensuring compliance with the Trust 'IT Security Policy', Corporate Governance and to facilitate FOI requests.

Southern Health & Social Care Trust IT Department Personal Information redacted by the USI

serious incidents

From: Joanne McClean
Sent: 14 March 2017 14:45
To: serious incidents
Subject: RE: Amended ToR and Membership - Trust Ref: SHSCT SAI [redacted] HSCB Ref: [redacted]

Categories: Work in progress

Roisin,
Thanks. These are fine.
Joanne

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PORTADOWN
BT63 5QQ

☎ Personal Information redacted by the USI

Personal Information redacted by the USI

Southern Health & Social Care Trust IT Department Personal Information redacted by the USI

serious incidents

From: serious incidents
Sent: 15 March 2017 15:45
To: 'Corporate.Governance'
Subject: ToR Approval: Amended ToR and Membership SAI ID [redacted]; HSCB REF: [redacted]

Further to receipt of the Terms of Reference and Team Membership for the above incident, I would confirm the DROs approval.

Regards.
Elaine Hyde
Governance Office
Health and Social Care Board - Southern Office
Tower Hill
Armagh BT61 9DR
Tel: [redacted]
Email: [redacted]
www.hscboard.hscni.net

From: Corporate.Governance [mailto:[redacted]]
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Southern Health & Social Care Trust IT Department Personal Information redacted by the USI

serious incidents

From: Corporate.Governance <Personal Information redacted by the USI>
Sent: 16 March 2017 11:49
To: serious incidents
Cc: ClientLiaison, AcutePatient
Subject: Encryption SAI Reports And Checklist ID Personal Information redacted by the USI 2
Attachments: Report to HSCB.pdf

Categories: Work in progress

Please find attached approved report and checklist in respect of SAI ID Personal Information

Regards

Eileen Conlon
Corporate Governance

From: Farrell, Roisin
Sent: 16 March 2017 09:22
To: Corporate.Governance
Subject: SAI Patient 10 Personal Information SAI Report

Dear Colleague
Please find attached approved report & Checklist for submission to HSCB on our behalf.

Kind Regards

Roisin Farrell
Clinical & Social Care Governance Team
Directorate of Acute Services
The Maples
Craigavon Area Hosptial
Personal Information redacted by the USI

Southern Health and Social Care Trust

Root Cause Analysis report on the review of a Serious Adverse Incident

Organisation's Unique Case Identifier: ID [redacted]

Date of Incident/Event: 6 January 2016

HSCB Unique Case Identifier: [redacted]

Service User Details:

D.O.B: [redacted] Gender: F Age: [redacted] yrs

Responsible Lead Officer: Connie Connolly

Designation: Lead Nurse Acute Governance

Report Author: Review Team

Date report signed off: 15 March 2017

Date submitted to HSCB: 16 March 2017

Southern Health and Social Care Trust

1.0 EXECUTIVE SUMMARY

Patient 10 is a Personal Information redacted by the old lady with a past medical history of colon cancer in 2010 and breast cancer in 2013.

While Patient 10 was under review and follow up by the Breast Surgeons in June 2014, a Computer Tomography Scan (CT Scan) of the abdomen and pelvis was arranged and this was performed on 24 June 2014. This CT scan reported a number of cysts in both kidneys. On the right side, there was a large upper pole cyst, a small lower pole cyst and a cyst on the anterior aspect of the right lower pole which had increased in size with increased complexity from scans completed in 2010. An Ultra Sound Scan (USS) of kidneys was recommended and this was completed on 24 July 2014. A Magnetic Resonance Image with contrast (MRI) was advised, and this was done on 26 September 2014. The MRI report did not comment on the anterior cyst about which concerns were raised, but did confirm a cyst with no abnormal enhancement.

On the basis of this incomplete MRI report, Patient 10's GP made routine referral to the Urology Team in Craigavon Area Hospital (CAH). This GP letter was received by the CAH Booking Centre on 29 October 2014. This letter was given to the Urology Surgeon of the week on 30 September 2014 to triage. There is no evidence that this GP referral letter was triaged or returned to the Booking Centre for processing. As a result of triage omission, Patient 10 was managed as a 'New Routine' patient as per the Trust's process in place at the time and waited until 6 January 2016 to be seen by a Consultant Urologist. A wait of 64 weeks.

