Urology PIG Meeting

Wednesday 8 November 2023

Via Teams

Attendees

David McCormick – Chair
Alex MacLeod, WHSCT
Anthony Glackin, SHSCT
Chris Thomas, BHSCT
David Connolly, BHSCT
Ajay Pahuja, BHSCT
Joanne Elliott, DOH
Colleen McDonnell, DOH
Brian Duggan, SEHSCT
Mark Haynes, SHSCT
Samantha Sloan, BHSCT
Matthew Tyson, SHSCT
Hugh O'Kane, BHSCT
Rachel Hutton, SEHSCT
Tracey Hawthorne, DOH
Matthew Stewart, DOH

Apologies: Christine Allam, SEHSCT, Katherine Dane, SEHSCT

David McCormick welcomed members to the meeting and noted the apologies.

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Getting it Right First Time (GIRFT) Urology Update and Recommendations

David McCormick stated that the final draft was ready and was going to Permanent Secretary before issuing and publishing. Joanne advised the group that the GIRFT report had been finalised, with factual inaccuracies and wording being agreed. The recommendations were shared among the group and discussed. There are forty recommendations cover maximising surgical assessment, diagnostic pathways, efficiency, skills mix and regionalisation of services. Some actions are strategic, and many are operational, and several are already underway. Some actions will require

Received from SHSCT 16/02/2024. Annotated by the Urology Services Inquiry.

recurrent funding to function. Joanne advised that the Programme Implementation Group (PIG) for Urology would help implement some of these and would need its Terms of Reference (ToR) revised and membership re-assessed.

ACTION – *Revised Terms of Reference to be drafted and circulated.*

David McCormick noted the GIRFT recommendations and told members that the next step would be to work through the recommendations and agree their priority. No formal timescales had been identified on the report but it is expected that the priorities will have to be grouped as short, medium and long term. Task and Finish Groups will be set up by each Trust Urology team, but the focus will also need to be regional.

Discussion moved to regional pathways and protocols for NHSCT. It was agreed that input would be sought from NHSCT on what Urology service the Trust had prior to 2015, compared to service now and desired service in the future. Additionally, guidance to Emergency Departments on Urological procedures will be re-issued. David Connolly and Brian Duggan agreed to share the previous guidance with the group for consideration and update by PIG in the first instance.

ACTION – *David Connolly and Brian Duggan to circulate Regional Urology guidance to PIG members for update.*

ACTION – *Meeting with NHSCT Emergency Clinical Leads, Senior Management, General Surgery Leads and Urology Leads regarding Urology provision to be arranged.*

ESWL service Update

Mark Haynes updated on progress in the Extracorporeal ShockWave Lithotripsy (ESWL) service in Craigavon Area Hospital (CAH). Progress was significant and a further update would be provided at the next meeting.

PCNL service Update

Mark further updated on the Percutaneous Nephrolithotomy (PCNL) service. David Connolly had been attending CAH twice monthly since August to do 2 PCNL sessions each time. Currently the emphasis was on clearing SHSCT long-waits patients, but David advised in 6-9 months regional viability can be re-assessed with Trust patient transfer, along the Day Procedure Centre (DPC) Model. 2 all-day lists were currently being delivered generally, alongside complex stones lists. It was noted that staff training has improved massively.

LVH Update

Brian updated on LVH. The next aim for Urology on the site was increasing Trans-Urethral Removal of Bladder Tumours (TURBT) and Benign Prostate Hyperplasia (BPH). Stones lists were going well, as were Rezum treatments. Encompass would have an effect on productivity after Go Live on 9th November. Concern was raised about current capacity to get through multiple lists of long-wait patients. Evenings/weekend lists were raised for the short-term. Concerns were also expressed regarding patient fitness for surgery, with clinical validation needing revalidated if there is a significant gap before surgeries. Mark queried whether LVH could take red flag TURBT, Brian advised he had no objection to this.

Ajay advised that consideration was being given to Rezum procedures in a treatment room setting. Regional pathway guidance for BPH procedures such as Rezum and HoLEP was discussed. Rachel and Ajay agreed to formalise and share this with the group, to ensure regional alignment and agreed access criteria. Subject to agreed pathways, the group agreed to the principle of pooled lists.

ACTION – *Rachel Hutton and Ajay Pahuja to share guidance on BPH patient suitability with PIG members.*

A regional Waiting List for Rezum was discussed, and it was agreed to set up a unique code for Rezum patients and carefully track patient flow throughout the service into the South Eastern Trust. It was agreed that Rezum was a low-risk

procedure and therefore there was normally no clinical need to reassess the patient again in clinic by the SET team.

It was agreed that there was little point undertaking a large scale clinical validation of those patients currently waiting for a TURP as there was no capacity to treat these patients. It was agreed that each Trust should undertake a gradual validation and patients who were deem suitable for Rezum should be transferred to SET.

ACTION – *Unique Waiting List code for Rezum patients to be created.*

Omagh Update

Alex updated on Omagh. There had been no recruitment yet, but the team were covering seven Urology lists (three extra sessions were offered by General Surgery). Stones, TURPs and general daycase procedures were being performed.

Renal Cancer Update

Mark updated on renal cancer work. GIRFT have issued a renal cancer document separately in recent months. Mark stated it is important to change renal cancer pathways across the region. There were governance and decision-making concerns, as well as issues with volumes of cases. Currently the cases are included in a wider cancer MDT, however there is a need for a single Renal Cancer MDT. A regional Multi-Disciplinary Team (MDT) would likely require limited extra cost. Mark agreed to feed back to the group on this at the next meeting.

AOB

Holmium Laser Enucleation of the Prostate (HoLEP) was discussed under AOB. Brian advised that there were a couple of issues with the service, including the volume of irrigation fluid which is required. A chronological, regional waiting list based in SEHSCT for HoLEP would be established soon. There are still concerns in the Trust about bed capacity, but it was agreed this should be prioritised.

ACTION – *David McCormick to discuss HoLEP with Brian Duggan offline.*

Date of Next Meetings

David thanked everyone for attending. Next dates of meetings are as follows:

Friday 12th January – 1pm-3pm

Thursday 8th February – 1pm-3pm

Friday 8th March – 1pm-3pm

Thursday 11th April – 1pm-3pm

Friday 10th May – 1pm-3pm

Thursday 6th June – 1pm-3pm

This concluded the meeting.

Received from SHSCT 16/02/2024. Annotated by the Urology Services Inquiry.

*Information supplied by Ms Emma Stinson, Document Librarian, SHSCT Public inquiry Team

30.5 My line manager is the Clinical Director for Urology, who in turn is responsible to the Medical Director.

30.6 Clinical Director with responsibility for Urology: Robin Brown Mid 2011 – January 2014, Sam Hall January 2014 – March 2016, Colin Weir June 2016 – December 2018, Ted McNaboe December 2018 – December 2021 – Currently Vacant

*Information supplied by Ms Emma Stinson, Document Librarian, SHSCT Public inquiry Team

31. During your tenure did medical managers and non-medical managers in Urology work well together? Whether your answer is yes or no, please explain with examples.

31.1 In my opinion the senior managers did not work well with Urology. Engagement with the department by the Clinical Directors, Medical Directors, Assistant Directors for Surgery and Directors for Acute Services was very limited and infrequent in my experience. I do not know how much job planned time they had allocated to management activity.

31.2 Mr Young tried his best to lead the Urology team. However, despite his best efforts Mr O'Brien, Mr Haynes and Mr O'Donoghue frequently failed to attend departmental meetings or arrived late. All too often I sat across the table from Mr Young wondering why my colleagues had not shown up. Due to the number of fronts on which the service was failing to deliver (growing waiting lists for appointments and surgery), it was difficult to achieve a consensus as to how to move forward without engagement from our colleagues.

a particular example later this morning, but help us with this: A complaint or the outcome of an SAI review or a death, or a morbidity case, is discussed at a Patient Safety meeting and learning is noted amongst its members as you indicate here. The learning I suppose is described by the person, the clinician presenting the case, this is what we learned from this case and this is what we really should be doing in the future, might be one way of phrasing it. 11:23

But how does what is discussed at the Patient Safety meeting translate into real practical effective action, what is the join between the PSM meeting and what's discussed there and what needs to happen?

A. Well, one, it all goes back to the Clinical Governance team. It is disseminated to various people, management plus the Urology team. You are probably talking about stents that have been left in too long. But things have changed for the better to try and -- as a result of that, so stents are not dwelling too long or excessively long in patients. 11:23 11:24

115 Q. We'll come to the stents one in a moment. I don't want to claim your thunder too early on that. But can you help the Inquiry with another example of how the learning that is noted in this forum you said goes to the governance team. But if something requires, if the learning is that this requires a change of approach, it may require resources, it may require training or equipment, how is that change delivered and who ensures 11:24

please sort that out. So there is now a governance safety net in place. But it shouldn't take that long, should it?

A. It probably shouldn't. In an ideal world it shouldn't take that long and I suppose it should have been sorted faster. 11:29

119 Q. Yes. What I'm sort of poking at a little here is, I'm asking you a question I suppose about the effectiveness of the patient safety meeting. It is an ideal forum or opportunity to corral the problems and identify the learning. But I'm anxious to, I suppose, take your view on whether that is sufficient if there is a disconnect between that and the implementation of the solution? 11:30

A. I suppose the patient safety meeting can make recommendations and inform the appropriate people, but it can't police it. In other words, you know, if something is sorted, it can come back to the Patient Safety meeting. But I don't think the Patient Safety meeting is well enough resourced so that -- you know, I'm doing it now, so I can't go and chase up all the time that something is being done. You know, I depend on people to contact me and say "we have now done this". But I don't have either the time or the resources. 11:30 11:31

120 Q. In terms of -- I mean, one can imagine that those clinicians attending the Patient Safety meeting are in a good position to articulate, I suppose, their concern, their alarm, their worry about any issue of

now coming in to the currency of the Trust?

A. Yeah, you need support to collect these important bits of data. You need somebody to collect them. You need, obviously, somebody to analyse them and then present them to the team. You know? So, it's well recognised in surgery that if you ask surgeons to collect their own data you get a very skewed view of what's happening, and that probably applies to other disciplines, but it certainly applies to surgery. 16:43

579 Q. What do you think the implications are of not collecting the data and presenting it? 16:43

A. So if you don't know what your outcomes are like you don't really know if you're doing a good job, and if you don't ask the patients what their experience is then you're not going to know whether or not the patients thought you were doing a good job. So you have to collect the data to know that. 16:43

580 Q. You say that within the world you were operating in, and notwithstanding the health warning you put against it a second or two ago, you did feel it appropriate to carry out your own personal outcome related audits? 16:44

A. Yeah. So BAUS, which is the British Association of Urological Surgeons, ran a number of audit projects in the past. Certainly I did nephrectomy, I continue to do nephrectomy surgery and I would have contributed to the national audit, so did Mark Haynes, and we would have been able to compare our data to that of peers across the UK and Ireland, and we would have been able to compare our unit to comparator units in the same 16:44

participate in audits across four domains, the first of which would be national audits, and they go all the way down to, like, local audits is number four. So, we now have a structured programme. We've been pushing for that for a long time. But without the support of the audit department, or the governance team, we wouldn't have been able to deliver on that. So that has been really helpful. We've had the first of those audits being presented in the past year. And on a similar vein, in the cancer services domain, we have support for audit within cancer services, which is very welcome, and it allows us to demonstrate patient safety. Because that's really what the audits are about. 16:46 16:47

583 Q. Yes, and we'll come to that in the context of the SAI recommendations perhaps tomorrow. But we have heard, and I think your evidence around the lack of support for audits echoes evidence that the Inquiry has received from several of the governance co-ordinators within the acute directorate who have, I suppose, said that resources simply weren't available to do audit, which I suppose viewed from another perspective, it could be articulated as them not being seen as important or as important as other things that the Trust -- 16:47 16:47 16:48

A. I think my point on that would be that audit is important and quality improvement is important. But when you're in a service that is struggling, and you have too few people to deliver that service, then it is

answer. Why is that?

A. Yeah.

524 Q. It seems relatively obvious that this should be done, but maybe I'm missing something.

A. So, it has begun. Last week perhaps we had our first meeting where this kind of data was presented. Okay? And I congratulated the person who did it and I said - because this is exactly what we need to see, this is what we need to hear, okay, we need to be aware of this. It hadn't happened I think in our department before this, because for one, Martina Corrigan had far too much on her plate. She was being pulled from pillar to post looking after ourselves, ENT, ophthalmology, and outpatients. Everything was reactive. She didn't have the time to have this prepared and bring it to us in a structured manner on a monthly basis. 15:42 15:42

When we had departmental meetings, Martina would often not be able to be present for the meeting because she had a conflicting meeting with ENT, and we were therefore not getting, to my mind, the full benefit of having the head of service present at the meeting. 15:42

525 Q. I know that you're not saying that as a criticism of Mrs. Corrigan? 15:43

A. It's not a criticism of her, because in my experience she was extremely hard-working, she worked often 18-hour days. It was -- she was -- there was just simply too much being asked of one person. The

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4. Taking account of the findings referred to at (1) and (3) above, please address the following matters:

d) The MHPS investigation which led to Dr Khan's determination, and the Root Cause Analysis/SAI process concerning nine patients treated by or within Urology SHSCT Cancer Services, each identified shortcomings in the practices of Mr. Aidan O'Brien. Additionally, these processes pointed to systemic failures by managers and failures of governance. The Inquiry notes that each of these processes have focused on the patients which made up the case load of Mr. O'Brien. The Inquiry is unaware of any steps undertaken by the Trust to obtain and provide assurance that the shortcomings of Mr. O'Brien were not also to be found in the practices of any other clinician, although it is noted that the RCA review team has referred to seeking and obtaining assurances. Accordingly, with reference to each clinician working within Urology Services generally, as well as Urology Cancer Services as at 1 July 2020, please address the following:

I. What specific steps, if any, have been taken by the Trust to obtain assurance that each clinician concerned has adhered to all relevant Trust, regional and national standards (or guidance).

In answering this question you are required to specify for each named clinician within these clinical areas what processes, audits or other tools have been applied and what particular Trust, regional or national standard has been taken into account. You are also required to specify the areas of administrative and clinical practice which have been examined or audited (e.g. triage, or practices in association with MDM) against the standard, and the period of time frame which has been considered. If steps have not yet been taken to obtain assurance of the kind referred to for any particular clinician, or at all, please make this clear.

A comprehensive audit of individual clinician practice within urology services has not yet been undertaken. Historically, audits involving an individual clinician(s) have only been undertaken where there have been specific concerns raised in relation to any element of an individual's practice.

As a result of a Trustwide external review of its Clinical and Social Care Governance functions and processes, a programme has commenced to develop a standalone clinical audit team to support operational teams with clinical assurance functions.

The Trust has committed to developing an audit programme of urology services to be enacted over the next number of months and we will report the results of audits carried out to the USI in due course.

4. Taking account of the findings referred to at (1) and (3) above, please address the following matters:

Now, touching on the issue of clinical audit which goes to, if you like, quality assurance, what about that? He seemed to be thinking that the degree to which audit was supported as part of Patient Safety and into the Patient Safety meeting was poor. Quite often audits would be performed unilaterally by the clinician for their own purposes, but really they weren't fit for purpose, they didn't complete the audit loop, as he described it. Has audit been poorly supported historically for Urology and has that changed? 11:34 11:34

A. Well what has changed from when he wrote that, so we can talk about it now. So as I said, the Audit Manager comes to our meetings. We have a programme of audits. We ensure that the registrars all have audits. We ensure that they present the audits and, in fact, at our next Patient Safety meeting one of our registrars in Leicester is presenting on Teams, so we ensure that it's not just an audit that is actually presented. So he is presenting in a week's time. So it is much more robust. And I think because the audit Department are professional, they ensure it is done properly. 11:35 11:35

123 Q. Okay. So what is the importance of their now attendance at the Patient Safety meeting?

A. That it is done in a professional way in that they are now -- everybody doing audits, they have to register the audits so that the Audit Department is aware of that, they have forms to fill out. We chase them, I chase them constantly to ensure that they are 11:35

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Examples of the minutes are *118. Appendix 2018 11 09 Acute Clinical Governance Action Notes*

Acute Audit Committee

3.59 Clinical audit is the cornerstone of assurance. Clinical audit is a way to find out if healthcare is being provided in line with standards. Audit is used to promote quality improvement. The Corporate Governance Team (Effectiveness and Evaluation) provide support on audit mostly to medical staff including support with National

08/12/2016	09/06/2017	11/05/2018
12/09/2016	14/07/2017	08/06/2018
	11/08/2017	10/08/2018
	13/10/2017	07/09/2018
	08/12/2017	10/10/2018
	08/12/2017	06/11/2018
		14/12/2018

Audits, e.g., The National Confidential Enquiry into Patient Outcome and Death (NCEPOD), as well as morbidity and mortality meetings.

3.60 When I commenced post as Acute Governance Coordinator I recognised that there was limited acute audit support. There previously had been a strong audit commitment within the medical teams as reported by various medical and operational staff. I met with Dr G Browne on 02/02/2017, I do not have a note of the meeting but recollect that she highlighted that teams were still committed to audit but it was felt that lack of administrative support for audit teams and senior leadership support. The example given was that the Medical Director did not attend the audit forum annual meeting/poster presentation.

3.61 I discussed with Mrs Gishkori and asked if she would support and chair a new audit committee, Mrs Gishkori highlighted she was committed to audit and would chair the audit committee to evidence senior commitment to audit.

Received from Trudy Reid on 16/05/2023. Annotated by the Urology Services Inquiry.

I suppose this is written, I think I said early in November - October 2018 - just after the last meeting of the Audit Committee on 22nd September 2018, just after that last meeting had happened and then, as 11:08
I heralded in my earlier remarks, the Audit Committee collapsed, I just want to look at that briefly. You appear to recognise in your witness statement the importance of resources to support audit, you talk about audit being the cornerstone of assurance and 11:08
clinical audit is a way to find out if healthcare is being provided in line with standards, it's at paragraph 3.129. You go on to say that, when you started in your role, you recognised that there was limited audit support in acute, although there had 11:08
previously been a strong commitment to it. Did you get any understanding of why the support for audit had fallen away? Or what was it that had fallen away to leave audit in the poor state in which you found it?

A. I think at that time there seemed to be a move from 11:09
audit to quality improvement. I think that was sort of nationally, it wasn't just locally. The resource sort of followed the quality improvement lines as opposed to the audit at the time. So any resource that would have gone towards the teams in relation to developing and 11:09
recording, doing posters and presentations in relation to audit seemed to disappear and be focussed towards more a QI approach. And they are not mutually exclusive, one feeds the other and vice versa.

know. There is no point writing a report for a family if you don't answer their questions. Again, we hadn't the resource to really engage with the family. There was that whole side of doing dealing with the reactive piece. As I mentioned earlier, we should have been much more proactive, themeing our incidents or complaints as well, because quite often complaints are a good way to spot an emerging issue before real harm happens. Then, developing proactive things. 10:59

The other thing that came under governance at that time was audit. Clinical audit had completely collapsed within Acute Services in terms of there used to be an excellent audit committee led by one of the anaesthetists, Gail Brown, which was really good. I think there was some confusion as well because quality improvement had come along and there was sort of where does audit fit, you know, and it had sort of lost support. Then, because the consultant team who were running it weren't getting the buy-in, then it just sort of petered out. That's a shame because audit is really useful in governance as your assurance piece. So, if you had done a piece of work and you've decided on your recommendations, then you should be able to use your audit capacity. So maybe your junior medical staff, or like my pharmacists or whatever, you would have directed them to audit something for you because they need to, they have to do audits as part of their job and their training. So, you use that resource if 11:00 11:00 11:00

you are doing it properly to then assure yourself that a recommendation either (1) is fit for purpose but (2) continues to be followed.

It was very much we weren't doing anything well. It was doing the basics but not really doing the stuff that meant long-term things were going to be safer. 11:01

77 Q. Of course, the concern from those kinds of shortcomings, ultimately it is in and around the safety of clinical practice -- 11:01

A. Yes.

78 Q. -- and risk of harm to patients. Is it fair to infer from what you have said that the absence of these activities in the governance arena led you to be concerned that the Trust didn't have available to it the full picture? 11:01

A. Yes, I think so. I think that would be a fair point. I mean, I would say the lack of governance wasn't making anything more dangerous, I think it was more we could have be making it safer. Also protecting the staff because, I mean, staff are very traumatised if they are involved in an incident. If we get it right, they don't have to go through that. Obviously, patient safety is the key priority but it is assistance to the staff as well in terms of their experience at work. 11:02 11:02

79 Q. Your description just now suggests that there was no lack of appetite --

A. No.

80 Q. -- and no lack of knowledge --

Then there was another one in relation to - and it was regional as well - ventilator acquired pneumonia, but it was a bundle too. Do you know what the thing was, the doctors did do audit in their own small way because they have to, but it just didn't ever come up through - like, she mentions Gail Brown there, that's right - the governance team as a whole. So, there was bits and pieces of it happening because practitioners wanted to deliver evidence-based practice but we had no idea of what was going on and how much of it. As she says, it had collapsed, and that's very sad because audit is one of the best tools you have in governance, for sure. 11:34 11:34

85 Q. And standards and guidelines --

A. Yes. 11:34

86 Q. -- that was another area that was under significant pressures; isn't that right?

A. That is right. Standards and guidelines, I am assuming everybody knows what those are, but the standards and guidelines came from NICE, the National Institute For Clinical Excellence. They normally came down from the Department and the lead doctor or the lead nurse of the province. They were all to do with like, you know, this is the first line in dealing with glaucomas, is everybody doing this. Or we need you to tell us how you are dealing with fractured neck and femurs, what's your rate. All of those things because there was a standard in relation to all of those. We were duty bound to make sure we were delivering that standard. 11:35 11:35

recommendation succinctly put by Dr Johnson in the Root Cause Analysis that "*The Trust must set in place a robust system within its medical management hierarchy for highlighting and dealing with difficult colleagues and difficult issues, ensuring patient safety problems uncovered anywhere can make their way to the Medical Director and Chief Executives Table. This needs to be open and transparent with patients safety issues taking precedence over seniority, reputation and influence." (The underlined is my emphasis)*

407. Given the breath of specialties contained within ATICs/SEC, the clinically high risk areas contained with the Division (Theatres, Intensive Care, Pre-operative assessment, General Surgery, Urology, ENT, ENT, Trauma and Orthopaedics, in-patient wards and outpatients clinics), an annual budget of £66m, and approximately 1000 staff, I have held the view for a substantial period of time that the governance resource allocated to the ATICS/SEC Division were inadequate.

408. I have repeatedly asked over a number of years for governance officers to be appointed to each Clinical Division across acute (ATICS-SEC, Medicine and Unscheduled Care, Integrated Maternity and Women's Health & Cancer and Clinical Services. This dedicated resources would have the primary role of ensuring all aspects of governance, e.g., recommendations from complaints and SAI's, were progressed, embedded and audited. Within ATICs/SEC this governance role is too important and cannot be an "add on" to the Head of Service. Each Head of Service is battling deteriorating performance targets, endeavouring to rebuild elective series in the wake of the devastation brought by the pandemic to elective surgical services, workforce gaps (medical and nursing) across all specialties, whilst ensuring their service remains in budget or at best to minimise their specialty's overspend. To date these Governance officers have not been appointed.

409. I would also go so far as to say that, along with Divisional Governance officers, we need governance auditors who would and should bring a high degree of independent assurance with respect to key aspects of governance.

S21 5 of 2022 – 20220405 Q69 email B5 governance posts
S21 5 of 2022 – 20211001 Q69 email governance post and live database
S21 5 of 2022 – 20211001 Q69 email governance post and live database A1
S21 5 of 2022 – 20180315 Q69 email governance structure in acute services
S21 5 of 2022 – 20180624 Q69 email Acute governance structure
S21 5 of 2022 – 20180624 Q69 email Acute governance structure org chart A1
S21 5 of 2022 – 20180624 Q69 email Acute governance structure proposal discussion A2

410. I would suggest the Trust needs to review its Governance structures and decide;

a) Whether Governance needs more resourcing, to which my answer is yes.
b) Whether a centralised corporate controlled model is preferable to a Directorate/Programme of Care model with feedback back to the centre.

Received from SHSCT on 16/05/22. Annotated by the Urology Services Inquiry.

c) From a governance perspective there is also learning to be obtained by having clarity between medical and non-medical managers in regard to who is responsible for Clinical Governance and all the elements that make up this umbrella term.

411. Central to Clinical Governance and therefore patient safety is how management is structured, professional management *vs* general management. I have had experience pre The Review of Public Administration in the legacy Newry and Mourne Trust in Daisy Hill Hospital where the Medical Director and the Executive Director of Nursing had clear operational and professional responsibility for all medical staff and nursing staff. There is strength in this model as one clear line of reporting.

412. General management where health professionals report to an operational manager (who may or may not be a health professional) and then have line (often dotted) to a professional manager can be confusing. With experience of having worked in both systems, I hold the view that the health professionals reporting to one manager, both operationally & professionally, is a better model. I would suggest that in health care every operational decision or issue has a professional consequence or impact, which can be positive or negative.

413. To strengthen Clinical Governance medical managers need more time in their Job Plan's allocated to being managers. The current allocation of 2PAs is insufficient. I appreciate that many clinicians do not wish to be managers, or if they do, they only want to be a very part-time one, but management and governance are too important not to have the correct resource allocated to these functions. Having medical managers with greater amounts of management time allows for greater structure in the Division as there would be time to meet frequently to discuss, review and plan the Division's business.

[70] Given the Inquiry's terms of reference, is there anything else you would like to add to assist the Inquiry in ensuring it has all the information relevant to those Terms?

414. I believe that I have addressed all questions to assist the Inquiry honestly and fully to the best of my ability.

NOTE:
By virtue of section 43(1) of the Inquiries Act 2005, "document" in this context has a very wide interpretation and includes information recorded in any form. This will include, for instance, correspondence, handwritten or typed notes, diary entries and minutes and memoranda. It will also include electronic documents such as emails, text communications and recordings. In turn, this will also include relevant email and text communications sent to or from personal email accounts or telephone numbers,

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[69] Having had the opportunity to reflect, do you have an explanation as to what went wrong within urology services and why?

69.1 On reflection, and setting out the range and number of issues in urology services, I believe that the following is clear:

a. The service was under considerable pressure due to increasing referrals; and was insufficiently resourced to meet the catchment population needs. The long term absence of the ICATS urology doctor (contracted for 7 sessions per week), contributed to the consultant pressures as they had to see all referrals in outpatients.

b. There was also additional pressure due to the consultant clinical behaviour of Mr O'Brien which meant that smaller numbers of patients were seen in each outpatient clinic and more patients were reviewed than consultant peers would review. There was also little appetite in the service to agree protocols with primary care to review certain cohorts of patients.

c. There was poor professional practice which had been longstanding. It proved to be difficult to get agreement with Mr O'Brien to change this behaviour. When change in his behaviour was agreed, the specific behaviour was not always sustained and he would revert to previous poor practice. An example of this was when Mr O'Brien agreed to triage referrals within the required time standards; it became apparent subsequently that this change in behaviour was not sustained and required regular checking.

[70] What do you consider the learning to have been from a governance perspective regarding the issues of concern within urology services and the unit, and regarding the concerns involving Mr. O'Brien in particular?

Received from Dr Gillian Rankin on 14/06/22. Annotated by the Urology Services Inquiry.

method by which this issue could be managed, other than waiting for further development of the functionality of the radiology system.

72.4 Whilst remaining vigilant across the range of issues and weekly monitoring for many of them, the overriding issue was that of entrenched clinical behaviour by the consultant which was made more difficult to manage as often a change in behaviour towards improvement was not sustained permanently, despite it being agreed by Mr O'Brien. On reflection, this type of behaviour should have been recognised for what it was, and identified and discussed by me with SMT colleagues when more formal action could have been considered. Formal action could have been considered with the Medical Director and the Director of HR and Organisational Development. In conclusion, I did not fully utilise the arrangements which were available at the time in order to address the continuing clinical behaviour which did not meet the standards required.

[73] Do you think, overall, the governance arrangements were fit for purpose? Did you have concerns about the governance arrangements and did you raise those concerns with anyone? If yes, what were those concerns and with whom did you raise them and what, if anything, was done? If not, please explain why.

73.1 The governance arrangements were reviewed in 2010 through the Review of Clinical and Social Care Governance. This resulted in organisational change resulting in the following:

a. The developing culture of openness and learning from mistakes;
b. Clear lines of accountability and reporting through the Chief Executive to Trust Board for both operational and professional lines of accountability;
c. Embedding of deeper systems of governance and staff training in these, e.g., Datix completing to report on clinical incidents;
d. Easier recognition of SAIs and processes to investigate and learn from them;

Received from Dr Gillian Rankin on 14/06/22. Annotated by the Urology Services Inquiry.

35. 20150127 Aob and charts at home

40. 20150304 MR AOB

35. What could improve the ways in which concerns are dealt with to enhance patient safety and experience and increase your effectiveness in carrying out your role?

35.1 Improvement could come in the way of having confirmation that the concern is raised and an outcome of the discussion provided, and to see a change in practice with the concern being resolved. I feel that concerns should be raised in a more formal platform withformal feedback being received regarding the concern rather than verbal conversations35.2 In hindsight I feel I should have been much more formal in my approach to this concern, detailing every conversation, asking for follow up, requesting a formal meeting to discuss when things did not change.

Staff

36. As relevant, what was your view of the working relationships between urology staff and other Trust staff? Do you consider you had a good working relationship with those with whom you interacted within urology? If you had any concerns regarding staff relationships, did you speak to anyone and, if so, what was done?

36.1 I had a good working relationship with the Head of Service, Martina Corrigan and due to the close proximity of our offices our interaction tended to be informal.

36.2 I had no working relationship issues with other staff in urology. I did not have contact with urology staff with the exception of Martina Corrigan, and I was not aware of any working relationship issues with urology staff and other Trust staff.

A. No.

243 Q. Why is that? What is the culture that is existent at the time? I suppose you may say this is a relevantly small issue, and I'm sure the Inquiry might accept that, but what is the difficulty that causes you to fail to sit down with the clinician and say listen, you have to do something different? 15:29

A. I suppose it's complex. If it was easy, we would fix it.

15:29

In terms of the life of anybody working in hospitals, there are many, many, many challenges that you face on a daily basis. I suppose everybody is guilty. If the issue isn't sorted there and then, it tends not to be completed, the loop tends not to be completed because there's something else very quickly falls in behind it. If Mr. O'Brien was the only thing that occupied my life, that would be one thing, but it wasn't. There were many other challenges, not least, you know, Dr. McAllister's state of the nation was only a small part of the challenges which we faced on a daily basis in the health service. 15:30 15:30

Two months of my working life each year was taken up on the role of the Assistant Director of the Week, where I stopped doing my AD of the week role and I was occupied looking after flow. That was one full week every six weeks. So, if you didn't sort out the problem at source there and then, unfortunately to get 15:30

150 Q. Not just the charts issues, but all of the issues that you became aware of --

A. Yeah.

151 Q. Do you feel that you did everything that you could to draw them both to the attention -- well, number 1, to deal with them at your level, if possible, and also, as much as you could, to draw them to the attention of people who may be able to do something about them? 11:45

A. I do, and it was just something, though, that struck home yesterday with Mrs. Burns was why we never raised any Datix about the triage. I genuinely don't know why we didn't. I think it was because it was always addressed at the time and sorted out and then it slipped back over the years. So, that is a regret that we didn't, and I really don't know why. I think it's because, exactly what you've said there, I think I escalated it as much as I could and I expected once it was escalated, that they would help me resolve it. 11:45 11:46

I think I was in a position with Mr. O'Brien that, and I think I said this the last time, that people used the good working relationship that I had with him for me to try and address it informally, which I always did, and then when it got to a stage where I couldn't, I would have escalated it, which left me in a position -- obviously, I had to work with him as well and take him along with us with regards to the work. 11:46 11:46

152 Q. Now, Ester Gishkori in her evidence -- I'll just give you the reference, TRA-06786 and TRA-06913, line 4 to

12.6 There was a regular report (PTL a report of every referral registered in the RBC and this showed any patients untriaged, as that referral would not have a waiting list code) on untriaged referrals run by the RBC and this was shared with each HOS from circa 2010/11. The PTL is still available but with the introduction of eTriage (2016, 2017 in Urology), triage status is visible to each clinician/HOS on eTriage etc. This report was also available to be run and viewed by OSLs/HOS, as this report was available on business objects on PAS. On 13/9/2013 I wrote to all AMDs, Service ADs and the DAS reminding everyone about the IEAP rules for triaging patients within 72 hours of receipt of referral, and I asked that this was discussed within all Clinical teams and Clinicians reminded of this protocol. In February 2014, Deborah Burns DAS instigated a new triage flow chart and this was shared with all ADs see paragraph 8.11.
Further detail in relation to late/non-return of triage can be found at paragraph 8.9.
Relevant documents are located at
20130913 E fAC Triage Process located at Relevant to PIT/ Evidence added or renamed 19 01 2022/ Evidence no 77/No 77 - Eamon Mackle
20130913 E fAC Triage Process A1 located at Relevant to PIT/Evidence Added or Renamed 19 01 2022/Evidence no 77/No 77 - Eamon Mackle

12.7 In January 2015, the HSCB under Mr Michael Bloomfield, Director of Performance and Corporate Services commissioned a Review of Outpatients Booking and Maria Wright from HSCB lead a piece of work in the Southern Trust undertaking a review and outcome report which was sent to Aldrina Magwood Director of Performance and Reform on 26/6/15 who shared the report with the Service Directors including Deborah Burns DAS who in turn shared the report with Acute ADs. The report made specific reference to triage as follows, “for the majority of urology referrals, daily triage is now achieved, but there is a long-standing issue with turnaround time from one Consultant and referrals not returned from triage continues to be a key issue for Booking staff”.

Relevant documents are located at
79. 20141208 E fHSCB Review of Outpatient Booking Processes located at S21 15 of 2022 Attachments

Received from Anita Carroll on 26/06/2022. Annotated by the Urology Services Inquiry.

and senior management challenge that, at that time, was not forthcoming in regard to referral triage management and notes at home in particular.

497. I do not think there was a failure to engage fully with the problems of the Urology service from an Acute perspective. I think there could have been a much more constructive interest in recurring concerns from the senior management team level including the Chief Executive with associated support.

[51] Do you consider that mistakes were made by you or others in handling the concerns identified? If yes, please explain. What could have been done differently?

498. I have reflected much on the handling of the concerns raised and noted in this statement.

499. When I read the emails of that time from myself and others, I can see a frustration regarding the lack of capacity across the board, a frustration with the practice of Mr O'Brien regarding delays in triage, leaving patient notes at home, and his often dismissive attitude to core systems and processes (which were often regionally directed and locally agreed). I also see a relatively small number of clinicians and managers working extremely hard to manage many services, elective and unscheduled care flow across 2 acute hospitals, under-funding, and staffing constraints.

500. I also see a consultant who struggled to adjust to the use of technology and to working in a multidisciplinary team who were there to support his practice (to allow his expertise to focus on the aspects of care that only he could do, leaving other aspects of care that could be done by others to those others). I believe that he genuinely struggled to adjust to the volume of patients needing to be managed. I think that, while other consultants adjusted their practice to meet time slots at clinics etc., Mr O'Brien was just unable or unwilling to adjust.

501. On reflection, I believe the Head of Urology and ENT, myself and the Associate Medical Director handled the concerns to the best of our ability at

the time and within the culture of Acute Services during those years; a culture that was focussed on Performance and Financial Efficiency. Both the Head of Service and I, as non-medics, found it very difficult to challenge Mr O'Brien's clinical practice. We were reliant on his clinical colleagues to provide that clinical challenge and this, I believe, did come, but only at a later stage when a number of new consultants came into post, who had experience outside the Trust and outside Northern Ireland, who knew what was acceptable practice and what was not, and who were not afraid to speak up.

502. I believe that, at the time, concerns were escalated appropriately by ourselves, solutions sought, support offered and work-around processes put in place. However, 6 to 13 years later, experiencing the developments in clinical governance systems, learning from national reports, and through my experience in my current role as Director of Nursing, Midwifery and AHPs, I believe there was too much tolerance for his resistance to change and not enough focus on the patient pathway, experience and outcome and this was reflective to the culture of the organisation at that time.

503. I take my share of responsibility for that and, on reflection, I could have challenged more and suggested increased independent audit into patient outcomes and patient experience. I also refer to my response in paragraph 485

504. Whilst I do not believe that I could have done more to meet the demands of the service with the resources available, including eradicating the review backlog, having reflected on the matter and with what I know now, I regret not having zero tolerance for triage delay, with robust weekly checking mechanisms and monitoring of it in place in the same way that we monitored patient access data. So I accept there were missed opportunities to fully address the risk to patient safety.

52. In your view, would the systems of governance now in place prevent these concerns arising again? If yes, please explain. If no, please explain why not

process to Dr Khan and Mrs Hynds, Dr Khan and/or Mrs Hynds as the receivers of the audit outcome could similarly have reminded me of its absence earlier.

402. When in December 2016 I became aware of Mr Glackin's email and having received Mr Haynes email directly I quickly escalated to my superiors and rapid action was taken including oversight committee meetings, an Investigation using the 'Maintaining High Professional Standard' Framework and a SAI review chaired by Dr Johnston all of which resulted in Mr O'Brien's closer supervision and monitoring. But as we are now aware there are other elements of Mr O'Brien's practice, as reflected in Dr Hughes SAI (February 2021), which were not identified or escalated at this stage.

403. In retrospect and reflecting, I would hold the view that the decision made on 13 September 2016 by the oversight committee to meet with and advise Mr O'Brien (during the week commencing 19th September 2016) of the Trust's intention to proceed with a formal investigation under MHPS should have been acted upon. The meeting would have included advising Mr O'Brien of a 4 week timescale to address the 4 main areas of his practice that were causing concern. I say this because, had these decisions been actioned the formal process would have commenced approximately 4 months earlier than it did in 2017 and the magnitude of what was discovered in late 2016 / early 2017would likely have been known to the Trust 4 months earlier. It also would have meant that the 5 patients who were the subject of a SAI chaired by Dr Johnston (Personal Information redacted by the USI) would have been triaged much earlier than what was the case.

S21 5 of 2022 – 91. 20160913 Q68 Action Note Oversight committee
S21 5 of 2022 – 92. 20161012 Q68 Action Note Oversight committee

[69] Do you think, overall, the governance arrangements were fit for purpose? Did you have concerns about the governance arrangements and did you raise those concerns with anyone? If yes, what were those concerns and with whom did you raise them and what, if anything, was done?

404. In the light of this public inquiry having to take place, it is difficult to state that the Trust's governance arrangements were fully fit for purpose, I accept mistakes were made by myself and possibly others. However, I am also reminded that all the circumstances that have brought us to this point have involved one clinician who had a very long history of 'doing his own thing'.

405. Governance arrangements are only fit for purpose if they monitor and audit the right things along with total reliance upon those staff in positions of authority ensuring that all the elements of good governance are not only in place but employed, utilised, monitored and audited and applied equally across all staff as applicable to their role.

406. Where individual staff fall short in that regard, as I believe was the case with Mr O'Brien over time, in the interests of patient safety the individual must be managed but must have personnel responsibility also, especially where they hold positions on Professional Registers. I respectfully concur with the

Received from SHSCT on 16/05/22. Annotated by the Urology Services Inquiry.

Budget Agreement). Whilst I have a vague recollection of this– I cannot recall the details and have no documentary evidence to confirm.

(e) How did you assure yourself that any systems and agreements that may have been put in place to address concerns were working as anticipated?

49.11 Monthly performance and clinical governance meetings were providing assurance that as each concern arose mitigations as far as possible were being put in place to address, for example, I refer to March 2015 performance reports *please see 82. 20150326 Performance Report a and 83. 20150326 Performance Report b).* As previously indicated concerns and learning through complaint investigation and SAI reviews were ongoing in the Directorate as evidenced by agendas and minutes.

49.12 In relation to the Default Process, as described above, I was not aware of and did not instruct this process to be implemented. It is my view this process would have disadvantaged patients as they did not have the benefit of a Consultant triage which may or may not have reviewed or changed their GP referral priority. I indicated both these issues to Julian Johnston in my interview in 2019. I stopped Mr O'Brien triaging in February 2014 so would not have needed this process. I was not made aware or authorise him to restart triaging nor alerted to any other issues – apart from the email from Fiona Reddick in July 2015 (referenced at paragraph 24.1 (viii) before I went on leave, which indicates he was triaging red flags and this was being tracked. I did not pick this up in July 2015.

49.13 I did not receive any evidence of issues with triage through performance reports apart from the Cancer 62 day pathway red flag triage issue which was reported by OSL Wendy Clayton in January 2014 and was further analysed by Ronan Carroll in his report of 05-03-2014. This was mitigated by stopping AOB triaging on 20-02-2014. Waiting times for routine outpatients did not flag issues with triage. The only indication of issues I can see relating to the issue was, as referred to in paragraph 55, a flag from a GP to Paula Clarke in March 2015, however Martina Corrigan then confirmed Mr O'Brien was not triaging save for

named referrals on 29-03-2015. I could only address problems I was aware of or had escalated to me either via colleagues or reporting mechanisms.

(f) If you were given assurances by others, please name those individuals and set out the assurances they provided to you. How did you test those assurances?

49.14 See responses to questions 49b, d and e.

49.15 I refer also to my response at paragraph 40.2 in respect of an example of an email chain dated 26-11-2013 in which I was not included. This email indicates that the clinical managers and Assistant Director had not involved the Medical Director as I had asked, and they did not wish to do so at this time. I refer also to assurances obtained by email from Martina Corrigan in response to a query in March 2015 at question 55.

(g) Were the systems and agreements put in place to rectify the problems within urology services successful?

49.16 I refer to my responses at q49b and d. Yes- as indicated in our response to the commissioner in May 2015 with respect to new urology demand this was being met as was the Cancer 62 day pathway. We were simply unable to address the backlog review issue due to capacity, which is referred to a t paragraph 15.1c and d and 44.3.

(h) If yes, by what performance indicators/data/metrics did you measure that success? If not, please explain.

49.17 Please see response to q49 g.

50. Having regard to the issues of concern within urology services which were raised with you or which you were aware of, including deficiencies in practice, explain (giving reasons for your answer) whether you consider that these issues of concern were -

(a) properly identified,

Final Conclusions / Recommendations:

This MHPS formal investigation focused on the administrative practice/s of Mr O'Brien. The investigation report presented to me focused centrally on the specific terms of reference set for the investigation.

Within the report, as outlined above, there have been failings identified on the part of Mr O'Brien which require to be addressed, through a Trust conduct panel and a formal action plan.

The investigation report also highlights issues regarding systemic failures by managers at all levels, both clinical and operational, within the Acute Services Directorate. The report identifies there were missed opportunities by managers to fully assess and address the deficiencies in practice of Mr O'Brien. No-one assessed the extent of the issues or properly identified the potential risks to patients. Default processes were put in place to work around the deficiencies in practice rather than address them.

I am therefore of the view there are wider issues of concern, other than administrative practice concerns by Mr O'Brien, that must be considered and addressed. The findings of the report should not solely focus on one individual, Mr O'Brien.

In order for the Trust to understand completely the failings in this case, I recommend the Trust to carry out an independent review of the administrative processes with clarity of roles & responsibilities at all level within Acute Directorate, to look at the full system wide problems and to learn from the findings.

Received from Ahmed Khan on 08/07/2022. Annotated by the Urology Services Inquiry.

6. I was asked to explain what the Guidance details in terms of taking patients home. I explained that it shouldn't happen unless business needs require this. I outlined that all records should be taken back to the Trust immediately after any off site clinic. I referred to Section 3.1 of the Guidance.

7. I was asked to explain if large numbers of missing charts would be picked up. I outlined that if it is regularly found that charts are missing this should flag in the KPI's. I advised, I was not made aware of any bundle of charts not available within the Trust.

8. I outlined that that in my view, the greater the number of charts missing, the more serious the matter is for the Trust. I advised that there is no acceptable period of time to have charts off the Trust site but if it is necessary, it should be for the minimum period necessary for the purpose of treating a patient.

9. Following my initial meeting on 3 April 2017, I researched sources in relation to

    a. 'taking records outside the Trust' and
    b. 'record keeping responsibilities in relation to the need to update records in a timely manner'.

I provided this information to the case investigator via e-mail dated 21 April 2017.

10. I outlined that issue 'b' is encompassed in guidance on good record keeping including

- GMC 2013 (referenced in guidance by MDU titled 'Good record keeping, staying patient focused' states 'records should be made straight away or as soon as possible after patient care'. Also 'all records need to be kept secure and confidential at all times'.
- GMC 2013 'Good Medical practice. Working with doctors, working for patients. The duties of a doctor registered with GMC'. 25.03.2013

Trust Policy

- Records Management Policy section 5.1.10 page 6 covers responsibilities of individual member of staff including the need to ensure that
    - The record can be accessed
    - The record is accessible and meaningful, in the right format to those who need to use it

- Records Management Procedure
    - Recordkeeping 2.7 record kept correctly and legibly recorded, kept up to data and easily accessible when needed
    - Health Care records 2.7.2
    - Records in transit 4.0 'accurate recording of all record movements is essential…one of the main reasons why records are misplaced is because record movements are not recorded'

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

proposed actions. Please provide dates and details of any discussions, including details of any action plans, meeting notes, records, minutes, emails, documents, etc., as appropriate.

56.1 Please see responses at Q55.

Question 57

Did you consider that any concerns raised regarding Mr O'Brien may have impacted on patient care and safety? If so:

(i) what risk assessment did you undertake, and
(ii) what steps did you take to mitigate against this? If none, please explain. If you consider someone else was responsible for carrying out a risk assessment or taking further steps, please explain why and identify that person.

57.1 As AD FSS, from my support perspective there were 3 areas of concern in relation to Mr O'Brien that I was aware of:

Missing charts

57.2 In relation to missing charts that Mr O'Brien had taken home, I instructed Helen Forde HOS Health Records to complete a Datix incident report on each occasion that Mr O'Brien had a chart at home when the chart was needed for a clinic or for admission. I consider that this action was in line with Trust policy in 2013. Previously a Datix was only raised if the absence of a chart meant that the admission or clinic attendance was cancelled or the chart was never found, the impact of reporting every missing chart that Mr O'Brien had at home was to bring the issue to the attention of the HOS Urology / AD SEC to try to change Mr O'Brien's practice. I had two general risks relating to missing charts logged on the FSS Divisional Risk Register (extract from Risk Register attached). Relevant documentation is located at

154. Extract from Divisional FSS Risk Register located at S21 15 of 2022 Attachments

57.3 To highlight this risk, these incident reports (Datix) were sent to the HOS for Urology and the AD SEC and for any chart not available, a Datix incident form was raised

Received from Anita Carroll on 26/06/2022. Annotated by the Urology Services Inquiry.

additional clinics and the request for charts at the additional clinics. Charts that were tracked to a consultant but not found in his/her office are referred to at paragraph 8.8. Such issues were raised with Martina Corrigan HOS Urology for her to address with the Consultant or for her to escalate with the AD SEC.

8.6 My HOS, Katherine Robinson for RBC and Helen Forde for Health Records would have communicated with the HOS for Urology Services in relation to a range of issues including clinic templates, theatre schedules, backlogs, delays in triage, charts for clinics etc.

8.7 Two key issues of concern frequently raised were the unavailability of charts and late/non-return of triage. I have spoken to Katherine Robinson HOS RBC and Helen Forde with reference to triage and unavailability of charts in May 2022 to refresh myself on some issues for the purpose of my Section 21 Notice response.

Unavailability of charts

1. 8.8 Helen Forde Head of Health Records had received an email from Pamela Lawson Health Records Manager on the 27/8/13 to advise her staff were wasting time searching for charts, which were not tracked properly, and this was causing extra work, as although these were tracked to Mr O'Brien they were not in his office. Helen Forde emailed this to Heather Trouton AD SEC and Martina Corrigan HOS Urology and copied me into this email. I emailed Deborah Burns DAS on 3/9/2013 and she advised she would discuss with CD / AMD. On 12/2/14, I asked Pamela Lawson Health Records Manager for an update regarding Mr O'Brien and Mrs Lawson sent me a full list of charts Mr O'Brien had to bring in from his home, which I shared with Heather Trouton AD SEC, and Mr Eamon Mackle Associate Medical Director (AMD) and Martina Corrigan HOS Urology. The following are more examples of issues regarding charts and the escalation which followed. On 14/10/14, Helen Forde HOS Health Records emailed me regarding a patient who was attending Mr Glackin's clinic and whose chart was in Mr O'Brien's home. She was made aware of this by the Health Records Manager Pamela Lawson who had e-mailed Martina Corrigan HOS Urology about this issue earlier that day. On the same day, I brought this to the attention of Heather Trouton, AD SEC so she was

Received from Anita Carroll on 26/06/2022. Annotated by the Urology Services Inquiry.

aware that this was an ongoing issue. On 21/1/15 Helen Forde HOS Health Records, emailed Martina Corrigan HOS Urology and copied to me in relation to a patient in ED Majors. Mr O'Brien had this patient's chart at home. On 21/1/15, I copied this email to Heather Trouton AD SEC to ensure she was aware of the situation. Whenever a chart was not available and it was clear that Mr O'Brien had the chart at home, whilst the case note tracking process advised it was in his office or his Secretary's office, a Datix incident form was raised. This was an attempt to highlight the incident and to quantify how frequently this was happening. In January 2015, Helen Forde HOS Health Records advised me that Deborah Burns DAS had advised her to stop this process. On 27/1/2015, I emailed Heather Trouton AD SEC and Martina Corrigan HOS Urology to ask should they have a risk relating to Mr O'Brien having charts at home logged on the risk register. Heather Trouton AD SEC did respond on 27/1/15 to say she had spoken to Mr Young Clinical lead for Urology and he had agreed to speak to Mr O'Brien.

The relevant documents are located at

20150121 E AOB Chart located at Relevant to Acute/Evidence added or renamed 19 01 2022/Acute/Retired staff/Helen Forde

20141014 Es BM, PL, HF and Ors re charts located at Relevant to Acute/Evidence added or renamed 19 01 2022/Acute/FSS/Anita Carroll Emails

20150127 E AOB and charts at home located at Relevant to Acute/Evidence Added or Renamed 19 01 2022/ Acute/ Retired Staff/ Helen Forde

23. 20140212 E fPL to AC Charts AOB located at S21 15 of 2022 Attachments

24. 20130903 E fAC to DB Charts located at S21 15 of 2022 Attachments

25. 20150127 E fHT tAC AOB and Charts at Home and Risk Register located at S21 15 of 2022 Attachments

26. 20141014 E fAC to HT Charts with AOB located at S21 15 of 2022 Attachments

Late/non-return of triage

8.9 There was a regular report (PTL Primary Targeting List a report of every referral registered in the RBC and this showed any patients untriaged at patient level detail, as that referral would not have a waiting list code) on untriaged referrals run by the RBC and this was shared with each HOS from circa 2010/11 until the introduction of eTriage. He

Received from Anita Carroll on 26/06/2022. Annotated by the Urology Services Inquiry.

Forde, Helen

From: Carroll, Anita [redacted]
Sent: 27 January 2015 11:55
To: Trouton, Heather; Corrigan, Martina
Cc: Forde, Helen
Subject: Aob and charts at home

Heather

Do you think you ? Should have something on risk register in relation to this

Anita

Received from SHSCT on 02/02/2022. Annotated by the Urology Services Inquiry

From: Carroll, Anita <[redacted]>
Sent: 27 January 2015 12:54
To: Trouton, Heather <[redacted]>
Subject: RE: Aob and charts at home

I know A

-----Original Message-----
From: Trouton, Heather
Sent: 27 January 2015 12:28
To: Carroll, Anita
Subject: RE: Aob and charts at home

I spoke to Mr Young about this last week and he is going to speak to Aidan again.

I will consider the Risk register although with that you are supposed to address the risk and eliminate it. This is down to a personal way of working which seems impossible to stop.

Heather

-----Original Message-----
From: Carroll, Anita
Sent: 27 January 2015 11:55
To: Trouton, Heather; Corrigan, Martina
Cc: Forde, Helen
Subject: Aob and charts at home

Heather

Do you think you ? Should have something on risk register in relation to this

Anita

ii) 12/05/2013- 13/5/2013 I offer to help address- but asked Martina Corrigan and Clinical Director Robin Brown to address the issue which Martina says has been ongoing.

iii) 03/09/2013- AD functional services Anita Carroll emailed me regarding 14 charts and 8 IR1 from May 13 – Aug 13 being at Mr O'Brien's home over this 4-month period. This had already been escalated to AD Heather Trouton and Head of Service by Helen Forde, Anita's Head of service. On the same day I escalated the issue to Martina Corrigan HOS, AMD Eamon Mackle and CD Robin Brown. I asked them to discuss and agree with Mr O'Brien or escalate further as "it was a governance issue". On 04/09/2013 Robin Brown replies indicating he cannot address the issue for 2 weeks. On 05/09/2013 I re escalate to AMD and HOS to address immediately. Martina Corrigan replies 05/09/2013 saying she will follow up with Robin Brown and let the AMD and myself know. She also goes on to state that Mr O'Brien is not the only one who participates in this practice.

iv) 11/11/2013 - AD Functional services Anita Carroll highlighted an issue with a missing patient chart which was with Mr O'Brien and not available for a clinic. I replied on 12/11/2013 asking was the patient was seen and instructed Heather Trouton to escalate to the Medical Director, John Simpson after ensuring the Clinical Director had already raised with Mr O'Brien. Heather Trouton agreed to do so. I note from an email trail on 26/11/2013 which I was not included in that the clinical managers Michael Young and Robin Brown and Heather Trouton had not involved the Medical Director and did not wish to do so at this time. I have no recollection of these email interactions, nor do I recollect if I was made aware that my instructions were not followed. I have no recollection of what follow up to these issues took place. No further email documentation was provided to me.

v) 22/01/2014- An email update of performance was sent to me from the OSL for Cancer prior to the normal weekly performance meeting. It alerted me to 6 urology patients waiting over 62 days for treatment with 3 over 85 days. Of the 6 one is named to Mr O'Brien, 1 to Mr Glackin and 1 to Mr Suresh. 3 were unnamed. I emailed the Urology Head of Service, OSL Sharon Glenny and AD Heather Trouton to meet me the next day re a plan for these patients.

We will have to closely monitor the returns of the named referrals though and Anita can you please ask Katherine to let us know early if there are any problems arising?

Re charts at home, I think we all agree this is just not acceptable.

Thankyou all for your help

Heather

From: Young, Michael
Sent: 02 December 2013 15:28
To: Brown, Robin; Trouton, Heather
Subject: RE: **URGENT NEEDING A RESPONSE**** MISSING TRIAGE

Have spoken and offered help with the triage issue – will reinforce again this week

From: Brown, Robin
Sent: 30 November 2013 14:00
To: Young, Michael; Trouton, Heather
Cc: Corrigan, Martina; Carroll, Anita
Subject: RE: **URGENT NEEDING A RESPONSE**** MISSING TRIAGE

Heather
I wonder if could you call me on the phone to discuss this I had a lengthy one-to-one meeting with AOB in July on this subject and I talked to him again on the phone about it week before last.
I agree that we are not making a lot of headway, but at the same time I do recognise that he devotes every wakeful hour to his work – and is still way behind.
Perhaps some of us – maybe Michael Aidan and I could meet and agree a way forward.
Aidan is an excellent surgeon and I'd be more than happy to be his patient Personal information redacted by USI Personal information redacted by USI so I would prefer the approach to be "How can we help".

Robin

From: Young, Michael
Sent: 26 November 2013 12:35
To: Trouton, Heather; Brown, Robin
Cc: Corrigan, Martina; Carroll, Anita
Subject: RE: **URGENT NEEDING A RESPONSE**** MISSING TRIAGE

Understand
I will speak

From: Trouton, Heather
Sent: 26 November 2013 11:40
To: Young, Michael; Brown, Robin
Cc: Corrigan, Martina; Carroll, Anita
Subject: FW: **URGENT NEEDING A RESPONSE**** MISSING TRIAGE

Dear Both

In confidence please see below.

I personally have spoken to Mr O'Brien about this practice on various occasions and Martina has also much more often. While we very much appreciate Aidan's response, I suspect that without further intervention by his senior colleagues it will happen again.

I also spoke to him not more than 4 weeks ago both about timely triage and having charts at home and he promised me he would deal with both, however we find today that patients are still with him not triaged from August , he would have known that at the time of our conversation yet no action was taken. I am also advised today that a further IR1 form has been lodged by health records as 6 charts cannot be found.

As stated by Aidan we have been very patient and have offered any help in the past with regard to systems and processes to assist Aidan with this task but it has not been taken up and the delays continue.

Despite the fact that patients sitting not triaged from August mean that we have breached the access standard before we even start to look for appointments I am more concerned about the clinical implications for patients who need seen urgently and possibly even needing upgraded to a red flag status.

We really need you to speak with Mr O'Brien both in the capacity of a colleague but also in your capacity of Clinical lead and Clinical Director for Urology as well of course as patient advocates.

I also really need a response within 1 week on how this is being addressed for now and the future or I will be forced to escalate to Debbie and Mr Mackle as Director and AMD for this service. It has already been suggested that Dr Simpson be involved which I have not progressed to date but it may have to come to that unless a sustainable solution can be found.

Thank you for your assistance

Heather

From: Corrigan, Martina
Sent: 26 November 2013 08:02
To: Robinson, Katherine; Glenny, Sharon
Cc: Trouton, Heather
Subject: FW: **URGENT NEEDING A RESPONSE**** MISSING TRIAGE

Dear both

Please see below – Katherine can you advise if you receive these?

Thanks

Martina

Martina Corrigan
Head of ENT, Urology and Outpatients

in my answer to question 59). As also described in my response to question 59 there were no robust systems put in place for other issues prior to 2017.

61.2 As outlined in question 60, in my opinion the agreements and systems put in place from 2017, whilst Mr O'Brien was being monitored weekly and whilst he knew that he was being monitored, *did* remedy the concerns that they were set in place to address. Whether other concerns (then unknown to me and, I assume, the others involved in monitoring Mr O'Brien) ought also to have been addressed at this time is a matter that I consider at question 70 below.

61.3 As also stated in response to question 60, it appears that as soon as Mr O'Brien thought that the monitoring was over, the concerns that the monitoring was designed to address emerged again - in 2018, when I was off [redacted], and again in 2019.

61.4 In my opinion, I think that there was over-reliance on one individual (me) who had a demanding operational day job. This should have been more fully considered and appreciated as a risk. Whilst I believe I am a very diligent and hardworking member of staff, the system failed when I went off [redacted], revealing this weakness in the system. The storage of patients' notes was always a concern of mine. Whilst, in principle, the Trust supported the move to electronic tagging, there was never the funding made available to implement this so I had to use the work around of physically visiting Mr O'Brien's office at 6:30am on a Friday morning to perform a check, something which also didn't happen when I was off.

62. Did Mr O'Brien raise any concerns regarding, for example, patient care and safety, risk, clinical governance or administrative issues or any matter which might impact on those issues? If yes, what concerns did he raise and with whom, and when and in what context did he raise them? How, if at all, were those concerns considered and what, if

Received from Martina Corrigan on 07/07/2022. Annotated by the Urology Services Inquiry.

bit concerned. It was just, look, are we doing the right thing here, are we not? What's going on, whatever?

262 Q. We will come on to the email. It was 2019.

A. '19, right, okay. 11:58

263 Q. We will come on to that in a second. From your perspective, your lens was entirely systems functioning?

A. Yes.

264 Q. And things continuing to operate smoothly? 11:58

A. Yes.

265 Q. You have said in your statement at paragraph 26.3 that Mr. O'Brien instructed his secretary not to use DARO. Was that something that was reported to you or did Noleen Elliott tell you that directly? 11:58

A. Noleen Elliott told Colette McCaul, who was her line manager at the time, and Colette McCaul then told me.

266 Q. Was there an expectation that Noleen Elliott - we discussed this slightly earlier - would follow the guidance that DARO was the system in place? Or was 11:59 there an expectation that she would use systems to better reflect the clinic practice of her consultant?

A. Well, it's a very tricky one but I believe the secretary should be listening to us because we are the admin people and you should be following your 11:59 instruction from us. However, I understand it's very difficult because she worked very closely with the consultant; you see them as 100 times more important than we will ever be. But you have to follow process

Corrigan, Martina

From: Haynes, Mark <[redacted]>
Sent: 26 November 2015 06:42
To: Young, Michael; Corrigan, Martina
Subject: Queue jumpers

Morning Michael

I emailed you on 2nd June 2015 about the ongoing issue of patients on waiting lists not being managed chronologically and in particular private patients being brought onto NHS lists having significantly jumped the Waiting List. As I have been through our inpatients in preparation for taking over the on-call today I have once again come across examples of this behaviour continuing. Specific patient details are;

[redacted] AOB
Referred Sept 2015, Seen OP ([redacted]) Sat 10/10/15, Urodynamics @thorndale unit 6/11/15, Cystodistension 25/11/15.

[redacted] AOB
Referred 28/10/15, Seen OP ([redacted]) Sat 7/11/15, GA cystoscopy 25/11/15 (?recurrent stricture)

I have expressed my view on many occasions. This is Immoral and unacceptable. Aside from the immorality of patients who have the means to seek private consultations having their operations on the NHS list to the detriment of patients without the means, who sit on the waiting list for significant lengths of time, the behaviour is apparent to outsiders looking in. The HSC board can see it when they look at our service and any of our good work is undone by this.

Can you advise me what action has been taken since I raised this?

Mark

Received from Mr Mark Haynes on 16/09/22. Annotated by the Urology Services Inquiry.

Corrigan, Martina

From: Haynes, Mark <[redacted]>
Sent: 27 May 2015 20:54
To: Young, Michael; Corrigan, Martina
Subject: FW: UROLOGY TOTAL URGENT WAITING LIST - AS AT 27.05.15
Attachments: UROLOGY LONGEST URGENT WAITERS WITHOUT DATE FOR SURGERY - FOR SCHEDULING - 27.05.xlsx; UROLOGY TOTAL URGENT WAITING LIST - AS AT 27.05.15.xls

Importance: High

Dear Michael / Martina

I feel increasing uncomfortable discussing the urgent waiting list problem while we turn a blind eye to a colleague listing patients for surgery out of date order usually having been reviewed in a Saturday non NHS clinic. On the attached total urgent waiting list there are 89 patient listed for an Urgent TURP, the majority of whom will have catheters insitu. They have been waiting up to 92 weeks.

However, on the ward this week is a man ([redacted]) who went into retention on 16th March 2015, Failed a TROC on 31st March 2015. He was seen in a private clinic on Saturday 18th April and admission arranged for 25th May with a view to Surgery 27th May. The immorality of this is astounding and yet this is far from an isolated event, indeed I recognise it every time I am on the wards and discussing with various members of the team it is 'accepted' as normal practice. I would not disagree with any argument that this patient got the treatment we should be able to offer to all but it is indefensible that this patient waited 5 weeks while another patient waits 92 weeks. Both with catheters insitu for retention. An argument that this man was very distressed with his catheter does not hold with me. All of our secretaries can vouch for many patients in this situation being in regular contact because of catheter related problems.

This behaviour needs to challenged a stop put to it. I am unwilling to take the long waiting urgent patients while a member of the team offers preferential NHS treatment to patients he sees privately. I would suggest that this needs challenging by a retrospective audit of waiting times / chronological listing for all of us and an honest discussion as a team, perhaps led by Debbie. The alternative is to remove waiting list management from all of us consultants and have an administrative team which manages the waiting list / pre-op / filling of waiting lists in a chronological order.

Happy to discuss and plan a strategy for taking this forward.

Mark

From: Glenny, Sharon
Sent: 27 May 2015 14:32
To: Glackin, Anthony; Haynes, Mark; O'Brien, Aidan; ODonoghue, JohnP; Suresh, Ram; Young, Michael
Cc: Dignam, Paulette; Elliott, Noleen; Hanvey, Leanne; Loughran, Teresa; Robinson, NicolaJ; Troughton, Elizabeth
Subject: UROLOGY TOTAL URGENT WAITING LIST - AS AT 27.05.15
Importance: High

Hi Everyone

Following the departmental meeting last week and discussion re urgent waiting times and volumes with consultants for elective surgery – I have attached a total urgent waiting list for your review.

Received from Mr Mark Haynes on 16/09/22. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

Guidelines for Management of Private Patients

Southern Health and Social Care Trust –v1.14
[06th APRIL 2011]

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

[redacted]

Guidelines for Management of Private Patients

Southern Health and Social Care Trust

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Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

Definitions

Private Practice

Private Practice is defined for consultants and other hospital doctors in the Terms and Conditions of Hospital Medical and Dental staff as “the diagnosis or treatment of patients by private arrangement”.

Private Patient

A private patient is defined in the NHS Act as a patient who gives (or for whom is given) an undertaking to pay charges for accommodation and services. This also includes parents of children who have signing authority for their children.

Category 2 Work

A report on a patient not under observation or treatment at the hospital, often for a third party, which may involve a special examination, is category 2 work, in which case a fee may be charged.

Category II work includes investigations or tests for non-clinical reasons. (If the patient is under observation or treatment at the hospital, reports for a third party not requiring a special examination are usually category 1 work).

Examples of category 2 work include medical examinations for life insurance purposes, x-rays made on behalf of insurance companies and reports and examinations for coroners.

Category 3 Work

Category 3 work is a term used to describe extra work undertaken by separate arrangement on NHS patients outside the principal contract of employment. An example includes work undertaken as part of waiting list initiatives.

Amenity Beds

Accommodation made available to patients, who undertake to pay a charge for a single room, which is not needed, by any patient on medical grounds

The Southern Health and Social Care Trust welcomes private patients and uses the income generated from private patients for the benefit of all patients within the Trust.

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

1 Overview

This guidance has been produced to provide clear guidelines to all staff groups on the management of private practice within the Trust.

This document aims to standardise the manner in which private practice is conducted and to improve the awareness of all those participating in Private Practice of their duties and obligations within the Health Service.

2 Code of Conduct for Private Patients

2.1 Key Principles

The key principles to be observed in using health service facilities for the treatment of private patients have been agreed between the Government and the medical and dental professions.

Consultants should conduct their private practice within the Health Service in full accordance with these principles.[1]

- HSC consultants and HSC employing organisations should work on a partnership basis to prevent any conflict of interest between private practice and HSC work. It is also important that HSC consultants and HSC organisations minimise the risk of any perceived conflicts of interest; although no consultant should suffer any penalty (under the code of conduct) simply because of a perception;

- the provision of services for private patients should not prejudice the interest of HSC patients or disrupt HSC services;

- with the exception of the need to provide emergency care, agreed HSC commitments should take precedence over private work;

- HSC facilities, staff and services may only be used for private practice with the prior agreement of the HSC employer. Trust staff involved in the care of private patients is covered by the organisations vicarious liability insurance if working for the Trust. Consultants may not use NHS staff or Trust facilities for the provision of private services without the prior written consent of the Chief Executive.

[1] Extract – A Code of Conduct for Private Practice – Recommended Standards of Practice for HSC Consultants – November 2003

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

Consultants should note that Private Patient work is not covered by the NHS Clinical Negligence Scheme for Trusts. They, therefore, need to consider making their own arrangements for insurance.

2.2 Responsibilities of the Southern Health and Social Care Trust

The Trust has a responsibility to ensure that there are proper arrangements for conducting private patient activity satisfactorily, including the admission and identification of private patients and the recovery of charges. To this end, it is recommended that a Private Patient Officer should be designated for each of the Trust's operating divisions.[1]

There are private patient officers based at each of the 2 main Acute Hospital sites

Craigavon Area Hospital	Carol Ritchie	Personal information redacted by the USI
Daisy Hill Hospital	Bridget Quinn	Personal information redacted by the USI

The Trust and the Consultant will provide services to patients with professional standards of medical care generally accepted in the medical community and in accordance with Standard Clinical Guidelines.

2.3 Responsibilities of Consultants undertaking Private Practice

The Trust is dependent on the cooperation of its consultants, visiting consultants and other staff in identifying private patients so that management can obtain the necessary undertaking from the patient to pay charges for treatment and calculate and collect the income due.

- The Consultant is responsible for ensuring that the provision of Private Professional Services or Fee Paying Services for other organisations – does not;
  - Result in detriment of NHS patients or services
  - Diminish the public resources that are available for the NHS[2]
- Where there would otherwise be a conflict or potential conflict of interest, NHS commitments must take precedence over private work. The consultant is

[1] Extract Management of Private Practice in Health Service Hospitals in Northern Ireland; A Handbook – November 2007
[2] Consultant Terms & Conditions of Service [Northern Ireland] 2004

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responsible for ensuing that private commitments do not conflict with Programmed Activities[].

2.4 Disclosure of Information about Private Practice

- Consultant must declare any private practice work in their annual job planning review or where such a review has not taken place in the past twelve month in a letter to the Trust Medical Director detailing their current and future private practice commitments

- Relevant information relating to private practice must be brought forward to annual Appraisal, in line with National Guidelines

- Consultants have a contractual responsibility to co-operate with the Trust by identifying their patients' private status, or any change in status. Failure to do so is a disciplinary matter and will be dealt with under the Trust Disciplinarily Policy,

- Consultants should ensure that private patients have been given details and other information necessary for them to understand the financial liability they are entering into. The Trust should provide tariff information to consultants in a timely manner.

2.5 Scheduling of Work and On-Call Duties:

Consultants should ensure:

- Private commitments, including on-call duties are not scheduled during times at which they are scheduled to be working for Southern Trust

- There are clear arrangements to prevent any significant risk of private commitment disrupting HSC commitment - Regular private commitments should be noted in a consultants job plan

- Private commitments do not prevent them from being able to attend a HSC emergency while they are on call for the HSC including an emergency cover that they agree to provide for HSC colleagues. In particular private commitments that prevent an immediate response should not be undertaken at these times

2.6 Provision of Private Services alongside HSC Duties:

The Southern Trust recognises that in some circumstances some private practice may be undertaken alongside a consultant's scheduled HSC duties. Providing

[] Consultant Terms & Conditions of Service [Northern Ireland] 2004

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that there is no disruption to HSC services this is permissible. Consultants should ensure that Southern Trust are aware of private services provided and that there is no detriment to the quality of timeliness of services for HSC patients.

2.7 Clinic/Session Bookings

Private patient services must take place at times that do not impact on the normal services for NHS patients

Private patient clinics/sessions must take place either before a NHS in which case it must not in any way delay the start of the NHS clinic/session] or after the NHS Clinic Session has completed. NHS clinic/session times must not be reduced to accommodate private patient/session times.

3 Information for NHS Patients about Private Treatment

In the course of their NHS duties and responsibilities Consultants should not initiate discussions about providing private services for Trust patients, nor must they ask other Trust staff to initiate such discussions on their behalf.

Except where immediate care is justified on clinical grounds, Consultants must not, in the course of their NHS duties and responsibilities, make arrangements to provide private services.

Consultants may discuss the option of private access to treatments that are not funded within the NHS. Consultants should exhaust all reasonable avenues for securing NHS funding [e.g, seeking HSC Board approval] before suggesting to a patient that the only option is to pay for care privately.

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4 Change of Status

When an episode has commenced in a private capacity the patient must either complete the episode as

4.1 Episode

A patient who sees a consultant privately shall continue to have private status throughout the entire treatment episode.

4.2 Waiting List

A patient seen privately who then becomes an NHS patient joins the waiting list at the same point as if his/her consultation had taken place as an NHS patient.

4.3 Inpatient Transfer

A private inpatient has a similar legal entitlement to change his status during the course of his stay in hospital And this should be supported by the return of a PP4 form.

4.4 Clinical Priority

A change of status from Private to NHS must be accompanied by an assessment of the patients clinical priority for treatment as an NHS patient.

A Change of Status Form [PP4] must be completed and signed by the Patient and Consultant.

5 Charges for the Use of Hospital Facilities

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

5.1 Private Patients. – Inpatient and Day Case Episodes

Where patients who are private to a consultant are admitted to the hospital, as an outpatient or day case, charges will be levied by the hospital.

These charges will not be the same as for NHS patients. The Health and Medicines Act 1988 provides for Trusts to set their own charges on what they consider to be the appropriate commercial basis.

5.2 Use of Trust Premises

Where a Consultant uses Trust premises [either formal outpatient setting or in office] for private consultations or clinics a charge will be levied to recover the full cost of providing these facilities, including staffing support.

Consultants will make an annual return of the number of outpatient consultations to facilitate the billing. This will be audited on an annual basis to ensure fees are appropriate.

If the patient has private status in the hospital – the Trust will not make a separate charge for use of Trust premises for consultations by the doctor in charge of the case or any other consultant during that episode. Similarly if the patient has paid for an amenity bed, the Trust will not make a separate charge for the use of Trust premises for private consultations.

If an outpatient requires procedures and/or diagnostics a PP/Undertaking to Pay form must be completed and the patient should be advised of the additional charges

5.3 Category 2 work:

Where consultants use NHS services, accommodation or facilities in carrying out Category 2 work, a reasonable fee is payable to the hospital for hospital costs, the minimum being the NHS cost of providing the service.

Consultants will annually declare the approximate number of Category 2 patients per annum to facilitate the billing of an annual fee. This will be audited on an annual basis to ensure fees are appropriate.. The Trust will no longer bill patients directly in respect of Category 2 work.

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If a Category 2 patient requires procedures and/or tests a PP/Undertaking to Pay form must be

5.4 Category 3 work

Patients treated under Category 3 earnings of whole-time practitioners in the career grades remain NHS patients and should continue to be treated as such. There is therefore no hospital charge for such patients.

5.5 Amenity Beds

These are single room facilities for which a charge is made,, but the patient does not make a private

A consultant may not raise a fee for professional services to a patient who has elected to be treated within the NHS and has been provided with enhanced/amenity accommodation.

If a patient has paid a fee for an Amenity Bed the Trust will not additionally bill the consultant for use of Trust premises for consultations undertaken during that spell of care.

Ward Clerk/Midwifery or Nursing staff are responsible for the full completion of the Undertaking to Pay for Amenity Bed Form [Appendix 6]

6 Responsibilities of the Private Patient

6.1 Undertaking to Pay

Private patients may cover their bills personally, or they may carry private insurance. In all cases they must sign an “PP/Undertaking to pay” form and are personally liable for any debt due to the Trust.

Except in emergencies, the Consultant should seek an undertaking to pay form a potential private patient before or on admission or before diagnosis and treatment are started.

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The Private Patient Officer must ensure that signed undertakings have been given, and should witness them wherever practicable. One copy of the undertaking should be kept by administration, one copy kept with the patient's notes and a third copy passed to the relevant consultant for information.

Patients should be fully informed before they give an undertaking to pay, of:

- The nature of the facilities being made available
- The charges to which they will be liable
- They should also be advised that the charges from the Trust are separate from any professional fees levied directly by the consultant and/or any other professional medical charges [e.g. radiology, anaesthetics]

A patient should be given an estimate of the total charges that are likely to be incurred.

The patient should also be made aware that if his or her stay is longer than expected the charges will be higher. If treatment is expected to continue beyond 1st April in any year, the patient should be advised that charges are reviewed each year, and may be increased on that date by a small amount to take account of inflation.

6.2 Private Patients covered by Medical Health Insurance

The PP/Undertaking to Pay form will also capture details of insurance policies held. The PPO will raise invoices directly to the insurance company where relevant. Increasingly, insurers are offering cheaper policies as an incentive to join insurance schemes, and patients' insurance may not in all cases cover the full costs of their treatment.

While the Trust accepts that consultants cannot be expected to be aware of the minutia of patients insurance policies, since the consultant is in charge of the treatment provided, he/she should ensure that the patient has obtained their insurance company's permission for the specified treatment to take place within the specified timescale and in a specified location. This will safeguard the income due to both the Consultant and the Trust.

6.3 Payment

The PPO co-ordinates the collation of financial information relating to patients' treatment, ensures that uninsured patients pay in full while in hospital and ensures that invoices are raised accordingly. The financial accounts department

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will ensure all invoices raised are paid and will advise the Private Patients Officer in the event of a bad debt.

7 Identification of Private Patients

7.1 Inpatient and Day Case Admissions

The PP/Undertaking to Pay form should be forwarded promptly to the Private Patient Officer (PPO) prior to admission

- It is essential to identify private patients at the outset and to be noted on the PAS system. The consultant with primary responsibility for a patient must ensure that the private status of any patient that he/she admits to the hospital is established.

- It is the responsibility of the admitting consultant to ensure that the Trust is advised of the private status of their patient. And that the PP/Undertaking to Pay form has been completed [Appendix 1]

- The Private Patients Manager will contact the patient to check the details of payment for their treatment. If the patient is insured, full details will be taken of the insurance cover and contact made with the insurer to gain authorisation to treat the patient. When an insurer requests a medical report from the Consultant prior to granting authorisation, the Consultant has a duty to provide the report in a timely fashion and prior to commencing any private treatment.

- The Private Patients Officer will liase with the Consultant and all other relevant departments to ensure that appropriate arrangements are made for the admission of the private patient.

- The consultant with primary responsibility for a private patient is responsible for informing the private patient officer that, in his/her clinical judgment, an episode of illness is completed. In the case of maternity admissions the discharge will be considered notification of the end of private treatment, The private patient officer should then arrange for the private number, or other indicator of status, to be cancelled. Until that happens, the patient should continue to be regarded as private for that condition, and therefore liable to pay charges, unless he/she seeks to change to Health Service status

- Any patient who elects to change to Health Service status should confirm in writing their intention to become Health Service patients. This notification

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should be sent to the private patient officer via their consultant PP4 form [Appendix 2]

7.2 Outpatients

Consultants are obliged to advise the Trust on an annual basis of the numbers of private patients seen in Trust premises. [See Section 5.2]

If a private outpatient requires any intervention and/or diagnosis a PP/Undertaking to Pay form must be completed.[See Section 7.4 below]

7.3 Services & Diagnostics for Private Out-Patients

The requesting Consultant must ensure that the private patient status is noted on requests for Physiotherapy, Dietetics, Orthotics, Occupational Therapy, Imaging and Pathology.

For Imaging and Pathology a tick on the referral form will suffice [PP/Undertaking to Pay form is not required]

Consultants are required to ensure the PP/Undertaking to Pay form has been completed before Physiotherapy, Dietetics, Orthotics, and Occupational Therapy is requested for a private patient.

Private patient specimens or samples that are taken at private dwellings or in Trust facilities e.g. blood tests and cervical smears and sent to HSC facilities for testing or examination should also be appropriately identified by both the consultant and the Trust before transmission to the hospital.

The Trust will invoice the consultant directly for laboratory tests and will bill the patient directly for all other services and diagnostics.

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7.4 Prescriptions for Private Patients on Trust Premises

Any prescriptions arising from private outpatients must be paid for by the patients, these include medication prescriptions and other therapies. The Trust will bill patients directly

All requests for Pharmacy for private outpatients should be clearly marked as to allow the Trust to ascertain the cost of the drugs supplied to private patients.

Consultants are required to ensure the PP/Undertaking to Pay form has been completed before prescriptions for private outpatients are requested.

The only exception to this is when the patient advises of his/her intention to become Health Service patients through the completion of the PP4 form.

7.5 Category II Patients

Consultants set their own charges for Category II work.

Consultants must identify all such patients as private and adhere to the same process as they would with any other private patient attending an outpatient clinic.

Current Hospital Tariffs for inpatient/Day Case care cover all costs including diagnostics and pharmacy

8 Self-Funding Private Patients

If a patient is self-funding, a deposit of payment for the treatment must be made by the patient before their admission. The charge will be as follows:

- £300 for inpatient procedure
- £150 for day case procedure

Doctors should advise self-funding patients of their responsibility to pay deposit prior to their admission [the office is open Monday – Friday 9:00 – 4:00] and bring proof of same on admission

Should a self-funding patient be admitted out of hours – arrangement for payment of deposit should be made on the next working day.

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Cash, cheques, debit and credit cards are all accepted methods of payments.

Should the actual charge be greater, the balance will be paid on discharge. A fixed price package may be offered for a range of procedures for patients who are otherwise fit and well. The charge must be paid on or before admission.

9 Emergency/Out of Hours Admission

9.1 Emergency Admissions

If a patient is admitted privately in an emergency, the Consultant must advise the Private Patients' Officer immediately in order that arrangements can be made to ensure payment.

When such an admission occurs out of office hours (9 a.m. - 5 p.m., Monday to Friday), the patient wishing to be admitted privately should be asked by ward staff to sign an PP/Undertaking to Pay Hospital Charges form confirming that they will pay any charges not covered by their health insurance company. Out of Hours the nursing staff should ensure this form is completed.

The Private Patients' Officer will seek authorisation from the health insurance company for payment of the treatment the next working day.

9.2 Ward Attendees

In some instances patients may attend directly to ward having completed a previous private episode of care with a consultant. In these instances the Ward Staff should request the patient complete PP/Undertaking to Pay form. The patient will be billed directly for the duration of their stay [basic outpatient attendance charge if less than overnight] and all associated costs associated with this new episode of care. The consultant will be asked by the private patient office to sign the form at their earliest convenience.

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

10 Record Keeping

10.1 Private Patients Officer

Records will be maintained by the Private Patients' Officer in such as way that the following information can be accessed quickly and accurately:

- Patient's name, address and telephone number.
- Completed undertaking to pay form.
- Health insurance details for insured patients.
- Name of Consultant.
- Details of all treatment received, admission and discharge dates.
- Invoices raised and settlement dates.

The Private Patients' Officer will maintain a record of all activity by Consultant, including In-Patient, Out-Patient and day case episodes, together with income generated for the Trust by each Consultant and produce regular reports for submission to the Director of Finance and Chief Executive.

10.2 The Consultant

The Trust would expect Consultants to maintain Records that the following information can be accessed quickly and accurately:

- Number of private outpatients/ in-patients/day cases treated within Trust premises annually
- Identification of Category 2 work undertaken annually

10.3 Private Patient Medical Records

While obtaining care in the Trust premises as an inpatient or day case – patients will be allocated a Hospital NHS chart.

In the event of a Serious Adverse Incident or legal proceedings the Trust may require access to private patient medical records which should be held in accordance with GMC Good Record Keeping guidance.

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11 Audit and Escalation Procedure

The Trust will undertake an annual audit of private patient workload by consultant.

The following will be reviewed on a Consultant by Consultant basis:

- Identification of Private Patients
- Completion of Undertaking to Pay Forms
- Accurate, timely completion of PP/Undertaking to Pay forms
- Accuracy of identification of diagnostic/pharmacy charges associated with private patients

Poor compliance will be dealt with on a one-to-one basis with individual consultants

The Trust reserves the right to deny a consultant not adhering to these guidelines the right to undertake private practice in Trust premises

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

12 Appendix 1: PP/Undertaking to Pay Form

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

Private/Not Ordinarily Resident in UK Notification & Undertaking to Pay Form

Private Patient yes/no
Non-Ordinarily Resident in UK yes/no

Name of Patient	
Address	
Postcode	
Date of Birth	
H & C Number	
Name of Insurer	
Insurer Policy Number	

I have been seeing this person as a private patient. They are to be admitted/referred to _____Hospital on_____[date] as an

Inpatient Referral		Obstetrics	Medical	Surgical
		Estimated Duration of Stay	Estimated Duration of Stay	Estimated Duration of Stay
Day Case Referral				
Diagnostics		Laboratory [please detail]	Radiology [please detail]	Other [please specify]

Undertaking to Pay Confirmation To be completed by Consultant	
I have advised the patient named above of the estimated hospital charges and of my fees	
Signed Consultant	
Date	
Undertaking to Pay To be completed by the person who will pay the account	
I understand and agreed to pay Southern Health and Social Care Trust all charges[5] associated with this episode of care[6] as explained to me by my consultant.	
Signed Patient	
Date	

[5] A list of Tariffs is available from the Private Patients office

[6] Episode of Care – The total treatment of either an inpatient or day case patient from diagnosis through to discharge

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

13 Appendix 2: PP4 Form

Notification of Patient Referred to Hospital as an NHS patient following Consultation as a Private Patient

Name of Patient	
Address	
Postcode	
Date of Birth	
H & C Number	

Name of Consultant	
Date of Last Private Consultation	

I have been seeing this person as a private patient. He/She has now been referred to Hospital as an NHS patient

		Clinical Priority
Inpatient Referral		
Outpatient Referral		
Day Case Referral		

Signed Consultant	
Effective Date	

Consultants are reminded that in good practice a patient who changes from private to NHS status should receive all subsequent treatment during that episode of care under the NHS as outlined in A Code of Conduct for Private Practice

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

14 Appendix 5 – Undertaking to Pay for Amenity Bed

UNDERTAKING TO PAY CHARGES FOR AN AMENITY BED

To be completed by WARD CLERK OR NURSEMIDWIFE witnessing the patient's signature when they are allocated an amenity bed.

I (full name)

_____

Of (home address)

_____

_____

Was allocated an amenity bed on (date) _____ (time) _____

Patient's Casenote Number _____

Ward _____ Consultant _____

I undertake to pay the Southern Health and Social Care Trust £39 per night for an amenity bed, which has been provided for me at my request.

Number of days Amenity Bed Required _____

I understand that if I am required to stay in hospital more days than anticipated, the midwifery staff will ask me if I wish to continue and pay for the amenity bed, or if I wish to be transferred to the open ward.

Patient's Signature_____Date _____

Midwife's Signature_____Date _____

To be completed by WARD CLERK OR MIDWIFE when patient is being transferred/discharged from an amenity bed.

Date transferred/discharged from amenity bed _____

Signed by midwife/ward clerk when transferred/discharged _____

Received from SHSCT 02/06/2023. Annotated by the Urology Services Inquiry.

HSC Business Services Organisation

Southern Health & Social Care Trust

Review of Mr A's Compliance with Relevant Authorities/Guidance in terms of his Private Work 2020/21

nqa ISO 9001 Registered Quality Management

Received from Dr Maria O'Kane on 01/04/22. Annotated by the Urology Services Inquiry.

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Acknowledgement

Internal Audit wishes to thank management and staff at the Southern Health and Social Care Trust for their assistance and co-operation during the course of the assignment.

Control Log

Working Draft Issued to Inform Exit Meeting:	28 April 2021
Exit Meeting Held On:	29 April 2021
First Draft Issued On:	30 April 2021
Management Actions Received:	13 July 2021
Final Report Issued On:	31 August 2021

Distribution List

Shane Devlin	Chief Executive
Helen O'Neill	Director of Finance, Procurement & Estates
Dr Maria O'Kane	Medical Director
Melanie McClements	Director of Acute Services
Heather Trouton	Director of Nursing

Received from Dr Maria O'Kane on 01/04/22. Annotated by the Urology Services Inquiry.

Introduction

In November 2020, at the request of the Urology Assurance Group, the SHSCT Chief Executive requested a review of Mr A's patients transferring into SHSCT as HSC patients. In addition, the review will consider any Trust involvement with the Craigavon Urological Research & Education organisation.

Terms of Reference

The audit focused primarily on Mr A's change of status private patient's work during the period 1 January 2019 to 30 June 2020 in order to:

1. Establish the extent of SHSCT awareness of Mr A's private work, through the job plan process and their private patient identification and management processes.
2. Establish the extent to which Mr A's private work interacted with HSC services and facilities.
3. To identify all of Mr A's patients that changed status (private/NHS) and check that there is evidence that relevant guidance/authorities have been adhered to. This will include providing assurance that:
    - The appropriate Change of Status paperwork has been completed and authorised and that this is supported by an assessment, by the consultant, of the patient's clinical priority for treatment as a Health Service patient.
    - For all private work identified above, the patient joined the HSC waiting list at the same point as if their consultation had taken place as an NHS patient.
    - The Consultant fulfilled all obligations with regard to recording and identifying private activity.
    - Where private work was conducted on HSC premises, ensure the patient has been invoiced for relevant costs.

Internal Audit also considered whether the Trust has any involvement with CURE - Craigavon Urological Research & Education, to understand if there was a flow of money into the Trust and to check, as much as is possible from review of Trust records and engagement with Trust staff, whether any Directors/staff benefited from the operation of the company.

Limitation of Scope: Internal Audit would caution that the analysis conducted is largely based on the data provided by the Trust. Internal Audit did not walk through each individual patient's journey on their patient file and therefore the analysis may not be fully complete.

Executive Summary

Internal Audit has identified issues with Mr A's compliance with relevant guidance around private practice. Significant issues with the timing, completion and approval of change of status paperwork were identified when patients transferred from private to NHS care. Occasions were also found when patients that had been seen privately, were treated more quickly that than the Trust standard waiting times.

Significant issues were also found around the Trust's management and monitoring of compliance with private patient guidance in particular the change of status process and their ability to monitor that patients transferring from private to NHS care, are treated in an equitable manner. The findings in this report indicate issues around patients being able to pay to see a Consultant privately and then receiving preferential treatment in the NHS. The Trust should consider whether these issues are isolated to this one Consultant or indicative of a wider cultural issue.

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In total in the review period, 5 of Mr A's private patients were identified as having been treated at the Trust without/prior to receipt of a change of status form. A further 8 patients were potentially private when they were seen in the Trust (excluding those cases that the Trust believe are poor administration rather than private work). 5 patients switched status more than once (from NHS-private-NHS). 6 change of status patients were seen ahead of Trust waiting times. A further 2 patients were added to PAS retrospectively effectively being placed on the waiting list ahead of where they should have been placed.

In addition to private practice issues, there are also patient safety matters identified in the report primarily around performance of Pre Operative Assessments.

The findings of the review are summarised as:

Trust Processes and Awareness of Mr A's Private Work

Trust Knowledge of Mr A's Private Work

1. The Trust were aware that Mr A holds a private outpatient clinic at his home. It is unclear what happened these private outpatients if they required diagnostics and/or inpatient/daycase procedures. The Trust does not appear to have explored or challenged the potential interaction with the Trust in the scenario where private outpatients may require diagnostics/procedures etc. There is learning for the Trust in this matter in terms of considering circumstances when a Consultant conducts private outpatients work only.

Job Planning & Payment

2. In line with job planning guidance and Consultant terms and conditions, a job plan review should take place annually. The most recent job plan available for Mr A is an unsigned job plan, dated 1 April 2018.
3. Personal Information redacted by USI [redacted]

The Trust's Change of Status Process

4. The Trust's Change of Status form for when a private patient transfers to NHS treatment, has limited monitoring or control value. The Change of Status activity is not effectively approved by the Medical Director or reviewed by the Trust Clinical/Directorate Management. The Change of Status form itself and the Change of Status process require strengthening.
5. The Trust is not compliant with the regional guidance issued in 2018 which requires all Change of Status patients to be identified with a 'PTN' code on PAS.
6. The Trust does not have a process in place to ensure all change of status patients have been identified for monitoring purposes and to ensure that the process for changing status is effectively controlled and documented, as an assurance that the delivery of service is equitable.

Identification of Private Work

7. Laboratories, Radiology and Pharmacy are reliant on Consultants highlighting any private activity. There is a risk therefore that private activity in these departments may not be identified.
8. There is insufficient control over prescriptions pads to prevent the use of Trust prescription pads for private work.

Mr A's Change of Status Patient Activity

Approved Effective Change of Status Date

9. Contrary to Trust written procedure, the date the patient is added to PAS as an NHS patient is the effective date as per the Change of Status form, not the date the Change of Status form was approved by Medical Director.

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Change of Status Patients who had Diagnostic (Radiology) Tests

10. In 10 out of the 21 Change of Status cases during the period from January 2019 to June 2020, the patient was referred for 1 or more imaging tests. In 3 of these 10 cases, the patient had the imaging tests in the Trust prior to changing status to NHS ie whilst still private patients. A further 5 out of the 10 patients had diagnostic requests made on the same date as the effective change of status date and the same date the patient was last seen privately. Given that these 5 Change of Status forms are unlikely to have been submitted and approved by the Medical Director on the same day as the patients' private appointments, these patients should potentially have been treated by the Trust as private patients.
11. 3 (including 1 of the 3 patients found to be private) out of the 10 patients were seen sooner than the Trust waiting time for the diagnostic/imaging test.

Patients who changed Status and had Inpatient/Daycase Procedure

12. Out of the 13 Change of Status cases transferred into the NHS for an inpatient/day procedure, 5 had their procedure during the review period (ie up to June 2020). The Trust Consultant Urologist assisting Internal Audit in this review considered that 2 of the 5 patients were not seen in line with the Trust waiting list time. These cases were not Urgent/red flag procedures (as categorised on PAS) and were seen significantly sooner than other patients on the waiting lists.

Retrospective Entry to PAS

13. Two change of status forms had been added retrospectively to PAS. Most significantly, one of these patients was added to the waiting list from September 2018 but this was not actually added to PAS in May 2020. At December 2020 this Change of Status had not been approved by Medical Director.

Protected Reviews

14. The Trust does not monitor the use of protected review appointments and there is a risk that private patients or Change of Status patients could potentially be seen quicker in a protected review appointment slot.
15. Internal Audit identified 1 case where a routine outpatient was seen in a protected review slot, 15 days after being added to the waiting list and therefore seen ahead of NHS patients with the same clinical priority.

Multiple Switches in Status

16. Contrary to guidance, in 5 of the 21 cases where a change of status form had been completed, the patient moved between NHS to Private to NHS for the same referral.

Analysis of Mr A Activity Data

Pre-Operative Assessments (POAs)

17. In 86 (25%) of the 351 procedures conducted by Mr A during the period January 2019 to June 2020 which required a Pre-Operative Assessment, a POA was not completed.
18. Upon further analysis, 1 of these 86 cases related to a private patient who was subsequently treated in the NHS. No Change of Status form had been completed.
19. 95% of the POAs completed on Mr A patients during the review period were completed less than 3 weeks before admission for surgery. The Trust requires POAs to be competed at least 3 weeks before (and up to 13 weeks before) admission for surgery,
20. The lack of POA or the short time scales between the completion of a POA and the date of admission for surgery is a potential indicator that a patient may have been seen privately and then had their procedure in the NHS.

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Elective Surgery With No Outpatient Appointment

21. Out of a sample of records where a patient had surgery but there was no evidence on PAS of an outpatient appointment, we found:
    - 1 patient changed from NHS to private and back to NHS status in one day, with no Change of Status forms. This is a blatant breach of proper process and is an example whereby a significant advantage has been gained in terms of speed of treatment, by paying privately for an outpatient appointment. In the absence of an approved Change of Status form, this is arguably a private patient having a procedure using trust facilities and staffing.
    - In 2 cases, there was no outcome letter completed for the procedure potentially indicating that the patient may have transferred back to the private sector for review. *It should be noted that the Trust believe that these are poor administration issues rather than private patients.*

Elective Surgery with an Outpatient Appointment

22. Out of a sample of 29 patients who had an elective procedure and an outpatient appointment in the period under review, 4 occasions were found where the patient may potentially have been a private patient. In one case the patient was a Personal Information redacted by the USI and in another case the patient was a Personal Information redacted by the USI *It should be noted that the Trust believe that one of these cases associated with non completion of an outcome letter is poor administration rather than a private patient.*

Other Observations

23. Other issues have been noted by Internal Audit around the audit trail when ordering scans on NIPACS (Sectra); changes being made to the referral date on PAS (which should not be changed); registrations for episodes of care on PAS that remain open rather than being closed; and use and monitoring of electronic sign off on NIECR.