Patient 10 was diagnosed with a probable cystic renal tumour. Surgery was scheduled for 25 January 2106 but this was postponed due to the recurrence of breast cancer at this same time. Right partial nephrectomy was performed on 31 October 2016.

The Review Panel agree that there are 3 main contributing factors which directly impacted Patient 10's delay in diagnosis. The first contributing factor was the content of the MRI report dated on the 29 September 2014. The wording of the report appears truncated and does not reference the main clinical focus, which was anterior cyst on the right kidney. The Reporter did not grade the cyst. As a result, the Breast Surgeon Dr 3 and the GP Dr 5 reading this report, did not appreciate there was growth in size of the right cyst. This was a significant missed opportunity for clinicians to expedite Patient 10's referral to Urology.

Secondly, following the CT of chest and abdomen of 29 October 2014 which noted a complex right renal cyst, the letter to Patient 10 from Dr 3 did not include this information and the result did not trigger a referral to Urology. Again this represents a missed opportunity to expedite Patient 10's care.

The third contributory factor is that Patient 10's GP referral letter was not triaged by the Urology Consultant on call. The Review Panel agree that review of radiology at triage is likely to have resulted in an upgrade of the referral to Red Flag in October 2014. As a result of no triage and the Trust's reliance on the routine category assigned by the GP to the referral, Patient 10 waited 16 months to be assessed by the Urology Team and diagnosed with renal carcinoma.

Southern Health and Social Care Trust

2.0 THE REVIEW TEAM

Mr Anthony Glackin Consultant Urologist

Dr Aaron Milligan Consultant Radiologist

Christine Rankin Acting Booking Manager

Connie Connolly Lead Nurse Acute Governance

3.0 SAI REVIEW TERMS OF REFERENCE

Terms of Reference for the Serious Adverse Incident Investigation are as follows:

- To carry out a review into the care provided to Patient 10 in Craigavon Area Hospital, from 24 June 2014 until 6 January 2016

- To carry out this review into the care provided to Patient 10 using the National Patient Safety Agency Root Cause Analysis methodology

- To use a multidisciplinary team approach to the review

- To provide an agreed chronology based on documented evidence and staff accounts of events

- To identify the key contributory factors which may have had an influence or contributed to Patient 10's delay in treatment.

- To ensure that recommendations are made in line with evidence based practice.

- To set out the findings, recommendations, actions and lessons learnt in an anonymous report

- To adhere to the principles of confidentiality throughout the review.

- To report the findings and recommendations of the review through the Director of Acute Services SHSCT, to the relatives of Patient 10 and the staff associated with Patient 10's management

Southern Health and Social Care Trust

4.0 REVIEW METHODOLOGY

- To carry out a review into the care provided to Patient 10 within the SHSCT from 8 April 2014 until 1 March 2016. Records electronic records available on the Patient Administration System (PAS), Northern Ireland Electronic Care Record (NIECR) the Northern Ireland Picture Archiving and Communication System (NIPACS) will be examined in conjunction with all Clinical and Nursing documentation.

- To carry out this review into the care provided to Patient 10 using the National Patient Safety Agency Root Cause Analysis methodology

- To use a multidisciplinary team approach to the review

- To provide an agreed chronology based on documented evidence and staff accounts of events

- To identify the key contributory factors which may have had an influence or contributed to the timing of Patient 10's clinical management.

- To ensure that recommendations are made in line with evidence based practice. Accompanying appendices to the report will provide evidence of recent researched-based management of

- To set out the findings, recommendations, actions and lessons learnt in an anonymous report

- To adhere to the principles of confidentiality throughout the review.

- To report the findings and recommendations of the review through the Director of Acute Services SHSCT, to Patient 10 and the staff associated with Patient 10's care

This list is not exhaustive

Southern Health and Social Care Trust

5.0 DESCRIPTION OF INCIDENT/CASE

On 18 November 2010 Patient 10 had CT of Abdomen and Pelvis (CTAP) and was reported on 3 December 2010 which stated simple renal cyst particular on the right.

On 13 January 2013 CTAP reported by Dr 10. Bosniak type 1 cyst right kidney noted.

On 24 June 2014, Patient 10 had a CTAP with contrast as ordered by Dr 1. Dr 7's report in relation to the CTAP was issued on 7 July 2014 and reported multiple and bilateral simple cysts. A cyst arising from the anterior aspect of the right lower pole demonstrates subtle layering with high density in its medial aspect. The cyst appears minimally larger. A cyst in the anterior aspect of the right lower pole appears minimally larger and complex with high density in its medial aspect. Localised ultrasound was recommended to ensure no soft tissue component.

On 24 July 2014, Dr 1 ordered at ultrasound of the urinary tract. Dr 2's report on 30 July 2014 concluded a right lower pole complex renal cyst? Solid component. Advised MRI with intravenous (i/v) contrast to determine if the solid component enhances.

On 23 September 2014, Patient 10 seen by Dr 3 who ordered CT of Chest and Abdomen (CT CA).

On 26 September 2014 Patient 10 had a MRI of renal tract completed at the request of, or requested on behalf of, Dr 1. Dr 2's report on 29 September 2014 compared the previous CT 25/06/14 and USS 24/07/14. There is a large well-defined ovoid cystic mass, arising from the upper pole cortex of the right kidney. Appearances are consistent with cyst.

On 29 October 2014 Patient 10 attended for CT CA with i/v contrast. Dr 4 compared CT on 20/06/14 and on 1 November 2014 reported simple cyst seen in the upper pole. Complex cyst right kidney. On the same day, a routine GP referral was received in CAH Booking Centre from Dr 5 requesting assessment and advice in relation to the MRI findings reported on 26/09/14 re: large renal cyst and mentioning a history of bowel cancer and breast cancer.

On 7 November 2014, letter sent to Patient 10 from Dr 3 informing her of unchanged findings of CT CA done on 29 October 2014, and that there would be further Surgical Outpatient review. The CT reported a complex right renal cyst. This finding was not included in the letter Patient 10 and was not escalated to either Urology or Radiology for further opinion.

On 6 January 2016, Patient 10 was seen by Dr 8 in Urology Outpatients in response to GP referral on 29 October 2014. The MRI images were reviewed by Dr 8 in advance of the consultation. Dr 8 noted that the MRI report from 29/09/14 did not comment on the anterior lower pole of the right kidney. Dr 8 spoke with Dr 7 regarding the findings. In retrospect, Dr 7 reported the complex cyst on the right kidney had internal solid nodules with one area showing some enhancement with contrast. This raised the possibility of cystic renal cancer. Surgery arranged for 13th January 2016.

On 12th January 2016, Patient 10 was reviewed by Dr 3 with an enlarged left axillary noted

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on CT. A malignant node in the let axilla with invasive lobular carcinoma was confirmed.

15 February 2016 Patient 10 had a left axillary node clearance. Staging and further management of Patient 10's renal cyst has been postponed.

Patient 10 is recovering from a laparoscopic partial nephrectomy for confirmed papillary renal cell carcinoma which was performed on 31 October 2016.

6.0 FINDINGS

The Specialists within the Review Panel individually assessed each of Patient 10's radiological investigations in the timeframe between 24 June 2014 and 6 January 2016. The report by Dr 2 on 29 September 2014 references the findings of the USS and CT images done in June and July 2014. The Panel agree that when Dr 2 mentioned the earlier findings within the 29 September 2014 MRI report, it implied that the ovoid cystic mass noted had been seen and had been investigated. The inclusions of previous imaging findings are ambiguous. The consensus is that Dr 2's reported findings in relation to Patient 10's MRI of both kidneys were misleading and were inappropriately condensed. The Panel contribute this to human error. This error was the primary contributing factor to the delayed recognition of a potential renal cancer and its subsequent management.

The Review Panel agree that the absence of a complete right kidney assessment, and the wording of the MRI report, made it extremely difficult for clinicians to detect the missing clinical detail. This provides sufficient rationale to why Patient 10 was not referred to Urology for immediate assessment by Dr 3 or the GP Dr 5. The CT chest and abdomen of 29 October 2014 reported a complex right renal cyst. This important finding was not included in the letter by Dr 3 to Patient 10 on 7 November 2014 and was not referred on for urological opinion. This represents a missed opportunity to expedite investigation of a reported abnormality.

The Review Panel reviewed the GP Referral Letter management for Patient 10 in October 2014 .In summary; Dr 6 was the Consultant Urologist on-call on 30 October 2014 and was responsible for the triage of the GP letters for that week. Patient 10 was one of eight letters for Triage.