Extent of Trust Involvement with CURE

24. CURE - Craigavon Urological Research & Education – is an independent entity, separate from the Trust. Whilst a number of Trust staff sit on the CURE Committee, these roles are independent from their role in the Trust. From discussion with Trust Management and Trust staff involved with CURE, there is no indication of any flow of money into the Trust or Trust involvement in fund raising in recent years. Internal Audit understands from the Committee members that Trust staff may apply to CURE for funding and if granted, a cheque will be written from CURE to the applicant. Trust procedures do not provide guidance in respect of staff involvement in independent organisations with a potentially perceived affiliation to the Trust by their nature.
    Internal Audit did not have access to CURE financial records as part of this review and therefore do not have visibility over any payments made by CURE to Trust staff.

Received from Dr Maria O'Kane on 01/04/22. Annotated by the Urology Services Inquiry.

Detailed Findings Of The Review

1. TRUST'S AWARENESS OF MR A'S PRIVATE WORK AND MANAGEMENT OF COMPLIANCE WITH PRIVATE PATIENT GUIDANCE

1.1 Job Plan Document

The Consultant Job Planning - Standards of Best Practice (November 2003) and Consultant Terms and Conditions of Service (Northern Ireland) 2004 states that a job plan review should take place annually. A similar requirement is contained in the Medical and Dental terms and conditions 2008.

Internal Audit requested a copy of Mr A's job plan for the period 1 January 2019 to 30 June 2020. In line with the annual job plan review schedule, there should be 2 job plans to cover this period. There is no signed off job plan held by the Trust for the period 1 April 2011 to 30 June 2020. The most recent job plan available for Mr A is an unsigned job plan, dated 1 April 2018 and there is no end date recorded. This document is not signed by Mr A or his Clinical Director.

The most recent job planning meeting appears to have been held in November 2018. Regular, annual job plan meetings have not been held.

1.2 Trust Knowledge of Mr A's Private Practice

"A Code Of Conduct For Private Practice - Recommended Standards Of Practice For HPSS Consultants (An Agreement between the BMA(NI) Northern Ireland Consultants and Specialists Committee and the Department of Health, Social Services and Public Safety for consultants in Northern Ireland) (November 2003)" requires that Consultants declare any private practice and as part of the annual job planning process, consultants should disclose details of regular private practice commitments, including the timing, location and broad type of activity, to facilitate effective planning of NHS work.

Trust procedures "Trust Guidance on Paying/Private Patients – 2018 states:
In section 2.2 "Under the appraisal guidelines agreed in 2001, NHS consultants should be appraised on all aspects of their medical practice, including private practice. In line with the requirements of revalidation, consultants should submit evidence of private practice to their appraiser"
In Section 5.1 "While Medical Consultant staff have the right to undertake Private Practice within the Terms and Conditions of the Consultant Contract (2004) as agreed within their annual job plan review, it is the responsibility of Consultants, prior to the provision of any diagnostic tests or treatment to:

- *ensure that their private patients are identified and notified to the Paying Patients Officer.*
- *ensure full compliance with the Code of Conduct for Private Practice (see Appendix 2) in relation to referral to NHS Waiting Lists.*
- *ensure that patients are aware of and understand the range of costs associated with private treatment including hospital costs and the range of professional fees which the patient is likely to incur, to include Surgeon/Physician, Anaesthetist, Radiologist, hospital charges.*
- *Ensure that information pertaining to their private patient work is included in their annual whole practice appraisal.*

Although there is no private work identified in Mr A's most recent job plan, the Trust were aware that Mr A conducted private work outside the Trust:

- Mr A submitted a Trust "Declaration of Private Practice" in February 2018. In this declaration form, Mr A advised that he did not complete private practice within the Trust, however he did

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treat private patients outside of the Trust. The declaration form is not sufficiently clear to clarify the type of private practice undertaken (ie outpatient/daycases/inpatients). On the Declaration Mr A did not confirm that he had read and understood the Trusts Guidance on Paying/Private patients. He did declare that he understood that any private patient work whether undertaken inside or outside of the Trust must be included in his job plan. *The Trust Declaration of Private Practice process should be conducted every year. A declaration therefore should have been made by Mr A in 2019 however this was not submitted to the Trust and the annual declaration process was not conducted in 2020 due to COVID-19.*

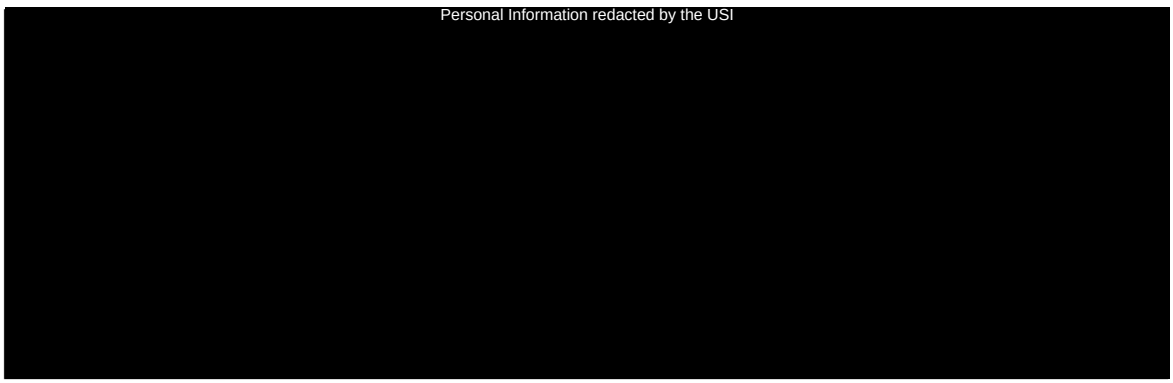
- The most recent appraisal completed for Mr A was in 2018. Internal Audit do not require access to this appraisal document, however the Trust have confirmed that Mr A declared that he conducted a private outpatient clinic at his home.

In the event that a private outpatient seen at Mr A's home clinic required diagnostics including blood tests or a daycase/inpatient procedure, it is unclear how this private activity was administered and whether or not such work entered the Trust either as private or NHS work. This issue is considered further in sections 2 and 3 of this report.

The Trust does not appear to have explored or challenged the potential interaction with the Trust in the scenario where private outpatients may require diagnostics/procedures etc. There is learning for the Trust in this matter in terms of considering circumstances when a Consultant conducts private outpatient work only.

1.3 Reconciliation of Job Plan to Payroll

Personal Information redacted by the USI



1.4 Change of Status Process

The "Management of Private Practice in Health Service Hospitals in Northern Ireland: A Handbook – November 2007" requires that patients changing status from Private to NHS must have a Change of Status form completed by the consultant. The form must also detail the clinical priority for treatment as a health service patient. The Trust should be able to clearly identify these patients for monitoring purposes. It is important that the process of changing patient status is effectively controlled and documented as an assurance that the delivery of service is equitable.

The Trust Guidance on Paying/Private Patients procedures require Consultants to complete a Change of Status form when a private patient transfers to NHS treatment. However, effectively this form has limited monitoring or control value because:

1. The form is signed by the Consultant and stamped as approved by the Medical Directors office. It is not possible to establish who applied this stamp or the date it was applied. The change of status forms are filed in the cash offices at Craigavon Area Hospital/Daisy Hill Hospital and no

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action or reporting takes place within the Trust. The Change of Status activity is not effectively approved by the Medical Director or reviewed by the Trust Clinical/Directorate Management.

2. The form contains no detail of the reason for the change of status.
3. The date the patient changes status to NHS is recorded on PAS as the effective date as per the Change of Status form, not the date the Change of Status form was approved by the Medical Director. This appears contrary to Trust Guidance on Paying/Private Patients procedures which state *"It is important to note that until the change of status form has been approved by the Medical Director, the patient's status will remain private and they may well be liable for charges."* The Change of Status form is confusing this matter, by including an effective date of change of status rather than, an approved date. The form does not clearly state that the approval date will be the date of transfer to NHS from private status.
4. There are no dates applied to the change of status form by either the Paying Patient Officer on receipt of the form or by the Medical Director's Office on approval of the form. Therefore Internal Audit were unable to establish whether the Change of Status forms were approved prior to the patient receiving an appointment/treatment, potentially impacting on income that may have been due to the Trust.

Prior to 11 September 2018 when the regional PAS Technical Guidance approved a code (PTN) to identify private patients transferring to NHS status, the Patient Administration System (PAS) did not require a change of status to be recorded on the system. The change of status may have been entered in a free text field which is not a mandatory field. The Southern HSC Trust has not yet implemented the regional code 'PTN' for patients transferring from private practice to NHS. A PAS report cannot therefore be run showing all change of status patients.

The Trust does not have a process in place to ensure all change of status patients have been identified for monitoring purposes and to ensure that the process for changing status is effectively controlled and documented, as an assurance that the delivery of service is equitable.

1.5 Private Patient Identification Processes

In line with the "Management of Private Practice in Health Service Hospitals In Northern Ireland: A Handbook (November 2007)" Consultants have a contractual obligation to cooperate in recording all private outpatient and day patient attendances, treatments and procedures. The patient's records and referral forms etc should always be suitably marked. Records kept in departments away from the main outpatient area (e.g. x-ray, pathology and physiotherapy) should identify private patients.

Internal Audit met with senior staff in Laboratories, Radiology and Pharmacy to discuss the processes in these departments for the identification and management of private patients. All three departments are reliant on Consultants highlighting any private activity. There is a risk therefore that private activity in these departments may not be identified.

Pharmacy:

When a consultant prescribes medication to a private/NHS patient at an outpatient clinic, there are 2 different prescription pads used:-

- Prescription which can be written and given to the patient to take to the hospital pharmacy for dispensing. These are numbered but there is no control over the issue of the prescription pads. These are in quadruplicate – White copy –to GP, yellow copy to Pharmacy, Blue copy community nursing and pink copy patient notes.
- Prescription letter which the patient must take to their GP and the GP writes a prescription for dispensing at the community pharmacist.

There are inadequate controls surrounding the issue and use of prescription pads. Pads are held in consulting rooms and may be used by multiple consultants who apply their own name labels to the scripts.

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If a patient takes the script to the Trust pharmacy for dispensing, the pharmacy have no mechanism to identify whether the patient is private or has come from a NHS outpatient appointment. Similar to the rest of private practice, the Trust are reliant on the Consultant declaring activity as private and in this case, writing the prescription advising that the patient is private so that pharmacy can ensure that the cost of the medications are invoiced.

Internal Audit discussed 6 sampled cases with Pharmacy to identify if any of these patients had received medication while still private patients. No issues were identified.

Laboratory Services:

The Head of Laboratory Services advised that within the Trust they are reliant on the Consultant/doctor who completes the laboratory request ticking a box to identify a private patient. There is no other mechanism to identify private patients.

Laboratory results are put on NIECR and there is nothing to identify private tests unless the consultant has declared this on the lab request.

Diagnostic Services:

The Head of Acute Information in conjunction with the NIPACS Manager confirmed referrals received for scans etc are all completed on the same referral form and there is no mechanism to identify private or change of status patients on the system. Consultants order scans etc directly themselves on the NIPACS (Sectra) system.

As per Section 2 of this report, radiology activity was identified that should potentially have been declared and treated as private.

Recommendations Specific to Review of Mr A's Practice:

Recommendation 1.1	The Trust should review Mr As job plan and actual APAs worked in order to ascertain if overpayments have occurred, and seek recompense if required.
Management Action	ACEPTED
Responsible Manager	Medical Director and Director of Acute Services
Implementation Date	October 2021

General Recommendations Regarding Trust Process:

Internal Audit completed an audit in 2019/20 (finalised in October 2020 following delay in obtaining Management Response to the report due to COVID-19) and provided limited assurance in relation to Management of Private Medical Practice (including patient change of status processes). A number of the recommendations included in the 2019/20 report have been restated throughout this report.

Recommendation 1.2	As previously recommended in the 2019/20 Management of Private and Paying Patients audit report and as per the 'Code of Conduct for Private Practice - recommended standards of practice for HPSS consultants (November 2003)', the Trust must ensure that: • All consultants have an annual job planning review. • All consultants completing private practice declare any private practice and as part of the annual job planning process, consultants should

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	disclose details of regular private practice commitments, including the timing, location and broad type of activity, to facilitate effective planning of HPSS work and out of hours cover. • As part of the job planning process, the Trust should consider total working hours across HSC and private practice. Job plans should be signed and dated by the consultant and their Clinical Director.
Management Action	**ACCEPTED**
Responsible Manager	Medical Director/Deputy Medical Director and all Divisional Medical Directors
Implementation Date	Februaury 2022

Recommendation 1.3	The Trust should strengthen their management arrangements in scenarios where a Consultant declares that they conduct private outpatient work only, specifically where the work is carried out outside the NHS including premises not regulated by RQIA. The following specific measures are suggested: • Assurances should be sought as to how associated diagnostics/subsequent required treatment are managed. • Medical Director approval should be introduced in the event that Consultants conduct outpatient work privately. • Trust monitoring processes should be alert to ensuring Change of Status patients are placed on the waiting list based on clinical priority. • The Trust "Declaration of Private Practice" form should be amended to clearly identify the type of private practice undertaken (ie outpatient/daycases/inpatients). Trust management should review these declaration as and triangulate the information with appraisals and job plans.
Management Action	ACCEPTED
Responsible Manager	Medical Director/Deputy Medical Director and all Divisional Medical Directors
Implementation Date	February 2022

Recommendation 1.4	The findings in this report indicate issues around patients being able to pay to see a Consultant privately and then receiving preferential treatment in the NHS. The Trust should consider whether these issues are isolated to this one Consultant or indicative of a wider cultural issue. The Trust should review and strengthen management of private patient procedures. As part of this process the new procedures should be shared with all relevant trust staff and roles and responsibilities should be reiterated where required. Specifically consulants must be reminded of their responsibility to ensure that all private work and change of status patients are declared. Consideration should be given as to how Radiology, Laboratories and Pharmacy can strengthen their processes, scrutiny and challenge of service requests that could potentially originate from the private sector.

Received from Dr Maria O'Kane on 01/04/22. Annotated by the Urology Services Inquiry.

Management Action	ACCEPTED
Responsible Manager	Assistant Director Systems Assurance,
Implementation Date	February 2022

Recommendation 1.5	As previously recommended in the 2019/20 Management of Private and Paying Patients audit report, Consultants should be instructed to complete the required declaration in relation to Private practice for the current year.
Management Action	**ACCEPTED**
Responsible Manager	Medical Director/Deputy Medical Director and all Divisional Medical Directors
Implementation Date	October 2021

Recommendation 1.6	The Change of Status process should be strengthened. Specifically: • The Change of Status form currently in use within the Trust for patients transferring from Private Practice to NHS must be reviewed and updated to include all relevant information including clear documentation of the reason for change. The effective date of change of status should be amended to the approved date for change of status and it should be clear on the form that the effective date of change will be the date that the form is approved by the agreed appropriate senior clinical and operational leads. The agreed appropriate senior clinical and operational leads should sign and date all change of status forms. Patients should only be added to the HSC waiting list when the change of status form has actually been signed and dated by the by the agreed appropriate senior clinical and operational leads. *Previously reported in 2019/20* • The Trust should increase scrutiny and challenge over Change of Status forms that have been completed and sent to the Private Patient Office. The Trust should appropriately enforce the stated condition on the Change of Status form, namely until the form is approved, the patient will remain private and may be liable for charges. *Previously reported in 2019/20*
Management Action	**ACCEPTED**
Responsible Manager	Assistant Director Systems Assurance
Implementation Date	February 2022

Recommendation 1.7	As previously recommended in the 2019/20 Management of Private and Paying Patients audit report, the Trust should develop a process to monitor change of status patients and to ensure that the process for changing status is effectively controlled and documented as an assurance that the delivery of service is equitable.

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	The Trust should implement the regional PAS code for patients transferring from private to NHS and develop a mandatory requirement to indicate changes of status on PAS. A printout from PAS should then be regularly reviewed and reconciled to Change of Status forms received.
Management Action	**ACCEPTED** The Trust have now set up two codes PHS & PTN, 1 for Inpatients and 1 for Outpatients. A report has been set up in Business Objects and shared with the Private Patient Officer to cross check. All secretaries have reminded of codes and when to use them.
Responsible Manager	Assistant Director Systems Assurance, Assistant Director Functional Support Services
Implementation Date	February 2022

Recommendation 1.8	The Trust should increase controls over prescription pads held in consulting rooms. These should be maintained as controlled stationery.
Management Action	**ACCEPTED**
Responsible Manager	Assistant Diector ATICS
Implementation Date	February 2022

Received from Dr Maria O'Kane on 01/04/22. Annotated by the Urology Services Inquiry.

2 REVIEW OF MR A's COMPLIANCE WITH RELEVANT PRIVATE PRACTICE GUIDANCE/AUTHORITIES – CHANGE OF STATUS PATIENTS

2.1 Change of Status Activity During the Period January 2019 to June 2020

The "Management of Private Practice in Health Service Hospitals in Northern Ireland: A Handbook – November 2007" requires that patients changing status from Private to NHS must have a Change of Status form completed by the consultant. The form must also detail the clinical priority for treatment as a health service patient. The Trust should be able to clearly identify these patients for monitoring purposes. It is important that the process of changing patient status is effectively controlled and documented as an assurance that the delivery of service is equitable.
The Trust's procedures and Change of Status form states "It is important to note that until the change of status form has been approved by the Medical Director, the patient's status will remain private and they may well be liable for charges."

Internal Audit requested all of Mr A's patient Change of Status forms for the period January 2019 to June 2020, from the cash office at Daisy Hill Hospital. Internal Audit were provided with the database which recorded 21 Change of Status Patients.

Internal Audit requested and reviewed the 21 Change of Status forms completed by Mr A from January 2019 to June 2020 and noted the following issues:

- 16 Change of Status forms had the Medical Director stamp on them as evidence of approval but it is not possible to establish who applied this stamp or the date it was applied.
- 4 Change of Status forms were still with the Medical Director at the 7 December 2020 awaiting approval. The dates that these patients transferred to NHS as per the change of status forms ranged from 2 - 14 months earlier than December 2020. Internal Audit were unable to establish when the forms were received in the Medical Directors Office.
- 1 Change of status form had been physically signed by the Medical Director, approximately 10 weeks after the effective Change of Status date.

2.2 Management of Patients Transferring from Private to NHS, Joining the HSC waiting list

Management of Private Practice in Health Service Hospitals In Northern Ireland: A Handbook (November 2007) states:
"A change of status from private to Health Service must be accompanied by an assessment, by the appropriate consultant, of the patient's clinical priority for treatment as a Health Service patient. It is important that any private patient who wishes to become a Health Service patient should gain no advantage over other Health Service patients by so doing."
"No patient should proceed –except in emergencies – to an investigation or treatment in a Health Service hospital until some mechanism has been applied which makes their status clear. Whichever system is introduced it must be capable of identifying the patient's status at every stage."

Internal Audit reviewed PAS data (provided by the Trust) for the 21 patients who changed status from private practice to NHS during the audit period January 2019 to June 2020. 13 of the 21 Change of Status forms related to day case or inpatient referrals and the remaining 8 forms were for outpatient appointments.

A range of issues were found in respect of Mr A's practice and administration of these 21 Change of Status cases (as outline below). However the issues also demonstrate the inadequacies in Trust monitoring processes around Change of Status patients and the limited control in the current process. The following issues were identified on review of the Change of Status forms:

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Approved Effective Change of Status Date

The date the patient is added to PAS as an NHS patient is the effective date as per the Change of Status form, not the date the Change of Status form was approved by Medical Director. *This is contrary to Trust's procedures and Change of Status form which state "It is important to note that until the change of status form has been approved by the Medical Director, the patient's status will remain private and they may well be liable for charges."*

On all 21 Change of Status forms, the effective date of transfer to NHS was the same as the date the patient was last seen privately.

Change of Status Patients who had Diagnostic (Radiology) Tests

In 10 of the 21 change of status cases, the patient had been referred for a diagnostic test (radiology) in the period 1 January 2019 to 30 June 2020:

- In 3 of the 10 cases, the diagnostic work was performed prior to the date of change of status. This diagnostic work was performed at a time when there was no referral on PAS for the patient ie whilst they were still a private patient.
  - One patient had a change of status date of 31/08/2019 – this patient had 2 imaging tests requested and performed in June 2019 whilst still private.
  - One patient had a Change of Status date of 09/11/2019 - this patient had 3 imaging tests requested and performed in June 2019 whilst still private.
  - One patient had a change of status date 09/11/2019 and had 1 imaging test requested in June 2019 with the test performed in July 2019 whilst still private.
- 5 of the 10 diagnostic tests were requested on the same date as the effective change of status date and the same date the patient was last seen privately (according to the Change of Status Form). Given that these Change of Status forms are unlikely to have been submitted and approved by the Medical Director on the same day as the patients' private appointments, these patients should potentially have been treated by the Trust as private patients.
- 2 of the 10 Change of Status patients had an exam/diagnostic test requested after the effective date on the Change of Status form (1 was 3 weeks, 1 was 4 months). However given the weaknesses in the Change of Status process, it is unclear if this NHS test was performed after the change of status was approved.

3 (including 1 of the 3 patients found to be private) out of the 10 patients were seen sooner than the Trust waiting time for the diagnostic/imaging test:-

- 1 of the 3 patients identified as private (above) was seen within 6 weeks against a waiting list of 21-32 weeks (at least 15 weeks earlier than Trust waiting time). This patient was seen in South Tyrone Hospital.
- For 1 patient the Trust waiting time for the imaging was 16-20 weeks and the patient had their imaging test within 5 weeks of request (at least 11 weeks earlier than Trust waiting time).
- For 1 patient the Trust waiting time was 5-10 weeks and the patient had their imaging test within 3 weeks of request (at least 2 weeks earlier than Trust waiting time).

Patients who changed Status and had Inpatient/Daycase Procedure

Out of the 13 Change of Status cases transferred into the NHS for an inpatient/day procedure, 5 had subsequently had their procedure. The other 8 patients, whilst added to waiting list, had not had their procedure as at June 2020.

Internal Audit in conjunction with Senior Trust staff reviewed the patient journeys of the 5 cases who have had their inpatient/daycase procedures. All 5 cases were classed as URGENT on PAS per the report received by Internal Audit.

As part of this audit review, a Trust Urology Consultant considered the waiting times for treatment in the context of the clinical priority and Trust standard waiting times. The Consultant advised that:

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- 3 cases were in line with Patient Target List (PTL) waiting times/ for the procedure for the relevant clinical priority.
- 2 of the 5 patients were not seen in line with the Trust waiting list time. The Trust Consultant Urologist assisting Internal Audit in this review considered that these cases were not Urgent/red flag procedures and were seen significantly sooner than other patients on the waiting lists:
  - Patient 1 - the time between being added to waiting list and the procedure taking place was 23 days (approx. 3 weeks). The PTL waiting times for the same procedure for Mr A patients at this time were between 15 weeks and 217 weeks so we can conclude this Change of Status patient was seen much quicker than other patients waiting on the same procedure.
  - Patient 2 - the time between being added to the waiting list and the procedure taking place was 12 days. The Consultant Urologist advised that given the symptoms, this patient was seen much quicker than other patients requiring the same procedure at that time.

Retrospective Entry to PAS
Through review of change of status patients on PAS, it was noted that two change of status forms had been added retrospectively to PAS:

- One patient was added to the waiting list from 09/09/2018 but this was not actually added to PAS until 12/05/2020. At December 2020 this Change of Status had not been approved by Medical Director.
- One patient had a Change of Status on 11/10/2019 however the patient was not added to PAS by the consultant secretary until 01/02/2020, 4 months after the Change of Status.

See section 6 for related registration issue.

2.3 Protected Reviews

Internal Audit understand from the Trust that most Consultants retain a number of protected review appointments at each of their outpatient clinics. These slots should be for patients that the Consultant needs to see urgently (for example cancer patients) however there is no documented Trust procedure around the use of protected review clinic slots. The Trust does not monitor the use of protected review appointments and there is a risk that private patients or Change of Status patients could potentially be seen quicker in a protected review appointment slot.

Internal Audit were advised that the central booking team at the Trust are responsible for booking new and review outpatient appointments. However Mr A's secretary was responsible for booking Mr A's Protected Review appointments.

Internal Audit have not specifically tested Protected Review bookings however we identified 1 case where a routine outpatient was seen in a protected review slot, 15 days after being added to the waiting list. Internal Audit queried this case with the Trust and the Consultant Urologist agreed that the protected review appointment had not been used for the correct purpose and therefore the patient would have been seen ahead of NHS patients with the same clinical priority.

2.4 Capturing and Invoicing of Private work Conducted on HSC Premises

In line with the "Management of Private Practice in Health Service Hospitals In Northern Ireland: A Handbook (November 2007)" Consultants have a contractual obligation to cooperate in recording all private outpatient and day patient attendances, treatments and procedures. The patient's records and referral forms etc should always be suitably marked. Records kept in departments away from the main outpatient area (e.g. x-ray, pathology and physiotherapy) should identify private patients.

As per Trust procedures no private activity was declared to the Cash Office in Daisy Hill Hospital during the audit period by Mr A and no invoices have been raised for private treatment – both indicating that Mr A did not perform private work on HSC premises.

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However, as outlined above, upon review of the 21 Change of Status Forms, Internal Audit noted cases whereby Mr A's Private Patients had received treatment in the NHS while still being a private patient.

Furthermore as described below, there are examples of patients seemingly switching several times between private and NHS and potentially receiving private treatment on the NHS, without declaration or charging. As per the *NHS A Code of Conduct for Private practice and* The Trust Change of Status Form – *"Consultants are reminded that in good practice a patient who changes from private to NHS status should receive all subsequent treatment during that episode of care under the NHS as outlined in A Code of Conduct for Private practice"*

In 5 of the 21 cases where a change of status form had been completed, the patient moved between NHS to Private to NHS for the same referral.

- In one case the patient had been under the care of another urology consultant within the Trust around the time of seeing Mr A privately.
- In one case from the review of PAS it was determined that the patient has seen a number of urology consultants and had been NHS and moved to Private and then subsequently transferred back to NHS.
- One patient had been seeing another Urology Consultant in 2018 and was called for a follow up outpatient appointment in July 2018 but didn't attend. It would appear that this patient then attended Mr A privately who completed a Change of Status form with an effective date of 17/08/2019.
- One patient had been under the care of the Trust at 31/01/2019 and was due for review at the end of 2019. This appointment was delayed and it would appear that this patient then attended Mr A privately who completed a Change of Status form with an effective date of 15/02/2020 and added the patient to the waiting list.
- One patient who had been added to the Elective waiting list for a procedure on 09/11/2019 (effective date of Change of Status) but had a consultation with Mr A in early March 2020 which is not on PAS. This patient would have had a procedure done in late March 2020 except for COVID-19 resulting in all elective procedures being cancelled from approximately w/c 16 March 2020.

Recommendations Specific to Review of Mr A's Practice:

Recommendation 2.1	The Trust should consider charging for the identified private activity. Internal Audit appreciate that this needs to be considered, and may not be feasible, in the wider context of a patient recall.
Management Action	**ACCEPTED** This has been considerd by the Trust and it was felt it would not be appropriate to charge these patients.
Responsible Manager	Medical Director
Implementation Date	July 2021

Received from Dr Maria O'Kane on 01/04/22. Annotated by the Urology Services Inquiry.

General Recommendations Regarding Trust Process:

Recommendation 2.2	The Trust should develop a written procedure around the use of protected review clinic appointments. The Trust should also introduce monitoring of compliance with the procedure.
Management Action	**ACCEPTED**
Responsible Manager	Assistant Director Functional Support Services and Operational ADs
Implementation Date	February 2022

Recommendation 2.3	Trust Guidance and Management of Private Practice in Health Service Hospitals In Northern Ireland: A Handbook (November 2007) should be re-issued and sign-off by doctors engaging in private practice. Where concerns are raised about a consultants' compliance, the Department of Health's framework *Maintaining High Professional Standards in the Modern HPSS should be followed*.
Management Action	**ACCEPTED**
Responsible Manager	Assistant Director Systems Assurance
Implementation Date	February 2022

Also see recommendations in section 1

Received from Dr Maria O'Kane on 01/04/22. Annotated by the Urology Services Inquiry.

3 REVIEW OF MR A's COMPLIANCE WITH RELEVANT PRIVATE PRACTICE GUIDANCE/AUTHORITIES – DATA ANALYSIS

Internal Audit completed data analysis using information provided by the Trusts Acute Informatics department. Internal Audit were provided with the following reports from PAS, TMS, Pre Operative Assessment Unit:

- Patient Level List of Elective Inpatient Admissions, Daycases and Regular Attenders for Mr A Date of Admission only between 01/01/2019 and 30/06/2020 from PAS
- Patient Level List of Outpatient Attendances (Including Outpatient Urodynamic Attendances) for Mr A Appointment Date only between 01/01/2017 and 30/06/2020 from PAS
- Patient Level List of Outpatient Urodynamic Attendances for Mr A Appointment Date Only between 01/01/2019 and 30/06/2020 from PAS
- Patient Level List of Imaging Exams Performed which were Requested by Referring Clinician Mr A Exams Performed between 01/01/2019 and 30/06/2020 from NIPACS
- Patient Level Report of Theatre Cases Carried out by Mr A – By hospital, theatre and operation date based on operation date between 01/01/2019 and 30/06/2020 from TMS.
- Pre-operative Assessment Database for Urology with the Trust Identifying Mr A's patient's for pre-op assessments performed between 01/01/2019 and 30/06/2020

3.1 Pre-Operative Assessments

All elective patients who require a General Anaesthetic whilst undergoing a procedure are required to have a Pre-Operative Assessment (POAs) to assess their fitness for surgery. The Trust deem the optimum time to complete a patients' POAs is between 13 weeks and approximately 3 weeks ahead of planned admission date for surgery. Consequently to ensure this happens in a timely manner and no patients scheduled for theatre are overlooked, it is essential that all elective theatre lists are prepared and notified to the POA team 6 weeks in advance of the theatre date.

Theatre rotas are compiled by the Head of Service for Theatres, detailing which surgeons have access to the theatres at each session. When Consultants become aware of the theatre rota they then select the patients for each list, any who require pre op should be sent to the pre op assessment unit. Mr A selected his own patients and arranged his own theatre lists. It is understood that Mr A would have provided his secretary with a list of patients to be booked into his theatre lists and she would have completed an "Arrange Admission List".

Completion of POA

According to Trust PAS report provided, during the period January 2019 to June 2020, there were a total of 1,096 elective procedures performed on 576 of Mr A's patients. In consultation with the Head of Urology and Pre-operative Assessment Manager, Internal Audit analysed a PAS report of all elective procedures performed on Mr A's patients during January 2019 to June 2020. With the Trust's expert input, we were able to eliminate procedures where a pre op assessment was not required from our analysis. These cases related to procedures done under a local anaesthetic; or where the patient had previous surgery and the previous POA was still valid.

For 351 of the 1,096 procedures performed by Mr A, a POA was required. In 86 (25%) of these 351 cases, a POA was not completed. Internal Audit reviewed these 86 cases with the Pre-Operative Assessment Manager and found:

- In 24 procedures, the patient was assessed upon admission rather than having a scheduled POA ahead of time. An appropriate POA in line with Trust requirements was not therefore conducted.
- 62 procedures required a POA for the procedure but this was not completed. In 2 of these procedures, the patient did not attend/complete their POA but a POA had been requested in both cases. Both patients underwent surgery nonetheless.

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Lack of POA as Potential Indicator that Patient was Seen Privately and then Treated in NHS

Internal Audit reviewed these 86 cases further from information on PAS and NIECR to establish if there was any information that pointed to these 86 cases being private patients. This work identified:

- In 49 procedures, the patient had an appropriate footprint on PAS.
- For the remaining 37 procedures, the patient had either no outpatient appointment (according to the PAS data provided by the Trust) or there was a short timeframe between being seen at an outpatient appointment and the date of surgery. Internal Audit selected a sample of 23 of these procedures for further analysis on PAS and NIECR in conjunction with the Head of Urology. In 22 of the 23 procedures whilst a pre-op assessment was required, the patient was not deemed to be private as they had come in initially through ED and been given date for surgery on discharge, another Speciality or another Consultant was involved in their care. 1 of the 23 procedures related to a private patient who was subsequently treated in the NHS. No Change of Status form had been completed.

Timeliness of POA

As outlined above, the optimum time for a patients' POAs to take place is between 13 weeks and approximately 3 weeks ahead of planned admission date for surgery. In effect, PoAs are valid for a period of 13 weeks pre-admission for surgery.

On review of 265 procedures where a POA was undertaken for Mr A's patients, Internal Audit noted:-

- There were only 8 procedures (3%) where the POA was conducted within the timescale required by the Trust, in advance of surgery.
- 252 procedures (95%) were added to the POA list less than 21 days before their admission:
  - 105 procedures (40%) were added to POA list 5 days or less before admission
  - 131 procedures (49%) were added to POA list 10 days before admission
  - 16 procedures (6%) were added to POA list between 11 and 20 days before admission
- In 5 (2%) cases, there was insufficient information to confirm the timeliness of the POA.

3.2 Elective Surgery With No Outpatient Appointment

From the PAS data received from the Trust Acute Information Department, Internal Audit joined elective surgery data in the period 01/01/2019 to 30/06/2020 to outpatient appointments in the period 01/01/2017 to 30/06/2020. The purpose of this analysis was to establish patients who had surgery but did not have an outpatient appointment potentially indicating that they may have been seen privately for an outpatient appointment by Mr A prior to surgery.

Note: We considered outpatient information for a longer period than the audit period to factor in the waiting list times.

We found that there is no record of a Trust outpatient appointment (either pre or post surgery) for 220 patients who had at least one elective procedure (total 284 procedures) between 1 January 2019 and 30 June 2020.

Where a patient had surgery and no outpatient appointment, the patient could potentially have been a private patient as the normal patient route for elective surgery is to be seen at an outpatient appointment and then if required, listed for elective surgery.

Internal Audit reviewed the 284 procedures where there was no recorded Trust outpatient appointment on PAS. With the expert input of Head of Service for Urology, 138 records were excluded from further analysis because the nature of the procedure did not involve the need for an outpatient appointment (for example stent replacement/removal); or the waiting time for the procedure appeared in line with Trust waiting list; or the patient (5 cases) was declared as a Change of Status patient.

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Out of the remaining 146 records, Internal Audit selected a sample of 54 records (relating to 50 patients) which the Head of Service for Urology then reviewed on PAS and NIECR, particularly considering whether referrals had been received for these cases and where patients had been seen in relatively short-timeframe that there were valid clinical reasons for this. Internal Audit then walked through 21 of these 50 patients with the Head of Urology to validate the data. This work identified:

- 1 patient who was initially referred by a GP in January 2018 but was then discharged from this referral on PAS in July 2019 to attend Mr A privately. This patient was added to Mr A's Day Surgery waiting list from the same date in July 2019 as an Urgent case. This was done retrospectively on PAS on 20 August 2019, approximately a week before the patient had their Pre-Op Assessment in late August 2019. The patient had their procedure in early September at CAH Day Surgery Unit, 2 weeks after being entered onto the waiting list on PAS (albeit the entry was made retrospectively to an earlier time in July). The Trust has advised that the normal waiting time for this procedure is 91 weeks.
  In effect, this patient changed from NHS to private and back to NHS in one day, with no Change of Status forms. This is a blatant breach of proper process and is an example whereby a significant advantage has been gained in terms of speed of treatment, by paying privately for an outpatient appointment.
  In the absence of an approved Change of Status form, this is arguably a private patient having a procedure using trust facilities and staffing.
- In 2 cases, there was no outcome letter completed for the procedure potentially indicating that the patient may have transferred back to the private sector for review. It should be noted that the Trust believe that these are poor administration issues rather than private patients.

3.3 Elective Surgery with an Outpatient Appointment

There were 812 records (356 patients) out of the 1,096 (576 patients) that had elective procedures who also had an outpatient appointment in the period under review.

From review of a sample of 29 of these patients, Internal Audit noted 4 occasions where the patient may have potentially been a private patient:

- 1 patient ([redacted]) who had been seen privately by Mr A in 2017 was then seen in 2020 in the Trust as an NHS patient. A change of status form had not been completed.
- 1 patient was under the care of another urology consultant on PAS but the patient was seen by Mr A. There was no rationale as to why Mr A became involved in the patient's care.
- 1 patient was seen within 2 days of a red flag referral. Internal Audit observed that as per a letter on NIECR, this patient was a [redacted].
- In 1 case, there was no outcome letter completed following the procedure, which potentially could be an indicator that the patient may have been reviewed privately following the procedure. It should be noted that the Trust believe that these are poor administration issues rather than private patients.

3.4 Other Observations

During the course of the audit, Internal Audit identified a number of other issues:

- There were 371 radiology diagnostic tests requested by Mr A from Urology Outpatients in the period 1 January 2019 to 30 June 2020 where the patient had no outpatient/surgical procedure, as per the PAS reports provided by the Trust. Upon further investigation and sample checking by Internal Audit in conjunction with the Head of Service for Urology, Head of Diagnostics and a Urology Consultant, it was identified that these cases were not all Mr A patients. When a junior doctors signs in with their own log-in into NIPACS (Sectra), their request will default to the last Consultant they ordered a scan on behalf of. The junior doctor should amend this to the name of the consultant they are actually making the request on behalf of, however Internal Audit was advised that this is not routine practice. Therefore scan requests are being attributed to

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consultants when the patient wasn't actually under their care. If a consultant makes the request themselves, this is not an issue as system maps directly to them it doesn't default to the last user. This means the audit trail on the system in terms of the requesting Consultant is incorrect in some cases and could mean that the test results go to the wrong Consultant, potentially creating a patient safety issue.

- The referral date on PAS, which is the date the referral of the patient is received by the hospital and will be the date the patient enters any relevant waiting lists, should not be changed however the date can be changed on the system. Internal Audit noted instances where the date had been changed, affecting the patient's position on the waiting lists. In the context of this audit, Internal Audit observed referral dates being changed to later dates rather than earlier dates.
- When a patient is entered onto PAS, a registration will be opened for the episode of care, this registration should be closed when a patient is discharged with their treatment complete. Open registrations on PAS should be reviewed on an ongoing basis. Instances were observed where the patient had been discharged but the registration had not been closed.
- Up to 2020 there was no mechanism for electronic signoff on NIECR. From 2020 this became available and is reportedly monitored however it is not routinely used across the Trust. Internal Audit queried how the Trust ensures that consultants are getting their own patient results – and where advised that there is a monthly check completed of all patients who are recorded as "DISCHARGE AWAITING RESULT" by Consultant secretaries. Internal Audit were advised that this is not conducted routinely. Internal Audit were advised that there 1,000 records on NIECR not signed off by Mr A.

General Recommendations Regarding Trust Process:

Recommendation 3.1	As previously recommended in the 2019/20 Management of Pre-Op Assessments audit report, Management should ensure all patients due for elective surgery have an up to date pre-operative assessment completed no more than 13 weeks ahead of planned admission date for surgery. Management should focus on improving processes in those specialties with higher volumes of exceptions including Urology.
Management Action	**ACCEPTED**
Responsible Manager	Assistant Director of ATICS
Implementation Date	September 2021

Recommendation 3.2	As previously recommended in the 2019/20 Management of Pre-Op Assessments audit report, Management should review processes to ensure all private outpatients transferring to NHS inpatient waiting lists are promptly notified to the Pre-operative Assessment team.
Management Action	**ACCEPTED**
Responsible Manager	Assistant Director of ATICS
Implementation Date	September 2021

Recommendation 3.3	The Trust should liaise with BSO in order to resolve this referring Consultant recording error in the NIPACS system.
Management Action	**ACCEPTED**

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Responsible Manager	Director Performance & Reform
Implementation Date	February 2022

Recommendation 3.4	The processes for registration should be reviewed and training given to all appropriate staff on the correct use of PAS, including consultant secretaries.
Management Action	**ACCEPTED**
Responsible Manager	Assistant Director Systems Assurance
Implementation Date	February 2022

Recommendation 3.5	The processes surrounding electronic and manual sign off and review of the **"DISCHARGE AWAITING RESULT"** should be strengthened and monitored.
Management Action	**ACCEPTED**
Responsible Manager	Assistant Medical Director Clinical Directors and Assistant Operational Directors
Implementation Date	February 2022

See also recommendation 1.4

4 INTERACTION OF MR A's PRIVATE WORK WITH HSC SERVICES AND FACILITIES

A Code Of Conduct For Private Practice - Recommended Standards Of Practice For HPSS Consultants (November 2003) states that HSC facilities, staff and services may only be used for private practice with the prior agreement of the HSC employer.

Internal Audit were advised by the Trust that Mr A's private practice did not interact with HSC services and facilities. However as per the findings in this report, there are a number of issues and exceptions that would indicate a degree of interaction – particularly for services that could not be performed or delivered from Mr A's home practice.

The queries around the timing of changes of status outlined in this report, mean there is a risk that Trust staff have been involved in the administration or treatment of patients that should have been categorised as private.

General Recommendations Regarding Trust Process:

See recommendations in section 1-3

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5 CRAIGAVON UROLOGICAL RESEARCH EDUCATION (CURE)

In line with the Terms of reference of this review, Internal Audit also considered whether the Trust has any involvement with CURE - Craigavon Urological Research & Education, to understand if there was a flow of money into the Trust and to check, as much as is possible from review of Trust records and engagement with Trust staff, whether any Directors/staff benefited from the operation of the company.

According to the Companies House website/Articles of Association, a previous Trust Chairperson and Mr A set up CURE in 1996 as a 'Charitable Company Limited by Guarantee and not having Share Capital'.

The objectives of CURE are:

- To advance education for the public benefit in Urological disorders.
- Conducting and commissioning research into Urological disorders and the effective treatment of persons suffering from Urological disorders and to disseminate the useful results of such research.
- Raising public awareness and understanding of Urological disorders and their treatment and promoting training in the treatment of Urological disorders.

The CURE committee is currently made up of Mr A and three other people - 2 of whom are current Trust employees (1 Consultant Urologist and 1 Specialist Nurse in Health Promotion). The CURE committee secretary is a previous Trust employee.

Whilst these Trust staff are members of the CURE Committee, Internal Audit were advised by Senior Trust staff that their role should be separate and independent from their roles in the Trust. Internal Audit met with the two Trust staff who are currently on the Committee of CURE who both confirmed that their role within CURE is entirely independent of their job with the Trust. The Trust advised of some historical Trust involvement with CURE (pre-creation of SHSCT) including preparation of CURE accounts. Internal Audit also note that the registered office of CURE (until July 2012) was on the Craigavon Area Hospital site.

From discussion with Trust Management and Trust staff involved with CURE, there is no indication of any flow of money into the Trust or Trust involvement in fund raising in recent years.

Internal Audit understands from the Committee members that Trust staff may apply to CURE for funding. A written request is completed and will be reviewed/approved by the CURE committee. If approval is granted by the Committee, the staff member will pay for the course and on submission of relevant paperwork invoices, a cheque from the CURE bank account is made payable to the applicant.

It should be noted that Internal Audit did not have access to CURE financial records as part of this review and therefore do not have visibility over payments made by CURE to Trust staff.

Trust procedures do not provide guidance in respect of staff involvement in independent organisations with a potentially perceived affiliation to the Trust by their nature.

General Recommendations Regarding Trust Process:

Recommendation 5.1	The Trust should remind staff that all donations received from the public in respect of their care should be lodged to the Trust's Charitable Trust Funds only and that staff are not permitted to use their position of employment within the Trust to advance personal interests, causes or charities as it could give rise to

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	reputational damage to the Trust.
Management Action	ACCEPTED
Responsible Manager	Director of Finance
Implementation Date	December 2021

Received from Dr Maria O'Kane on 01/04/22. Annotated by the Urology Services Inquiry.

Note to Report

This audit report should not be regarded as a comprehensive statement of all weaknesses that exist. The weaknesses and findings set out are only those which came to the attention of Internal Audit staff during the normal course of their work. The identification of these weaknesses and findings by Internal Audit does not absolve Management from its responsibility for the maintenance of adequate systems and related controls. It is hoped that the audit findings and recommendations set out in the report will provide Management with the necessary information to assist them in in fulfilling their responsibilities.

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Number	Responsible	Recommendation	Date for Completion	Revised Date for Completion	Update 01.03.2022
Recommendation 1.1	Medical Director and Director of Acute Services	The Trust should review Mr As job plan and actual APAs worked in order to ascertain if overpayments have occurred, and seek recompense if required.	Oct-21	Complete	Surgical Division undertook a review of Mr As job plan and did not find any overpayment
Recommendation 1.2	Medical Director/Deputy Medical Director and all Divisional Medical Directors	As previously recommended in the 2019/20 Management of Private and Paying Patients audit report and as per the 'Code of Conduct for Private Practice - recommended standards of practice for HPSS consultants (November 2003)', the Trust must ensure that: • All consultants have an annual job planning review. • All consultants completing private practice declare any private practice and as part of the annual job planning process, consultants should disclose details of regular private practice commitments, including the timing, location and broad type of activity, to facilitate effective planning of HPSS work and out of hours cover. • As part of the job planning process, the Trust should consider total working hours across HSC and private practice. Job plans should be signed and dated by the consultant and their Clinical Director.	Feb-22	Jul-22	As part of ongoing medical leadership review and strengthening exercises the following has been actioned: • Clinical directors will have an increased focus on ensuring compliance with job planning processes including ensuring that job planning considers the whole of a clinicians practice and any potential impact of private work activities on their Trust commitments. • A memo has been issued by the Medical Director regarding the Trust 'Declaration of Private Practice' which is to be completed by all substantively employed medical staff for return to the Medical Revalidation team stating if private practice is undertaken in addition to HSC employment. • The declaration requires confirmation that any private patient work must be included within their job plan and declared as soon as possible. • This memo also reminded all staff of the importance of completion of an Annual Declaration on Private Practice (including those doctors who do not undertake private practice) and all clinicians undertaking private practice must have read and are familiar with Regional Guidance and the Trust Private Patient Guidance as per private practice declaration requirements. • In support of our work to strengthen governance arrangements around private practice, the Trust Appraisal round for 2021 incorporates a structured reflective template for those doctors who undertake private practice. A pilot of a structured reflective template for this purpose has been developed and isued to staff for consideration. • As part of the Trust's commitment to strengthen and improve professional governance processes, from 2022 onwards regular routine audits will be completed. • Job planning for 2020/21 is currently 89%: The Revalidation Team are actively pursuing follow up to achieve the expected 100% compliance.
Recommendation 1.3	Medical Director/Deputy Medical Director and all Divisional Medical Directors	The Trust should strengthen their management arrangements in scenarios where a Consultant declares that they conduct private outpatient work only, specifically where the work is carried out outside the NHS including premises not regulated by RQIA. The following specific measures are suggested: • Assurances should be sought as to how associated diagnostics/subsequent required treatment are managed. • Medical Director approval should be introduced in the event that Consultants conduct outpatient work privately. • Trust monitoring processes should be alert to ensuring Change of Status patients are placed on the waiting list based on clinical priority. • The Trust "Declaration of Private Practice" form should be amended to clearly identify the type of private practice undertaken (ie outpatient/daycases/inpatients). Trust management should review these declaration as and triangulate the information with appraisals and job plans.	Feb-22	Jul-22	As part of our work to strengthen governance arrangements in relation to the Trust Appraisal and Revalidation process will for Appraisal round 2021 incorporate a structured reflective template for those doctors who undertake private practice. This template requires the clinician to detail volume and type of private practice completed over previous 12 month period including private practice location, inclusion in job plan, governance arrangements and scope. A pilot of the proposed structured reflective template for this purpose has been completed: Feedback from this pilot has been taken and implemented. Alongside side the structured reflective template, a reflective practice guidance sheet has been developed to assist in the completion of whole practice reflection for Appraisal. In addition, all staff have been reminded of the importance of: • The completion of Structured reflective template incorporating private practice as per guidance sheet • The completion of the Annual Declaration on Private Practice (including those doctors who do not undertake private practice) • Clinician's undertaking private practice have read and are familiar with Regional Guidance, Trust Private Patient Guidance and other associated documentation as per private practice declaration requirements. The declaration of private practice has been amended to ask clinician to confirm the following: • Where private practice is undertaken and type of private practice • Laboratory tests are not forwards to the Trust laboratory • Have read and understood Trust guidance on paying and private patients • Have read and understood regional guidance • Use of medical sectaries in private/ paying patient work is completed outside of NHS working time and prior approval is required • Any private patient work must be declared and included in job plan Work is in progress in to ensure mechanism are robust in relation to change of status patients to ensure equitable provision of NHS services. This has included the creation on an electronic change of status form that should be completed in respect of all private patient transfers including priority rating. It is proposed once this has been submitted the clinical director, who will have speciality oversight in relation to waiting list priority, can raise issue where required in relation to appropriateness of change of status and clinical priorities. An audit proposal has been created to provide assurance around these processes. This is pending agreement with Finance and Support Services to commence.
Recommendation 1.4	Assistant Director Systems Assurance	The findings in this report indicate issues around patients being able to pay to see a Consultant privately and then receiving preferential treatment in the NHS. The Trust should consider whether these issues are isolated to this one Consultant or indicative of a wider cultural issue. The Trust should review and strengthen management of private patient procedures. As part of this process the new procedures should be shared with all relevant trust staff and roles and responsibilities should be reiterated where required. Specifically consulants must be reminded of their responsibility to ensure that all private work and change of status patients are declared. Consideration should be given as to how Radiology, Laboratories and Pharmacy can strengthen their processes, scrutiny and challenge of service requests that could potentially originate from the private sector.	Feb-22	Jul-22	The Trust is in the process of reviewing its private practice guidance and reporting processes to identify any non-compliance. The proposed electronic change of status form will be reviewed by the relevant Head of Service and Clinical Director. As part of the revised medical declaration process consultants are required to assure they are aware of the parameters of which their private practice should be conducted within. The importance of clinicans ensuring each private patient referred to an elective service has an appropriate formal referral letter submitted via the Trust Referral and Booking Centre using the same process as all NHS referrals. Each referral must be clearly marked 'PRIVATE TO NHS TRANSFER'. Private patients should not join a waiting list via any other entry point including being directly booked by secretarial staff. An audit proposal has been created to provide assurance around these processes. This is pending agreement with Finance and Support Services to commence. Once processes have been finalised a series of information roadshows will be offered to inform consultants of changes and to remind all of their responsibility pertaining to private patients. Pharmacy have a good process for charging identified private patients working in conjunction with the private patient officers and the cashiers. This relies on others to identify that the patient is private and inform Pharmacists. If there was no 'history' on patient centre when a specialist script has been submitted, this would be raised with the consultant's secretary to check if it could be a private case. It is not feasible to check if each discharge or outpatient script received is private or NHS, so can reult in supplying to a private patient. To scope if ECM/electronic discharges and paper scripts could have a tick box for the prescriber to confirm that the patient is eligible - HSCB require prescribers to confirm that on their IFR drug applications. Radiology and Laboratories - current considering how to strengthen their process as per 3.3

important for the purposes of the Inquiry because it raises a compliance issue. There are rules associated with the management of private patients into the NHS, just as there are rules about triage, there are rules about whether you retain records at home, there are rules about dictation. You are bringing your concerns to a medical manager in the form of Mr. Young and it's your view that the matter was not effectively handled. Mr. Young, just in fairness, I should say, has accepted candidly in his evidence that he dropped the ball, to use his expression, around this, that he should have taken steps; he should have, perhaps, escalated it to more senior management. 10:10 10:11

Can I ask you this: Has anything changed within the Southern Trust Urology Service? If a senior clinician, one of your colleagues, was today being seen to be breaking any of those rules or potentially breaking any of those rules - it might be private patients, it might be any of the other practice areas that I've referred to - have you confidence that it would be better addressed? 10:11 10:12

A. So if you look at this private patient issue here, yes, there is a procedure that was supposed to be followed. If a patient transfers into NHS care, a patient transfer form was supposed to be filled and I don't believe any were filled in at this point by Mr. O'Brien. We know that that procedure has been tightened up within the Trust. There is a -- I know 10:12

that my colleagues who undertake private practice, when they transfer the patients in for NHS care, are completing that form. That form is collated through a central -- I think it is linked to the Medical Director's office. There are audits that are undertaken to check that they have gone through the right steps. In terms of the expediting or bringing people ahead of patients who have been waiting longer for the same procedure, if we look within Urology, we, as a team, function from a pooled waiting list. While someone may be added to the list under my name, that doesn't mean that they are getting their operation under me. They will get their operation when they come to the top of the waiting list by an appropriately trained clinician on the next available list. We have a scheduler who plans and schedules our list rather than us having a direct point. So the ability for a consultant to transfer a patient from their private practice into NHS care and then on to their next operating list is much more limited. 10:13 10:13 10:13 10:14

9 Q. Okay, that's helpful. That's a response centrally to the private patients points. But a little more broadly, as was the focus of my question, the mischief here I'm identifying is -- and, as I say, it is not just private patients, the evidence seems to suggest that it's divergence or compliance issues across a number of practice areas; management, whether operational or professional, knew about them but the private patients example, in your own words, is an 10:14

supporting information that comes into the appraisal process. I think there was perhaps some difficulty reflected on Mr. Young during the early stages of the appraisal process, in terms of his accessing all of the information that might have sounded on Mr. O'Brien's appraisal. There is a, I thought curiously within the appraisal materials, a process for dealing with paying and private practice. Why - I use the word "shoehorn", why is that shoehorned in there? 11:25

A. Well it takes us back to the 2017 Action Plan that came out of the Maintaining High Professional Standards Review in relation to Mr. O'Brien, and the concerns that were raised at that point in time about paying and private practice patients because, again, one of the things that we knew, and was subjected internally to an internal audit that we requested, was about the process of all of this and how private patients were dealt with across the Trust in terms of the interface between the private sector and the public sector. And, again, we did not have clear lines of sight in relation to all of that in terms of who had started off their journey as a private patient and who didn't, you know, in relation to Mr. O'Brien's practice at that point in time, and we were concerned that that was exposing medical staff in particular to probity issues. So, on the basis of all of that we now have a much more robust system in terms of picking those patients up, having them signed off by the Clinical Director and Head of Service as they come into the system, so that we know where they've started 11:26 11:26 11:27 11:27

their journey and we know that their information may not be within our system in terms of holding that together and making sure that they are not either prioritised or disadvantaged because they have started off in a private capacity. 11:27

74 Q. Thank you for that. So I'll leave appraisal now. 11:30, time for a short break?

CHAIR: Yes. We'll come back at a 11:45.

THE HEARING ADJOURNED FOR A SHORT PERIOD AND RESUMED AS FOLLOWS: 11:28

CHAIR: Thank you everyone. Mr. Wolfe.

75 Q. MR. WOLFE: Just continuing along the theme of the steps taken to enhance the ability on the part of, I suppose, the Senior Leadership Team to get to grips with what's going on with individual practitioners within the services generally from a medical professional governance perspective. Your witness statement, or one of them, reflects upon sort of initiatives that you either constructed or carried forward when you were a Medical Director in the Trust, and in particular you refer to fortnightly meetings with Divisional Medical Directors. 11:47 11:47

A. Mm-hmm. 11:48

76 Q. So that was the group of Medical Directors, or, sorry, the group of Divisional Medical Directors meeting with you, and then as Medical Director again scheduling monthly one-to-one meetings with each of the Divisional

Business Services Organisation

Southern Health & Social Care Trust

Management of Private & Paying Patients 2019/20

nqa ISO 9001 Registered Quality Management

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Acknowledgement

Internal Audit wishes to thank management and staff at the Southern HSC Trust for their assistance and co-operation during the course of the audit engagement.

Control Log

Exit Meeting Held On:	None held (due to corona virus)
Working Draft Report Issued On:	10 April 2020
Management Meeting Held On:	None held (due to corona virus)
Management Actions Received:	5 October 2020
Second Draft Issued On:	6 October 2020
Final Report Issued On:	7 October 2020

Distribution List

Shane Devlin	Chief Executive (Final Only)
Helen O'Neill	Director of Finance, Procurement and Estates
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Alison Rutherford	Assistant Director – Financial Accounting
Melanie McClements	Acting Director of Acute Services

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

Introduction

In accordance with the 2019/20 Annual Internal Audit Plan, BSO Internal Audit carried out an audit of Management of Private & Paying Patients during February and March 2020. The last Internal Audit of this topic was performed during January 2015 when a follow up review was conducted of the 2013/14 report of this topic when limited assurance was provided.

Medical Consultant staff have the right to undertake Private Practice and Fee paying services within the Terms and Conditions of the Consultant Contract (2004) as agreed within their annual job plan review and with the approval of the Medical Director. Within the Trust, Consultants are only permitted to undertake private outpatient work.

A Patient cannot be both a Private and an HSC patient for the treatment of the one condition during a single visit to an HSC hospital. However a private patient at an HSC hospital is legally entitled to change his/her status for any a subsequent visit and seek treatment under the HSC, subject to the terms of any undertaking he/she has made to pay charges. A change of status from Private to HSC must be accompanied by an assessment of the patient's clinical priority for treatment as an HSC patient.

The focus of this audit was to establish the extent of the Trust's awareness of consultants private work through the job plan process and their private patient identification and management processes. This included review of completion of change of status paperwork and ensuring that patients were placed on the waiting list at the correct point following approval of the change of status by the Medical Director.

In addition Internal Audit undertook review of patients accessing social care services to establish what processes were in place for the identification of these patients and the potential savings to the Trust through costs not incurred due to early notification or identification of these patients.

Scope of Assignment

The scope of this audit was to review the Trust's awareness of consultant's private work, though the job planning process, and their private patient identification and management processes and how change of status from private to HSC is identified and managed. Processes around identification of patients accessing social care provision were also reviewed.

The audit was based on the following risks:

- Risk that private patients/change of status patients are not entering the waiting list at appropriate points and that all Private and Paying Patients
- Risk that patients are accessing social care services they are not eligible to obtain.

The objectives of this audit were:

- To establish the extent of SHSCT's awareness of consultants private work, through the job plan process and their private patient identification and management processes.
- To establish the extent to which consultants private work interacts with HSC services and facilities
- To ensure that patients that change status (private/HSC) have done so through adherence with the relevant guidance.
- To ensure that Category II income is identified and collected.
- To ensure that there are appropriate mechanisms in place to identify patients who may not be eligible for social care provision within the Southern Trust.

The audit did not review debt in relation to private patients.
Note: We report by exception only, and where no issues and recommendations are made, the result of our work indicates that the key objectives and risks are being managed and that procedures are being adequately adhered to.

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Level of Assurance

Limited

There are significant weaknesses within the governance, risk management and control framework which, if not addressed, could lead to the system objectives not being achieved.

Executive Summary

Internal Audit can provide Limited assurance in relation to the Management of Private Medical Practice (including patient change of status processes). This assurance has been provided on the basis that the Internal Audit has identified issues with Consultant compliance with relevant guidance around private practice. Significant issues were identified with the timing and completion of change of status paperwork, when patients transferred from private to HSC care. There is no mechanism to monitor that patients who have changed status were treated equitably with HSC patients when added to waiting lists. The timing of changes of status also gives rise to queries over whether some HSC care should actually have been treated as private activity.

There are 2 significant findings in this report that impact on the assurance provided:

1. The Trust does not have a process in place to monitor change of status patients and to ensure that the process for changing status is effectively controlled and documented as an assurance that the delivery of service is equitable. The Patient Administration System (PAS) does not require a change of status to be recorded on the system although there is a code which can be used.
2. Change of status forms are not signed by the Medical Director, instead a stamp is applied and the forms are not dated. Patients are added to the HSC waiting list based on effective date recorded on the change of status form not based on when the Medical Director approves the transfer. In some instances reviewed by Internal Audit, this resulted in patients having had their outpatient appointment, diagnostic test or inpatient procedure prior to Medical Director approval of change of status.
   Consultants are not always recording the clinical priority on the change of status form ie (Red Flag, Urgent or Routine) therefore it is not possible to readily establish that the patient has been placed on the waiting list at the correct point. The Change of Status forms are stamped rather than being signed by the Medical Director.
   For 2 of the specialities reviewed Cardiology and Dermatology there had been no change of status forms completed in the 2019/20 financial year. Whilst this may be correct, the Trust should consider whether there is activity that is not being captured.

The other key findings of the audit are:

3. Declarations in relation to undertaking private medical practice are completed retrospectively as they are completed as part of the appraisal process within the Trust rather than as part of the job planning process. At the date of internal audit, the declarations had only been completed for the 2018 year. 12 of the 19 job plans reviewed had not been updated from January 2019 (7 of the 12 were dated 2018, 2 were dated 2017 and 3 were dated 2016). Whilst the job plans reviewed identified private practice, this did not detail where the private practice was undertaken
4. It is the responsibility of the Consultant to ensure that the Trust is reimbursed for all costs associated with category II work and private outpatient attendances. The Consultant must pay for any costs and then reclaim from the third party. The Consultants are required to make a quarterly declaration to the PPO of the number of patients seen to enable invoicing. However at the date of audit in review of returns for April to September 2019, 7 of sampled 16 consultants had not submitted a return for Quarter 1 (April to June 2019) a further 13 had not submitted a return for Quarter 2 (July to September 2019) - this was despite reminders from the cashiers office and escalation to the Medical Director.
5. Where patients access social care in the Southern Trust, they have to prove that they are eligible or resident in the Trust area. The Access to healthcare team in the Trust work with community teams to ensure that provision is appropriate. In 2 cases where early identification had not occurred the total cost to the Trust was in the region of £200K. There is currently no way of recording potential savings in these cases.

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6. Trust procedures in relation to Private Medical Practice are currently held in draft format and have not been approved by the LNC or SMT.

There are no other findings in this report

Summary of Findings and Recommendations

Finding		Number of Recommendations		
		Priority 1	Priority 2	Priority 3
1.	Recording of Change of Status Private to NHS on PAS	-	4	-
2.	Review of Change of Status Forms	-	2	-
3.	Job Planning and Appraisals	-	3	-
4.	Category II Income	-	1	-
5.	Residency and Provision of Social Care Costs Not Incurred	-	2	-
6.	Private Medical Practice Procedures	-	1	-

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Detailed Findings and Recommendations

1 Recording of Change of Status Private to NHS

Finding

As required by *Management of Private practice in Health Service Hospitals in Northern Ireland: A Handbook – November 2007",* the Trust does not have a process in place to monitor change of status patients and to ensure that the process for changing status is effectively controlled and documented as an assurance that the delivery of service is equitable.

The Patient Administration System (PAS) does not require a change of status to be recorded on the system although there is a code which can be used. The change of status may be entered in a free text field which is not a mandatory field. This means that a PAS report cannot be run showing all change of status patients. Therefore it is difficult to monitor the completeness of change of status declarations and retrospectively ensure patients who have changed status are placed on the appropriate place on waiting lists etc. The Trust does not have a process in place to ensure all change of status patients have been identified for monitoring purposes and to ensure that the process for changing status is effectively controlled and documented as an assurance that the delivery of service is equitable.

Change of status referrals where diagnostic tests are required change of status forms are not completed are not completed, captured, monitored or recorded. All requests for diagnostic tests for patients changing status from private to NHS are ordered directly by the refer using the same process/form as for NHS patients.

There is currently no process in place for reviewing the practice of 'consultant to self' referrals, this is potentially where a significant number of patients changing from Private to NHS may occur.

The Trust operates a central booking system for all outpatient appointments. Internal Audit reviewed 55 referrals for outpatient appointments and noted:

- There were 9 cases where the appointment was booked directly by the Consultant's secretary, and did not come through the central booking centre.
- There was one case where the appointment was actually booked onto PAS after the patient had been seen. This appointment had been booked and recorded on PAS by the Consultants secretary.
- There were two cases where referral was routine and stayed routine after triage, however both received appointments less than 4 weeks after being initially referred.

Implication

Patients who change their status from Private to HSC are not being accurately captured and monitored on PAS, NIPACS etc.

Recommendation 1.1	The Trust should develop a process to monitor change of status patients and to ensure that the process for changing status is effectively controlled and documented as an assurance that the delivery of service is equitable. There should be a mandatory requirement to indicate changes of status on PAS. A report from PAS should then be regularly reviewed and reconciled to Change of Status forms received.
Priority	2
Management Action	**ACCEPTED** Southern Trust will review the current processes to ensure staff are aware of the requirement to use the newly available PTN code to identify patients being transferred from the Private sector to the NHS. This will allow reconciliations to take place.
Responsible Manager	Assistant Director – Workforce and Education/Assistant Director – Functional Support Services

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

Implementation Date	May 2021

Recommendation 1.2	To further enhance control, there is a case for reviewing the practice of 'consultant to self' referrals, from the private sector and introducing additional controls where a consultant does refer to self.
Priority	2
Management Action	**ACCEPTED** This will be reviewed to ensure that this code is only being used for the correct purpose.
Responsible Manager	Private Patient Office
Implementation Date	May 2021

Recommendation 1.3	Service Directorates and in particular specific services such as Radiology, should strengthen their scrutiny and challenge of service requests that could potentially originate from the private sector. Service areas should be particularly alert where services/treatments are only available on the HSC.
Priority	2
Management Action	**ACCEPTED** Consideration will be given to a process which may flag up when these circumstances arise, for a process of spot checking by appropriate managerial staff.
Responsible Manager	Assistant Director – Cancer and Clinical Services, Assistant Director – Workforce and Education
Implementation Date	May 2021

Recommendation 1.4	The Trust should ensure the Integrated Elective Access Protocol (IEAP) is adhered to for all appointments. The Trust should review and monitor non adherence to the IEAP and central booking process, with a view to providing training where required and enforcing the central role of the Appointments/Booking Office. Where Consultants ask for fixed appointments to be made for patients out of chronological order, this should be captured and monitored. The Trust should consider whether this is due to clinical need, consultant preference/practice, or potentially inequitable practice.
Priority	2
Management Action	**PARTIALLY ACCEPTED** All key staff will be communicated with, reminding them of the need to adhere to the IEAP. However, to put in place a mechanism for monitoring and capturing every appointment requested, to identify its chronological status, may not be feasible within existing resources. However, this will be considered
Responsible Manager	Assistant Director – Workforce & Education/Assistant Director – Functional Support Services
Implementation Date	May 2021

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

2 Review of Change of Status Forms

Finding

The Trust's procedures in relation to Change of Status states *"Where a change of status is required an 'Application for the Transfer of Private Patient to NHS Status Form' must be completed and sent to the Paying Patients Officer. This includes the reason for the change of status. The Paying Patients Officer will ensure that the Medical Director approves the change of status request. It is important to note that until the change of status form has been approved by the Medical Director the patient's status will remain private and they may well be liable for charges"*

Internal Audit reviewed Change of Status forms completed in the period 1 April to 31 December 2019 for the specialities of Cardiology, Dermatology and ENT and noted the following issues:

- For 2 of the specialities reviewed Cardiology and Dermatology there had been no change of status forms completed in the 2019/20 financial year. However, in review of job plans consultants in these 2 specialities had confirmed that they were undertaking Private Medical Practice.
- Change of status forms are not signed by the Medical Director - a stamp is applied and these are not dated. Patients are added to the HSC waiting list based on effective date recorded on the change of status form not based on when the Medical Director approves the change. In some instances reviewed by Internal Audit this resulted in patients having had their outpatient appointment, diagnostic test or inpatient procedure prior to Medical Director approval of change of status.
- Consultants are not routinely recording the clinical priority on the change of status form ie (Red Flag, Urgent or Routine) therefore it is not possible to readily establish that the patient has been placed on the waiting list at the correct point. In review of forms it was noted that the Medical Director stamp was applied even where no clinical priority had been recorded.

Implication(s)

There is limited control over the patient Change of Status process, increasing the risk of inequitable treatment in comparison to HSC patients regarding placement on waiting lists.

Recommendation 2.1	The Trust should increase scrutiny and challenge over Change of Status forms that have been completed and sent to the Private Patient Office. The Trust should appropriately enforce the stated condition on the Change of Status form ie "*NB: until this form is approved by the Medical Director the patient will remain private and may be liable for charges".*
Priority	2
Management Action	**ACCEPTED** The Medical Directors Office will introduce alternative processes for approving the Change of Status Form, with the delegation of the approval function to senior clinical managers within the team
Responsible Manager	Deputy Medical Director
Implementation Date	May 2021

Recommendation 2.2	The Medical Director should sign and date all change of status forms. Patients should only be added to the HSC waiting list when the change of status form has actually been signed and dated by the Medical Director.
Priority	2
Management Action	**ACCEPTED** The Medical Directors Office will introduce alternative processes for approving the Change of Status Form, with the delegation of the approval function to senior clinical managers within the team
Responsible Manager	Deputy Medical Director
Implementation Date	May 2021

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

3 Job Planning and Appraisals

Finding

As part of the Annual Job Planning process, consultants should advise of any private work they currently undertake and whether this is completed inside or outside the Trust. In addition consultants as part of their Trust appraisal process, must sign a declaration in relation to private work they undertake. A NIL return should be submitted by consultants who do not undertake private work. At the date of internal audit, the declarations had only been completed for the 2018 year.

Internal audit obtained Job Plans and Private Patient Declarations for the 19 Consultant Medical staff in the Specialities of Cardiology, Dermatology and ENT.

9 of the 19 consultants had recorded that they were undertaking Private Medical Practice on their most recent job plan. In comparison to the Revalidation Team register of Consultants undertaking private medical practice, the following discrepancies were noted:-

- 2 cases who had stated that they did not undertaken private practice on their job plan were recorded on the register as undertaking Private Medical Practice and had submitted declarations.

12 of the 19 job plans reviewed had not been updated from January 2019 (7 of the 12 were dated 2018, 2 were dated 2017 and 3 were dated 2016). Whilst the job plans reviewed identified private practice, this did not detail where the private practice was undertaken.

Implication(s)

Not all Consultant Private Practice may be being captured within the Trust.
Job plans are not updated on a timely basis to accurately reflect current working patterns.

Recommendation 3.1	The Trust should review and update all consultant job plans in line with the annual job planning process. This should include all details of private practice carried out. As part of this job planning process the Trust should consider' total working hours across HSC and private practice.
Priority	2
Management Action	**ACCEPTED** All Medical Managers will be communicated with, to ensure this recommendation in relation to job planning is complied with during the next annual round of job planning
Responsible Manager	Deputy Medical Director/Assistant Director – Workforce and Education
Implementation Date	May 2021

Recommendation 3.2	As per the Code of Conduct for Private Practice - recommended standards of practice for HPSS consultants (November 2003), the Trust must ensure that: • All consultants have an annual job planning review. • All consultants completing private practice declare any private practice as part of the annual job planning process, consultants should disclose details of regular private practice commitments, including the timing, location and broad type of activity, to facilitate effective planning of HPSS work and out of hours cover. Job plans should be signed and dated by the consultant and their Clinical Director.
Priority	2

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

Management Action	**ACCEPTED** All Medical Managers will be communicated with, to ensure this recommendation in relation to job planning is complied with during the next annual round of job planning
Responsible Manager	Medical Director/Deputy Medical Director/All AMDs
Implementation Date	May 2021

Recommendation 3.3	Consultants should be instructed to complete the required declaration in relation to Private practice for the current year.
Priority	2
Management Action	**ACCEPTED** All Medical Managers will be communicated with, to ensure this recommendation in relation to job planning is complied with during the next annual round of job planning
Responsible Manager	Medical Director/Deputy Medical Director/All AMDs
Implementation Date	May 2021

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

4 Category II Income

Finding

Category II work includes investigations or tests for non-clinical reasons for example medical examinations for life insurances or x-rays on behalf of insurance companies. Where Consultants use HSC services, accommodation or facilities in carrying out category II work, a fee is payable to the Trust. Similarly, where a Consultant has seen private outpatients on Trust premises, an accommodation fee is payable to the Trust.

It is the responsibility of the Consultant to ensure that the Trust is reimbursed for all costs associated with category II work and outpatient attendances. This includes the cost of the room and the cost of any tests undertaken. The Consultant must pay for any costs and then reclaim from the third party. The Consultants are required to make quarterly declaration to the PPO of the number of patients seen to enable invoicing, a nil return should be submitted where no patients have been seen. In review of quarterly returns for April to June and July to September 2019 the following was noted:-

- 7 of 16 consultants had not submitted a return for Quarter 1 (April to June 2019) a further 13 had not submitted a return for Quarter 2 (July to September 2019).
- Quarterly returns were not being submitted on a timely basis with the majority of Quarter 1 returns submitted between September and November 2019.

Implication

The Trust is not recovering all income due in relation to private patients/category II.

Recommendation 4.1	All consultants should be instructed to fulfil their responsibility and submit their returns promptly and to accurately declare all paying work on a timely basis, to ensure the Trust does not suffer a loss in income.
Priority	2
Management Action	**ACCEPTED** Consultants will be written to and reminded to submit their returns promptly and to accurately declare all paying work on a timely basis
Responsible Manager	Deputy Medical Director/Assistant Director – Workforce and Education
Implementation Date	May 2021

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

5 Residency and Provision of Social Care Costs Not Incurred

Finding

Under the Care Act Northern Ireland 2014 the financial responsibility for a patient's social care cannot be transferred when they move to another jurisdiction. There are 3 different scenarios where costs can be avoided through early notification:-

- Cross Trust (ie within Northern Ireland)
- UK- (ie moves from Scotland/England/Wales)
- Outside UK

The Access to Healthcare Team do not have access to the Community Information system PARIS and are reliant on community based staff referring cases to them where they have concerns or queries in relation to a new client/patients eligibility.

Internal Audit reviewed a sample of cases where the Trust had not incurred costs as community staff had identified these patients/clients to the Access to Healthcare Team prior to accessing services. Identification of these patients are vital to avoid high cost expenses year on year for the Trust however the overall efficiency of identifying these patients on a timely basis cannot easily be identified.

Internal Audit selected a sample of 8 cases where eligibility to social care had to be established:
In 6 of the 8 cases notification had been timely to enable entitlement to healthcare to be established before any provision of services had been agreed or costs were incurred these 6 cases identified approximate savings of 4 nursing homes placements at an approximate saving of £35,000 per patient per annum, 1 specialist learning disability placement, 1 case where domiciliary care costs for £400 had been saved.

In a further 2 cases early identification of the cases before acceptance within the trust would have resulted in significant savings to the Trust of approximately £200K to date these costs will continue to increase as ongoing care in nursing/specialist placements will continue to be required. In both these cases the patient was accepted as resident and settled in Northern Ireland when following review and investigation both patients were actually not eligible for social care provision.

Costs not incurred as a result of early notification can provide the Trust with significant savings in relation to provision of social care services provided.

Implication(s)

Not all community referrals for social care may be identified resulting increased costs on already stretched social care budgets if these cases are not identified.

Recommendation 5.1	The Trust should continue to ensure that all staff in the community setting are fully aware of their responsibility to identify new referrals to the paying patient officer where there is a query arising in respect of the "ordinarily resident" status of the patient to enable appropriate review before services are put in place which the Trust could ultimately become liable for and should also avail of training and support provided by the Finance Directorate.
Priority	2
Management Action	**ACCEPTED**
Responsible Manager	Head of Financial Services to issue a reminder to Directors regarding this service and training available.
Implementation Date	January 2021

Recommendation 5.2	The Trust should strengthen control over systems to capture potentially chargeable income in respect of patients not ordinarily resident in the UK. This includes exploring access for Finance staff to PARIS.
Priority	2
Management Action	**ACCEPTED**

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

Responsible Manager	Head of Financial Services
Implementation Date	February 2021

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

6 Private Medical Practice Procedures

Finding

Internal Audit obtained a copy of the Trust Guidance on Paying/Private Patients – V5 dated June 2018 – at the date of Internal Audit (March 2020) this guidance has not been approved by LNC or SMT and remains in Draft Format.

Implication(s)

Appropriate procedures may not be being adhered to by all staff.

Recommendation 6.1	The procedures in relation to private medical practice should be agreed, finalised and issued to all staff as a matter of priority.
Priority	2
Management Action	**ACCEPTED** This Guidance will be submitted to LNC and SMT for approval.
Responsible Manager	Assistant Director – Workforce and Education
Implementation Date	May 2021

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

Appendix A Definition of Levels of Assurance and Priorities

Level of Assurance

Satisfactory	Overall there is a satisfactory system of governance, risk management and control. While there may be some residual risk identified, this should not significantly impact on the achievement of system objectives.
Limited	There are significant weaknesses within the governance, risk management and control framework which, if not addressed, could lead to the system objectives not being achieved.
Unacceptable	The system of governance, risk management and control has failed or there is a real and substantial risk that the system will fail to meet its objectives.

Recommendation Priorities

Priority 1	Failure to implement the recommendation is likely to result in a major failure of a key organisational objective, significant damage to the reputation of the organisation or the misuse of public funds.
Priority 2	Failure to implement the recommendation could result in the failure of an important organisational objective or could have some impact on a key organisational objective.
Priority 3	Failure to implement the recommendation could lead to an increased risk exposure.

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

Note to Report

This audit report should not be regarded as a comprehensive statement of all weaknesses that exist. The weaknesses and other findings set out are only those which came to the attention of Internal Audit staff during the normal course of their work. The identification of these weaknesses and findings by Internal Audit does not absolve Management from its responsibility for the maintenance of adequate systems and related controls. It is hoped that the audit findings and recommendations set out in the report will provide Management with the necessary information to assist them in in fulfilling their responsibilities.

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Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

Director for Urology Improvement, we have a weekly audit, exactly as described there, where we have a report generated as to how many outstanding results are awaiting sign-off by the Consultant Urologist. I've developed that in a red, amber, green format so results that are less than two weeks old, results that are two to four weeks old, and results that are over four weeks old. I know that within Urology, we have a system working where all of the Consultants are working utilising the electronic sign-off and the print -- or the result yesterday, the result last week is the only outstanding results are less than two weeks old, so I know that, within Urology, we have developed that system, and I've started speaking across the other Divisional Medical Directors as to how that can be translated across into other Specialties. 14:19 14:20 14:20

122 Q. Yes. I think the Inquiry might accept that sometimes it's more difficult to develop a system-wide solution, you know, that goes through, no doubt, numerous committees and numerous obstacles before you get a solution at the other end, but it's perhaps easier to devise an individualised bespoke solution, so if you know that a particular Clinician is falling foul of the rule that you described earlier as sort of get to these things promptly, then it should be a straightforward matter of including that as part of a monitoring arrangement? 14:20 14:21

A. Yeah. So if you are monitoring arrangements, particularly if you are monitoring arrangement for the

Southern Health and Social Care Trust

APPENDIX 4

Revised November 2016 (Version 1.1)

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

SECTION 1

1. ORGANISATION: SHSCT	**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE: Personal Information redacted by the
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE: Personal Information redacted by USI	**4.** DATE OF INCIDENT/EVENT **5.** Personal Information redacted by USI
6. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: NO ***Please select as appropriate***	**7.** IF 'YES' TO 5. PLEASE PROVDE DETAILS:
8. DATE OF SEA MEETING / INCIDENT DEBRIEF	

9. SUMMARY OF EVENT:

Patient 90 was admitted to Craigavon Area Hospital (CAH) on 09 May 2018 for elective urology surgery (cystoscopy, replacement of ureteric stents and bilateral ureterolysis). Following the procedure on Personal Information Patient 90 condition deteriorated and he was admitted to the Intensive Care Unit (ICU) critically ill. Patient 90 suffered a cardiac arrest which was managed as per Adult Life Support (ALS) guidelines. Following discussion with Patient's Wife cardiopulmonary resuscitation (CPR) was stopped and Patient 90 died on Personal Information redacted by USI. Patient 90 was discussed with the coroner and a post mortem was requested.

The review team have drafted this report on the information available to them, the review team are aware that some of the clinical notes may not be available to them.

Causative Factor

The review team concluded Patient 90 had an unrecognised haemorrhage post operatively.

The review team note Patient 90 s post mortem report. Patient 90 death was discussed with the Coroner who recommended a post mortem.
The Cause of death was reported after post mortem as 1(a) Intra-abdominal and retroperitoneal haemorrhage following cystoscopy, insertion of ureteric stents and ureterolysis. 11 Cardiomegaly
The post mortem reported noted *'Death was due to bleeding, or haemorrhage, into the abdominal cavity itself and into the fatty tissues at the back of the abdomen……..The post-mortem examination also revealed that the heart, and in particular its two main pumping chambers the ventricles, was enlarged. Such enlargement of the heart, termed cardiomegaly, would without doubt have made him less able to withstand the stresses place upon the body by the effects of the blood loss. Indeed the severity of his heart disease was such that it could have caused his death at any time. Therefore as his pre-existing heart disease would have made him more susceptible to the effects of haemorrhage it would be best regarded as a contributory factor in his death'.*

Recommendation 1

The Trust should develop and implement guidance for clinical result sign off
Monthly audit of sign off will be presented to the Governance Fora

Recommendation 2

All patients undergoing elective surgery must have a formal pre-operative assessment completed prior to surgery, including liaison with other specialties to ensure maximal optimization of patients prior to procedure. The Trust will update the pre-operative guidance to recommend appropriately timely referral times and escalation of non-attendance.
Audit of surgical patient pre-operative assessment should be undertaken and be presented to the Governance Fora

Recommendation 3

Discussions regarding the risks and benefits of surgery must be clearly documented in the patient record and reflected on the patient consent form, to ensure patients are able to make informed consent.
Audit of surgical patient consent should be undertaken and be presented to the Governance Fora

Recommendation 4

Blood loss during procedure should be escalated during and at the end of the procedure, the blood loss must be recorded on the operation note.
Blood loss post operatively must be escalated to the surgical and anaesthetic teams.

Recommendation 5

VTE risk assessment must be completed for all patients prior to surgical intervention

SECTION 2

10. SEA FACILITATOR / LEAD OFFICER:
Mr Glackin Consultant Urologist

11. TEAM MEMBERS PRESENT:
Mr Glackin Consultant Urologist
Dr K O'Connor
(Coordinator Mrs T Reid Governance Coordinator

12. SERVICE USER DETAILS:
Complete where applicable
Patient 90 was a Personal Information redacted by the USI male with a past medical history of atrial fibrillation myelodysplasia and arthritis/gout.

WHAT HAPPENED?

Patient 90 was a Personal Information redacted by the USI male with a past medical history of atrial fibrillation (AF) (irregular heart beat) myelodysplasia and arthritis/gout. The chronology of events prior to his death is as follows.
The review team note on 30 December 2016 that a computerised tomography (CT) scan of chest and abdomen requested by doctor consultant physician Doctor 4 showed

1. Possible focal aortitis at the aortic bifurcation. (inflammation of the large artery)
2. Small ground-glass nodule in the right upper lobe - follow-up CT in 3 months is recommended to confirm persistence.
3. Clinical assessment of the right inguinal hernia is recommended as fluid and inflammation in the hernia sac raises the possibility of strangulation.
4. Potentially haemodynamically significant coronary atheroma.

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The discharge letter following this admission noted the potentially haemodynamically significant coronary atheroma, follow up noted Patient 90 was awaiting an outpatient echo.
Patient 90 had follow-up for the nodule in the right lung, on outpatient letter from a clinic on 14 April 2017 to Patient 90's General Practitioner noted '*The right lower lobe pulmonary nodule possible intra pulmonary lymph nodule…… follow-up of the pulmonary nodule in 6 months……. I will leave any further investigations in their hands".*

A BNP blood test (a blood test which measure proteins which can indicate heart failure) collected on 3 January 2018 was 1609pg/ml. The discharge letter notes Patient 90 was commenced on Aspirin and Frusemide (water tablet), this result was not documented on the patient discharge letter

Patient 90 was under the care of vascular surgery, rheumatology and urology in relation to his inflammatory periaortitis causing bilateral hydronephrosis (swelling of kidneys due to a build-up of urine), having repeat scans and medical follow up.

Patient 90 was under the care of haematology for management of myelodysplastic syndromes (MDS) are a type of rare blood cancer where you don't have enough healthy blood cells; he had a number of blood transfusions. Patient 90 was reviewed at haematology clinic on 4 May 2018 where it was noted 'He is due a pre op red cell transfusion on the 8th May 2018.'

On admission there is no evidence of a venous thromboembolism (blood clot) risk assessment.

Patient 90 was added to consultant urologist Doctor 1 urgent waiting list on 9 June 2017 and was pre-admitted for surgery on Thursday 3 May 2018 for the 9 May 2018.

Consultant anaesthetist Doctor 2 in a chronology of events highlighted that Patient 90 was a Personal Information redacted by the USI male with a past medical history of atrial fibrillation (AF) (on beta-blocker and aspirin), myelodysplasia (MDS) and arthritis/gout. He presented for surgery with a history of retroperitoneal fibrosis and peri-aortitis. Of note, he was transfused 2 units of blood pre-operatively on 08 May 2018 in view of his haemoglobin (Hb) of 86g/l secondary to MDS. Other than this, there was nothing else to optimise pre-operatively. AF was rate controlled, and his functional status was reasonable.

Patient 90 was consented by Doctor 1 for cystoscopy, replacement of ureteric stent, Laparotomy and bilateral Ureterolysis.

The operation notes recorded "*cystoscopy with no stent encrustation. Right ureteric stent replaced with ease. Replacement of left ureteric stent required ureteroscopic guidance due to tortuosity of middle third of left ureter. 16F catheter. Midline abdominal incision. Right ureter adherent to right lateral wall of abdominal aorta. Left ureter densely adherent to lateral aspect of aortic bifurcation and left common iliac artery. Both ureters released throughout their lengths. Omentum bifurcated. Both ureters wrapped in omentum. Bilateral 20F Robinsons drains. Wound closed. Plan: To continue on IV benzylpenicillen 1.8g BD until Friday*".
Anaesthetic start time was 14:10, knife to skin was 14:42, end of procedure was 18:27 and anaesthetic end time was 18:36.
Total estimated blood loss in theatre is recorded as 1298mls. Patient 90 received one unit of blood (311mls) at 15:20 which was completed at 16:05 and a 2nd unit of blood (294mls) at 18:00 which was completed at 18:12.

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DATE														
TIME														
RESP	26	26	25	25	28	26	26	28	28		21	28	25	
SPO2 %	96		99				99		99			99	96	
TEMP	37.6	37			37				37					
BP	51/37		85/68	Not reading			99/60		103/84	83/74		59/47	69/41	
HR	112	112	112		80		150	146	133	126	141	130	135	126
O2			10L	10L		10L	10L		10L	10L		10L	10L	

Doctor 2 in a chronology of events highlighted that Patient 90 '*Blood pressure became more labile in the last 20 minutes of the case, although not to a major degree – he responded to small doses of metaraminol* (drug used to increase blood pressure)... *Emergence from anaesthesia and extubation was uneventful. The patient did not look particularly unwell on transfer to his bed (of note, not clammy/pale.)'* He was successfully extubate at 18:30 and transferred to the recovery ward

At 20:32 arterial blood gas pH 7.207, pCO2 3.08, pO218.4, acid base -17.7, Hb 81, glucose 20, lactate 11.6, potassium 6.6, sodium 136.

	9/5/18 13:00	9/5/18 19:30	9/5/18 22:25
Hb	86	82	68
Troponin		25	81
CRP			9.84
Haematocrit	0.278	0.262	0.229
Platelets	394	448	347
Sodium		133	142
Potassium		5.6	4.9
Urea		14.2	13.7
Bicarbonate		13.7	10.1
Creat		176	195
eGFR		33	29

Doctor 2 in a chronology of events noted that Patient 90 *'Shortly after arrival in recovery, the patient became agitated, restless and clammy. Arterial blood pressure (ABP) dropped precipitously, and it was clear he was very unwell. As he was trying to climb out of bed, remove lines and oxygen, and was disoriented, he required 2 x 2.5mg doses of haloperidol for sedation, in addition to boluses and then a peripheral infusion of phenylephrine for hypotension. Once he settled, a right internal jugular central catheter (CVC) was sited under ultrasound guidance (USSG) and noradrenaline (NA) infusion commenced immediately. As the patient had pulled out his left radial arterial line, a new line was sited in the right radial artery under USSG'*… amiodarone (drug used to slow heart rate) was prescribed for AF with a ventricular rate of 120-150. 1000ml of Hartmann's solution was given. Once these initial measures were established, he appeared to settle somewhat – HR 100-120/min, BP 90/50, SpO2 100%. I discussed his care with doctor 3 in intensive care who accepted him for further care. However he quickly destabilised again, becoming increasingly hypotensive (low blood pressure) and acidotic (can occur when the body cannot control the acid levels in the blood) on arterial blood gas (ABG) analysis, despite maximal doses of noradrenaline and adrenaline (drugs used to maintain blood pressure). Although his Hb did not drop much further, Doctor 1 reviewed him again to exclude bleeding. Doctor 1, Doctor 2 and Doctor 3 agreed that given the patient's precarious state and lack of compelling evidence of haemorrhage (Robinson drains in situ, Hb static,

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abdomen not distended), not to perform an emergency laparotomy. The working diagnosis was of cardiogenic shock, likely secondary to a cardiac event.
The fluid balance chart record shows drains were emptied at approximately 21:00 with a total output 1220mls recorded on the fluid balance chart. Total input was 1500mls Hartmans, and two units of blood intraoperatively and 1000mls postoperatively.

Patient 90 was commenced on Tazocin (antibiotic) in addition to his surgical prophylactic antibiotics. Patient 90 was administered steroids and treated for high potassium with 10ml 10% calcium chloride.

Patient 90 was transferred to theatre for intubation and insertion of dialysis line. There was ongoing intensive care including supra-maximal doses of inotropes and other resuscitative measures. Patient 90 was transferred to ICU at approximately 22:30.

It was noted the bed side echocardiograph (echo) (scan of the heart) (views were extremely poor) showed "*no tamponade ….it was not possible to assess myocardial function".*

Following insertion of a central line Patient 90 developed a pneumothorax (collapsed lung); a left intercostal drain was inserted without complication. At this time Patient 90 was receiving 90mls noradrenaline and receiving adrenaline boluses. Approximately 10 minutes after the intercostal drain was inserted Patient 90 lost cardiac output and CPR was commenced. Cardiac rhythm was noted to be Pulseless Electrical Activity throughout. Patient 90 developed profound metabolic acidosis pH6.79, HCO_3 10.0, base excess -19.3 and lactate 17.Despite CPR there was no return to spontaneous circulation and Patient 90 died at 23:10.

Patient 90 death was discussed with the Coroner who recommended a post mortem.
The cause of death was reported after post mortem as 1(a) Intra-abdominal and retroperitoneal haemorrhage following cystoscopy, insertion of ureteric stents and ureterolysis. 11 Cardiomegaly

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SECTION 3 - LEARNING SUMMARY

13. WHAT HAS BEEN LEARNED:

Causative Factor

The review team concluded Patient 90 had an unrecognised haemorrhage post operatively.

The review team note Patient 90's post mortem report. The cause of death was reported after post mortem as 1(a) Intra-abdominal and retroperitoneal haemorrhage following cystoscopy, insertion of ureteric stents and ureterolysis. 11 Cardiomegaly
'*The post mortem reported noted 'Death was due to bleeding, or haemorrhage, into the abdominal cavity itself and into the fatty tissues at the back of the abdomen……..The post-mortem examination also revealed that the heart, and in particular its two main pumping chambers the ventricles, was enlarged. Such enlargement of the heart, termed cardiomegaly, would without doubt have made him less able to withstand the stresses place upon the body by the effects of the blood loss. Indeed the severity of his heart disease was such that it could have caused his death at any time. Therefore as his per-existing heart disease would have made him more susceptible to the effects of haemorrhage it would be best regarded as a contributory factor in his death'.*

Contributory Factors
Patient factors

Patient 90 had significant comorbidities which included:-
Inflammatory periaortitis causing bilateral hydronephrosis, myelodysplastic syndromes, atrial fibrillation (AF), insertion of ureteric stents, lower limb cellulitis and previous appendectomy.

A CT scan in December 2016 noted a *'Potentially haemodynamically significant coronary atheroma',* the review team can find no evidence that follow up investigations were organised for this finding. However, it appears that other findings on the CT scan were actioned for follow up.

Despite the patient discharge letter noting an outpatient echo was required, the review team were unable to identify that the echo was completed prior to surgery, there is no evidence of an outpatient echo being requested, and the last record of an echo being completed was in 2010 (EF 50%). Outpatient clinic letters highlight Patient 90 was under the care of cardiology for heart failure on the background of AF between 2010 and 2012.

There was a suspicion of coronary artery disease (CAD) in 2006 but he has no symptoms suggestive of angina at present.' He had a Direct Current Cardioversion (DC Cardioversion) for AF in 2012 and was on Bisoprolol (medication most commonly used for heart diseases) and aspirin, he had decline warfarinisation. Rate control was decided in 2012 Patient 90 was reviewed by cardiology to until 3 July 2012 when he was discharged from cardiology to his GP's care.

The review team notes the post mortem findings that Patient 90's pre-existing heart disease would have made him more susceptible to the effects of haemorrhage it would be best regarded as a contributory factor in his death.

Task Factors-Guidelines, Policies and Procedures

Results follow up

The review team note that all findings on the 2016 CT chest, abdomen and pelvis were not followed

up by the clinical teams.
The review team note there is no formal clinical result sign off guidance for the Southern Health and Social Care Trust (SHSCT), the Acute Directorate are developing guidance to implement clinical result sign off. The review team concluded that all results must be signed off and action taken to further investigate or manage findings.

A BNP blood test collected on 3 January 2017 was 1609pg/ml; this result was not documented on the patient discharge letter. The review team are of the opinion that here was no evidence to support if this was actioned.

Preoperative Assessment
Patient 90 was added to Doctor 1 urgent urology waiting list on 9 June 2017 and was pre-admitted for surgery at 15:50 on Thursday 3 May 2018 by Doctor 1's secretary. The review team noted that Patient 90 did not have a formal outpatient preoperative assessment as per Trust and National Institute for Clinical Excellence (NICE) guidance.
Patient 90 was booked for pre-operative assessment on the 4 May 2018. The review team considered that this referral did not give sufficient time to appropriately pre-operatively assess and optimise Patient 90 for surgery.