The Triage form for 30 October 2014 was not returned to medical records for processing. After 10 working days, the booking centre e-mailed Dr 6's personal secretary seeking management advice for the 8 patients with outstanding triage. After no reply, a second email request was sent to Dr 6's personal secretary seeking management advice which was outstanding from 30 October 2014. At this point the informal booking centre default process for patients with no referral triage was initiated. The informal default triage management process was introduced in May 2014 to ensure the GP's referrals were allocated to a 'waiting list' in the event that the triage was not returned. A default management process was formally circulated on 6 November 2015.The pathway for GP referrals without triage is for the medical records team to accept the GP Grading, code the patient specialty as 'General Urology' and allocate the next available new patient appointment. The length of time until

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6.0 FINDINGS

assessment is solely dependent on the Urology waiting time- which was a minimum of 42 weeks in 2014. The default management process provides an explanation to why Patient 10's 'Routine' referral letter was not upgraded and why Patient 10 was not seen by the Urology Team until 16 January 2016.

Patient 10 is now recovering from a laparoscopic excision of a papillary renal carcinoma which was done on 30 October 2016. This procedure was superseded by breast surgery in 2016 for breast lobular carcinoma on 14 February 2016. It had been agreed by the Oncology and Urology teams that the breast histology was priority and treatment proceeded in advance of renal surgery.

Relevant members of the Review Team completed a 'look-back' exercise in relation to the remaining 7 other GP letters to establish the patient management and outcome. The Panel can confirm that the other 7 patients have been seen by the Urology Team on or before 26 January 2016, and have not been known to have been exposed to significant harm.

7.0 CONCLUSIONS

The MRI report by Dr 2 on 29 September 2014 as previously discussed, was misleading and was inappropriately condensed. The quality of the information resulted in the evolving right renal cyst being overlooked by Drs 3 and Dr 5.

The SHSCT Radiology Team continuously review and audit the quality and accuracy of their reporting. On this occasion, the MRI report irregularities were not detected until viewed by a Urology Consultant.

All available evidence suggests that Dr 6 did not triage Patient 10's GP referral letter on the week ending 30 October 2014. The default triage management process was initiated which resulted in Patient 10 waiting 64 weeks for Urological assessment.

The Review Panel agree that in relation to Patient 10, the opportunity to upgrade the referral to red flag was lost by the omission of triage, this resulted in a 64 week delay to diagnosis of a suspicious renal mass.

While the remit of this Serious Adverse Incident (SAI) Review was to examine the factors in Patient 10's delayed management of papillary renal cancer. The Review Panel were provided evidence that a significant number of letters within Urology are not being triaged by the minority of the Team. It is clear that the default triage management process continues to be initiated secondary to the omission of Triage by individual members of the urology team and not the entire Urology Team.

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8.0 LESSONS LEARNED

There will always be an element of human error in the interpretation and reporting of radiological imaging.

Triage of GP referral letters remains a key element in validating appropriate utilisation of specialist services and ensuring patient safety. Triage also serves as an opportunity for early intervention for patients at risk of malignant disease or clinical deterioration.

9.0 RECOMMENDATIONS AND ACTION PLANNING

This SAI has demonstrated that patients will be at an increased risk of harm when the opportunity for early intervention at Triage is omitted. The Review Panel recommend that the Trust reviews the process which enables the clinical triaging and escalation of triage non-compliance in accordance with IEAP

In particular the fundamental issue of triaging GP referral letters remains a challenge within Urology. The urology operational and medical management teams immediately need to address the issue of un-triaged referrals not being processed in accordance with IEAP.

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10.0 DISTRIBUTION LIST

Patient 10

HSCB

SHSCT Litigation

SHSCT Medical Director

SHSCT Director of Acute Services

AMD for Surgery and Elective Care

AMD for Integrated Maternal/Women's Health and Clinical Services

AD's for Surgery and Elective Care, Integrated Maternal/Women's Health/Clinical Services and Functional Support Services

Chair of Surgical Morbidity and Mortality

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:	**ID** Personal Information redacted by the	**HSCB Ref Number:**	Personal Information redacted by the

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **date informed**: 6 January 2016						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						

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

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	x
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			x
	c) Report not shared but contents discussed (***if you select this option please also complete 'I' below***)			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			
	f) Withdrew fully from the SAI process			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE **(under section 7 of the Coroners Act (Northern Ireland) 1959)** *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	**x**
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	**x**
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	**x**
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	15 March 2017