Patient 90 was in the emergency department of Craigavon Area Hospital on 4 May 2018 and called with the preoperative team at 09:00, as his preoperative assessment appointment was booked for 13:45 they were unable to assess him. He was advised to contact the preoperative team later that day if he was unable to attend his 13:45 appointment. Patient 90 did not attend this appointment. The anaesthetist was informed by the pre-operative team that Patient 90 had not attended.

The review team note that on 3 January 2017 Patient 90 Brain Natriuretic Peptide (BNP) test was 1609 is a blood test that measures levels of a protein called BNP that is made by the heart and blood vessels. BNP levels are higher than normal when you have heart failure). SHSCT echocardiography in the preoperative assessment clinic guidance highlights heart failure (either systolic or diastolic dysfunction) is a major perioperative risk factor. The presence of heart failure doubles the risk of dying after major surgery Patient 90 BNP was 1609pg/ml).
National NICE Chronic heart failure in adults: management (CG108) recommended refer patients with suspected heart failure and a BNP level above 400 pg/ml (116 pmol/litre) or an NTproBNP level above 2000 pg/ml (236 pmol/litre) urgently, to have transthoracic doppler 2D echocardiography and specialist assessment within 2 weeks. This guidance has been superseded by NICE guideline chronic heart failure in adults: diagnosis and management published: 12 September 2018 (nice.org.uk/guidance/ng106). However the review team noted that certain medications and medical conditions such as atrial fibrillation can affect BNP levels even in the absence of heart failure.

NICE guideline routine preoperative tests for elective surgery published: 5 April 2016 (nice.org.uk/guidance/ng45) recommends not routinely offering resting echocardiography before surgery. However, consider resting echocardiography if the person has:
a heart murmur and any cardiac symptom (including breathlessness, pre-syncope, syncope or chest pain) or signs or symptoms of heart failure. SHSCT guidance recommends a patient with known heart failure with a significant change in symptoms and an increase in BNP should have a preoperative echocardiogram.

Consultant 1 noted '*I do not regret the surgery as his quality of life was terrible due to the effects of indwelling ureteric stents. I do however regret not sending him for cardiac workup, including echo*

and coronary angiography. When he did have CT scanning performed in December 2016, he was reported to have gross enlargement of his atrium, and appeared to have a haemodynamically significant, atheromatous plaque in his left main stem'.

The review team considered that waiting lists for elective urology surgery and a cancellation could lead to a significant delay in relisting of a patient, however doctor 2 noted '*There was no push/ pressure to get the case done regardless'*

The review team concluded particularly in view of his comorbidities that Patient 90 should have had a formal preadmission pre-operative assessment with optimisation of his clinical condition prior to surgery. This assessment should have been organised sufficiently in advance of the surgery to allow for all appropriate investigations to be completed. This allows for patient optimisation and discussion regarding specific anaesthetic risk.

The review team noted that the consultant anesthetist Doctor 2 noted on the preoperative assessment on the day of surgery the Patient 90 comorbidities including ischaemic heart disease. The review team noted that Patient 90 had had previous anaesthetics which were uneventful.
Doctor 2 reported that *'induction of anaesthesia and intra-operative progress was largely uneventful'* and that Patient 90 was anaesthetically stable throughout the procedure. *'Blood pressure became more labile in the last 20 minutes of the case, although not to a major degree – he responded to small doses of metaraminol. Emergence from anaesthesia and extubation was uneventful. The patient did not look particularly unwell on transfer to his bed (of note, not clammy/pale.)'*
Doctor 2 highlighted there were serial arterial blood gases that showed that the haemoglobin and lactate were stable throughout the operative procedure. The review team concluded that these blood tests were missing from the notes.

The review team noted doctor 2's preoperative plan for an arterial line and venous access, and the anaesthetic management. The team notes a small amount of inotropes was administered during the procedure but these were not significant. The procedure was relatively long with the total procedure time 3 hours 45 minutes and the anaesthetic time 4 hours 27 minutes. The review team notes that there were no previous clinical notes available to doctor 2 on the day of surgery.
The review team considered that with the information available to the anaesthetist it was reasonable to progress with the surgery, the anaesthetic assessment and management of Patient 90 was appropriate.

Management of Patient 90 post-operative care

Post operatively he developed a labile blood pressure. He subsequently became agitated, tachycardic (fast heart rate) and hypotensive (low blood pressure) (NIBP 51/37). Patient 90 required further boluses of phenylephrine and 2x doses of haloperidol 2.5mg for agitation. Noradrenaline for inotropic support and amiodarone were administered. Patient 90 initially responded well but he developed anuria (no urinary output) and confusion. He was requiring increasing doses of inotropes. Patient 90 was transferred to theatre for intubation and insertion of dialysis line. There was ongoing intensive care including supra-maximal doses of inotropes and other resuscitative measures. Patient 90 was transferred to ICU at approximately 22:30.
The review team note the plan was to attempt to stabilise the patient and transfer to ICU for haemofiltration/ dialysis. However, despite maximal efforts lost cardiac output and cardiopulmonary resuscitation (CPR) was commenced. Despite CPR there was no return to spontaneous circulation and Patient 90 died at 23:10.

The review team noted the clinical team's differential diagnosis of a sudden cardiac event.

The review team considered the discussion between Doctor 1, Doctor 2 and Doctor 3 who agreed that given the patient's precarious state and lack of compelling evidence of haemorrhage (Robinson drains in situ, Hb static, abdomen not distended), not to perform an emergency laparotomy. The review team noted the total output of 1220mls on the fluid balance chart of which 400mls was from surgical drains at approximately 21:00 plus the 1098mls at time of procedure (the review team note the blood volume lost in theatre was 1098 not 1298 on the measurement of blood loss in theatre). The review team note the World Health Organisation (WHO) surgical safety check list has questions on blood loss on the sign in and time out sections of the form but did not have this form available to them during the review. The review team have been informed it is custom to notify the surgical and anaesthetic team of blood loss of 500mls and 1000mls during the procedure and total blood loss at the end of the procedure. The escalation is not documented in the medical notes available to the review team, with the exception of the Measurement of Blood Loss in Theatre form. However, the review team noted there was equivalent fluid replacement.

The review team note that Hb appeared to be sustained at 82, however, haemodilution may not have occurred at that time. The review team note the Hb of 68 which was collected at 22:25. This result may not have been available to the clinical team before Patient 90's death.
The review team concluded that Patient 90 was at high risk of bleeding due to myelodysplastic syndromes, and the nature of the surgery. The intra operative blood loss, post-operative tachycardia and loss from operative drains indicated bleeding, which with Patient 90's history of heart failure would have been a contributory factor for hypovolemic shock. The review team note the post mortem findings '*death was due to bleeding, or haemorrhage, into the abdominal cavity itself and into the fatty tissues at the back of the abdomen*,.

Communication
Consent
Patient 90 was consented by Doctor 1for cystoscopy, replacement of ureteric stent, laparotomy and bilateral ureterolysis.
The review team was unable to find documentation of detailed discussion of Patient 90's individual risks based on his comorbidities in the medical notes.
Ureterolysis a high risk surgical procedure which is rarely performed in the SHSCT urology department, with only a few per year. There is no documentation of alternatives e.g. nephrostomies or referral to other centers being discussed with Patient 90.

Patient 90 did not have a full preoperative outpatient assessment which would have identified all his individual anaesthetic risks to be assessed and discussed with Patient 90 to ensure informed consent.

Liaison with other teams
The review team was unable to evidence communication between Doctor 1 and the haematology team regarding optimisation of Patient 90 preoperatively; however, the review team note that Patient 90 did receive a blood transfusion pre-operatively. Patient 90's Hb was 86 and there would have been an anticipated blood loss of approximately 500mls with the proposed procedure. During the procedure the actual blood loss was 1098mls.

Patient 90 was added to a urology waiting list on 9 June 2017 and was pre-admitted for surgery at 15:50 on Thursday 3 May 2018 by Doctor 1's secretary and referred to the preoperative team the same day. The preoperative team booked Patient 90 for an assessment at 13:45 on 4 May 2018. Patient 90 was in the emergency department of Craigavon Area Hospital on 4 May 2018 and called with the preoperative team at 09:00, as his preoperative assessment appointment was booked for 13:45 they were unable to assess him. He was advised to contact the preoperative team later that day if he was unable to attend his 13:45 appointment. Patient 90 did not attend his preoperative assessment later that day. The review team was informed that the pre-operative team informed the consultant

anaesthetist that Patient 90 did not attend his appointment.

The review team concluded that even if Patient 90 had been able to attend this appointment, it was not a timely referral to pre-operative assessment. The referral did not give sufficient time to appropriately pre-operatively assess and optimise Patient 90 for surgery considering his significant comorbidities.

14. WHAT HAS BEEN CHANGED or WHAT WILL CHANGE?

15. RECOMMENDATIONS (please state by whom and timescale)

Recommendation 1

The Trust should develop and implement guidance for clinical result sign off
Monthly audit of sign off will be presented to the Governance Forums

Recommendation 2

All patients undergoing elective surgery must have a formal pre-operative assessment completed prior to surgery, including liaison with other specialties to ensure maximal optimization of patients prior to procedure. The Trust will update the pre-operative guidance to recommend appropriately timely referral times and escalation of non-attendance.
Audit of surgical patient pre-operative assessment should be undertaken and be presented to the Governance Forums

Recommendation 3

Discussions regarding the risks and benefits of surgery must be clearly documented in the patient record and reflected on the patient consent form, to ensure patients are able to make informed consent.
Audit of surgical patient consent should be undertaken and be presented to the Governance Forums

Recommendation 4

Blood loss during procedure should be escalated during and at the end of the procedure, the blood loss must be recorded on the operation note.
Blood loss post operatively must be escalated to the surgical and anaesthetic teams.
Monthly audits will be conducted and result presented to the Governance Forums

Recommendation 5

VTE risk assessment must be completed for all patients prior to surgical intervention.
Monthly audit of VTE risk assessment in the patient record/medicine prescription and administration record and WHO surgical safety check list blood loss section will be presented to the Governance Forum

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

17. FURTHER REVIEW REQUIRED? YES / NO
Please select as appropriate

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

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

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

SECTION 6
25. DISTRIBUTION LIST: HSCB Coroner's Office Family AD – Surgical Director of Acute

HSC Business Services Organisation

Southern Health & Social Care Trust

Management of Waiting Lists - Pre-Operative Assessments & Patient Consent 2019/20

nqa ISO 9001 Registered Quality Management

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

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Acknowledgement

Internal Audit wishes to thank management and staff at the Southern HSC Trust for their assistance and co-operation during the course of the audit engagement.

Control Log

Exit Meeting Held On:	None held (due to corona virus)
Working Draft Issued On:	10 April 2020
Management Actions Received:	6 October 2020
Final Report Issued On:	7 October 2020

Distribution List

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Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

Introduction

In accordance with the 2019/20 Annual Internal Audit Plan, BSO Internal Audit carried out an audit of Management of Waiting Lists focusing on Pre-operative Assessments and Patient Consent during September 2019 to March 2020. These 2 areas have not previously been subject to review by Internal Audit.

It is important to note that this audit was conducted before the impact of Covid 19.

A recent SAI case and previous work by Internal Audit in relation to Theatre Utilisation had indicated issues with timeliness of pre-operative assessments particularly in the current scenario of lengthy waiting lists. This led to concerns regarding patient safety where the Trust was potentially reliant upon pre-operative self-assessments which were out of date and also instances where these had to be rushed just ahead of surgery to ensure maximum utilisation of theatre slots, because previous assessments had time lapsed due to Waiting List length. Also in such scenarios, there is a query as to whether time was taken to properly discuss risks with the patient.

The **pre-operative assessment** is an opportunity to identify co-morbidities that may lead to patient complications during the anaesthetic, surgical, or post-operative period. Patients scheduled for elective procedures generally attend a pre-operative assessment 2-4 weeks before their date of surgery. The objectives of a pre-operative assessment are:

- to perform a structured preoperative anesthetic assessment of a patient prior to surgery and recognise when further assessment/optimisation is required;
- to explain options and risks of routine anesthesia to patients, in a way they understand, and obtain their consent for anesthesia;
- to formulate a plan for the management of common co-existing diseases;
- to ensure all elective patients who must undergo a surgical intervention under general anaesthetic (GA) or local anaesthetic (in some cases) are passed fit to do so.

Within the SHSCT, the specialties for which pre-operative assessments are performed are:

- Orthopaedics
- Gynaecology
- ENT
- General Surgery inc. breast surgery
- Urology; and
- Maxi-facial surgery.

This will be for all referrals triaged as Routine, Urgent or Red Flag**.** In cases involving a local anaesthetic where a patient is on a blood thinning drug, they don't do a full assessment as the patient must cease all such drugs in advance of the operation. Also where a patient is due to undergo endoscopy and they are on a blood thinning drug they must have a pre-operative assessment performed. Pre-operative assessments are not performed for patients admitted as inpatient or daycases via Emergency Departments (EDs).

In practice pre-operative assessments are carried out using a range of methods based on a risk assessment of the patients' medical history –

- Pre-op health questionnaire (virtual – online review of NIECR etc);
- Pre-op health questionnaire (conducted over telephone by band 5 or 6 nurse);
- Pre-op health questionnaire (conducted face to face with band 5 or 6 nurse);
- Anaesthetist review of health questionnaire (for certain conditions);
- Pre-op assessment (conducted face to face with consultant anaesthetist) or where there is a need to perform additional tests for certain conditions;

The completed questionnaire is filed on the patients' file and type and date of pre-operative assessment performed is recorded on Patient Administration System (PAS).

The Pre-operative Assessment (POA) Team is part of Anaesthetics, Theatres & Intensive Care (ATICS) within the Surgery, Elective Care & ATICS Division of the Acute Services Directorate. It provides services from Craigavon Area (CAH), Daisy Hill (DHH) and South Tyrone (STH) Hospitals, primarily in close proximity to Outpatient Departments. The POA team comprises 18 qualified nurses (14.68 wte). There are also 6.0 wte administrative staff. A consultant anaesthetist provides one morning session per day (5

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days a week) conducting virtual clinics at CAH. They will also see / advise on booked face to face appointments (those patients where risks are greater) and conduct tests on booked appointments where necessary. During the 6 month period from 1st October 2018 to 31st March 2019 there were approximately 14,000 pre-operative assessments (POA) performed of which approximately 900 were performed by Anaesthetists *(based on PAS figures).*

In order to function efficiently and effectively the POA team must co-ordinate its work with a number of other services such as consultants and their secretaries and specialty theatre scheduling teams re timely notification of patients on upcoming consultant theatre sessions; specialty outpatient teams to perform timely pre-operative assessments for patients designated as red flag or urgent; and medical records. Failure to notify the pre-operative assessment team of patients who require a pre-operative assessment on a timely basis could result in patients not having their pre-operative assessment completed timely prior to surgery. If patients are admitted without being deemed as pre-op fit, this increases patient safety risk and potential for cancellation of surgery on the day. If patients require any blood tests or other tests, results may not be available prior to surgery where there are delays in notifications. Best practice guidance indicates pre-operative assessments are valid for a period of 13 weeks (3 months), and must then be re-performed, when the patient referred has not yet had surgery.

It is a general legal and ethical principle that valid **consent** must be obtained from a patient or their guardian before commencing an examination, starting treatment or physical investigation. For consent to be valid it must comply with the following principles:

- It must be given **voluntarily**, and freely without pressure or undue influence being exerted on the individual. Coercion from whatever source will invalidate consent.
- Given by an appropriately **informed** person (the individual or, where relevant, someone with parental responsibility for a young person under the age of 16). The patient/client needs to understand the nature and purpose of the procedure and the risks, benefits, alternatives and implications of no treatment or care. Any misrepresentation of these elements will invalidate consent. Information about anaesthesia should be given as well as information about the procedure itself. The Trust requires as evidence of good practice that patient/client records include a summary of the information given prior to gaining consent.
- The person must have **capacity** to consent and be able to comprehend and retain information relevant to the decision, understand the consequences, weigh up the information and arrive at a choice, and be able to communicate their choice.

Consent must be sought before commencing examination, treatment or care of a patient/client. If consent is sought after a patient/client is given routine pre-operative medication, it may be deemed to be invalid. For major activities, such as surgery under anaesthetic, it is good practice to fully inform the individual about the implications, potential risks and benefits well in advance of the proposed activity. This will allow the individual time to reflect on the information about the activity or event and for the professional to respond appropriately to questions. The health or social care professional should again check, before the activity starts, that the consent is still valid and that the patient/client has not had a change of mind about proceeding. If consent is not gained until just before the activity care event is due to start, at a time when the patient/client may be feeling particularly vulnerable, there may be doubt as to the validity of the consent gained.

The Southern Trust requires as evidence of good practice that information is provided to the patient to help inform consent and any decision by the patient to withdraw or refuse consent, is recorded in the patient record. It is important that a recording format is agreed and applied consistently and records should also include the information given to the patient or client to aid his/her decision and where refusal of consent by a patient/client prevents care being given.

Scope of Assignment

This audit covered Pre-operative Assessments and Patient Consent processes during the audit test period outlined below. Discussions took place with a number of consultants across the following specialties – ENT, Gynaecology, Urology, General Surgery and Anaesthetics. Discussions also took place with Pre-operative Assessment, Scheduling, and Booking Centre Teams, as well as consultants' secretaries. Reports were obtained from PAS through the Informatics Department showing:

i. All recorded pre-operative assessments for the 6 month period 1st October 2018 to 31st March 2019.

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ii. All elective inpatients and day cases recorded for the 3 month period 1st January 2019 to 31st March 2019.

Based on analysis of these reports, 105 patients' files were pulled and reviewed.
A copy of the Pre-operative Assessment Team database from CAH was obtained and used to supplement / verify reported data. Queries arising from testing were discussed with appropriate clinical staff.

The audit was based on the risks that due to increasing length of elective waiting lists, and pressure to maximise usage of limited elective theatre slots:

1. there is potential for increased patient safety issues during surgery due to issues with timeliness / elapsed pre-operative assessments performed on elective patients; and
2. failure to obtain timely informed patient consent resulting in patients' not fully understanding all surgical risks.

The objectives of this audit were:

- To ensure that pre-operative assessments are performed in a timely manner ahead of proposed surgery and are properly assessed by an appropriate individual well in advance of planned surgery.
- To ensure that valid patient consent is obtained and there is evidence of timely informed discussion of risks with the patient.

Note: We report by exception only, and where no issues and recommendations are made, the result of our work indicates that the key objectives and risks are being managed and that procedures are being adequately adhered to.

Level of Assurance

Pre-Operative Assessments

Limited	There are significant weaknesses within the governance, risk management and control framework which, if not addressed, could lead to the system objectives not being achieved.

Patient Consent

Satisfactory	Overall there is a satisfactory system of governance, risk management and control. While there may be some residual risk identified, this should not significantly impact on the achievement of system objectives.

Executive Summary

Internal Audit can provide limited assurance in relation to Management of Pre-operative assessments. Limited assurance has been provided on Pre-Operative Assessments on the basis that 25% of patient files examined where a pre-operative assessment was required did not have a completed assessment form on the file - 63.6% were Urology cases; in 8.4% of sampled surgical cases the pre-operative assessment had expired.

Satisfactory assurance has been provided in relation to Management of Patient Consent on the basis that consent forms signed by the patient were available on all patient files examined, although we noted that extent and quality of completion of consent forms varied significantly.

There are 2 significant findings in this audit, impacting on the assurance provided:

1. Specialties such as Urology, General Surgery and Orthopaedics routinely do not provide theatre lists to the Pre-operative Assessment Team 6 weeks in advance. Testing of 105 patient files found 7 cases where the pre-op was performed either on the same day or within 3 days of actual operation.

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As a consequence of high levels of red flags and urgent patients, some routine patients who are moved down the waiting list subsequently present through the ED pathway as their conditions deteriorate – testing found that of 17 patient files tested in Urology, 14 (88%) had presented through this pathway for stent insertions / replacements. Subsequently these patients must then have the stent removed typically 4-8 weeks later.
There are a number of other occasions when patients will only become known to PreOp Assessment team once a late theatre list is received, impacting on the ability to perform an appropriate PreOp assessment.
From 44 files tested which should have had a POA, there were 11 (25%) with none on file for the selected procedure - 7 (63.6%) were Urology procedures, and one each from Gynaecology, Orthopaedics, General Surgery and ENT.

2. An analysis of date of surgery against date of latest POA on PAS for the test period found that out of the 2,161 patient records matched i.e there was a POA completed, there were 182 records (8.4%) where the time between (date of surgery – date of latest pre-op) was greater than 91 days or 13 weeks. General Surgery, Gastro, ENT and Urology were the specialties with largest numbers of exceptions.

Other key findings of the audit are:

3. While all 100 sampled consent forms had been signed by the patients, the following exceptions were observed in completion of consent forms:
   - 9 consent forms were not signed by the consultant, evidencing the patient had consented to the procedure to be performed;
   - In 80 cases, the copy consent form had not been given to the patient;
   - 5 consent forms did not outline benefits / risks etc discussed with the patient;
   - 88 consent forms did not record evidence that relevant information leaflets on the surgery / procedures had been provided to the patient.
4. There are no documented procedures available for pre-operative assessment. A number of issues with the database system within the PreOp assessment team were observed.

There were no other findings in this report.

Summary of Findings and Recommendations

Finding		Number of Recommendations		
		Priority 1	Priority 2	Priority 3
1.	Notification of Elective Patients to Pre-operative Assessment	-	5	1
2.	Expiration of Pre-operative Assessments	-	1	-
3.	Patient Consent	-	2	-
4.	Documented Policies / Procedures for Pre-operative Assessment and Database	-	3	-

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Detailed Findings and Recommendations

1 Notification of Elective Patients for Pre operative Assessment (POA)

Findings

All elective patients who require a General Anaesthetic (GA) whilst undergoing a procedure are required to have a Pre-Operative Assessment (POAs) to assess their fitness for surgery. In practice the optimum time is to ensure patients' POAs takes place between 13 weeks and approximately 3 weeks ahead of planned surgery date. Consequently to ensure this happens in a timely manner and no patients scheduled for theatre are overlooked, it is essential that all elective theatre lists are prepared and notified to the POA team by the scheduling team or consultants' personal secretaries, 6 weeks in advance of the theatre date. In reality this does not happen in certain specialties such as Urology, General Surgery and Orthopaedics, as the lists are often prone to late changes. Testing identified one case where pre-op was performed on the same day as surgery, 2 cases one day in advance, 2 cases where 2 days in advance and 2 cases where pre-op was performed 3 days in advance of operating date.

The underlying reasons for late lists can be increasing numbers of red flag patients presenting, which when coupled with reduced availability of theatre sessions, often mean routine or less clinically urgent patients must be cancelled from lists at short notice. This has a knock on effect for those latter patients as not only does their waiting list time increase but quite often conditions deteriorate and they subsequently present through ED pathway and are admitted as an inpatient. *(See Urology stent cases below).*

There are a number of other occasions when patients will only become known to POA team once a late theatre list is received, such as:

- Private patients – they will not have been seen at the Trust Outpatient Department, and when they are subsequently referred as NHS inpatients will not have been assessed following a clinic attendance, as per urgent / red flag NHS patients;
- Patients admitted to wards (primarily through ED), who are subsequently discharged having had their immediate emergency resolved, but the consultant then adds them to the waiting list because they require further urgent surgery e.g. emergency Urology stent insertions, where the patient must return in typically 4-8 weeks for it to be removed (typically as a day case). Before the patient leaves hospital the discharging doctor should get them to complete a POA questionnaire, or to attend the POA Department in urgent / red flag cases;
- Patients who have had investigations either at the day procedure units or scope clinics, and are then referred following biopsy or other tests. In these instances as the test results are not known and consequently the consultant does not ask them to complete a POA questionnaire available at clinics;
- Outpatient attendees, whom the consultant refers for surgery but doesn't notify to POA at the time of their Outpatient visit – ideally all red flag / urgent cases should be sent immediately to POA team.

Using data analysis of PAS reports, Internal Audit reviewed a sample of 105 elective patient files for patients seen in the period 1st January to 31st March 2018 to ascertain whether the patient had required a pre-operative assessment prior to having their inpatient or day case procedure. Only 44/105 (42%) files examined required the patient to have a pre-operative assessment. Of the 44 files which should have had a POA, there were 11 (25%) with none on file for the selected procedure. These 11 cases can be analysed as follows:

- 7 (63.6%) were Urology procedures
- 1 was Orthopaedics
- 1 was Gynaecology
- 1 was ENT
- 1 was General Surgery

From the 61 cases where there was no pre-operative assessment, 17 urology stent removals / replacements were further examined to ascertain whether a Pre-Operative Assessment was carried out for the original stent insertions. 3/17 (12%) patient files did have a Pre-Operative Assessment booklet. The remaining 14 cases were all admitted through ED and consequently did not have a POA. Discussion with consultants indicated more patients, primarily because of the waiting time were presenting through ED route, and emergency temporary stent insertion was required to relieve immediate discomfort / pain. The

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stent is subsequently removed 4-8 weeks later. In some cases the stent may be routinely replaced every 3-6 months.

Implication(s)

Planning issues for POA Team when theatre schedules are presented late and new or updated POA is required at very short notice.
Patient safety risks where theatre schedules are not notified timely to the POA team and assessments are either not completed in advance of surgery or may be rushed in order to meet theatre scheduling e.g. all results of POA tests may not be known / completed etc.
Increased risk of cancellation of surgery on the day of operation because POA not completed, potentially resulting in loss of theatre time.

Recommendation 1.1	As previously reported in the 2018/19 Theatre Utilisation report, the surgical rotas should be prepared and made available on a timely basis, (4 weeks) to allow for efficient scheduling and booking of patients onto theatre lists and appropriate time for pre-operative assessments to be completed. **Responsible Officer**: Not stated **Original Implementation Date:** Not stated
Priority	*2*
Management Action	**ACCEPTED** Medical annual leave to be confirmed with 6 weeks' notice. This will then enable the Heads of Service to develop the emergency and elective rotas for their specialities. Their rotas are forwarded to Theatres who then develop the overall theatre/anaesthetic rota. The Trust will aim for the final theatre/anaesthetic rota to be developed at 4 weeks minimum.
Responsible Manager	Head of Service for ATICs and Surgical specialities
Implementation Date	April 2021

Recommendation 1.2	As previously reported in the 2018/19 Theatre Utilisation report, as per procedure, to allow timely completion of pre-operative assessments, patients listed in theatre sessions should be notified to Pre-Operative Assessment Team 4 weeks in advance of surgery date. **Responsible Officer**: Not stated **Original Implementation Date:** Not stated
Priority	*2*
Management Action	**ACCEPTED** Medical annual leave to be confirmed with 6 weeks' notice. This will then enable the Heads of Service to develop the emergency and elective rotas for their specialities. Their rotas are forwarded to Theatres who then develop the overall theatre/anaesthetic rota. The Trust will aim for the final theatre/anaesthetic rota to be developed at 4 weeks minimum.
Responsible Manager	Head of Service for ATICs and Surgical specialities

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Implementation Date	April 2021

Recommendation 1.3	Management should review processes to ensure all private outpatients transferring to NHS inpatient waiting lists are promptly notified to the Pre-operative Assessment team.
Priority	2
Management Action	**ACCEPTED**
Responsible Manager	Booking Centre Manager
Implementation Date	April 2021

Recommendation 1.4	Management should review and strengthen processes where ward admissions via ED, are subsequently re-booked for urgent surgery e.g. Urology Stent removals within 4-8 weeks, so they are promptly notified to the Pre-operative Assessment Team on discharge.
Priority	2
Management Action	**ACCEPTED**
Responsible Manager	Booking Centre Manager
Implementation Date	April 2021

Recommendation 1.5	Management should review and remind Surgical specialities in relation to limited use of pre-operative assessments given the high volume of exceptions found.
Priority	2
Management Action	**ACCEPTED**
Responsible Manager	Head of Service for ATICs and Surgical specialities
Implementation Date	April 2021

Recommendation 1.6	Management should retrospectively investigate the 11 exceptions noted where there was a pre-operative assessment expected but not performed, and identify learning.
Priority	3
Management Action	**ACCEPTED**
Responsible Manager	Lead Nurse and Pre-op Band 7 Sister
Implementation Date	April 2021

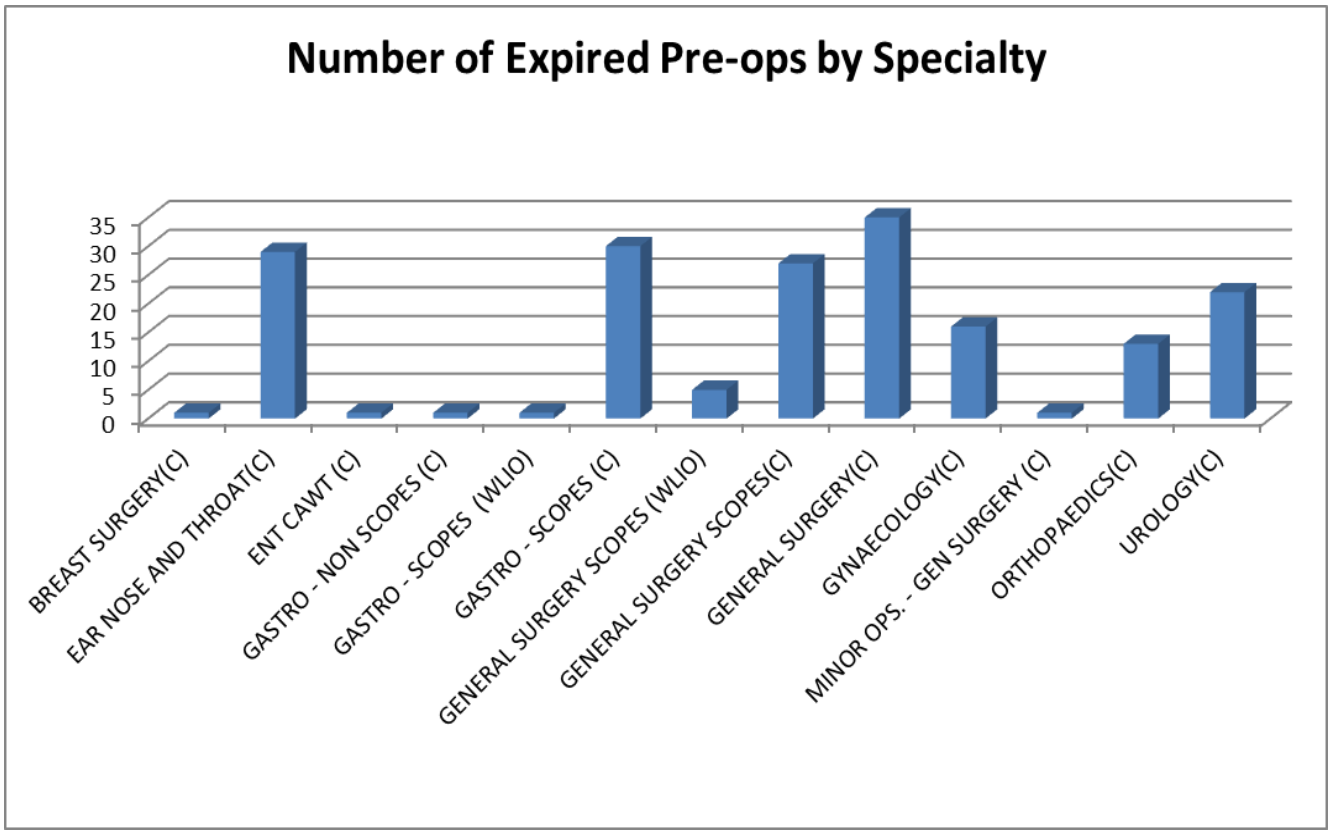
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2 Expiration of Pre operative Assessments

Findings

A paper Pre-op assessment questionnaire should be completed by patients following their attendance at a surgical outpatient clinic when advised that they require surgery. When the questionnaire /NIECR is reviewed by Pre Op Asssement staff, there is an escalation process in place for patients deemed more at risk or with certain conditions. Pre-operative assessments remain valid for a period of 3 months (13 weeks) from completion i.e. when the patient is passed fit for surgery. With the growth in waiting lists for urgent and routine procedures, particularly in specialties such as ENT, General Surgery, Orthopaedics, and Urology, there may have been significant change in the patient's condition over the intervening period since they were initially seen in POA or added to the inpatient waiting list, with in excess of 2 years or longer not unusual. This also means pre-op staff are reviewing patient data which is significantly out of date and consequently this increases the time necessary to review and update patient data.

An analysis of POAs from PAS for the 6 month period 1st October 2018 to 31st March 2019 against all elective inpatients and daycases recorded for the 3 month period 1st January 2019 to 31st March 2019 found there were 2,161 Elective Inpatient / Daycase patients that had a POA. In 182 (8.4%) of these cases, the time between (date of surgery – date of latest pre-op) was greater than 13 weeks. An analysis of exceptions by specialty is shown in the graph:



Implication(s)

Patient safety risks where POAs are out of date (greater than 13 weeks) particularly for routine / urgent patients who have been on waiting lists for considerable periods of time and their condition has changed / deteriorated significantly impacting their fitness for surgery.
Potential for greater risk of cancellation of surgery on the day of planned operation, resulting in loss of theatre time.
Increased time for aged referrals to be fully pre-operatively assessed / update patient clinical data. Also where time is limited ahead of theatre slot this potentially increases risk of rushing through patient's fitness for surgery.

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Where POAs must be completed more than once there is potentially a negative patient perception of the service efficiency and duplication of information.

Recommendation 2.1	Management should ensure all patients due for elective surgery have an up to date pre-operative assessment completed no more than 13 weeks ahead of planned surgery. Management should focus on improving processes in those specialties with higher volumes of exceptions including General Surgery, Gastro, ENT and Urology.
Priority	2
Management Action	**ACCEPTED**
Responsible Manager	Lead Nurse and Pre-op Band 7 Sister
Implementation Date	April 2021

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3 Patient Consent

Findings

It is a general legal and ethical principle that valid consent must be obtained before commencing an examination, starting treatment or physical investigation. For consent to be valid it must be voluntarily given by an appropriately informed person who has capacity. We observed that the Trust's Policy on Gaining Consent is dated November 2009, and has not been subject to review since then and no regular training for new doctors.

Discussions with 8 consultants found that they were very aware of the issues and risks around consent and when it should be discussed with patients etc.

Of the 105 patient files and corresponding procedures examined, there were 5 cases where there was no consent form completed. In discussion with clinical staff it was deemed appropriate that there was no consent form due to the nature of the procedures. While all remaining 100 consent forms had been signed by the patients, the following exceptions were observed in completion of consent forms:

- 9 consent forms were not signed by the consultant evidencing the patient had consented to the procedure to be performed;
- 80 consent forms the copy had not been given to the patient;
- 5 consent forms did not outline benefits / risks etc discussed with the patient;
- 88 consent forms did not record evidence that relevant information leaflets on the surgery / procedures had been provided to the patient.

Implications

Absence of up to date policy and corresponding training may expose the Trust and clinicians to additional risks.
Non-recording of all aspects of the consent process could call into question the validity of consent where there is a subsequent complaint or legal action by or on behalf of the patient.

Recommendation 3.1	Management should review and update its Policy on Gaining Consent to ensure all the latest legal and ethical standards have been incorporated into the policy.
Priority	2
Management Action	**ACCEPTED**
Responsible Manager	Associate Medical Director
Implementation Date	April 2021

Recommendation 3.2	All medical staff should be reminded of the importance of fully completing patient consent forms in order to fully comply with Trust procedures and minimise risk of future queries / concerns from patients.
Priority	2
Management Action	**ACCEPTED**
Responsible Manager	Associate Medical Director
Implementation Date	April 2021

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4 Pre operative Assessment Policies / Procedures and Database

Findings

There are no documented procedures available for pre-operative assessment. We did note that within the POA Team a patient pathway flow-chart has been developed for internal use.

The database system within the Pre-operative Assessment Department for managing the referral of patients has been developed using an Excel spreadsheet and is very basic in recording patients referred to the service and recording actions taken. Testing found issues such as inconsistent recording, use of colour coding and variable quality of notes. Additionally Internal Audit was unable to use the database to match patient records to corresponding PAS data to verify completeness of records. There are separate databases for CAH and DHHsites.

Implication(s)

Absence of clear documented policy and procedures resulting in ambiguity in processes for staff particularly new or inexperienced staff
Incomplete or inaccurate POA records e.g. not all attendees recorded or actions taken.

Recommendation 4.1	Management should produce comprehensive policy and procedures for pre-operative assessment processes and its interfaces with specialties and scheduling teams etc.
Priority	2
Management Action	**ACCEPTED**
Responsible Manager	Clinical Lead for Pre-Op, Head of Services, Lead Nurse for Pre-op & Pre-op Sister
Implementation Date	June 2021

Recommendation 4.2	Management should further document and strengthen its POA database procedures for managing and recording of pre-operative assessments to ensure quality and consistency of records.
Priority	2
Management Action	**ACCEPTED**
Responsible Manager	Clinical Lead for Pre-op and ATICS Head of Service
Implementation Date	April 2023 Implementation date will be dependent on the introduction of Encompass and any funding required for a database system

Recommendation 4.3	In the longer term Management should assess the need to develop a more comprehensive solution to managing and recording pre-operative assessments, integrated with PAS / NIECR etc.
Priority	2
Management Action	**ACCEPTED**
Responsible Manager	Clinical Lead for Pre-op and ATICS Head of Service
Implementation Date	April 2023 Implementation date will be dependent on the introduction of Encompass and any funding required for a database system

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Appendix A Definition of Levels of Assurance and Priorities

Level of Assurance

Satisfactory	Overall there is a satisfactory system of governance, risk management and control. While there may be some residual risk identified, this should not significantly impact on the achievement of system objectives.
Limited	There are significant weaknesses within the governance, risk management and control framework which, if not addressed, could lead to the system objectives not being achieved.
Unacceptable	The system of governance, risk management and control has failed or there is a real and substantial risk that the system will fail to meet its objectives.

Recommendation Priorities

Priority 1	Failure to implement the recommendation is likely to result in a major failure of a key organisational objective, significant damage to the reputation of the organisation or the misuse of public funds.
Priority 2	Failure to implement the recommendation could result in the failure of an important organisational objective or could have some impact on a key organisational objective.
Priority 3	Failure to implement the recommendation could lead to an increased risk exposure.

Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

Note to Report

This audit report should not be regarded as a comprehensive statement of all weaknesses that exist. The weaknesses and other findings set out are only those which came to the attention of Internal Audit staff during the normal course of their work. The identification of these weaknesses and findings by Internal Audit does not absolve Management from its responsibility for the maintenance of adequate systems and related controls. It is hoped that the audit findings and recommendations set out in the report will provide Management with the necessary information to assist them in in fulfilling their responsibilities.

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Received from SHSCT on 09/11/2021. Annotated by the Urology Services Inquiry.

30	18-19	Performance & Reform	IT Cyber Security 18-19	Limited	AD	3.2	No	Priority 2	SHSCT should establish a formal project to segregate all Network Assets. This should contain appropriate project management methodologies including realistic milestones and be subject to regular monitoring to completion.	SHSCT ICT are currently implementing Identity Services Engine (ISE) and ForeScout to identify and manage ALL network Assets. This will be drawn together into a project with an objective to adequately segregate all network assets. The project will have appropriate timescales, milestones, monitoring and	Cyber Security Manager	30/09/2020	30/09/2021	Partially Implemented														Partially Implemented				Partially Implemented	
30	18-19	Performance & Reform	IT Cyber Security 18-19	Limited	AD	5.1	No	Priority 2	This recommendation is being reported in BSO, HSCB and Trusts 1819 IT Audit reports. As strategic lead for IT in HSCNI, the HSCB eHealth and Care Lead is the owner of this recommendation. HSCNI should ensure a regional mechanism is in place to monitor the effectiveness of the Cyber Security Centre (NCSC) advice that is appropriately agreed.• Existing External Gateways are retrospectively approved. • Proposals for introducing new External Gateways are appropriately approved at a regional level.• Regular assurances on External Gateways (and the remediation of any identified vulnerabilities) against HSCNI policy requirements and an agreed schedule. • Appropriate arrangements are in place to ensure organisations in the HSCN organisations should provide regular assurances on live any unknown External Gateways are being proactively detected	HSCB, as strategic lead for IT in the HSCNI, will lead and co-ordinate these matters with the Shared Service Programme Board, the Cyber Security Programme Board, the Technology Infrastructure Board and DoH as appropriate. Given the ongoing work of these Programmes, implementation dates cannot be fixed at this point. It has been agreed that progress towards implementation of the recommendation will be followed up by Internal Audit in March 2020. If recommendations have not been fully addressed by this date, a fixed implementation date will be provided at this point.	eHealth and Care Lead (HSCB)	31/03/2020	31/12/2020	Not Implemented														Not Implemented				Not Implemented	
30	18-19	Performance & Reform	IT Cyber Security 18-19	Limited	AD	7.1	#REF!	Priority 2	This recommendation is being reported in BSO, HSCB and Trusts 1819 IT Audit reports. As strategic lead for IT in HSCNI, the HSCB eHealth and Care Lead is the owner of this recommendation. Information Security Operations Centre should be put in place. This is a function where information systems including applications, infrastructure, data centres and servers, networks, endpoints are monitored, assessed and protected.	HSCB, as strategic lead for IT in the HSCNI, will lead and co-ordinate these matters with the Shared Service Programme Board, the Cyber Security Programme Board, the Technology Infrastructure Board and DoH as appropriate. Given the ongoing work of these Programmes, implementation dates cannot be fixed at this point. It has been agreed that progress towards implementation of the recommendation will be followed up by Internal Audit in March 2020. If recommendations have not been fully addressed by this date, a fixed implementation date will be provided at this point.	eHealth and Care Lead (HSCB)	31/03/2020	28/02/2023	Not Implemented														Not Implemented				Not Implemented	
30	18-19	Performance & Reform	IT Cyber Security 18-19	Limited	AD	7.2	No	Priority 2	This recommendation is being reported in BSO, HSCB and Trusts 1819 IT Audit reports. As strategic lead for IT in the HSCNI, the HSCB eHealth and Care Lead is the owner of this recommendation. Network Access Control should be put in place. This is a network design with a view to understanding all data traffic flows (including clarity over Access Control Lists and ensuring that there is a current requirement) should be undertaken Once a holistic and transparent picture is achieved, appropriate arrangements to enhance security on core links should be put in place (including consideration of Firewalls and IPS installation).	HSCB, as strategic lead for IT in the HSCNI, will lead and co-ordinate these matters with the Shared Service Programme Board, the Cyber Security Programme Board, the Technology Infrastructure Board and DoH as appropriate. Given the ongoing work of these Programmes, implementation dates cannot be fixed at this point. It has been agreed that progress towards implementation of the recommendation will be followed up by Internal Audit in March 2020. If recommendations have not been fully addressed by this date, a fixed implementation date will be provided at this point.	eHealth and Care Lead (HSCB)	31/03/2020	28/02/2022	Partially Implemented														Partially Implemented				Partially Implemented	
30	18-19	Performance & Reform	IT Cyber Security 18-19	Limited	AD	8.1	No	Priority 2	SHSCT should risk assess all existing Third Party Providers with access to SHSCT network assets and take appropriate mitigation steps.	Accepted	IT Contracts & Governance Manager	31/12/2019	31/08/2021	Partially Implemented														Partially Implemented				Partially Implemented	
30	18-19	Performance & Reform	IT Cyber Security 18-19	Limited	AD	8.2	No	Priority 2	SHSCT should ensure that all relevant contracts should contain provisions to ensure minimum security standards are in place.	Accepted	IT Contracts & Governance Manager	31/12/2019	30/09/2021	Partially Implemented														Partially Implemented				Partially Implemented	
30	18-19	Performance & Reform	IT Cyber Security 18-19	Limited	AD	8.3	No	Priority 2	This recommendation is being reported in BSO, HSCB and Trusts 1819 IT Audit reports. As strategic lead for IT in HSCNI, the HSCB eHealth and Care Lead is the owner of this recommendation. A formal framework for Third Party Providers connecting to the HSCNI WAN should be put in place. This should incorporate:• Minimum security requirements for Third Parties connecting to HSCNI network should be documented and agreed with each third party before access to the network is allowed should be introduced. • All contracts should clearly state the minimum security standards.• Appropriate methods to ensure compliance with minimum security standards should be introduced.	HSCB, as strategic lead for IT in the HSCNI, will lead and co-ordinate these matters with the Shared Service Programme Board, the Cyber Security Programme Board, the Technology Infrastructure Board and DoH as appropriate. Given the ongoing work of these Programmes, implementation dates cannot be fixed at this point. It has been agreed that progress towards implementation of the recommendation will be followed up by Internal Audit in March 2020. If recommendations have not been fully addressed by this date, a fixed implementation date will be provided at this point.	eHealth and Care Lead (HSCB)	31/03/2020	31/08/2021	Partially Implemented														Partially Implemented				Partially Implemented	
30	18-19	Performance & Reform	IT Cyber Security 18-19	Limited	AD	9.1	No	Priority 2	SHSCT ICT should strengthen how ICT Administrators connect and authenticate only all management consoles (including Cisco Prime, ISE and ForcePoint). Multifactor authentication should be implemented.	Implement Local Administrator Password Solution (LAPS) solution to randomise the local administrator password to prevent an attacker from using the credentials of the local administrator to move laterally across the network. Implement hardened workstations for ALL IT staff (PAW) to improve hygiene for IT administrators when performing administrative tasks. Multifactor authentication utilising YOTI to be incorporated	IT Comms Manager	31/12/2019	31/12/2020	Partially Implemented														Partially Implemented				Partially Implemented	
30	18-19	Performance & Reform	IT Cyber Security 18-19	Limited	AD	12.1	#REF!	Priority 2	SHSCT ICT should review and establish the minimum level of knowledge, skills, experience and qualification required by staff with responsibility for managing networks. Any gaps should identified should be bridged with appropriate training and qualifications.	All ICT Comms staff have been appropriately trained any gaps are addressed within PDP - as part of ISO 20001 formal CISCO accreditation will be achieved for all communications staff.	IT Comms Manager	31/03/2021	31/03/2021	Imp Date Not Passed	Initial Implementation Date not passed at previous follow up exercise.													Imp Date Not Passed				Imp Date Not Passed	
31	18-19	Acute Services	Theatre Utilisation 18-19	Limited	AE	1.1	No	Not Prioritised	The Trust should regularly monitor delivery of theatre sessions against the funded sessions and ensure that the total annual funded sessions are delivered across the year.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														No comment received from Trust due to Covid 19.				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	1.4	No	Not Prioritised	Management should ensure that regular reports are generated and should be used by Management to take ally to address common issues and gain early to maximise theatre time by specialty and location.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														Management are developing regular reports to be used by Management to take action to address common issues and generally to maximise theatre time by specialty and location.				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	2.1	No	Not Prioritised	As previously recommended in Overseas Travel Audit 2018/19, in order to secure the benefits of the regional travel framework, all travel should be booked through the Regional Travel Office (unless there is a clear reason why this cannot be done with local booking tools). However, there is a need to ensure ALBs are satisfied that all travel arrangements represent value for money as part of their contract management arrangements. The framework agreement allows for cheaper alternatives to be identified to the booking company who will then endeavour to secure the same price, where possible.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														Discussed at the TMS Information meeting 27/8/2019. The information team has prioritised the emergency reports urgently for uploading on sharepoint. Due to covid 19 this has not been completed. However emergency utilisation reports are available on business objects for analysis.				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	2.2	No	Not Prioritised	Management report for emergency theatres should be regularly run and monitored by Management.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														Linked with 2.1. Information team are prioritising the emergency theatre utilisation report.				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	2.3	No	Not Prioritised	Based on the utilisation of DHH emergency theatre, there is a rationale for reviewing available emergency theatre hours in DHH and also considering utilising CAH more fully for expedited category patients.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														Linked with 2.1. Information team are prioritising the emergency theatre utilisation report.				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	3.1	#REF!	Not Prioritised	Management should review information provided to patients as part of pre-admission process, to reduce level of cancelled theatre slots.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														All patient information to be reviewed - pre-op/ patient information letters. There is a separate pre-op internal audit completed which was circulated in draft form in April 2020. Due to Covid 19 this has not been progressed				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	3.3	No	Not Prioritised	Management should review the processes in place for surgical pre admission in particular where there are significant waiting lists	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														During covid 19 the surgical waiting lists were validated and clinically prioritised. Business case only undertaken on the impact hospitals list who had a covid+ ?				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	3.4	No	Not Prioritised	The Trust should introduce renewed awareness campaigns for DNAs or CNAs and the overall impact this has on wasting bale etc.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														The IEAP is being reviewed regionally at present. Once new guidance to be circulated when agreed. In the meantime the Trust is to consider awareness to patients re- importance of DNA/ CNA. Trust to ensure that all patients scheduled are familiar with the campaign. However, since covid 19 the process is being reviewed due to patients not accepting surgery dates or cancelling due to covid fears.				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	4.1	No	Not Prioritised	The Trust should establish how these issues can be addressed in light of on-going pressures on inpatient beds.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														impact of high levels of emergency admissions. There are ongoing challenges due to bed pressures. The operational AD huddle takes place Monday/ Wednesday / Friday - ours bed pressures are discussed				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	5.1	No	Not Prioritised	Specific focus should be given to recruitment of theatre nursing staff.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														Ongoing recruitment fairs/ awareness throughout the Trust. Comparison tables have been developed illustrating increase in theatre nursing gaps from Dec 18 and July 19. AD for ATCs and SEC has brought the table and cahallenges to the attention of the Director of Acute Services and Executive Director and AD for Nursing Workforce				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	6.1	No	Not Prioritised	In order to achieve the required 8 week notice period for pre-operative assessments the Trust's utilisation of patients management should consider reviewing the Medical Directorate policy.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														Recommendation to be discussed with the Medical Director and AMD. AMD has implemented DNS rules to other specialties which locks down the rota with Eukedia rulings				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	6.2	No	Not Prioritised	The surgical rotas should be prepared and made available on a timely basis, to allow for efficient scheduling and booking of patients onto theatre lists and appropriate time for pre-operative assessments to be completed.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														Communication to be circulated to all relevant staff re: deadline for submission of rotas to the theatre team. Due to covid 19 theatre rotas have been more challenging to timetable due to specialty absence/ theatres				Partially Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	7.1	No	Not Prioritised	The Trust should explore options to allow timely completion of pre-operative assessments, patients listed in theatre sessions should be notified to Pre-Operative Assessment Team 6 weeks in advance of surgery date.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Not Implemented														Additional staff within the pre-op team. Trust to secure potential funding for enhancement of the pre-op service before planners complete a paper. The Director of acute services is going to discuss the Pre-op service with the Director of performance. An injection of funding is required to meeting the demand on the pre- op service				Not Implemented	
31	18-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	8.1	No	Not Prioritised	The governance arrangements around the management of theatre utilisation should be discussed and agreed.	Accepted	Assistant Director of Acute Services	30/09/2019	31/03/2021	Partially Implemented														KS to be discussed and agreed at THSJUG. Theatre utilisation reports to be discussed at AD operational meeting and Directorate meetings. Ongoing				Partially Implemented	
31	19-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	9.1	No	Not Prioritised	The Trust should ensure that an overarching procedure which details the process for the patient surgical journey from when they are listed for surgery, through scheduling for theatre, pre-op assessment through to discharge is developed.	Accepted	Assistant Director of Acute Services			Partially Implemented														No comment received from Trust due to Covid 19.				Partially Implemented	
31	19-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	9.2	No	Not Prioritised	The Theatre Escalation procedure should be reviewed to ensure it is still appropriate and an agreed future review date included on the document.	Accepted	Assistant Director of Acute Services			Partially Implemented														No comment received from Trust due to Covid 19.				Partially Implemented	
31	19-19	Acute Services	Theatre Utilisation 18-19	N/A	AE	9.3	No	Not Prioritised	The Regional TMS guidance should be adopted by the Trust. A review date should be included on this document.	Accepted	Assistant Director of Acute Services			Partially Implemented														No comment received from Trust due to Covid 19.				Partially Implemented	
32	18-19	Chief Executive	Board Effectiveness 18-19	Satisfactory	AF	3.2	No	Priority 2	The Trust should seek to improve Trust Board's involvement in planning and strategy We understand this is the intended focus of the Board in their next phase of development.	Live existing workshops to focus on strategic direction. This will be the focus of the workshop on 12th December 2019	Chair and Chief Executive			Partially Implemented														The strategic planning process had commenced with Trust Board with the intention of developing a new Corporate Plan. This was overtaken by the Covid-19 environment				Partially Implemented	
32	18-19	Chief Executive	Board Effectiveness 18-19	Satisfactory	AF	7.1	No	Priority 2	The Trust should review its Clinical Governance structures, with a view to further developing and strengthening current arrangements.	Independent review of clinical and social care governance commissioned. Report to be available in October 2019.	Chief Executive			Partially Implemented														Independent Review of Clinical and Social Care Governance commissioned and draft report produced in November 2019. 3 areas of improvement work being forward on SAIs, Standards and Guidelines, and Complaints and subsequently presented to Governance Committee.				Partially Implemented	
33	19-20	Finance	Review of Client Monies at Parkanaur College 19-20	Limited	AG	3.1	No	Priority 2	Each Trust should review current processes in the facility for the management of their residents' bank accounts. Trusts should ensure that: • The Facility is not accessing resident bank accounts where they do not have Power of Attorney; • Monthly bank reconciliations should be put in place between resident ledgers and bank statements where facility is appropriately continuing to manage money on behalf of residents. These should be signed and reviewed by separate staff members independent of process. • Formal agreements should be put in place, where appropriate, to clarify and define how facilities should manage bank transactions on behalf of residents where appropriate.	Accepted	Assistant Director of Finance	30/11/2019	31/03/2021	Partially Implemented														Work is ongoing				Partially Implemented	
34	19-20	Finance	Charitable Funds 19-20	Satisfactory	AH	2.2	#REF!	Priority 2	The Trust should continue preparatory work and planning for the rationalisation of the Charitable Trust Funds incorporating any learning from BHSCT.	Accepted	Assitant Director Finance	31/03/2021	31/03/2021	Imp Date Not Passed	Initial Implementation Date not passed at previous follow up exercise.													Imp Date Not Passed				Imp Date Not Passed	
34	19-20	Finance	Charitable Funds 19-20	Satisfactory	AH	4.1	No	Priority 2	Management should review the systems for recording and reporting by directorates on a monthly basis for all non-cash donations over the value of £50 received by wards/facilities. This process should be communicated through updating the Charitable Trust Fund Management Guidance. Any non-cash donations in line with both the Gifts and Hospitality and Asset Management policies and procedures should be clarified.	Accepted	Assitant Director Finance	31/03/2020	31/03/2021	Not Implemented														Due to other priorities associated with COVID 19, there is a delay in updating CTF procedures.				Not Implemented	
35	19-20	Estates	Fire Safety 19-20	Limited	AI	3.1	No	Priority 2	Nominated Fire officers must ensure that Fire training and associated records are completed in a standardised format in line with Trust procedures. Nominated Fire officers must report to Fire safety Committee on a quarterly basis to confirm that fire training and the necessary documentation has been completed for their areas of responsibility.	Accepted	Nominated Fire Officers	31/10/2019	31/03/2021	Partially Implemented														Staff have been reminded of the need to complete mandatory Fire safety Training however uptake due to covid has been minimal.				Partially Implemented	
35	19-20	Acute Services	Fire Safety 19-20	Limited	AI	3.2	No	Priority 2	Directors should closely monitor staff attendance at Fire safety training within their directorates where there is low compliance actions should be taken to address the issues	Accepted	Director Acute Services	31/10/2019	31/03/2021	Partially Implemented														Staff have been reminded of the need to complete mandatory Fire safety Training however uptake due to covid has been minimal.				Partially Implemented	Staff have been reminded of the need to complete mandatory Fire safety Training however uptake due to covid has been minimal.
35	19-20	Finance	Fire Safety 19-20	Limited	AI	3.2	Yes	Priority 2	Directors should closely monitor staff attendance at Fire safety training within their directorates where there is low compliance actions should be taken to address the issues	Accepted	Director Finance	31/10/2019	31/03/2021	Partially Implemented														Staff are continually reminded of need to maintain CMT.				Split		Partially Implemented	Staff are continually reminded of need to maintain CMT.
35	19-20	Mental Health & Disability	Fire Safety 19-20	Limited	AI	3.2	Yes	Priority 2	Directors should closely monitor staff attendance at Fire safety training within their directorates where there is low compliance actions should be taken to address the issues	Accepted	Director Mental Health	31/10/2019	31/08/2020	Partially Implemented														Staff have been reminded of the need to complete mandatory Fire safety Training however uptake due to covid has been minimal.				Split		Partially Implemented	Staff have been reminded of the need to complete mandatory Fire safety Training however uptake due to covid has been minimal.
35	19-20	Medical	Fire Safety 19-20	Limited	AI	3.2	Yes	Priority 2	Directors should closely monitor staff attendance at Fire safety training within their directorates where there is low compliance actions should be taken to address the issues	Accepted	Medical Director	31/10/2019	31/03/2021	Partially Implemented														Staff have been reminded of the need to complete mandatory Fire safety Training however uptake due to covid has been minimal.				Split		Partially Implemented	Staff have been reminded of the need to complete mandatory Fire safety Training however uptake due to covid has been minimal.
35	19-20	Children and Young Peoples	Fire Safety 19-20	Limited	AI	3.2	Yes	Priority 2	Directors should closely monitor staff attendance at Fire safety training within their directorates where there is low compliance actions should be taken to address the issues	Accepted	Director Childrens and Young people	31/10/2019	31/03/2021	Partially Implemented														CYPS continue to monitor all levels of Corporate Mandatory Training and compliance is discussed at a monthly HR SMT meeting. Due to Covid, these meetings have been temporarily stood down but Assistant Directors continue to monitor .				Split		Partially Implemented	CYPS continue to monitor all levels of Corporate Mandatory Training and compliance is discussed at a monthly HR SMT meeting. Due to Covid, these meetings have been temporarily stood down but Assistant Directors continue to monitor .
35	19-20	Performance & Reform	Fire Safety 19-20	Limited	AI	3.2	Yes	Priority 2	Directors should closely monitor staff attendance at Fire safety training within their directorates where there is low compliance actions should be taken to address the issues	Accepted	Director Performance & Reform	31/10/2019	31/03/2021	Partially Implemented														Work is ongoing and staff have been reminded of the need to complete CMT.				Partially Implemented		Partially Implemented	Work is ongoing and staff have been reminded of the need to complete CMT.
35	19-20	Nursing	Fire Safety 19-20	Limited	AI	3.2	Yes	Priority 2	Directors should closely monitor staff attendance at Fire safety training within their directorates where there is low compliance actions should be taken to address the issues	Accepted	Director Nursing	31/10/2019	31/03/2021	Partially Implemented														Work is ongoing and staff have been reminded of the need to complete CMT.				Split		Partially Implemented	Work is ongoing and staff have been reminded of the need to complete CMT.
35	19-20	Human Resources	Fire Safety 19-20	Limited	AI	3.2	Yes	Priority 2	Directors should closely monitor staff attendance at Fire safety training within their directorates where there is low compliance actions should be taken to address the issues	Accepted	Director HROD	31/10/2019	31/03/2021	Partially Implemented														COVID 19 is also having an impact upon compliance, however monitoring of Corporate Mandatory Training for HR Staff is included as part of HROD Governance Framework.				Split		Partially Implemented	COVID 19 is also having an impact upon compliance, however monitoring of Corporate Mandatory Training for HR Staff is included as part of HROD Governance Framework.
36	19-20	Older People & Primary Care	Non Pay Expenditure 19-20	Satisfactory	AJ	1.2	No	Priority 2	For the non-social care procurement spend above, the Trust should ensure appropriate procurement processes to cover this expenditure in the future.	Accepted	Assistant Director Primary Care and Assistant Director Enhanced Services	31/03/2020	31/03/2021	Partially Implemented														Work is ongoing and a further update will be provided in March 21				Partially Implemented		Partially Implemented	
36	19-20	Older People & Primary Care	Non Pay Expenditure 19-20	Satisfactory	AJ	1.3	No	Priority 2	The Trust should liaise with FALs in relation to the 9 suppliers with multiple order lines to ensure appropriate procurement processes are in place or put in place for future expenditure.	Accepted	Assistant Director Primary Care and Assistant Director Enhanced Services	31/03/2020	31/03/2021	Partially Implemented														Work is ongoing and a further update will be provided in March 21				Partially Implemented		Partially Implemented	
36	19-20	Older People & Primary Care	Non Pay Expenditure 19-20	Satisfactory	AJ	2.1	No	Priority 2	The Trust should ensure that invoice approvers are aware of their responsibilities in respect of the verification of invoices including checking against the contract rates and fully verifying quantities or service delivery.	Accepted	Assistant OPPC Assistant Director Primary Care and Assistant Director Enhanced Services	31/12/2019	31/03/2021	Partially Implemented														Memo drafted for circulation to OPPC Heads of Services and their teams highlighting and containing invoice approver responsibilities policy. 29/09/20				Partially Implemented		Partially Implemented	
37	19-20	Finance	PPP MHD 19-20	Satisfactory	AK	4.2	#REF!	Priority 2	Older balances for discharged or potentially for deceased patients should be reviewed and actioned as appropriate.	Accepted	Head of Financial Services	31/12/2020	31/12/2020	Imp Date Not Passed	Initial Implementation Date not passed at previous follow up exercise.													Imp Date Not Passed				Imp Date Not Passed	
38	19-20	Human Resources	Travel Expenses 19-20	Satisfactory	AL	1.2	#REF!	Priority 2	Staff and managers should be reminded of the requirement for approvals to be obtained in advance of committing expenditure for training, courses and conferences. These approvals should detail as a minimum the anticipated costs for staff to attend.	Accepted	Head of Organisational Development & Learning	30/11/2019	31/08/2020	Implemented														Delayed due to COVID 19. However a SLWG had met and procedures have been drafted. In addition an email has been drafted for dissemination through Directorates but to COVID 19 outbreaks in CAH has not yet been issued. SLWG meeting is being re-arranged.				Implemented		Implemented	Delayed due to COVID 19. However a SLWG had met and procedures have been drafted. In addition an email has been drafted for dissemination through Directorates but to COVID 19 outbreaks in CAH has not yet been issued. SLWG meeting is being re-arranged. Implemented at Mid Year 2020/21
38	19-20	Human Resources	Travel Expenses 19-20	Satisfactory	AL	1.3	No	Priority 2	Management should review information provided to patients as part of pre-admission process, to reduce level of cancelled theatre slots.	Accepted	Short life Trust working group reporting to Director of Human Resources	31/12/2019	31/08/2020	Implemented														Delayed due to COVID 19. However a SLWG had met and procedures have been drafted. In addition an email has been drafted for dissemination through Directorates but to COVID 19 outbreaks in CAH has not yet been issued. SLWG meeting is being re-arranged.				Implemented		Implemented	Delayed due to COVID 19. However a SLWG had met and procedures have been drafted. In addition an email has been drafted for dissemination through Directorates but to COVID 19 outbreaks in CAH has not yet been issued. SLWG meeting is being re-arranged. Implemented at Mid Year 2020/21
38	19-20	Human Resources	Travel Expenses 19-20	Satisfactory	AL	3.1	No	Priority 2	Staff should be reminded of the requirement for an estimate of all costs for travel to be included in the course approval form prior to authorisation. A course approval form should always be completed in advance of a trip being undertaken and this should include reasons for travel.	Accepted	Head of Employee Relations	30/11/2019	31/08/2020	Implemented														Delayed due to COVID 19. However a SLWG had met and procedures have been drafted. In addition an email has been drafted for dissemination through Directorates but to COVID 19 outbreaks in CAH has not yet been issued. SLWG meeting is being re-arranged.				Implemented		Implemented	Delayed due to COVID 19. However a SLWG had met and procedures have been drafted. In addition an email has been drafted for dissemination through Directorates but to COVID 19 outbreaks in CAH has not yet been issued. SLWG meeting is being re-arranged. Implemented at Mid Year 2020/21
38	19-20	Human Resources	Travel Expenses 19-20	Satisfactory	AL	3.2	No	Priority 2	Staff should be reminded of the requirement for all course approval forms for overseas travel to be approved at Director level, prior to booking.	Accepted	Head of Organisational Development & Learning – AFC Staff	30/11/2019	31/08/2020	Implemented														Delayed due to COVID 19. However a SLWG had met and procedures have been drafted. In addition an email has been drafted for dissemination through Directorates but to COVID 19 outbreaks in CAH has not yet been issued. SLWG meeting is being re-arranged.				Implemented		Implemented	Delayed due to COVID 19. However a SLWG had met and procedures have been drafted. In addition an email has been drafted for dissemination through Directorates but to COVID 19 outbreaks in CAH has not yet been issued. SLWG meeting is being re-arranged. Implemented at Mid Year 2020/21
38	19-20	Human Resources	Travel Expenses 19-20	Satisfactory	AL	4.1	#REF!	Priority 2	All staff claiming and submitting claims for excess travel should be reminded on the need to submit details of the journey being travelled and that the miles claimed should be what is approved by Human Resources.	Accepted	Head of Employee Relations	30/11/2019	31/08/2020	Implemented														Reminder issued to staff claiming and submitting claims for excess travel on the need to submit details of the journey being travelled and that the miles claimed should be what is approved by Human Resources.				Implemented		Implemented	Reminder issued to staff claiming and submitting claims for excess travel on the need to submit details of the journey being travelled and that the miles claimed should be what is approved by Human Resources. Implemented at Mid Year 2020/21
39	19-20	Human Resources	Core HR 19-20	Satisfactory	AM	1.2	#REF!	Priority 2	The system cannot link posts after they have been input and payroll run. This will require the team to terminate one contract, re-enter it and link the posts at that time. This will also require communication of the issue with the affected staff.	Accepted	Head of Employee Relations	30/04/2020	31/03/2021	Partially Implemented														Partially complete (84 of 88 have been completed). Work is continuing to complete the remaining 4 actions.				Partially Implemented	
39	19-20	Human Resources	Core HR 19-20	Satisfactory	AM	2.1	No	Priority 2	HR should determine what is available within the system to enable them to carry out regular review and challenge of user activity for users where there is a contravention of the Segregation of Users (SOD) Matrix.	Accepted	Head of Workforce Information	30/04/2020	31/03/2021	Partially Implemented														Update emailed to IA 2/9/20 with proposal to close this recommendation – see attached evidence/paper - in summary, we hadnot identified any further useful reporting/checking for HRPTS User Activity, however we wasbelieved that if a specific issue or concern arises there are some further reportsinformation we could use to look into the matter further. The recommendation is to close as the SOD risk is already completed, and operational, which helps address the risk of potential fraud by HRPTS Core Users, and also noted some system limitation details. Internal audit considered this request and replied on 7/9/20 that WHSCT are able to carryout a level of HRPTS User Activity Monitoring – we have now agreed to link in with WHSCT again, and other regional HRPTS S&S colleagues, to see what they are doing in relation to activity monitoring. Revised 'Current Status' is therefore 'Partial Implementation'. Revised implementation date of February 2021 due to current COVID 19 Pandemic - however the further work will be progressed as soon as possible.				Partially Implemented	
40	19-20	Acute Services	Pharmacy Procurement & Contract management 19-20	Satisfactory	AN	1.1	#REF!	Priority 2	*This recommendation is being reported in all Trusts Pharmacy Procurement & Contract Management 2019/20 Audit reports. However, the NHSCT, as the host of RPPS will lead on the implementation of this recommendation. RPPS should review total HSC expenditure on individual product lines with the aim of promoting further savings across HSC.*	The regional non-contract compliance reports will be piloted to report and analyse Trust purchase spend every six months. This will then inform the regional procurement work-plan as agreed via RPCEG.	Southern Trust Director of Pharmacy, as Southern Trust representative on RPCEG.	30/04/2020	31/03/2021	Partially Implemented														Internal audit viewed minutes of Regional RPCEG from 25 February 2020 and 20 August 2020 which details the work ongoing to implement these recommendations.				Partially Implemented		Partially Implemented	
40	19-20	Acute Services	Pharmacy Procurement & Contract management 19-20	Satisfactory	AN	1.2	No	Priority 2	*This recommendation is being reported in all Trusts Pharmacy Procurement & Contract Management 2019/20 Audit reports. However, the NHSCT, as the host of RPPS will lead on the implementation of this recommendation. The risk associated with capacity of procuring and renewing pharmacy contracts in a timely manner should be recorded and managed.*	RPCEG reviews the work-plan at each quarterly meeting. It will develop a formal risk register to formally record the risks associated with capacity of procuring and renewing pharmacy contracts in a timely manner. This will include an associated management action plan which will be monitored at each RPCEG meeting.	Southern Trust Director of Pharmacy, as Southern Trust representative on RPCEG.	30/06/2020	31/03/2021	Partially Implemented														Internal audit viewed minutes of Regional RPCEG from 25 February 2020 and 20 August 2020 which details the work ongoing to implement these recommendations.				Partially Implemented		Partially Implemented	
40	19-20	Acute Services	Pharmacy Procurement & Contract management 19-20	Satisfactory	AN	1.3	No	Priority 2	*This recommendation is being reported in all Trusts Pharmacy Procurement & Contract Management 2019/20 Audit reports. However, the NHSCT, as the host of RPPS will lead on the implementation of this recommendation. RPPS should review total HSC expenditure on individual product lines with the aim of promoting further savings across HSC.*	RPPS will continue to review HSC expenditure on individual product lines with the aim of promoting further savings across HSC. We note that contract compliance exceeds 90% for all Trusts. Also the Medicines Optimisation Regional Efficiency Group (MOREG) Programme of Work for 2019/20 has been approved which includes the following projects: New Biosimilar Uptake; Biosimilar Switching; and Value Based Procurement. The Trust Pharmacy Procurement Leads currently review project scope with RPPS including the opportunity to propose additional lines not originally identified. Trust Pharmacy Procurement leads will pilot additional reporting methodology each month to review those new products and associated expenditure added to the Pharmacy system to inform the regional work.	Southern Trust Director of Pharmacy, as Southern Trust representative on RPCEG.	30/04/2020	31/03/2021	Partially Implemented														Internal audit viewed minutes of Regional RPCEG from 25 February 2020 and 20 August 2020 which details the work ongoing to implement these recommendations.				Partially Implemented		Partially Implemented	
40	19-20	Acute Services	Pharmacy Procurement & Contract management 19-20	Satisfactory	AN	2.2

Weekly Reportable COVID-19 deaths 7th January – 13th February 2022)	6	2

13/01/2022 - Chris has been asked to produce incident data to identify trends within ED. This will include all incidents including Medication.
Update 27/01/2022 – Acute are working on this report for all specialties including ED
17/02/2022: Chris has sent this information to Dr Gormley, also to be shared with Dr O'Kane

CCS2 Code search.xlsx

Covid Key Word Search.xlsx

17/02/2022: Trudy highlighted a lab contamination issue, working through mitigations and an Early Alert has been submitted (will be reported in next week's paper)

50. Internal Audit Recommendations

Operational Directorates IA relev

Discussion at meeting	Action
There was discussion around the need not to duplicate the work of the Trust's Internal Audit Forum which already follows up the status of internal audit recommendations for the mid-year and year end assurance process. There is no intention to usurp the purpose of that Internal Audit group. The purpose of including the IA recommendations on the Weekly Governance agenda is to ensure that we do not lose sight of those recommendations which relate to governance. This group will not be looking at the progress on each recommendation weekly – a quarterly update will probably be sufficient. Each Operational Directorate is to bring back their updates to next week's meeting. Their updates are to be sent through to Corporate Governance for collating for next week's Governance Meeting	Each Operational Directorate to update their area for next week's Governance Meeting **30/09/2021 –** It was agreed that each Directorate are to bring an update for 1 recommendation for their area to next weeks meeting. **07/10/2021** – Caroline and Dr O'Kane to discuss this offline to agree a process to move forward the recommendations that have not progressed. **14/10/2021** – Caroline and Dr O'Kane to meet to discuss the process for recording Internal Audit Recommendations, Learning from Litigation and Pressure Ulcers Data **29/10/2021** – No update.

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There are 35 Recommendations for all the Operational Directorates. 1 person from each directorate should be nominated to bring back updates. Caroline Doyle will be the person to update Internal Audit for the Master Copy of Report	**04/11/2021** – Caroline to link with Emma Campbell to get a date in the diary re this. **11/11/2021** – Emma coming back to Caroline with suitable date **18/11/2021** - Caroline continues to work with Emma to secure a meeting date **09/12/2021 –** Internal Audit Committee next meeting is 17th January all teams should progress with securing updates on all recommendations. **16/12/2021** – Teams encouraged to continue with Internal Audit progression. **17/02/2022 –** Teams to make a concerted effort to address internal audit recommendations

51. Reporting of Falls, Violence and Aggression and Pressure Ulcers Incidents

Falls

	Insignificant	Minor	Total
1 East Maternity/Gynae	1	3	4
2 North Respiratory	0	2	2
2 South Medical and Stroke	1	1	2
3 North Medical and Covid	0	1	1
3 South	0	2	2
Appleby SEC, Armagh	1	0	1
Aughnacloy House	2	0	2
Cloughmore Ward	1	0	1
Emergency Department CAH	0	2	2
Emergency Department DHH	0	1	1
Female Medical	0	1	1
Our Mother of Mercy Nursing Home	0	1	1
Rosemount Care Home	1	0	1

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and night, so whether I'm there at 9 or 10, it doesn't affect them in any way.

265 Q. Right. We're aware, looking at one particular case, of a patient who came in with a bleeding kidney tumour on a Thursday and -- this wasn't your week -- 15:42

A. No.

266 Q. -- that there didn't seem to be much consultant presence over the weekend. What's your comment there. Did it usually work well? The consultants would normally go in to either do a full round or see at 15:43 least the unwell patients at the weekend? What is your experience?

A. Well I can only speak for myself. So I went in on Saturday, spent all day on Saturday. On Sundays, if I had a locum, I would go in or if there were ill 15:43 patients. If I had an experienced registrar and the patients were unstable, I let him do the ward round on Sundays and I came in if the patients needed to go to theatre.

267 Q. Would you be surprised if there was a fairly sick 15:43 person who had not been seen by someone senior?

A. If I knew there was somebody sick, I would certainly be in. I wouldn't leave it to a registrar.

268 Q. Okay. Thank you. Just one more thing about pre-op assessment. We spoke about Patients 90 and 91, and 15:43 obviously things do slip through with pre-op assessments, but there's another hurdle that should be gone through, the World Health Organisation checklist before things finally click into action. Did you look

at that in terms of PATIENT SAFETY and say how did these two get through and perhaps think about that?

A. Absolutely. I mean the WHO happens automatically. I've never done an operation in the last few years without the WHO happening. But the WHO is a more sort of correct side, has the patient been given antibiotics, is the site marked. Any concerns, I suppose, yes, about the patient. But I think if you get on the table and if your comorbidities haven't been set out before, I think the WHO is not going to stop that, I think. 15:44 15:45

269 Q. A shame, though. Maybe a missed opportunity?

A. Maybe I am wrong because the anaesthetist will have seen the patient already on the ward, so if they get past the anaesthetist and get to the operating theatre, they've already got over the hurdles. 15:45

270 Q. Just it wasn't really mentioned in the SAI reports.

A. Yes.

271 Q. One last very quick one. Mr. Wolfe has mentioned, I think, Dr. Gray, a Belfast -- 15:45

A. Yes, he is a radiologist.

272 Q. You saw the email there. Something that wasn't read out was "debacle of the small renal masses". I wasn't quite sure what that meant. Was that a reference to radiology or the process of looking after that group of patients which, in Patient 7, I wondered whether that was a reference to the process of looking at that group of patients or was that a reference to the radiology particularly? 15:45

in the same room, and that would create a greater closeness -- out of proximity, but I don't, I don't see any reason why he may have come to that view and I don't recognise it.

94 Q. Yes. 12:02

A. Because I had no difficulty with the oncologists in Belfast and I valued their input and so forth.

95 Q. Yes. We've seen, and we'll explore your thinking in terms of your approach to prostate cancer management as we go on. 12:02

A. Hmm.

96 Q. But we've seen perhaps multiple examples of cases where you have maintained the patient on Bicalutamide, sometimes on 50mgs over a lengthy period of time, a lifetime in some cases, sometimes going from 50 to 150, maintaining on that monotherapy, and then, in some cases, the patient's PSA rising, arguably unexpectedly, but certainly rising to an extent where a referral is ultimately needed. One might infer from that, perhaps, that you're reaching management decisions in conjunction with your patient, whereas you really should be engaging with Oncology to discuss the wisdom in any particular case of that form of management? 12:03 12:03

A. Well, in all of those cases, that would have been the patient's preference. I would have outlined all of those prospects of patient management with the patient. That was -- I spent quite some considerable time doing so. And it's important to emphasise that in the doing of it, I avoided being subjective in my views in that 12:04

regard. I provided them with all of the objective information that is available with regard to management options. So, as I briefly explained to you in recent times, you know, I never -- I never embarked upon androgen deprivation therapy using Bicalutamide at either dose with the intent that this was going to be monotherapy. And the reasons why some patients were introduced at a dose of 50mgs was because they were concerned about embarking upon androgen deprivation therapy, never mind radical radiotherapy. You know, patients didn't want to be referred for radical radiotherapy. Now I do appreciate that there is counterview where the oncologists have said "I would have preferred to have seen this patient earlier", but if the patient doesn't want to be seen earlier by the oncologist, I mean, that doesn't negate the oncologist's view, but that is -- that is the reality. I think, actually, in my primary witness statement, I think I chronicle the case of -- oh, yes, Patient 35, whose son gave evidence to the Inquiry from Personal Information redacted by the USI. 12:04 12:05 12:05 12:05

97 Q. Yes.

A. You know, a perfect example of where all of those options and the recommendations of MDM were discussed with his father, that patient, many, many times over a period of years, where he chose to have active surveillance in the first instance. Remarkably I was criticised I think for that, because active surveillance had not been included in the 2008 Prostate Cancer Guidelines, the NICE guidelines, for that 12:06

Southern Health and Social Care Trust

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Urology Cancer MDT Operational Policy - Agreement Cover Sheet

This MDT Operational Policy has been agreed by:

Position	Director of Acute Services
Name	Mrs Esther Gishkori
Organisation	Southern Health & Social Care Trust
Date Agreed	1st September 2017
Signed	Personal Information redacted by USI

Position	Clinical Director Cancer Services
Name	Dr Rory Convery
Organisation	Southern Health & Social Care Trust
Date Agreed	1st September 2017
Signed	Personal Information redacted by USI

Position	MDT Lead Clinician (on behalf of MDT members)
Name	Mr Anthony Glackin
Organisation	Southern Health & Social Care Trust
Date Agreed	1st September 2017
Signed	Personal Information redacted by USI

The MDT members agreed this Operational Policy on:

Date Agreed	**1st September 2017**
Operational Policy Review Date	**1st September 2018**

Received from Tughans OBO Mr Aidan O'Brien on 26/01/2022. Annotated by the Urology Services Inquiry

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Introduction

This document outlines the Operational Policy for the Urology MDT and will be reviewed on an annual basis at the Annual General Meeting. It has been developed to ensure all relevant members of staff are aware of the purpose and organisation of the MDT meeting.

Background

The Southern Health and Social Care Trust (SHSCT) was formed on 1 April 2007. The Southern Trust (ST) is an integrated Trust, providing acute and community hospital services together with a range of community health and social services to a population of approximately 324,000 people.

Southern Trust Urological Cancer Services

The Southern Trust has provided a Urology service for patients living in the southern part of Northern Ireland since 1992. Outpatient services are located at a dedicated unit, the Thorndale Unit, based in Craigavon Area Hospital. The Unit is staffed by Consultant Urologists, Clinical Nurse Specialists, Staff Nurses and Health Care workers, in addition to visiting Radiographers and Radiologists.

Following a review of urological service provision in Northern Ireland in 2008/09, the trust took on responsibility for the provision of services to the population of County Fermanagh, with effect from 1st January 2013. County Fermanagh has a population of 61,175. More recently, the trust has agreed on a temporary basis to provide urological services to the population of and surrounding Cookstown, County Tyrone, bringing the entire catchment population to 427,000.

Within the SHSCT, urological cancer services include surgery to treat kidney, urothelial, penile and testicular cancers. The service does not provide radical pelvic surgery for prostate and bladder cancer.

In addition to all of the urological services provided at Craigavon Area Hospital, other services provided include endoscopic and day case surgery at South Tyrone Hospital in Dungannon, outpatient clinics at Banbridge Polyclinic, Armagh Community Hospital and South West Acute Hospital in Enniskillen, County Fermanagh.

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SECTION 1: STRUCTURE AND FUNCTION OF THE MDT

1.0 Purpose of the MDT

MDTs bring together staff with the necessary knowledge, skills and experience to ensure high quality diagnosis, treatment and care for patients with cancer. MDT working has been advocated in each of the NICE Improving Outcomes Guidance and is strongly supported by clinicians.

The primary aim of the SHSCT Urology Cancer MDT is to ensure equal access to diagnosis and treatment for all patients in the agreed catchment area with Urological cancer. In order to achieve this aim we provide a high standard of care for all patients including: efficient and accurate diagnosis, treatment and ensuring continuity of care.

The MDT ensures a formal mechanism for multidisciplinary input into treatment planning and ongoing management and care of patients with Urological cancer with the aim of improving outcomes and to:

- Provide an opportunity for multidisciplinary discussion of all new cases of Urological cancer presenting to the team
- To assess newly diagnosed cancers and determine, in the light of all available information and evidence, the most appropriate treatment and care plan for each individual patient
- Ensure care is delivered according to recognised guidelines
- Ensure that the MDT work effectively together as a team regarding all aspects of diagnosis, treatment and care
- Facilitate communication with other professional groups within the hospital and between the MDT and other agencies e.g. primary care, palliative care
- Facilitate collection and analysis of high quality data to inform clinical decision making and to support clinical governance/audit
- Promote multidisciplinary decision making regarding the team's operational policies
- Support implementation of service improvement initiatives
- Ensure incorporation of new research and best practice into patient care
- Ensure mechanisms are in place to support entry of eligible patients into clinical trials, subject to patients fully informed consent
- Provide education to senior and junior medical, nursing and allied health staff.

1.1 Membership Arrangements

Core and extended membership of the Urology cancer MDT is detailed below:

Core Membership **(14-2G-101)**

Position	Name	Cover
Consultant Urological Surgeon*/**	Anthony Glackin	Aidan O'Brien Mark Haynes

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Consultant Urological Surgeon	Aidan O'Brien	Anthony Glackin Mark Haynes
Consultant Urological Surgeon	Mark Haynes	Anthony Glackin John O'Donoghue
Consultant Urological Surgeon	John O'Donoghue	Mark Haynes Aidan O'Brien
MDT Co-coordinator	Shauna McVeigh	Member of Cancer Tracker Team
Consultant Clinical Oncologist**	Ciara Lyons (locum)	vacant
Consultant Radiologist	Dr Marc Williams	vacant
Consultant Histopathologist (EQA certified)	Dr Gareth McClean	Dr R.Shah Dr K.Dedic
Clinical Nurse Specialist***	Kate O'Neill	Dolores Campbell
Palliative Care Nurse	Stephanie Reid	Member of Palliative Care Nursing Team

** Lead Clinician*
*** Lead for clinical trial recruitment*
****Lead for patient involvement, information & service improvement*

Extended Membership **(14-2G-105)**

Position	Name	Cover
Consultant Urological Surgeon	Michael Young	Anthony Glackin Aidan O'Brien Mark Haynes
Consultant Psychologist	Dr Mary Daly	Mrs M.Duggan
Consultant in Palliative Care Medicine	Dr Tracy Anderson	Clinical Nurse Specialist
Stoma / Coloproctology Nurse Specialist	Claire Young	Clinical Nurse Specialist

1.2 Leadership Arrangements and Responsibilities (14-2G-101)

The Lead Clinician for the Urology Cancer MDT is Mr Anthony Glackin. The Trust and the Clinical Director for Cancer Services, Mr Rory Convery, have agreed the position and the responsibilities (See Appendix 1).

Key Responsibilities of the Lead Clinician:

- Chair the alternate week MDT meeting or delegate to a named deputy
- Ensure that patient management is planned and with input and consensus from the full panel of core members (or their nominated cover)
- Provide leadership for staff within the MDT and facilitate regular business meetings

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- Lead the clinical activity of the MDT, working to agreed guidelines, ensuring a high quality integrated service which meets, local, regional and national standards.
- Provision of clear communication to all staff within the MDT and facilitation of effective team working
- Actively participate in the NICaN Urology network meeting and contribute to its work
- Ensure that regional clinical management guidelines are produced and revised regularly
- To be responsible for MDT performance monitoring against activity for National, Network and Trust targets
- To ensure that there are mechanisms in place to assess all patients with cancer for eligibility into clinical trials or research projects
- To ensure the collection of the appropriate cancer minimum dataset, working with the teams and MDT Coordinator
- To establish an audit programme and review of outcomes (this will include audits carried out across the Network)
- To ensure that local policies and guidelines are written, agreed and followed by the MDT and that these complement the Network guidelines
- Working in partnership with key stakeholders to lead on and promote a programme of service improvement and development for the MDT
- Ensuring the integration of patients/users and carers in assessment of service and service improvement

The Clinical Lead may wish to delegate some of these duties but will remain responsible for their completion.

1.4 MDT Quorum and Attendance (14-2G-102) (14-2G-104)

It is intended that all core members of the MDT attend at least two thirds of all meetings. However, in the event that a core member cannot attend they will agree an individual who will be expected to cover the MDT meeting in their absence. In addition the core members needed for a quorum or their cover should aim to attend all meetings so the MDT will be quorate for at least 95% of meetings.

The quorum for the urology cancer MDT is made up of the following core members or their cover: urology surgeon, clinical oncologist (with responsibility for chemotherapy), imaging specialist, histopathologist, clinical nurse specialist and MDT Co-coordinator.

It is the responsibility of the individual to sign in on arrival. A record of attendance of meetings will be kept by the MDT coordinator. Attendance records of the MDT will be calculated on a quarterly basis and fed back to the individual core member.

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1.5 Chairing of meetings

The chairing of MDMs has been shared by Mr Glackin, Mr O'Brien and Mr Haynes on a rotational basis. Mr O'Donoghue joined in chairing on a rotational basis during 2016. The person appointed to chair each MDM is decided at least one month previously, when a period of time equivalent to one session is allocated to the appointed Chair to preview all cases one day prior to the MDM. Adequate preparation time is included in Job Plans and in a pro rata, annualised, quantitative manner.

1.6 MDT Review (14-2G-103)

The MDM takes place every Thursday, unless otherwise notified, and begins promptly at 14:15 in the tutorial room, Medical Education Centre in Craigavon Area Hospital. The meeting takes place in a room with video conferencing facilities, enabling communication by video to Daisy Hill Hospital, Newry, and with the Specialist MDM in Belfast.

Video conferencing with the Specialist MDT is scheduled to take place at 3.30 pm, or as soon as is mutually convenient thereafter.
It is the policy of the Southern MDT that all MDMs should finish by 5 pm at the latest. It has been the experience of the MDT that the number of cases to be discussed has had to be limited to 40 in order to enable the MDM to finish by 5 pm.

All new cases of Urological cancer and those following Urological biopsy will be discussed. Patients with disease progression or treatment related complications will also be discussed and a treatment plan agreed. Patient's holistic needs will be taken into account as part of the multidisciplinary discussion. The Clinician who has dealt with the patient will represent the patient and family concerns and ensure the discussion is patient-centred.

All meetings are supported and organised by the MDT Coordinator. The MDT Coordinator is responsible for collating the information on all patients being discussed and ensuring that all the necessary information is available to enable clinical decisions to be made.

Responsibilities of the MDT Coordinator:

- Ensuring all cancer patients are discussed at the MDT meeting
- Inserting notes onto the pro forma and ensuring it has been signed-off as being a correct record of the meeting's discussion (this forms the main body of the MDT letter to GP)
- Insertion of clinical summaries and updates onto CaPPs
- Filing the pro forma into the relevant notes and forwarding a copy to the oncology department of those patients who need to be referred to the oncologists
- Posting a summary sheet or the pro forma to the referring General Practitioner within 24 hours of the MDT discussion taking place
- Recording the MDT attendance for every meeting
- Adding any patient on the MDT list not discussed (notes, films or results missing, lack of time), to the following week's list

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- Prospectively track all patients with cancer or suspected cancer in achieving the regional cancer access targets
- Ensuring that all patients with cancer or suspected cancer have pre booked appointments and treatment in line with cancer access targets and to raise delays with the MDT
- Ensuring that direct referrals or inter trust transfers are implemented
- Liaising with the Specialist MDT Co-ordinator prior to any MDM when it is intended to discuss patients with that MDM
- Maintaining timely and accurate data collection, within the databases

Referrals to the MDT meeting

All referrals to the MDT meeting should be through any core member of the team to the MDT Coordinator who will then add the patient to the MDT list for discussion.

Clinicians will place cases for presentation onto the meeting agenda by informing the MDT Coordinator of the relevant case details by the day before the MDM at 12.00 hrs. In all instances it is the responsibility of the presenting clinician to ensure all appropriate clinical results are available for the meeting.

MDM Documentation

It is the responsibility of the MDM Co-ordinator to make a documentary record of the MDM, including a record of attendance, and it is the responsibility of the Chair to approve that record.

It is the responsibility of both the MDM Chair and the MDT Co-ordinator to ensure the accuracy of the completed textual record of Clinical Summaries, Updates and MDM Plans of all patients discussed at the MDM, and so that the documentation, in correspondence format, may be sent without delay to Family Doctors and to other clinicians to whom it had been agreed patients would be referred (see Appendix 2).

1.7 Protocol for taking action between meetings (14-2I-203)

When clinical circumstance dictates it may be necessary to give patients results and decide treatment plans prior to the next MDT meeting. The clinician responsible for the patient's care may contact the relevant member by telephone to arrange the management. These decisions will be recorded in the patient notes. Additionally this decision will be subsequently discussed and endorsed at the next MDT meeting. The MDT Coordinator will ensure that results from any investigations (including those initiated as part of the agreed emergency plan) are available.

1.8 Virtual MDM

As the numbers of patients discussed at each MDM has increased, it has been necessary to limit the number discussed at each meeting to 40 in order to ensure and maintain the quality of discussion of each patient. On occasion, when it has not been possible to have a MDM this has resulted in a backlog that may take a number of weeks to clear, resulting in delays in progressing the investigation, diagnosis and management of patients in a timely manner. In 2015, the MDT decided to experiment with the concept of a Virtual MDM where an appointed Chair would preview all cases who would have been discussed on the date on which it was not

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possible to hold a MDM, arriving at considered MDM Outcomes, which are circulated by email, as soon as is possible thereafter, to all core members, seeking their comments and proposed amendments, before being recorded on CaPPS, the Northern Ireland Electronic Care Record and sent to Family Doctors. It was also the experience of the MDT that the availability of histopathological reports enabled the further assessment and management of many patients to be advanced without controversy or further delay. Dr McClean has ensured that histopathological reports have been agreed and issued to the Chair of Virtual MDM. The MDT has found this practice to be successful and it has been adopted as its routine practice on such occasions.

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SECTION 2: CO-ORDINATION OF CARE/PATIENT PATHWAYS

2.1 Clinical Guidelines and Pathways (14-2G-106) (14-2G-110)

The MDT has participated through the Northern Ireland Cancer Network in the development of Clinical Guidelines and Pathways for Urology cancer. This includes referral to the regional Teenager & Young Adult service as appropriate for patients aged between 14-25 years.

2.2 Regular Prostate Clinic & Regular Haematuria Clinic(14-2G-107) (14-2G-108)

There are four New Clinics held each week in the Thorndale Unit. The maximum configuration of a New Clinic is that it will be staffed by two Consultant Urologists and by one Specialist Registrar, and at which a maximum of 24 patients will attend, 9 for each Consultant and 6 for the Registrar. The numbers of patients appointed are reduced pro rata depending upon attending doctors. Red Flag referrals are given priority of appointment. Each Consultant Urologist has one New Clinic each week.

The New Clinics are also staffed by Clinical Nurse Specialists and Practitioners, Health Care Assistants and Radiographers, in order to facilitate patients having further assessment during their visit to the New Clinic. Further investigations include ultrasound scanning of the urinary tract, mictiometry, flexible cystoscopy and transrectal, ultrasound guided, prostatic biopsies. It is also usual to have scrotal ultrasound scanning performed if there is a suspicion of testicular tumour. The purpose of advanced triage and of attendance at the New Clinic is that the New Clinic appointment has an enhanced prospect of having the patient reassured and discharged, requiring more complex assessment, listed for MDM discussion or placed on a waiting list for surgery.

2.3 Agreed Policy for Patient Access to MDT to Discuss Treatment Options (14-2G-109)

Patients with early (organ-confined) prostate cancer, high risk superficial bladder cancer and muscle invasive bladder cancer are referred to the Specialist Urology MDT in Belfast Trust whereby patients will be offered a meeting to discuss treatment options prior to deciding which modality of treatment to use. Patients with early (stage 1) penile cancer are discussed at the local MDT and will be offered a meeting with relevant specialities to discuss treatment options

Patient Review following MDM discussion

If it has been agreed at MDM that the patient is to be reviewed to be advised of the further assessment or management as recommended by the MDT and stipulated in the MDM Plan, a Review Appointment will be made at the Oncology Review Clinic of the responsible Consultant Urologist. Each is provided with six oncology review slots per week. It is the policy of the MDT that all patients are reviewed by the end of the first week following their MDM discussion. If that is not possible, the Chair of MDM

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may exercise the right to allocate the review of any patient to that of another consultant, if possible, and if it is considered pertinent to do so.

When it has been concluded by the MDT that a patient's further management may have options, as may be the case in organ confined, prostatic carcinoma, then the patient will be advised of all of those options at review, and will be provided with written information regarding each option. Importantly, it is the policy of MDT that such patients are offered the opportunity of referral to consultant specialists relating to each management modality, such as oncologists, for their further advice, so that the patient may arrive at an optimally informed choice.

2.4 Treatment Planning (14-2G-111)

All applicable patient information should be available for the case discussion to proceed.

Case discussion incorporates the patient's age, clinical condition and any psychosocial aspects impacting on clinical management. All patients are discussed at diagnosis or prior to this where confirmation of malignancy is complex.

The MDT should agree and record the multidisciplinary treatment planning decision (i.e. to which modality of treatment - surgery, oncology, best supportive care).
The CaPPS system is used for collecting data on patients and documenting MDT decisions.
The MDT outcome report (Appendix 2) acts as the patient's individual treatment plan and includes:

- The patient's identity
- The diagnosis at the time of making the referral decision: benign, malignant (with histological confirmation), malignant (without histological confirmation)
- The multidisciplinary treatment planning decision (i.e. to which modality(s) of treatment – surgery, radiotherapy, chemotherapy, hormone therapy or supportive care or combinations of the same, that are to be referred for consideration)
- Confirmation that the holistic needs of the patient have been taken into account

Investigation plans and treatment recommendations are formulated during the meeting and recorded in narrative format by the MDT Co-coordinator.
The chairperson should articulate a summary of the recommendations arising from the discussion before proceeding to the next case.

2.5 Attendance at the Network (14-2G-110)

A representative from the team will attend the Network Meetings as follows:

- The MDT will provide representation from either the Lead Clinician or a deputy to all the meetings with minimum attendance of two thirds of meetings.
- The MDT will engage with the Network to develop and implement network-wide clinical, referral, imaging and pathology guidelines.

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Mr Aidan O'Brien was Clinical Lead of the network's Urology Clinical Reference Group from January 2013 – January 2016. Mr Mark Haynes has taken up the Clinical Lead post from September 2016.

2.6 Supportive Care and Rehabilitation Services

A comprehensive range of supportive care and rehabilitation services are available for Urology cancer patients. Referral to these services can be made by members of MDT, directly or by way of MDM, by Key Workers, while some can be accessed by patients directly.

2.6.1 Physiotherapy Services

A wide range of physiotherapy is available at Craigavon Area Hospital and to varying degrees at all the other hospitals within the catchment area of the Urology Service.

2.6.2 Stoma Care Services

A readily accessible, stoma care service is available at Craigavon Area Hospital.

2.6.3 Clinical Psychology & Counselling Services

Dr. Mary Daly, Consultant Clinical Psychologist, is an extended member of the Urology MDT, and is based in the Bluestone Unit at Craigavon Area Hospital.
Two nurse counsellors, Mrs Mavis Dougan and Ms Terri Deehan, have been funded by Cancer Focus NI, are based at Craigavon Area Hospital.

2.6.4 Community Continence Services

There is a Community Continence Service serving the entire catchment area and its population. Referrals are made by email and by any member of the MDT, Key Workers and other nursing staff, at any time. The response to referrals is impressively prompt. The service is highly regarded by MDT.

2.6.5 Pre-chemotherapy Education Sessions & Helpline

All patients requiring chemotherapy are invited to attend a pre-chemotherapy education session in the Mandeville Unit at Craigavon Area Hospital. A 24 hour Helpline service is available for advice and support for patients who are receiving chemotherapy.

2.6.6 Complimentary Therapies

A reflexologist provides complimentary therapies on Mondays and Tuesdays in the Mandeville unit at Craigavon Area Hospital. Cancer Focus NI also provides Art therapy at Craigavon Area Hospital.

2.6.7 Welfare Services

Citizens Advice Bureau (CAB) representative offers financial and benefits advice. Referrals are e-mailed to a central Macmillan/CAB address and allocated from there. The CAB representative contacts the patient to arrange a suitable appointment.

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2.6.8 Macmillan Cancer Support

Macmillan Cancer has an information centre located in the reception foyer of Craigavon Area Hospital. In association with the Southern Trust, Macmillan also conduct a six-week course called **H.O.P.E** (Helping to Overcome Problems Effectively) aimed at helping patients with cancer manage the day-to-day impact of living with the disease.

2.6.9 Other Support Services

The Southern Trust has developed strong partnerships with local charities and support centres which offer a range of services such as complementary therapies, counselling, family support, welfare rights advice and short courses etc.
Information about these groups and services are available in the Macmillan Information Centre.

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SECTION 3: PATIENT EXPERIENCE

3.1 Key Worker (14-2G-113)

The identification of the Key Worker(s) will be the responsibility of the designated MDT Core Nurse member.

It is the joint responsibility of the MDT Clinical Lead and of the MDT Core Nurse Member to ensure that each Urology cancer patient has an identified Key Worker and that this is documented in the agreed Record of Patient Management. In the majority of cases, the Key Worker will be a Urology Clinical Nurse Specialist (Band 7) or Practitioner (Band 6). It is the intent that all Key Workers will have attended the Advanced Communications Skills Course.

Patients and families should be informed of the role of the Key Worker. Contact details are given with written information, and in the Record of Patient Management.

As patients progress along the care pathway, the Key Worker may change. Where possible, these changes should be kept to a minimum. It is the responsibility of the Key Worker to identify the most appropriate healthcare professional to be the patient's next Key Worker. Any changes should be negotiated with the patient and carer prior to implementation, and a clear handover provided to the next Key Worker.

Urology Clinical Nurse Specialists and Practitioners should be present or available at all patient consultations where the patient is informed of a diagnosis of cancer, and should be available for the patient to have a further period of discussion and support following consultation with the clinician, if required or requested. They may also be present, and should be available, when patients attend for further consultations along their pathway.

Key responsibilities of the Key Worker:

- Act as the main contact person for the patient and carer at a specific point in the pathway
- Should be present when the cancer diagnosis is discussed and any other key points in the patients journey
- Offer support, advice and provide information for the patient and their carers, referring to Macmillan Information and Support Service as appropriate to enable access to services
- Ensure continuity of care along the patients pathway and that all relevant plans are communicated to all members of the MDT involved in the patients care
- Ensure that the patient and carer have their contact details, that these contact details are documented and available to all professionals involved in that patients care

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- Support the patient in identifying their needs, review these as required and co-ordinate care accordingly
- Liaise and facilitate communication between the patient, carer and appropriate health professionals and vice versa
- Offer verbal and written information with regard to diagnosis, investigations, treatment options and support groups
- Assist to empower patients as appropriate

3.2 Patient Information **(14-2G-114)**

The key worker will offer the patient and their carers a core information pack and a variety of information at various stages of their pathway, pertaining to their condition as well as any diagnostic procedures or treatments.

This information includes information specific to the MDT's cancer site and its treatment options (including names and functions / roles of the team treating them), information specific to that MDT about local provision of services, information about patient involvement groups / self-help groups, information about services offering psychological, social/cultural, financial information and effects of living with cancer and dealing with its emotional effects.

For patients with sensory, cognitive or language difficulties bespoke information can be arranged via the Macmillan Health & Wellbeing Manager.
Additionally a regional interpreting service is offered with trained health related interpreters. The Trust also has a contract with the 24 hour telephone interpreting service to ensure that patients have support in the planned or emergency situation.

Patients are offered information by appropriate staff in a phased manner relevant to the stage of their journey. For teenager and young adults, additional support is provided through the Regional Teenager and Young Adult (TYA) service, and appropriate information leaflets are available (see TYA regional pathway Appendix 5).

3.3 Permanent Record of Consultation **(14-2G-115)**

At a results clinic an identified member of the multidisciplinary team will effectively convey the patient diagnosis and recommendations of the meeting to the patient, to assist them in participating in decision making about ongoing treatment and care. This should be undertaken in line with the Trust Breaking Bad News policy. The patient should be given the opportunity to have a family member or friend with them.

During 2016, the MDT discussed the developmental priority of ensuring that all newly diagnosed patients had a key worker, had core and tumour specific information provided, had a holistic needs assessment conducted and any needs addressed. The MDT also discussed the format of a Record which would include details of the patients' diagnoses and management, and would include a check list of key worker, information, holistic needs assessment and actual needs or concerns (Appendix 3). The MDT agreed to initially pilot the implementation of the patient record for three

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months (from 1st October – 31st December 2016) and to seek feedback from all clinicians before fully implementing.

3.4 Patient Feedback (14-2G-116)

Feedback from service users is obtained on a regular basis both formally and informally. Feedback on patient's experience will be sought using a range of mechanisms including patient surveys, focus groups, complaints, compliments, and participation in the patient and public involvement processes within the Trust.

The Trust has participated in a regional Cancer Patient Experience Survey exploring the patient experience throughout their cancer journey, and completed a local patient feedback survey. Findings have been presented and discussed at an operational meeting and an action plan agreed.

Complaints and compliments will be monitored by the Head of Service and lessons learned will be discussed in the Operational Meetings.
There is the opportunity via the Cancer Services User Forum to present new service developments or information leaflets to capture patients' views.

SECTION 4: CLINICAL OUTCOMES/INDICATORS

4.1 Clinical Indicators Review/Audit (14-2G-217)

The MDT will annually review its data and discuss progress of audits or discuss the completed results, as relevant, of audits. These should be presented at one of the regular network group meetings.
Data on compliance with the Cancer Access Standards in relation to the 31 and 62 day targets will also be reviewed.

4.2 Clinical Trials (14-2G-218)

Clinical trials in Urological Cancers are conducted in Northern Ireland, either as participants in UK and International studies, or designed by the Cancer Centre in Belfast. Recruitment of Urological Cancer patients to clinical trials now accounts for over 20% of all cancer patients recruited to cancer clinical trials in Northern Ireland.

The MDT will promote recruitment to clinical trials both locally and regionally with support from the Clinical Trials Research Nurse. The MDT should produce a report at least annually on clinical trials, for discussion with the network group.

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4.3 Attendance at Advanced Communication Skills Training (14-2G-219)

All core members of the team who have direct clinical contact with patients will have attended the national advanced communications skills training.

4.4 Communication with Primary Care (14-2G-220)

The importance of timely communication with primary care is essential.
Where a patient is given a diagnosis of Urology cancer it will be the responsibility of the relevant MDT member to ensure that the patients GP is informed in writing by the end of the next working day of the diagnosis being given (Appendix 4).
An audit of timeliness of GP notification will take place annually.

Received from Tughans OBO Mr Aidan O'Brien on 26/01/2022. Annotated by the Urology Services Inquiry

APPENDIX 1: Clinical Lead appointment letter

Southern Health
and Social Care Trust

.....
Consultant Urology Surgeon,
Craigavon Hospital.

October 2016

Dear Mr Glackin

Re: Clinical Lead for the Urology Cancer Team

Further to our recent discussion, I understand that the Urology cancer team members have nominated you as the clinical lead for the service.

I would like to confirm your position as Clinical Lead for the Urology Cancer Service from the XXXXX. This term of office will be for an initial 3 years, after which time it will be reviewed.

The role and responsibilities for the lead are detailed in the operational policy for the service.

I would like to welcome you to the wider Cancer team and thank you for your agreement to act as the Clinical Lead.

Yours sincerely



Rory Convery (Dr)
Clinical Director
Cancer Services

Received from Tughans OBO Mr Aidan O'Brien on 26/01/2022. Annotated by the Urology Services Inquiry

APPENDIX 2: MDT Outcomes Proforma

MDM Report from Urology MDM @ The Southern Trust

RE: xxxxxxxxxxxxxx
Address:xxxxxxxxxxxxx
DOB, Hospital Number: xxxxxxx , HCN: xxxxxxx
Contact Tel: xxxxxxxxxxx

MDM Report from the Urology MDM @ The Southern Trust on 13/10/2016
Diagnosis Renal clear cell carcinoma
Histology Clear cell adenocarcinoma, NOS,
Laterality: left

MDM Update
CONSULTANT MR GLACKIN: This 50 year old man was found to have a solid, left renal lesion on ultrasound scanning in April 2016. His previous medical history included recurrent bouts of vertigo.

Renal CT scanning on 11 May 2016 confirmed the presence of an enhancing mass lesion in the upper pole of the left kidney, highly suspicious for renal cell carcinoma.

Discussed @ Urology MDM 26.05.16. This gentleman has been found to have a lesion of the upper pole of his left kidney, characteristic of a renal cell carcinoma, and considered suitable for partial nephrectomy. For review by Mr Glackin to arrange a CT chest, a DMSA renogram and to arrange surgery.

There was no evidence of thoracic metastatic disease on CT scanning of his chest in July 2016. Renography in August 2016 indicated that his left renal differential function was 45%. Mr XXXXXXXXX was admitted on the 30th September 2016 for a Left Open Partial Nephrectomy.

Histology showed a clear cell adenocarcinoma. Fuhrman nuclear grade III. Tumour necrosis - no. Local invasion - pT1a. Lymphovascular invasion - no. Lymph nodes - none submitted. Margins – on macroscopic examination, tumour was present at the base margin. This was confirmed microscopically. pT1a.

MDM Action
Discussed at Urology MDM 13.10.16. This gentleman has had a renal cell carcinoma of his left kidney resected by partial nephrectomy. The patient has been advised of the pathological findings.

For review by Mr Glackin in 6 weeks to request a renal CT scan in January 2017. To be rediscussed at MDM with CT report.

Radiology
CT Findings
Latest Findings from CT performed on 25/07/2016

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CT chest without contrast.
Findings
No lung mass seen. There is no hilar or mediastinal lymphadenopathy.
No bony lesion visualised.

Conclusion
No thoracic metastasis seen.

Comorbidity Summary
Vertigo

Received from Tughans OBO Mr Aidan O'Brien on 26/01/2022. Annotated by the Urology Services Inquiry

APPENDIX 3: MDT Letter to GP

Urology/Head & Neck MDM @ the Southern Trust

<GP Name>
<GP Address>
<GP Address>
<GP Address>
<GP postcode>

RE: <Patient Name>
<Patient Address>
<DOB>, <Hospital Number>, <HCN>

Dear <GP Name>

This patient was discussed at the Urology MDM @ The Southern Trust
On 13/10/2016.

Diagnosis: Renal clear cell carcinoma

MDM Update:
CONSULTANT MR GLACKIN: This 50 year old man was found to have a solid, left renal lesion on ultrasound scanning in April 2016. His previous medical history included recurrent bouts of vertigo. Renal CT scanning on 11 May 2016 confirmed the presence of an enhancing mass lesion in the upper pole of the left kidney, highly suspicious for renal cell carcinoma.

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MDM Plan:
Discussed at Urology MDM 13.10.16. This gentleman has had a renal cell carcinoma of his left kidney resected by partial nephrectomy. The patient has been advised of the pathological findings. For review by Mr Glackin in 6 weeks to request a renal CT scan in January 2017. To be rediscussed at MDM with CT report.

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Appendix 4

Department of Urology

Patient Record Of Management

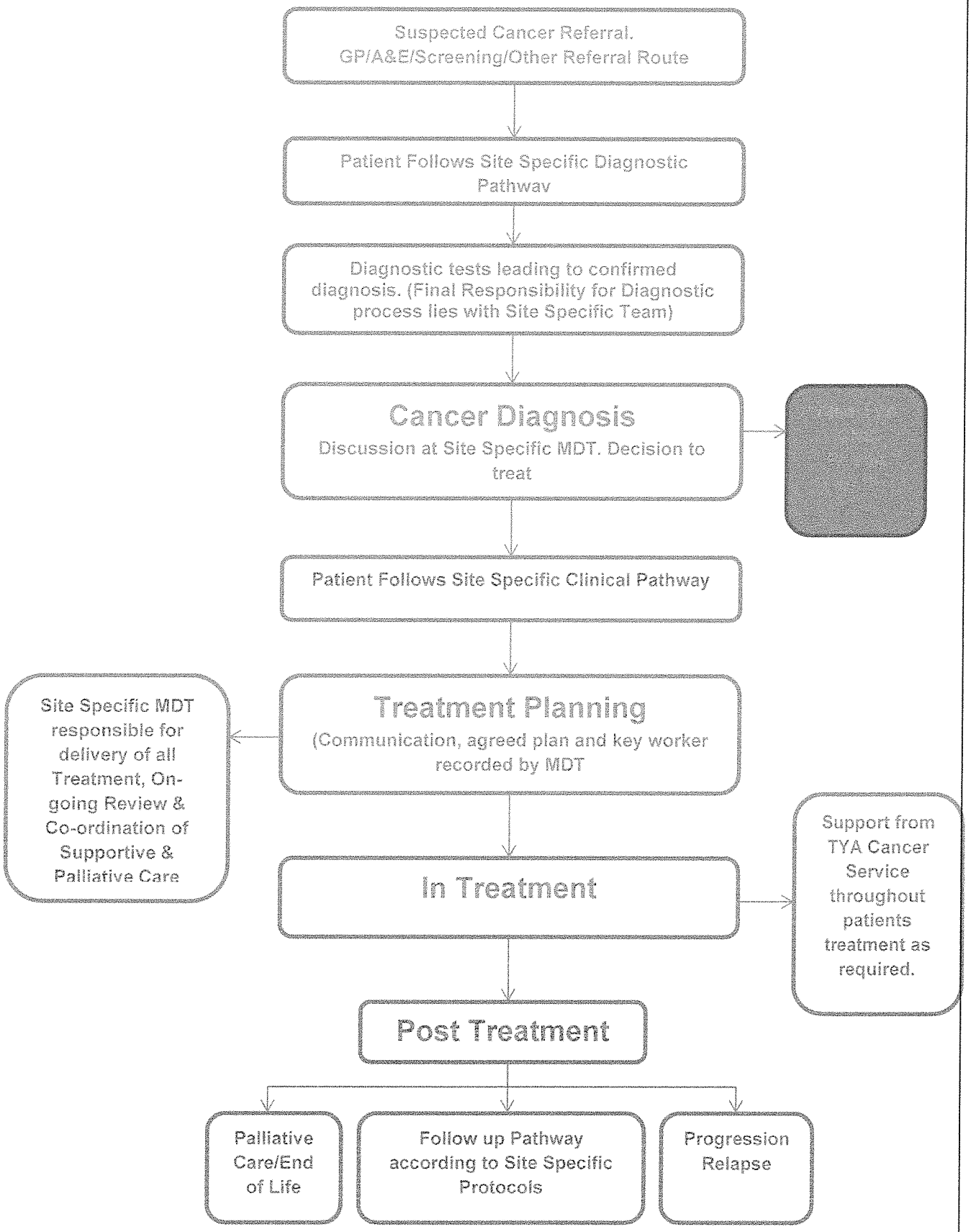
Addressograph label or patient details
Patient Name
DOB
H&C Number

Consultant Name:	
Diagnosis:	
Management Plan:	
Key worker contact details given? Yes ☐ No ☐ **Key worker name:**_____	
Cancer Specific Information given: Yes ☐ No ☐ **Comments:**	
Core/general Information Pack given: Yes ☐ No ☐ **Comments:**	
Plan for Holistic needs assessment: Yes ☐ No ☐ **Comments:**	
Areas of concern identified:	**Actions:**
Signed by:	**Date:**

To contact your specialist or clinical team during working hours please phone Craigavon Area Hospital Urology Nurse Specialist on [Personal Information redacted by the USI]

Received from Tughans OBO Mr Aidan O'Brien on 26/01/2022. Annotated by the Urology Services Inquiry

Appendix 5: Regional referral pathway for Teenagers & Young Adults



Received from Tughans OBO Mr Aidan O'Brien on 26/01/2022. Annotated by the Urology Services Inquiry

Belfast Health and Social Care Trust

Teenager and Young Adult (TYA) Service

Referral information

Referral criteria

- Age14-25th birthday
- Availing of Oncology/Haematology service

How to refer

-email: DL-TYA.Service@belfasttrust.hscni.net

-Contact:

- Simon Darby-(CLIC Sargent SW Oncology) 07917647695
- Laurena Kane-(CLIC Sargent SW Haematology) 07585445319
- Renée Reid-(TYA CNS FCC) 07585008375

Please include;

- Patients name
- Patients age and hospital number
- Diagnosis

Friends cancer centre

CLIC Sargent for children with cancer

Received from Tughans OBO Mr Aidan O'Brien on 26/01/2022. Annotated by the Urology Services Inquiry

The surgeons undertake two clinics per month at SWAT and try to ensure that patients are seen closer to home where appropriate.

Surgery including radical and partial (laparoscopic or open) nephrectomy, ureteric surgery, bladder tumour resection and radical inguinal orchidectomy are all performed on the Craigavon Hospital site. Nephron sparing surgery is being undertaken locally and this should all be undertaken by the specialist MDT as indicated by national Guidance and this is outlined in the draft NICaN agreed clinical guidelines.

All radical pelvic urological surgery is referred to the Belfast City specialist MDT and patients are transferred for surgical and radiotherapy treatment.

Any patients choosing a Robotic Assisted Laparoscopic Prostatectomy will be referred to a robotic centre in the mainland UK. As yet there are no clear regional guidelines or arrangements on how these patients will be followed up on their return and this needs to be addressed by the NICaN NSSG.

Any patient requiring non-surgical oncological treatment is referred via the MDT to the Cancer Centre at Belfast City Hospital.

The MDT did not include a named stoma nurse in their extended team membership but were able to describe how patient would have access to this nurse if required.

Patient experience

The Trust participated in the regional National Cancer Patient Experience Survey and has also carried out a local survey. The MDT is currently looking at how to implement the recommendations, in particular regarding the lack of privacy for breaking of bad news on the ward.

Holistic needs assessment (HNA) has taken time to be implemented and this is being done in conjunction with introducing the key worker role. CNSs are present at diagnosis and therefore patients know who to contact and this is recorded in the patient records but not on the MDT proforma.

Patients are given written information on disease, support and are directed to national and local services. There is a Macmillan Information Unit on site where patients can access further support. There is no leaflet about the MDT explaining roles and members.

The Trust has developed strong partnerships with local charities and support centres. Generic support groups meet once a month on the Craigavon site and occasionally in Southern Area Hospice in Newry. Cancer Choices in Donaghmore, County Tyrone, and Charis near Cookstown, County Tyrone, both offer support to patients, their families and carers. A range of services are offered such as complementary therapies, counselling, welfare rights advice and short courses. Action Cancer provides complementary therapies for children and young people at its outreach centre in Lurgan, County Armagh.

Patients are not routinely copied into their consultation letters and the MDT needs to decide how to resolve this.

Psychological support for patients is readily available as required by onward referral.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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

- Operational Policy - Urology Cancer Services

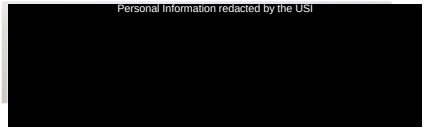
Policy Author: Mr Anthony Glackin

Position: Consultant Urology Surgeon and Clinical Lead

Organisation: Southern Health & Social Care Trust

Date 22nd September 2022

Signed:



The Urology MDT members agreed this Operational Policy at the AGM held on:

Date Agreed: 22nd September 2022

Version: 3.0

Operational policy review date: September 2023

Received from SHSCT on 24th November 2023. Annotated by the Urology Services Inquiry.

The following Operational Policy for the Southern Health and Social Care Trust's Urology Multidisciplinary team provides an overview of the service, how it is accessed by patients and coordinated across the Trust services.

The Operational Policy for the Urology MDT and will be reviewed on an annual basis at the Annual General Meeting. It has been developed to ensure all relevant members of staff are aware of the purpose and organisation of the MDT meeting.

Two other documents have been developed, which should be read in conjunction with this operational policy. They are the annual work plan, which outlines the direction of the service in the incoming year and the annual report, which details the work completed in the past year, achievements and areas of work outstanding which need to be rolled into the incoming year.

Received from SHSCT on 24th November 2023. Annotated by the Urology Services Inquiry.

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Introduction

Background

The Southern Health and Social Care Trust (SHSCT) was formed on 1 April 2007. The Southern Trust (ST) is an integrated Trust, providing acute and community hospital services together with a range of community health and social services to a population of approximately 324,000 people.

Southern Trust Urological Cancer Services

The Southern Trust has provided a Urology service for patients living in the southern part of Northern Ireland since 1992. Outpatient services are located at a dedicated unit, the Thorndale Unit, based in Craigavon Area Hospital. The Unit is staffed by Consultant Urologists, Clinical Nurse Specialists, Staff Nurses and Health Care workers.

Within the SHSCT, urological cancer services include surgery to treat kidney, urothelial and testicular cancers. The service does not provide radical pelvic surgery for prostate and bladder cancer or penile cancer surgery.

In addition to all of the urological services provided at Craigavon Area Hospital, other services provided include endoscopic and day case surgery at Daisy Hill Hospital in Newry and South Tyrone Hospital in Dungannon. The urology service provides outpatient clinics at Banbridge, Armagh and Dungannon.

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SECTION 1: STRUCTURE AND FUNCTION OF THE MDT

1.0 Purpose of the MDT

MDTs bring together staff with the necessary knowledge, skills and experience to ensure high quality diagnosis, treatment and care for patients with cancer. MDT working has been advocated in each of the NICE Improving Outcomes Guidance and is strongly supported by clinicians.

The primary aim of the SHSCT Urology Cancer MDT is to ensure equal access to diagnosis and treatment for all patients in the agreed catchment area with Urology cancer. In order to achieve this aim we provide a high standard of care for all patients including: efficient and accurate diagnosis, treatment and ensuring continuity of care.

The MDT ensures a formal mechanism for multidisciplinary input into treatment planning and ongoing management and care of patients with Urology cancer with the aim of improving outcomes and to:

- Provide an opportunity for multidisciplinary discussion of all new cases of Urology cancer presenting to the team
- To assess newly diagnosed cancers and determine, in the light of all available information and evidence, the most appropriate treatment and care plan for each individual patient
- Ensure care is delivered according to recognised guidelines
- Ensure that the MDT work effectively together as a team regarding all aspects of diagnosis, treatment and care
- Facilitate communication with other professional groups within the hospital and between the MDT and other agencies e.g. primary care, palliative care
- Facilitate collection and analysis of high quality data to inform clinical decision making and to support clinical governance/audit
- Promote multidisciplinary decision making regarding the team's operational policies
- Support implementation of service improvement initiatives
- Ensure incorporation of new research and best practice into patient care
- Ensure mechanisms are in place to support entry of eligible patients into clinical trials, subject to patients fully informed consent
- Provide education to senior and junior medical, nursing and allied health staff.

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1.1 Membership Arrangements

Core and extended membership of the Urology cancer MDT is detailed below:

Core Membership **(14-2G-101)**

Position	Name	Cover
Consultant Urological Surgeon*/**	Anthony Glackin	Mark Haynes
Consultant Urological Surgeon	John O'Donoghue	Anthony Glackin
Consultant Urological Surgeon	Mark Haynes	John O'Donoghue
Consultant Urological Surgeon	Matthew Tyson	Anthony Glackin
MDT Co-coordinator	Shauna McVeigh	Member of Cancer Tracker Team
Consultant Clinical Oncologist	Dr Baird	Vacant
Consultant Medical Oncologist**	Dr Adam Uprichard *(medical oncology rep from May 2020)*	vacant
Consultant Radiologist	Dr Marc Williams	Dr Ryan Connolly
Consultant Radiologist	Dr Ryan Connolly	Dr Marc Williams
Consultant Histopathologist (EQA certified)	Dr Gareth McClean	Member of the Pathology team
Clinical Nurse Specialist	Kate O'Neill ***	Leanne McCourt Patricia Thompson
Palliative Care Nurse	Stephanie Reid	Member of Palliative Care Nursing Team

** Lead Clinician*
*** Lead for clinical trial recruitment*
****Lead for patient involvement, information & service improvement*

1.2 Extended Membership **(14-2G-105)**

Position	Name	Cover
Consultant Urological Surgeon	Mr Khan (locum)	Anthony Glackin Mark Haynes John O'Donoghue
Consultant Psychologist	Dr Mary Daly	Nurse Counsellor (Cancer Focus)
Consultant in Palliative Care Medicine	Dr Osmond Morris Dr Sarah Cousins	Clinical Nurse Specialist

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Stoma / Coloproctology Nurse Specialist	Claire Young	Clinical Nurse Specialist

1.3 Leadership Arrangements and Responsibilities (14-2G-101)

The Lead Clinician for the Urology Cancer MDT is Mr Anthony Glackin. The Trust and the Clinical Director for Cancer Services at that time, Mr David McCaul, agreed the position and the responsibilities (See Appendix 1).

Key Responsibilities of the Lead Clinician:

- Chair the weekly MDT meeting or delegate to a named deputy
- Ensure that patient management is planned and with input and consensus from the full panel of core members (or their nominated cover)
- Provide leadership for staff within the MDT and facilitate regular business meetings
- Lead the clinical activity of the MDT, working to agreed guidelines, ensuring a high quality integrated service which meets, local, regional and national standards.
- Provision of clear communication to all staff within the MDT and facilitation of effective team working
- Actively participate in the NICaN Urology network meeting and contribute to its work
- Ensure that regional clinical management guidelines are produced and revised regularly
- To be responsible for MDT performance monitoring against activity for National, Network and Trust targets
- To ensure that there are mechanisms in place to assess all patients with cancer for eligibility into clinical trials or research projects
- To ensure the collection of the appropriate cancer minimum dataset, working with the teams and MDT Coordinator
- To establish an audit programme and review of outcomes (this will include audits carried out across the Network)
- To ensure that local policies and guidelines are written, agreed and followed by the MDT and that these complement the Network guidelines
- Working in partnership with key stakeholders to lead on and promote a programme of service improvement and development for the MDT
- Ensuring the integration of patients/users and carers in assessment of service and service improvement

  The Clinical Lead may wish to delegate some of these duties but will remain responsible for their completion.

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1.4 MDT Roles

Designated Surgeon / Clinician – Mr Glackin, Mr Haynes and Mr O'Donoghue are the designated lead surgeons.

Designated Specialist Nurses – Kate O'Neill, Leanne McCourt and Patricia Thompson are the core Nurse Specialists for the Urology service to provide information and support for patients and hold the following responsibilities:

- Contributing to the multidisciplinary discussion and patient assessment/care planning decision of the team at their regular meetings.
- Providing advice, support and symptom control to patients throughout their cancer journey
- Providing expert nursing advice and support to other health professionals in the nurse's specialist area of practice
- Involvement in clinical audit
- Leading on patient communication issues and co-ordination of the patient pathway for patients referred to the team – acting as the keyworker or responsible for nominating the key worker for the patient's dealings with the team
- Leading on the patient and user involvement in the service
- Leading on the management of patients suitable for self-directed aftercare (SDA)
- Contributing to the management of the service
- Utilising research in the nurse's specialist area of practice.
- Holding the relevant qualifications and undertaking additional training as required to provide expert advice and support

Designated Radiologist - Dr Marc Williams is the Lead designated radiologist. His role is to ensure compliance with the regional network imaging guidelines. Dr Ryan Connolly will provide cover in his absence.

Designated Cellular pathologist - Dr Gareth McClean is the designated Lead Cellular pathologist; his role is to ensure compliance with diagnostic assessment and reporting within the regional network pathology guidelines. All members take part in External Quality Assessment Scheme relevant to Urology cancer.

Designated Oncologist – Dr Baird is the designated Clinical Oncologist who provides clinical oncology input to the local MDT. Dr Adam Uprichard is the designated Medical Oncologist. Oncology cover is provided through the regional Oncology team based in Belfast HSC Trust.

MDT Co-ordinator Responsibilities

All meetings are supported and organised by the MDT Coordinator. The MDT Coordinator is responsible for collating the information on all patients being

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discussed and ensuring that all the necessary information is available to enable clinical decisions to be made.

Responsibilities of the MDT Coordinator:

- Ensuring all cancer patients are discussed at the MDT meeting
- Inserting notes onto the pro forma and ensuring it has been signed-off as being a correct record of the meeting's discussion (this forms the main body of the MDT letter to GP)
- Insertion of clinical summaries and updates onto CaPPs
- Filing the pro forma into the relevant notes and forwarding a copy to the oncology department of those patients who need to be referred to the oncologists
- Posting a summary sheet or the pro forma to the referring General Practitioner within 24 hours of the MDT discussion taking place
- Recording the MDT attendance for every meeting
- Adding any patient on the MDT list not discussed (notes, films or results missing, lack of time), to the following week's list
- Prospectively track all patients with cancer or suspected cancer in achieving the regional cancer access targets
- Ensuring that all patients with cancer or suspected cancer have pre booked appointments and treatment in line with cancer access targets and to raise delays with the MDT
- Ensuring that direct referrals or inter trust transfers are implemented
- Liaising with the Specialist MDT Co-ordinator prior to any MDM when it is intended to discuss patients with that MDM
- Maintaining timely and accurate data collection, within the databases

1.5 MDT Quorum and Attendance (14-2G-102) (14-2G-104)

It is intended that all core members of the MDT attend at least two thirds of all meetings. However, in the event that a core member cannot attend they will agree an individual who will be expected to cover the MDT meeting in their absence. In addition the core members needed for a quorum or their cover should aim to attend all meetings so the MDT will be quorate for at least 95% of meetings.

The quorum for the urology cancer MDT is made up of the following core members or their cover: urology surgeon, clinical oncologist (with responsibility for radiotherapy), radiologist, histopathologist, clinical nurse specialist and MDT Co-coordinator.

A record of attendance of meetings will be kept by the MDT coordinator. Attendance records of the MDT will be calculated on a quarterly basis and fed back to the individual core member.

1.6 Chairing of meetings

The chairing of MDMs is shared by Mr Glackin, Mr O'Donoghue, Mr Haynes and Mr Tyson on a rotational basis. The person appointed to chair each MDM is decided at

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least one month previously. Adequate preparation time is included in Job Plans in a pro rata, annualised, quantitative manner.

1.7 MDT Review (14-2G-103)

The MDM takes place every Thursday, unless otherwise notified, and begins promptly at 14:15 in the MDT room, Mandeville Annex Building in Craigavon Area Hospital. The meeting takes place in a room with video conferencing facilities, enabling communication with the Specialist MDM in Belfast and remote working by members of the MDT.

Video conferencing with the Specialist Urological Cancer MDT is scheduled to take place at 3.30 pm every Thursday. Testis Cancer cases are discussed by video-conference at 2pm every other Thursday.
It is the policy of the Southern MDT that all MDMs should finish by 5pm at the latest. It has been the experience of the MDT that the number of cases to be discussed has had to be limited to 40 in order to enable the MDM to finish by 5pm.

All new cases of urological cancer and those following urological biopsy will be reviewed. Patients with disease progression or treatment related complications will also be discussed and a treatment plan agreed. Patient's holistic needs will be taken into account as part of the multidisciplinary discussion. The Clinician who has dealt with the patient will represent the patient and family concerns and ensure the discussion is patient-centred.

There may be a range of options for treatment available and this is dependent on patient choice as to which is accepted. If a patient does not accept any of the recommended treatment options this is brought back to the MDT for documentation.

1.8 Referrals to the MDT meeting

An MDT proforma has been developed to ensure that the locally agreed minimum dataset is available for each patient being discussed at the MDM. This must be completed for all new referrals to the MDM and forwarded to the MDT Co-coordinator who will then add the patient to the MDT list for discussion.

Clinicians will place cases for presentation onto the meeting agenda by informing the MDT Coordinator of the relevant case details by midday on the Tuesday before the MDM. In all instances, it is the responsibility of the presenting clinician to ensure all appropriate clinical results are available for the meeting.

Extended members / non-members will attend the MDT as required to present cases when relevant.

1.9 MDM Documentation

It is the responsibility of the MDM Co-ordinator to make a documentary record of the MDM, including a record of attendance, and it is the responsibility of the Chair to approve that record.

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It is the responsibility of both the MDM Chair and the MDT Co-ordinator to ensure the accuracy of the completed textual record of the clinical summaries, updates and MDM Plans of all patients discussed at the MDM.

This is to ensure that the documentation, in correspondence format, may be sent without delay to Family Doctors and to other clinicians to whom it had been agreed patients would be referred (see Appendix 2).

It is the responsibility of the CNS to identify the key worker for each patient and to liaise with the MDT Co-ordinator to ensure that this is ticked in the relevant field on CAPPs.

1.10 Protocol for taking action between meetings (14-2I-203)

When clinical circumstance dictates it may be necessary to give patients results and decide treatment plans prior to the next MDT meeting. The clinician responsible for the patient's care may contact the relevant member by telephone to arrange the management. These decisions will be recorded in the patient notes. Additionally this decision will be subsequently discussed and endorsed at the next MDT meeting. The MDT Coordinator will ensure that results from any investigations (including those initiated as part of the agreed emergency plan) are available.

1.11 Protocoled care

Non muscle invasive bladder cancer
Utilising the categories described in NICE Guideline NG2:

The Consultant Chairing the MDM will be responsible for assigning and recording the risk category for bladder cancer cases based on the information provided to the MDM.

New or recurrent low risk urothelial cancer cases are to be listed for noting at MDM. The responsible Consultant Urologist will arrange appropriate endoscopic surveillance and further management.

New intermediate risk urothelial cancer cases are to be listed for noting at MDM. The responsible Consultant Urologist will arrange a 6 week course of intravesical therapy, with either mitomycin C or epirubicin, to be followed by endoscopic surveillance and further management.

If intermediate-risk non-muscle-invasive bladder cancer recurs after a course of intravesical therapy, refer the person's care to a specialist urology multidisciplinary team.

All cases of high risk urothelial cancer are to be listed for discussion at MDM. Offer the choice of intravesical BCG (Bacille Calmette-Guérin) or radical cystectomy to people with high-risk non-muscle-invasive bladder cancer, and base the choice on a full discussion with the person, the clinical nurse specialist and a urologist who performs both intravesical BCG and radical cystectomy.

If induction BCG fails (because it is not tolerated, or bladder cancer persists or recurs after treatment with BCG), or if the patient wishes to consider primary radical

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cystectomy, the person's care can be referred to the specialist Urology Multidisciplinary Team at the Belfast Trust.

Muscle invasive bladder cancer
All cases must be listed for MDM and notified to the specialist urology multidisciplinary team at the Belfast Trust as soon as possible in order to expedite timely treatment (do not wait for staging investigation results before advising the specialist urology multidisciplinary team of the case). All cases will require discussion at the specialist urology multidisciplinary team meeting at the Belfast Trust.

Penile Cancer
Direct referral to the regional penile cancer service is the preferred option. In cases of clinical uncertainty initial assessment may be required by the designated local penile cancer lead (Mr Glackin, SHSCT) followed by referral to the regional penile cancer service in accordance with the NW Penile Cancer operational policy 2019-2020.

Testis Cancer
All cases of confirmed testis cancer are to be listed for discussion at MDM following completion of staging, histology and tumour markers, and for referral to the Testis Cancer specialist multidisciplinary team at the Belfast Trust.

Kidney cancer
All cases must be discussed at MDM.

Prostate Cancer

Clinicians should utilise the grid below to guide the choice of staging investigations. Following completion of staging all cases of confirmed prostate cancer must be listed for discussion of management options at MDM.

		PSA			
Gleason Grade	Grade group	<10	≥10, <20	≥20, <40	≥40
3+3=6	1	MRI	MRI	MRI, BS	BS, CT, MRI if no mets on BS / CT
3+4=7	2	MRI	MRI	MRI, BS	BS, CT, MRI if no mets on BS / CT
4+3=7	3	MRI	MRI, BS	MRI, BS	BS, CT, MRI if no mets on BS / CT
3+5=8 4+4=8 5+3=8	4	MRI, BS	MRI, BS	MRI, BS	BS, CT, MRI if no mets on BS / CT
4+5=9 5+4=9 5+5=10	5	MRI, BS	MRI, BS	MRI, BS, CT	BS, CT, MRI if no mets on BS / CT

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SECTION 2: CO-ORDINATION OF CARE/PATIENT PATHWAYS

2.1 Clinical Guidelines and Pathways (14-2G-106) (14-2G-110)

The MDT has participated through the Northern Ireland Cancer Network in the development of Clinical Guidelines and Pathways for Urology cancer. This includes referral to the regional Teenager & Young Adult service as appropriate for patients aged between 14-25 years.

2.2 Regular Prostate Clinic & Regular Haematuria Clinic (14-2G-107) (14-2G-108)

New urgent suspected cancer referrals are triaged electronically by Consultant Urologists who may choose to request imaging or laboratory tests prior to the patient's attendance at a New Patient Clinic in order to expedite timely management. There are four New Patient Clinics held each week in the Thorndale Unit. New urgent suspected cancer referrals are given priority of appointment. Each Consultant Urologist provides one New Patient Clinic each week for a total of 9 patients. In addition middle grade urologists see 6 new patients at each clinic under the supervision of a Consultant. Weekly haematuria clinics are provided on the Craigavon and South Tyrone sites.

2.3 Agreed Policy for Patient Access to MDT to Discuss Treatment Options (14-2G-109)

In keeping with regional guidelines patients with prostate, kidney, testis and high risk non-muscle invasive or muscle invasive urothelial cancers requiring radical treatment or management of advanced/metastatic disease are referred to the Specialist Urology MDT in Belfast Trust whereby patients will be offered a meeting to discuss treatment options prior to deciding which modality of treatment to use.

Patients with suspected penile cancer are referred to the newly established regional service in the Western Trust at the time of initial referral and assessment.

Patient Review following MDM discussion

If it is agreed at MDM that the patient is to be reviewed, the patient should be advised of the further assessment or management as recommended by the MDT and this should be stipulated in the MDM Plan. An appointment will be made at the Review Clinic of the responsible Consultant Urologist. It is the policy of the MDT that all patients are reviewed by the end of the first week following their MDM discussion. If that is not possible, the Chair of MDM may exercise the right to allocate the review of any patient to that of another consultant if it is considered pertinent to do so.

When it has been concluded by the MDT that a patient's further management may have options, as may be the case in organ confined, prostatic carcinoma, then the patient will be advised of all of those options at review, and will be provided with written information regarding each option. Importantly, it is the policy of MDT that such

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patients are offered the opportunity of referral to consultant specialists relating to each management modality, such as oncologists, for their further advice, so that the patient may arrive at an optimally informed choice.

2.4 Treatment Planning (14-2G-111)

All applicable patient information should be available for the case discussion to proceed.

Case discussion incorporates the patient's age, clinical condition and any psychosocial aspects impacting on clinical management. All patients are discussed at diagnosis or prior to this where confirmation of malignancy is complex.

The MDT should agree and record the multidisciplinary treatment planning decision (i.e. to which modality of treatment - surgery, oncology, best supportive care).
The CaPPS system is used for collecting data on patients and documenting MDT decisions.
The MDT outcome report (Appendix 2) acts as the patient's individual treatment plan and includes:

- The patient's identity
- The diagnosis at the time of making the referral decision: benign, malignant (with histological confirmation), malignant (without histological confirmation)
- The multidisciplinary treatment planning decision (i.e. to which modality(s) of treatment – surgery, radiotherapy, chemotherapy, hormone therapy or supportive care or combinations of the same, that are to be referred for consideration)
- Confirmation that the holistic needs of the patient have been taken into account

Investigation plans and treatment recommendations are formulated during the meeting and recorded in narrative format by the MDT Co-coordinator.
The chairperson should articulate a summary of the recommendations arising from the discussion before proceeding to the next case.

2.5 Attendance at the Network meetings (14-2G-110)

A representative from the team will attend the Network Meetings as follows:

- The MDT will provide representation from either the Lead Clinician or a deputy to all the meetings with minimum attendance of two thirds of meetings.
- The MDT will engage with the Network to develop and implement network-wide clinical, referral, imaging and pathology guidelines.

Mr Mark Haynes is the Clinical Lead of the network's Urology Clinical Reference Group.

2.6 Supportive Care and Rehabilitation Services

A comprehensive range of supportive care and rehabilitation services are available for Urology cancer patients. Referral to these services can be made by members of MDT,

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directly or by way of MDM, by Key Workers, while some can be accessed by patients directly.

2.6.1 Physiotherapy Services

A wide range of physiotherapy is available at Craigavon Area Hospital and to varying degrees at all the other hospitals within the catchment area of the Urology Service.

2.6.2 Stoma Care Services

A readily accessible, stoma care service is available at Craigavon Area Hospital.

2.6.3 Clinical Psychology & Counselling Services

A Clinical psychology service is provided by the Psychology Department based in Moylinn House, Craigavon and referrals can be made by members of the MDT. Counselling services for people affected by cancer are provided on the Craigavon Area Hospital site in partnership with Cancer Focus NI. Staff complete an electronic referral to the service on behalf of the patient. Referrals are triaged and prioritised as appropriate by the Nurse Counsellors.

2.6.4 Community Continence Services

There is a Community Continence Service serving the Southern Trust catchment area. Referrals are accepted by email. The service is highly regarded by MDT.

2.6.5 Pre-chemotherapy Education Sessions & Helpline

All patients requiring chemotherapy are invited to attend a pre-chemotherapy education session in the Mandeville Unit at Craigavon Area Hospital. A 24 hour Helpline service is available for advice and support for patients who are receiving chemotherapy.

2.6.7 Macmillan Benefits Service

Macmillan Cancer Support in partnership with Community Advice provides Benefits Service advisers based in Craigavon Area Hospital. A telephone helpline is also available and advisers can arrange office appointments or ward visits so that everyone affected by cancer can access financial help. Referrals are accepted by staff on behalf of the person affected by cancer or by self-referral.

2.6.8 Macmillan Information and Support Service

The Macmillan Information and Support Service is available to anyone affected by cancer and living within the Southern Trust area. There are Information and Support centres based in Craigavon Area Hospital and Daisy Hill Hospital. The service also provides information and support over the phone or by email for those not able to access the service in person.

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2.6.9 Other Support Services

The Southern Trust has developed strong partnerships with local charities and support centres which offer a range of services such as complementary therapies, counselling, family support, welfare rights advice and short courses etc.
Information about these groups and services are available by contacting the Macmillan Information and Support Service.

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SECTION 3: PATIENT EXPERIENCE

3.1 Key Worker (14-2G-113)

The identification of the Key Worker(s) will be the responsibility of the designated MDT Core Nurse member.

It is the joint responsibility of the MDT Clinical Lead and of the MDT Core Nurse Member to ensure that each Urology cancer patient has an identified Key Worker and that this is documented in the agreed Record of Patient Management. In the majority of cases, the Key Worker will be a Urology Clinical Nurse Specialist (Band 7) or Practitioner (Band 6). It is the intent that all Key Workers will have attended the Advanced Communications Skills Course.

Patients and families should be informed of the role of the Key Worker. Contact details are given with written information, and in the Record of Patient Management.

As patients progress along the care pathway, the Key Worker may change. Where possible, these changes should be kept to a minimum. It is the responsibility of the Key Worker to identify the most appropriate healthcare professional to be the patient's next Key Worker. Any changes should be negotiated with the patient and carer prior to implementation, and a clear handover provided to the next Key Worker.

Urology Clinical Nurse Specialists and Practitioners should be present or available at all patient consultations where the patient is informed of a diagnosis of cancer, and should be available for the patient to have a further period of discussion and support following consultation with the clinician, if required or requested. They may also be present, and should be available, when patients attend for further consultations along their pathway.

Key responsibilities of the Key Worker:

- Act as the main contact person for the patient and carer at a specific point in the pathway
- Should be present when the cancer diagnosis is discussed and any other key points in the patients journey
- Offer support, advice and provide information for the patient and their carers, referring to Macmillan Information and Support Service as appropriate to enable access to services
- Ensure continuity of care along the patients pathway and that all relevant plans are communicated to all members of the MDT involved in the patients care
- Ensure that the patient and carer have their contact details, that these contact details are documented and available to all professionals involved in that patients care
- Support the patient in identifying their needs, review these as required and co-ordinate care accordingly
- Liaise and facilitate communication between the patient, carer and appropriate health professionals and vice versa

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- Offer verbal and written information with regard to diagnosis, investigations, treatment options and support groups
- Assist to empower patients as appropriate

3.2 Patient Information (14-2G-114)

The key worker will offer the patient and their carers a core information pack and a variety of information at various stages of their pathway, pertaining to their condition as well as any diagnostic procedures or treatments.

This information includes information specific to the MDT's cancer site and its treatment options (including names and functions / roles of the team treating them), information specific to that MDT about local provision of services, information about patient involvement groups / self-help groups, information about services offering psychological, social/cultural, financial information and effects of living with cancer and dealing with its emotional effects.

For patients with sensory, cognitive or language difficulties bespoke information can be arranged via the Macmillan Health & Wellbeing Manager.
Additionally a regional interpreting service is offered with trained health related interpreters. The Trust also has a contract with the 24 hour telephone interpreting service to ensure that patients have support in the planned or emergency situation.

Patients are offered information by appropriate staff in a phased manner relevant to the stage of their journey. For teenager and young adults, additional support is provided through the Regional Teenager and Young Adult (TYA) service, and appropriate information leaflets are available (see TYA regional pathway Appendix 5).

3.3 Permanent Record of Consultation (14-2G-115)

At a results clinic an identified member of the multidisciplinary team will effectively convey the patient diagnosis and recommendations of the meeting to the patient, to assist them in participating in decision making about ongoing treatment and care. This is undertaken in line with the Trust Breaking Bad News policy. The patient is given the opportunity to have a family member or friend with them.

Patients will also be offered the opportunity of a permanent record or summary of the consultation when their diagnoses and management is discussed.
Following the initial pilot of a patient record to capture all key information, the MDT has agreed to work towards full implementation.

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3.4 Patient Feedback (14-2G-116)

Feedback from service users is obtained on a regular basis both formally and informally. Feedback on patient's experience will be sought using a range of mechanisms including patient surveys, focus groups, complaints, compliments, and participation in the patient and public involvement processes within the Trust.

The Trust has participated in two regional Cancer Patient Experience Surveys exploring the patient experience throughout their cancer journey, and completed a local patient feedback survey. Findings have been presented and discussed at an operational meeting and an action plan agreed.

Complaints and compliments will be monitored by the Head of Service and lessons learned will be discussed in the Operational Meetings.
There is the opportunity via the Cancer Services User Forum to present new service developments or information leaflets to capture patients' views.

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SECTION 4: CLINICAL OUTCOMES/INDICATORS

4.1 Clinical Indicators Review/Audit (14-2G-217)

The MDT will annually review its data and discuss progress of audits or discuss the completed results, as relevant, of audits. These should be presented at one of the regular network group meetings.
Data on compliance with the Cancer Access Standards in relation to the 31 and 62 day targets will also be reviewed.

4.2 Clinical Trials (14-2G-218)

Clinical trials in Urological Cancers are conducted in Northern Ireland, either as participants in UK and International studies, or designed by the Cancer Centre in Belfast. Recruitment of Urological Cancer patients to clinical trials now accounts for over 20% of all cancer patients recruited to cancer clinical trials in Northern Ireland.

The MDT will promote recruitment to clinical trials both locally and regionally with support from the Clinical Trials Research Nurse. The MDT should produce a report at least annually on clinical trials, for discussion with the network group.

4.3 Attendance at Advanced Communication Skills Training (14-2G-219)

All core members of the team who have direct clinical contact with patients will complete advanced communications skills training.

4.4 Communication with Primary Care (14-2G-220)

The importance of timely communication with primary care is essential.
Where a patient is given a diagnosis of Urology cancer it will be the responsibility of the relevant MDT member to ensure that the patients GP is informed in writing by the end of the next working day of the diagnosis being given (Appendix 3).
An audit of timeliness of GP notification will take place annually.

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APPENDIX 1: Clinical Lead appointment letter

Southern Health and Social Care Trust

……..

Consultant Urology Surgeon,

Craigavon Area Hospital

October 2019

Dear Mr Glackin

Re: Clinical Lead for the Urology Cancer Team

Further to our recent discussion, I understand that the Urology cancer team members have nominated you as the clinical lead for the service.

I would like to confirm your position as Clinical Lead for the Urology Cancer Service from 1st October 2019. This term of office will be for an initial 3 years, after which time it will be reviewed.

The role and responsibilities for the lead are detailed in the operational policy for the service.

I would like to welcome you to the wider Cancer team and thank you for your agreement to act as the Clinical Lead.

Yours sincerely

Personal Information redacted by the USI

Mr David McCaul

Clinical Director

Cancer & Clinical Services

Received from SHSCT on 24th November 2023. Annotated by the Urology Services Inquiry.

APPENDIX 2: MDT Outcomes Proforma

MDM Report from Urology MDM @ The Southern Trust

RE: xxxxxxxxxxxxxxx
Address:xxxxxxxxxxxxxx
DOB, Hospital Number: xxxxxxx , HCN: xxxxxxx
Contact Tel: xxxxxxxxxxx

MDM Report from the Urology MDM @ The Southern Trust on 13/10/2016
Diagnosis Renal clear cell carcinoma
Histology Clear cell adenocarcinoma, NOS,
Laterality: left

MDM Update
CONSULTANT MR GLACKIN: This 50 year old man was found to have a solid, left renal lesion on ultrasound scanning in April 2016. His previous medical history included recurrent bouts of vertigo.

Renal CT scanning on 11 May 2016 confirmed the presence of an enhancing mass lesion in the upper pole of the left kidney, highly suspicious for renal cell carcinoma.

Discussed @ Urology MDM 26.05.16. This gentleman has been found to have a lesion of the upper pole of his left kidney, characteristic of a renal cell carcinoma, and considered suitable for partial nephrectomy. For review by Mr Glackin to arrange a CT chest, a DMSA renogram and to arrange surgery.

There was no evidence of thoracic metastatic disease on CT scanning of his chest in July 2016. Renography in August 2016 indicated that his left renal differential function was 45%. Mr X was admitted on the 30th September 2016 for a Left Open Partial Nephrectomy.

Histology showed a clear cell adenocarcinoma. Fuhrman nuclear grade III. Tumour necrosis - no. Local invasion - pT1a. Lymphovascular invasion - no. Lymph nodes - none submitted. Margins – on macroscopic examination, tumour was present at the base margin. This was confirmed microscopically. pT1a.

MDM Action
Discussed at Urology MDM 13.10.16. This gentleman has had a renal cell carcinoma of his left kidney resected by partial nephrectomy. The patient has been advised of the pathological findings.

For review by Mr Glackin in 6 weeks to request a renal CT scan in January 2017. To be rediscussed at MDM with CT report.

Radiology
CT Findings
Latest Findings from CT performed on 25/07/2016

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CT chest without contrast.
Findings
No lung mass seen. There is no hilar or mediastinal lymphadenopathy.
No bony lesion visualised.

Conclusion
No thoracic metastasis seen.

Comorbidity Summary
Vertigo

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APPENDIX 3: MDT Letter to GP

Urology MDM @ the Southern Trust

<GP Name>
<GP Address>
<GP Address>
<GP Address>
<GP postcode>

RE: <Patient Name>
<Patient Address>
<DOB>, <Hospital Number>, <HCN>

Dear <GP Name>

This patient was discussed at the Urology MDM @ The Southern Trust
On 13/10/2016.

Diagnosis: Renal clear cell carcinoma

MDM Update:
CONSULTANT MR GLACKIN: This 50 year old man was found to have a solid, left renal lesion on ultrasound scanning in April 2016. His previous medical history included recurrent bouts of vertigo. Renal CT scanning on 11 May 2016 confirmed the presence of an enhancing mass lesion in the upper pole of the left kidney, highly suspicious for renal cell carcinoma.

Discussed @ Urology MDM 26.05.16. This gentleman has been found to have a lesion of the upper pole of his left kidney, characteristic of a renal cell carcinoma, and considered suitable for partial nephrectomy. For review by Mr Glackin to arrange a CT chest, a DMSA renogram and to arrange surgery.

There was no evidence of thoracic metastatic disease on CT scanning of his chest in July 2016.

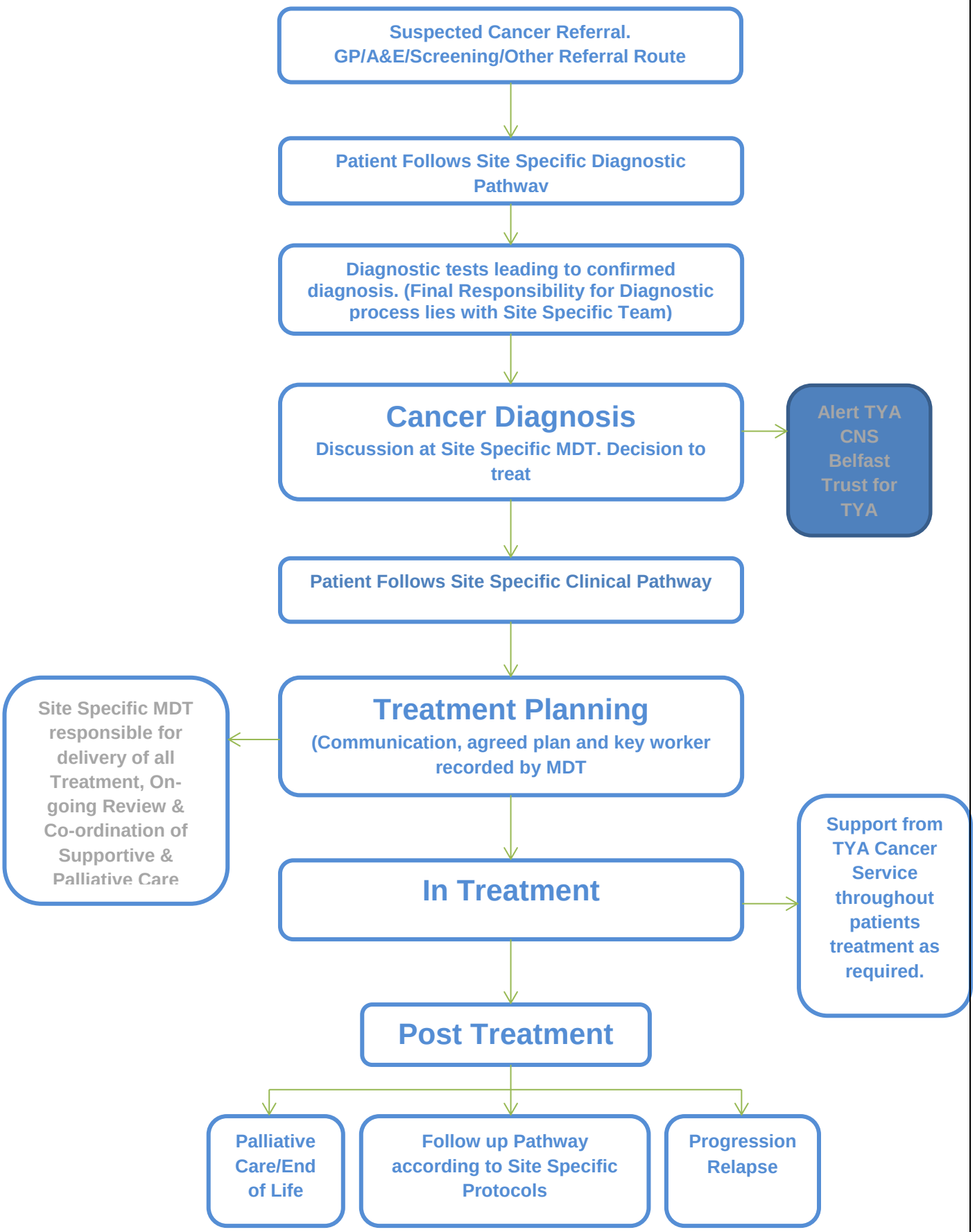
Renography in August 2016 indicated that his left renal differential function was 45%. Mr X was admitted on the 30th September 2016 for a Left Open Partial Nephrectomy.

Histology showed a clear cell adenocarcinoma. Fuhrman nuclear grade III. Tumour necrosis - no. Local invasion - pT1a. Lymphovascular invasion - no. Lymph nodes - none submitted. Margins - on macroscopic examination, tumour was present at the base margin. This was confirmed microscopically. pT1a.

MDM Plan:
Discussed at Urology MDM 13.10.16. This gentleman has had a renal cell carcinoma of his left kidney resected by partial nephrectomy. The patient has been advised of the pathological findings. For review by Mr Glackin in 6 weeks to request a renal CT scan in January 2017. To be rediscussed at MDM with CT report.

Received from SHSCT on 24th November 2023. Annotated by the Urology Services Inquiry.

Appendix 4: Regional referral pathway for Teenagers & Young Adults



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Patients being unaware of care varying from above recommendations and unable to give informed consent

- Patients were not aware that the care given varied from Regional Standards and MDM recommendations. They could not have given informed consent to this.

Patients receiving care without input from a Cancer Nurse Specialist / Key worker

- All patients were not referred to Urology Cancer Nurse Specialists despite this resource being increased by the Southern Health and Social Care Trust. Peer Review 2017 was informed that this resource was available to all. Their contact numbers were not made available.

Lack of resource within the SHSCT to adequately track cancer patients through their journey

- The Urology MDM was under resourced for appropriate patient pathway tracking. The Review Team found that patient tracking related only to diagnosis and first treatment (that is 31- and 62-day targets). It did not function as a whole system and whole pathway tacking process. This resulted in preventable delays and deficits in care.
- Safe cancer patient care and pathway tracking is usually delivered by a three-pronged approach of MDT tracking, Consultants and their Secretaries and Urology Specialist Nurses, in a Key Worker role. The Review found that these 9 patients were not referred to Specialist Nurses and contact telephone numbers were not given. Therefore, the CNS were not given the opportunity to provide support and discharge their duties to the 9 patients, who suffered as a consequence. The MDM tracking system was limited. The consultant / secretary led process was variable and resulted in deficits. The weakness of the latter component was known from previous review.

Non-Quorate Multidisciplinary Meetings

- The Urology MDM was under resourced and frequently non quorate due to lack of professionals. The MDM had quorate rates of 11% in 2017, 22% in 2018 0% in 2019 and 5% in 2020. This was usually due to lack of clinical oncology and medical oncology. Radiology had only one Urology Cancer Specialist Radiologist impacting on attendance but critically meaning there was no independent Quality Assurance of images by a second radiologist prior to MDM.

Lack of Assurance Audits within the MDT process

- Assurance audits of patient pathways within the Urology Cancer Services were limited between 2017 and 2020. They could not have provided assurance about the care delivered.
- Because of resource, the MDM was very focused on first presentation at MDM and did not have a role in tracking subsequent actions if it lay outside 31- and 62-day targets.

your broad experience? Can you help us with that?
MR. GILBERT: By broad concerns is that it becomes very difficult to raise concerns at all levels. That's not particularly about protecting your own reputation, your own income. Yes, consultants are usually appointed in 12:06
their late 30s, they have young children, they have been moving around often, apart from their families for many years, and finally they get this job that allows them to settle. Risking that is quite a big step to take, school and children, mortgages to pay and so on 12:07
and so forth. The Health Service should have systems in place in order to protect those individuals in those circumstances when they wish to raise a concern. I am not confident that the Health Service has those mechanisms working in place. They may be there in name 12:07
but I do not believe that they are functioning.
MR. WOLFE KC: Thank you for that.

Dr. Hughes, is there anything you can further assist us with in that sort of particular respect, how the Health 12:07
Service can build greater confidence into its systems to encourage people to speak when it is appropriate to speak?
DR. HUGHES: We have to recognise we wouldn't be in this place if the Health Service wasn't so 12:08
hierarchical. There are known and problematic issues, especially in Northern Ireland where 80 percent of the medical graduates come from one medical school and everybody knows everybody else, and that adds another

difficulty. I think what you need to take it back, what is an issue? It is actually a patient issue. Park the name, park the person, park whatever. If something is affecting patient care or patient outcomes, or potentially, people should be in a flat environment where they can have these difficult conversations. 12:08

For a multi-disciplinary team to have that conversation, it needs to be fully cognisant of their roles and responsibilities; it needs to know how their behaviours affect everybody else, and they need to be reminded of what their primary duty is, it is to keep patients safe. If anybody has a concern around that matter, that should transcend any other issues. 12:08 12:09

That being said, human beings being human beings, you have to deal with the human factors around that and we're not good at doing that. I think this is a case in point. People had concerns but didn't have a meaningful way of escalating them, and didn't really want to deal with them in a confrontational manner because that will not resolve anything. I think this is a much wider conversation we're having than just this issue, because how do you -- you know, a stressed environment, an MDT that's not fully functioning, is not appropriately resourced and doesn't have oncologists on a regular basis, how does that address its own internal problems? It's probably not going to 12:09 12:09

be able to do so.
MR. WOLFE KC: It appears, I suppose, that in this particular MDT, it needed to be better supported, both within the urology side of the fence and from Cancer Services Management? 12:10
DR. HUGHES: Yes.
MR. WOLFE KC: Before I turn to the recommendations that emerged from your reports, gentlemen, can I ask you just to consider your meeting, Dr. Hughes, with one of the families that were part of the nine that led to 12:10
reports. You will recall that on Monday, 11th January 2021, you met with the family of Patient 5. I want to ask you some questions about that specific case.

If we could have up on the screen, please, PAT-001954. 12:11
This is the start of a seven-page record of that meeting. PAT-001954. I gave you a hard copy of that document this morning because it didn't form part of your bundle for these hearings. I think you have had an opportunity to look at it, albeit briefly. 12:11

You say, if I could turn your attention to just over halfway down the page, "As doctor Hughes explained". This is part of a series of meetings that you were having with patient families; isn't that right? 12:12
DR. HUGHES: Yes.
MR. WOLFE KC: You say in that paragraph, beginning "The review will involve the treatment and care of nine patients". Do you see that?

A. DR. HUGHES: If you scroll down.

20 Q. I was going to bring you to INQ-231. This is the section which tells you what the guidance is about. It explains that being a good doctor means more than simply being a good clinician. 10:34

"Doctors can provide leadership to their colleagues and vision for their organisations. However, unless doctors are willing to contribute to improving the quality of services and to speak up when things are wrong, patient care is likely to suffer". 10:34

Is that something that I suppose you went into this task for the Trust worrying that that's the kind of thing that you might find? 10:34

A. DR. HUGHES: Possibily. I think that opening statement is to emphasise to everybody, all doctors, that the first and foremost responsibility is to patient care and patient safety, and that the culture that Leadership must bring to it is an open culture, and 10:35 a culture where people can put their hand up and say, I am concerned about things, and that there is a process for that to be escalated and to be heard.

21 Q. If you scroll down a little. Back up again, please, sorry. I think it may not be on that page but there's 10:35 a reference to speaking up when things go wrong. Is that something that --

A. DR. HUGHES: Yes.

22 Q. -- is relevant in this context?

Health and Social Care Board

Procedure for the Reporting and Follow up of Serious Adverse Incidents

November 2016
Version 1.1

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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SECTION THREE - ADDENDUM

ADDENDUM 1	A Guide for HSC Staff – Engagement / Communication with the Service User/Family/Carers Following a SAI

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

FOREWORD

Commissioners and Providers of health and social care want to ensure that when a serious event or incident occurs, there is a systematic process in place for safeguarding services users, staff, and members of the public, as well as property, resources and reputation.

One of the building blocks for doing this is a clear, regionally agreed approach to the reporting, management, follow-up and learning from serious adverse incidents (SAIs). Working in conjunction with other Health and Social Care (HSC) organisations, this procedure was developed to provide a system-wide perspective on serious incidents occurring within the HSC and Special Agencies and also takes account of the independent sector where it provides services on behalf of the HSC.

The procedure seeks to provide a consistent approach to:

- what constitutes a serious adverse incident;
- clarifying the roles, responsibilities and processes relating to the reporting, reviewing, dissemination and implementation of learning;
- fulfilling statutory and regulatory requirements;
- tools and resources that support good practice.

Our aim is to work toward clearer, consistent governance arrangements for reporting and learning from the most serious incidents; supporting preventative measures and reducing the risk of serious harm to service users.

The implementation of this procedure will support governance at a local level within individual organisations and will also improve existing regional governance and risk management arrangements by continuing to facilitate openness, trust, continuous learning and ultimately service improvement.

This procedure will remain under continuous review.

Valerie Watts
Chief Executive

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

SECTION ONE - PROCEDURE

1.0 BACKGROUND

Circular HSS (PPM) 06/04 introduced interim guidance on the reporting and follow-up on serious adverse incidents (SAIs). Its purpose was to provide guidance for HPSS organisations and special agencies on the reporting and management of SAIs and near misses.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/hss(ppm)06-04.pdf

Circular HSS (PPM) 05/05 provided an update on safety issues; to underline the need for HPSS organisations to report SAIs and near misses to the DHSSPS in line with Circular HSS (PPM) 06/04.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/hssppm05-05.pdf

Circular HSS (PPM) 02/2006 drew attention to certain aspects of the reporting of SAIs which needed to be managed more effectively. It notified respective organisations of changes in the way SAIs should be reported in the future and provided a revised report pro forma. It also clarified the processes DHSSPS had put in place to consider SAIs notified to it, outlining the feedback that would then be made to the wider HPSS.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/qpi_adverse_incidents_circular.pdf

In March 2006, DHSSPS introduced Safety First: A Framework for Sustainable Improvement in the HPSS. The aim of this document was to draw together key themes to promote service user safety in the HPSS. Its purpose was to build on existing systems and good practice so as to bring about a clear and consistent DHSSPS policy and action plan.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/safety_first_-_a_framework_for_sustainable_improvement_on_the_hpss-2.pdf

The Health and Personal Social Services (Quality Improvement and Regulation) (Northern Ireland) Order 2003 imposed a 'statutory duty of quality' on HPSS Boards and Trusts. To support this legal responsibility, the Quality Standards for Health and Social Care were issued by DHSSPS in March 2006.

www.health-ni.gov.uk/publications/quality-standards-health-and-social-care-documents

Circular HSC (SQS) 19/2007 advised of refinements to DHSSPS SAI system and of changes which would be put in place from April 2007, to promote learning from SAIs and reduce any unnecessary duplication of paperwork for organisations. It also clarified arrangements for the reporting of breaches of patients waiting in excess of 12 hours in emergency care departments.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/hss__sqsd__19-07.pdf

Under the Provisions of Articles 86(2) of the Mental Health (NI) Order 1986, the Regulation & Quality Improvement Authority (RQIA) has a duty to make inquiry into any

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case where it appears to the Authority that there may be amongst other things, ill treatment or deficiency in care or treatment. Guidance in relation to reporting requirements under the above Order previously issued in April 2000 was reviewed, updated and re-issued in August 2007. (Note: Functions of the previous Mental Health Commission transferred to RQIA on 1 April 2009).

http://webarchive.proni.gov.uk/20101215075727/http://www.dhsspsni.gov.uk/print/utec_guidance_august_2007.pdf

Circular HSC (SQSD) 22/2009 provided specific guidance on initial changes to the operation of the system of SAI reporting arrangements during 2009/10. The immediate changes were to lead to a reduction in the number of SAIs that were required to be reported to DHSSPS. It also advised organisations that a further circular would be issued giving details about the next stage in the phased implementation which would be put in place to manage the transition from the DHSSPS SAI reporting system, through its cessation and to the establishment of the RAIL system.

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2022-09.pdf

Circular HSC (SQSC) 08/2010, issued in April 2010, provided guidance on the transfer of SAI reporting arrangements from the Department to the HSC Board, working in partnership with the Public Health Agency. It also provided guidance on the revised incident reporting roles and responsibilities of HSC Trusts, Family Practitioner Services, the Health & Social Care (HSC) Board and Public Health Agency (PHA), the extended remit of the Regulation & Quality Improvement Authority (RQIA), and the Department.

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2008-10.pdf

Circular HSC (SQSD) 10/2010 advises on the operation of an Early Alert System, the arrangements to manage the transfer of Serious Adverse Incident (SAI) reporting arrangements from the Department to the HSC Board, working in partnership with the Public Health Agency and the incident reporting roles and responsibilities of Trusts, family practitioner services, the new regional organisations, the Health & Social Care (HSC) Board and Public Health Agency (PHA), and the extended remit of the Regulation & Quality Improvement Authority (RQIA).

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2010-10.pdf

In May 2010 the Director of Social Care and Children HSCB issued guidance on 'Untoward Events relating to Children in Need and Looked After Children' to HSC Trusts. This guidance clarified the arrangements for the reporting of events, aligned to delegated statutory functions and Departmental Guidance, which are more appropriately reported to the HSCB Social Care and Children's Directorate.

In 2012 the HSCB issued the 'Protocol for responding to SAIs involving an alleged homicide'. The 2013 revised HSCB 'Protocol for responding to SAIs involving an alleged homicide' is contained in Appendix 14.

Circular HSS (MD) 8/2013 replaces HSS (MD) 06/2006 and advises of a revised Memorandum of Understanding (MOU) when investigating patient or client safety incidents. This revised MOU is designed to improve appropriate information sharing and co-ordination when joint or simultaneous investigations/reviews are required when a serious incident occurs.

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www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-8-2013.pdf

DHSSPS Memo dated 17 July 2013 from Chief Medical Officer introduced the HSCB/PHA protocol on the dissemination of guidance/information to the HSC and the assurance arrangements where these are required. The protocol assists the HSCB/PHA in determining what actions would benefit from a regional approach rather than each provider taking action individually.

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/002%20%20HSCB-PHA%20Protocol%20for%20Safety%20Alerts.pdf

Circular HSC (SQSD) 56/16 (21 October 2016) from the Deputy Chief Medical Officer advises of the intention to introduce a Never Events process and that information relating to these events will be captured as part of the Serious Adverse Incident Process. The circular indicates the Never Events process will be based on the adoption of Never Event List with immediate effect.

https://www.health-ni.gov.uk/sites/default/files/publications/health/HSC-SQSD-56-16.pdf

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

2.0 INTRODUCTION

The purpose of this procedure is to provide guidance to Health and Social Care (HSC) Organisations, and Special Agencies (SA) in relation to the reporting and follow up of Serious Adverse Incidents (SAIs) arising during the course of their business or commissioned service.

The requirement on HSC organisations to routinely report SAIs to the Department of Health (DoH) {formerly known as the DHSSPS} ceased on 1 May 2010. From this date, the revised arrangements for the reporting and follow up of SAIs, transferred to the Health and Social Care Board (HSCB) working both jointly with the Public Health Agency (PHA) and collaboratively with the Regulation and Quality Improvement Authority (RQIA).

This process aims to:

- Provide a mechanism to effectively share learning in a meaningful way; with a focus on safety and quality; ultimately leading to service improvement for service users;

- Provide a coherent approach to what constitutes a SAI; to ensure consistency in reporting across the HSC and Special Agencies;

- Clarify the roles, responsibilities and processes relating to the reporting, reviewing, dissemination and implementation of learning arising from SAIs which occur during the course of the business of a HSC organisation / Special Agency or commissioned/funded service;

- Ensure the process works simultaneously with all other statutory and regulatory organisations that may require to be notified of the incident or be involved the review;

- Keep the process for the reporting and review of SAIs under review to ensure it is fit for purpose and minimises unnecessary duplication;

- Recognise the responsibilities of individual organisations and support them in ensuring compliance; by providing a culture of openness and transparency that encourages the reporting of SAIs;

- Ensure trends, best practice and learning is identified, disseminated and implemented in a timely manner, in order to prevent recurrence;

- Maintain a high quality of information and documentation within a time bound process.

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3.0 APPLICATION OF PROCEDURE

3.1 Who does this procedure apply to?

This procedure applies to the reporting and follow up of SAIs arising during the course of the business in Department of Health (DoH) Arm's Length Bodies (ALBs) i.e.

- ***HSC organisations (HSC)***
  - Health and Social Care Board
  - Public Health Agency
  - Business Services Organisation
  - Belfast Health and Social Care Trust
  - Northern Health and Social Care Trust
  - Southern Health and Social Care Trust
  - South Eastern Health and Social Care Trust
  - Western Health and Social Care Trust
  - Northern Ireland Ambulance Service
  - Regulation and Quality Improvement Authority

- ***Special Agencies (SA)***
  - Northern Ireland Blood Transfusion Service
  - Patient Client Council
  - Northern Ireland Medical and Dental Training Agency
  - Northern Ireland Practice and Education Council

The principles for SAI management set out in this procedure are relevant to all the above organisations. Each organisation should therefore ensure that its incident policies are consistent with this guidance while being relevant to its own local arrangements.

3.2 Incidents reported by Family Practitioner Services (FPS)

Adverse incidents occurring within services provided by independent practitioners within: General Medical Services, Pharmacy, Dental or Optometry, are routinely forwarded to the HSCB Integrated Care Directorate in line with the HSCB Adverse Incident Process within the Directorate of Integrated Care (September 2016). On receipt of reported adverse incidents the HSCB Integrated Care Directorate will decide if the incident meets the criteria of a SAI and if so will be the organisation responsible to report the SAI.

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3.3 Incidents that occur within the Independent /Community and Voluntary Sectors (ICVS)

SAIs that occur within ICVS, where the service has been commissioned/funded by a HSC organisation must be reported. For example: service users placed/funded by HSC Trusts in independent sector accommodation, including private hospital, nursing or residential care homes, supported housing, day care facilities or availing of HSC funded voluntary/community services. These SAIs must be reported and reviewed by the HSC organisation who has:

- referred the service user (this includes Extra Contractual Referrals) to the ICVS;

or, if this cannot be determined;

- the HSC organisation who holds the contract with the IVCS.

HSC organisations that refer service users to ICVS should ensure all contracts, held with ICVS, include adequate arrangements for the reporting of adverse incidents in order to ensure SAIs are routinely identified.

All relevant events occurring within ICVS which fall within the relevant notification arrangements under legislation should continue to be notified to RQIA.

3.4 Reporting of HSC Interface Incidents

Interface incidents are those incidents which have occurred in one organisation, but where the incident has been identified in another organisation. In such instances, it is possible the organisation where the incident may have occurred is not aware of the incident; however the reporting and follow up review may be their responsibility. It will not be until such times as the organisation, where the incident has occurred, is made aware of the incident; that it can be determined if the incident is a SAI.

In order to ensure these incidents are notified to the correct organisation in a timely manner, the organisation where the incident was identified will report to the HSCB using the HSC Interface Incident Notification Form (see Appendix 3). The HSCB Governance Team will upon receipt contact the organisation where the incident has occurred and advise them of the notification in order to ascertain if the incident will be reported as a SAI.

Some of these incidents will subsequently be reported as SAIs and may require other organisations to jointly input into the review. In these instances refer to Appendix 13 – Guidance on Joint Reviews.

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3.5 Incidents reported and Investigated/ reviewed by Organisations external to HSC and Special Agencies

The reporting of SAIs to the 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 procedure.

3.5.1 Memorandum of Understanding (MOU)

In February 2006, the DoH issued circular HSS (MD) 06/2006 − a Memorandum of Understanding − which was developed to improve appropriate information sharing and co-ordination when joint or simultaneous investigations/reviews are required into a serious incident.

Circular HSS (MD) 8/2013 replaces the above circular and advises of a revised MOU Investigating patient or client safety incidents which can be found on the Departmental website:

www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-8-2013.pdf

The MOU has been agreed between the 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). It will apply to people receiving care and treatment from HSC in Northern Ireland. The principles and practices promoted in the document 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.

It sets out the general principles for the HSCS, PSNI, Coroners Service for NI and HSENI to observe when liaising with one another.

The purpose of the MOU is to promote effective communication between the organisations. The MOU will take effect in circumstances of unexpected death or serious untoward harm requiring investigation by the PSNI, Coroners Service for NI or HSENI separately or jointly. This may be the case when an incident has arisen from or involved criminal intent, recklessness and/or gross negligence, or in the context of health and safety, a work-related death.

The MOU is intended to help:

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- Identify which organisations should be involved and the lead investigating body.

- Prompt early decisions about the actions and investigations/reviews thought to be necessary by all organisations and a dialogue about the implications of these.

- Provide an understanding of the roles and responsibilities of the other organisations involved in the memorandum before high level decisions are taken.

- Ensure strategic decisions are taken early in the process and prevent unnecessary duplication of effort and resources of all the organisations concerned.

HSC Organisations should note that the MOU does not preclude simultaneous investigations/reviews by the HSC and other organisations e.g. Root Cause Analysis by the HSC when the case is being reviewed by the Coroners Service and/or PSNI/HSENI.

In these situations, the Strategic Communication and Decision Group can be used to clarify any difficulties that may arise; particularly where an external organisation's investigation/review has the potential to impede a SAI review and subsequently delay the dissemination of regional learning.

3.6 Reporting of SAIs to RQIA

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

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

- Any SAI that occurs within the regulated sector (whether statutory or independent) for a service that has been commissioned/funded by a HSC organisation.

  It is acknowledged these incidents should already have been reported to RQIA as a ***'notifiable event'*** *by the statutory or independent organisation where the incident has occurred (in line with relevant reporting regulations). This notification will alert RQIA that the incident is also being reviewed as a SAI by the HSC organisation who commissioned the service.*

- The HSCB/PHA Designated Review Officer (DRO) will lead and co-ordinate the SAI management, and follow up, with the reporting organisation; however for these SAIs this will be carried out in

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conjunction with RQIA professionals. A separate administrative protocol between the HSCB and RQIA can be accessed at Appendix 15.

3.7 Reporting of SAIs to the Safeguarding Board for Northern Ireland

There is a statutory duty for the HSC to notify the Safeguarding Board for Northern Ireland of child deaths where:

- a child has died or been significantly harmed (Regulation 17(2)(a)

AND

- abuse/neglect suspected **or** child or sibling on child protection register **or** child or sibling is/has been looked after Regulation (2)(b) (see Appendix 17)

4.0 DEFINITION AND CRITERIA

4.1 Definition of an Adverse Incident

'Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation'[1] arising during the course of the business of a HSC organisation / Special Agency or commissioned service.

The following criteria will determine whether or not an adverse incident constitutes a SAI.

4.2 SAI criteria

4.2.1 serious injury to, or the unexpected/unexplained death of:

- a service user, (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit)
- a staff member in the course of their work
- a member of the public whilst visiting a HSC facility;

4.2.2 unexpected serious risk to a service user and/or staff member and/or member of the public;

4.2.3 unexpected or significant threat to provide service and/or maintain business continuity;

[1] Source: DoH - How to classify adverse incidents and risk guidance 2006
http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/ph_how_to_classify_adverse__incidents_and_risk_-_guidance.pdf

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4.2.4 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;

4.2.5 serious self-harm or serious assault *(including homicide and sexual assaults*)

- on other service users,
- on staff or
- on members of the public

by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident;

4.2.6 suspected suicide of a service user who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident;

4.2.7 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.

ANY ADVERSE INCIDENT WHICH MEETS ONE OR MORE OF THE ABOVE CRITERIA SHOULD BE REPORTED AS A SAI.

Note: The HSC Regional Risk Matrix may assist organisations in determining the level of 'seriousness' refer to Appendix 16.

5.0 SAI REVIEWS

SAI reviews should be conducted at a level appropriate and proportionate to the complexity of the incident under review. In order to ensure timely learning from all SAIs reported, it is important the level of review focuses on the complexity of the incident and not solely on the significance of the event.

Whilst most SAIs will be subject to a Level 1 review, for some more complex SAIs, reporting organisations may instigate a Level 2 or 3 review immediately following the incident occurring. The level of review should be noted on the SAI notification form.

The HSC Regional Risk Matrix (refer to Appendix 16) may assist organisations in determining the level of 'seriousness' and subsequently the level of review to be

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undertaken. SAIs which meet the criteria in 4.2 above will be reviewed by the reporting organisation using one or more of the following:

5.1 Level 1 Review – Significant Event Audit (SEA)

Most SAI notifications will enter the review process at this level and a SEA will immediately be undertaken to:

- assess what has happened;
- assess why did it happened;
  - what went wrong and what went well;
- assess what has been changed or agree what will change;
- identify local and regional learning.

(refer to Appendix 5 – Guidance Notes for Level 1 – SEA & Learning Summary Report; Appendix 9 – Guidance on Incident Debrief); and Appendix 10 – Level 1 Review - Guidance on review team membership)

The possible outcomes from the review may include:

- closed – no new learning;
- closed – with learning;
- requires Level 2 or 3 review.

A SEA report will be completed **which should be retained by the reporting organisation** (see Appendices 4 and 5).

The reporting organisation will then complete a **SEA Learning Summary Report** (see Appendices 4 and 5 – Sections 1, 3-6), which should be signed off by the relevant professional or operational director and submitted to the HSCB within **8 weeks** of the SAI being notified.

The HSCB will not routinely receive SEA reports unless specifically requested by the DRO. This process assigns reporting organisations the responsibility for Quality Assuring Level 1 SEA Reviews. This will entail engaging directly with relevant staff within their organisation to ensure the robustness of the report and identification of learning prior to submission to the HSCB.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review, the review will move to either a Level 2 or 3 RCA review. In this instance the SEA Learning Report Summary will be forwarded to the HSCB within the timescales outlined above, with additional sections being completed to outline membership and Terms of Reference of the team completing the Level 2 or 3 RCA review and proposed timescales.

5.2 Level 2 – Root Cause Analysis (RCA)

As stated above, some SAIs will enter at Level 2 review following a SEA.

When a Level 2 or 3 review is instigated immediately following notification of a SAI, the reporting organisation will inform the HSCB within 4 weeks, of the Terms of Reference (TOR) and Membership of the Review Team for

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consideration by the HSCB/PHA DRO. This will be achieved by submitting sections two and three of the review report to the HSCB. (Refer to Appendix 6 – template for Level 2 and 3 review reports).

The review must be conducted to a high level of detail (see Appendix 7 – template for Level 2 and 3 review reports). The review should include use of appropriate analytical tools and will normally be conducted by a multidisciplinary team (not directly involved in the incident), and chaired by someone independent to the incident but who can be within the same organisation. (Refer to Appendix 9 – Guidance on Incident Debrief); and Appendix 11 – Level 2 Review - Guidance on review team membership).

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

On completion of Level 2 reviews, the final report must be submitted to the HSCB within 12 weeks from the date the incident was notified.

5.3 Level 3 – Independent Reviews

Level 3 reviews will be considered for SAIs that:

- are particularly complex involving multiple organisations;
- have a degree of technical complexity that requires independent expert advice;
- are very high profile and attracting a high level of both public and media attention.

In some instances the whole team may be independent to the organisation/s where the incident/s has occurred.

The timescales for reporting Chair and Membership of the review team will be agreed by the HSCB/PHA Designated Review Officer (DRO) at the outset (see Appendix 9 – Guidance on Incident Debrief); and Appendix 12 – Level 3 Review - Guidance on Review Team Membership).

The format for Level 3 review reports will be the same as for Level 2 reviews (see Appendix 7 – guidance notes on template for Level 2 and 3 reviews).

For any SAI which involves an alleged homicide by a service user who has a mental illness or disorder *(as defined within the Mental Health (NI) Order 1986)* and/or known to/referred to mental health and related services (*including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident, the Protocol for Responding to SAIs in the Event of a Homicide, issued in 2012 and revised in 2013 should be followed (see Appendix 14).

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5.4 Involvement of Service Users/Family/Carers in Reviews

- Following a SAI it is important, in the spirit of honesty and openness to ensure a consistent approach is afforded to the level of service user / family engagement across the region. When engaging with Service Users/Family/Carers, organisations should refer to addendum 1 – *A Guide for Health and Social Care Staff Engagement/Communication with Service User/Family/Cares following a SAI.*

- In addition a 'Checklist for Engagement/Communication with the Service User/Family/Carers following a SAI' must be completed for each SAI regardless of the review level, and where relevant, if the SAI was also a Never Event (refer to section 12.2).

- The checklist also includes a section to indicate if the reporting organisation had a statutory requirement to report the death to the Coroners office and that this is also communicated to the Family/Carer.

6.0 TIMESCALES

6.1 Notification

Any adverse incident that meets the criteria indicated in section 4.2 should be reported within **72 hours** of the incident being discovered using the SAI Notification Form (see Appendix 1).

6.2 Review Reports

LEVEL 1 – SEA

SEA reports must be completed using the SEA template which will be retained by the reporting organisation (see Appendices 4 and 5). A SEA Learning Summary Report (see Appendices 4 and 5 – Sections 1, 3-6) must be completed and submitted to the HSCB within **8 weeks** of the SAI being reported for all Level 1 SAIs whether learning has been identified or not. The Checklist for Engagement/Communication with Service User/Family/Carer following a SAI' must also accompany the Learning Summary Report.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review, timescales for completion of the RCA will be indicated by Trusts via the Learning Summary Report to the HSCB.

LEVEL 2 – RCA

For those SAIs where a full RCA is instigated immediately, sections 2 and 3 of the RCA Report, outlining TOR and membership of the review team, must be submitted **no later** than **within 4 weeks** of the SAI being notified to the HSCB.

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RCA review reports must be fully completed using the RCA report template and submitted together with comprehensive action plans for each recommendation identified to the HSCB **12 weeks** following the date the incident was notified. (see Appendix 6 – Level 2 & 3 RCA Review Reports and Appendix 8 – Guidance on Minimum Standards for Action Plans).

LEVEL 3 – INDEPENDENT REVIEWS

Timescales for completion of Level 3 reviews and comprehensive action plans for each recommendation identified will be agreed between the reporting organisation and the HSCB/PHA DRO as soon as it is determined that the SAI requires a Level 3 review.

Note: Checklist for Engagement/Communication with Service User/Family/Carer following a SAI must accompany all SAI Review/Learning Summary Reports which are included within the report templates.

6.3 Exceptions to Timescales

In most circumstances, all timescales for submission of reports **must be** adhered to. However, it is acknowledged, by exception, there may be occasions where a review is particularly complex, perhaps involving two or more organisations or where other external organisations such as PSNI, HSENI etc.; are involved in the same review. In these instances the reporting organisation must provide the HSCB with regular updates.

6.4 Responding to additional information requests

Once the review / learning summary report has been received, the DRO, with appropriate clinical or other support, will review the report to ensure that the necessary documentation relevant to the level of review is adequate.

If the DRO is not satisfied with the information provided additional information may be requested and must be provided in a timely manner. Requests for additional information should be provided as follows:

- Level 1 review within **2 week**
- Level 2 or 3 review within **6 weeks**

7.0 OTHER INVESTIGATIVE/REVIEW PROCESSES

The reporting of SAIs to the HSCB will work in conjunction with all other HSC investigation/review processes, statutory agencies and external bodies. In that regard, all existing reporting arrangements, where there are statutory or mandatory reporting obligations, will continue to operate in tandem with this procedure.

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In that regard, there may be occasions when a reporting organisation will have reported an incident via another process before or after it has been reported as a SAI.

7.1 Complaints in the HSC

Complaints in HSC Standards and Guidelines for Resolution and Learning (The Guidance) outlines how HSC organisations should deal with complaints raised by persons who use/have used, or are waiting to use HSC services. While it is a separate process to the management and follow-up of SAIs, there will be occasions when an SAI has been reported by a HSC organisation, and subsequently a complaint is received relating to the same incident or issues, or alternatively, a complaint may generate the reporting of an SAI.

In these instances, the relevant HSC organisation must be clear as to how the issues of complaint will be investigated. For example, there may be elements of the complaint that will be solely reliant on the outcome of the SAI review and there may be aspects of the complaint which will not be part of the SAI review and can only be investigated under the Complaints Procedure.

It is therefore important that complaints handling staff and staff who deal with SAIs communicate effectively and regularly when a complaint is linked to a SAI review. This will ensure that all aspects of the complaint are responded to effectively, via the most appropriate means and in a timely manner. Fundamental to this, will obviously be the need for the organisation investigating the complaint to communicate effectively with the complainant in respect of how their complaint will be investigated, and when and how they can expect to receive a response from the HSC organisation.

7.2 HSCB Social Care Untoward Events Procedure

The above procedure provides guidance on the reporting of incidents relating to statutory functions under the Children (NI) Order 1995.

If, during the review of an incident reported under the HSCB Untoward Events procedure, it becomes apparent the incident meets the criteria of a SAI, the incident should immediately be notified to the HSCB as a SAI. Board officers within the HSCB will close the Untoward Events incident and the incident will continue to be managed via the SAI process.

7.3 Child and Adult Safeguarding

Any incident involving the suspicion or allegation that a child or adult is at risk of abuse, exploitation or neglect should be investigated under the procedures set down in relation to a child and adult protection.

If during the review of one of these incidents it becomes apparent that the incident meets the criteria for an SAI, the incident will immediately be notified to the HSCB as an SAI.

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It should be noted that, where possible, safeguarding investigations will run in parallel as separate to the SAI process with the relevant findings from these investigations/reviews informing the SAI review (see appendix 17).

On occasion the incident under review may be considered so serious as to meet the criteria for a Case Management Review (CMR) for children, set by the Safeguarding Board for Northern Ireland; a Serious Case Review (SCR) for adults set by the Northern Ireland Adult Safeguarding Partnership; or a Domestic Homicide Review.

In these circumstances, the incident will be notified to the HSCB as an SAI. This notification will indicate that a CMR, SCR or Domestic Homicide Review is underway. This information will be recorded on the Datix system, and the SAI will be closed.

7.4 Reporting of Falls

Reporting organisations will no longer be required to routinely report falls as SAIs which have resulted in harm in all Trust facilities, (as defined in the impact levels 3 – 5 of the regional risk matrix - see appendix 16). Instead a new process has been developed with phased implementation, which requires HSC Trusts to do a timely post fall review debrief to ensure local application of learning. See links below to Shared Learning Form and Minimum Data Set for Post Falls Review:

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/033%20Falls_Shared%20Learning%20Template_%20V2_June%202016.rtf

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/032%20Regional%20Falls%20Minimum%20Dataset%202016_V2_June%202016.pdf

Local learning will be shared with the Regional Falls Group where trends and themes will be identified to ensure regional learning.

Reporting organisations will therefore manage falls resulting in moderate to severe harm as adverse incidents, unless there are particular issues or the subsequent internal review identifies contributory issues/concerns in treatment and/or care or service issues, or any identified learning that needs to be reviewed through the serious adverse incident process.

7.5 Transferring SAIs to other Investigatory Processes

Following notification and initial review of a SAI, more information may emerge that determines the need for a specialist investigation.

This type of investigation includes:

- Case Management Reviews
- Serious Case Reviews

Once a DRO has been informed a SAI has transferred to one of the above investigation s/he will close the SAI.

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7.6 De-escalating a SAI

It is recognised that organisations report SAIs based on limited information and the situation may change when more information has been gathered; which may result in the incident no longer meeting the SAI criteria.

Where a reporting organisation has determined the incident reported no longer meets the criteria of a SAI, a request to de-escalate the SAI should be submitted immediately to the HSCB by completing section 21 of the SAI notification form (Additional Information following initial Notification).

The DRO will review the request to de-escalate and will inform the reporting organisation and RQIA (where relevant) of the decision as soon as possible and at least within **10 working days** from the request was submitted.

If the DRO agrees, the SAI will be de-escalated and no further SAI review will be required. The reporting organisation may however continue to review as an adverse incident or in line with other HSC investigation/review processes (as highlighted above). If the DRO makes a decision that the SAI should not be de-escalated the review report should be submitted in line with previous timescales.

It is important to protect the integrity of the SAI review process from situations where there is the probability of disciplinary action, or criminal charges. The SAI review team must be aware of the clear distinction between the aims and boundaries of SAI reviews, which are solely for the identification and reporting learning points, compared with disciplinary, regulatory or criminal processes.

HSC organisations have a duty to secure the safety and well-being of patients/service users, the review to determine root causes and learning points should still be progressed **in parallel** with other reviews/investigations, ensuring remedial actions are put in place as necessary and to reduce the likelihood of recurrence.

8.0 LEARNING FROM SAIs

The key aim of this procedure is to improve services and reduce the risk of incident recurrence, both within the reporting organisation and across the HSC as a whole. The dissemination of learning following a SAI is therefore core to achieving this and to ensure shared lessons are embedded in practice and the safety and quality of care provided.

HSCB in conjunction with the PHA will:

- ensure that themes and learning from SAIs are identified and disseminated for implementation in a timely manner; this may be done via:
  - learning letters / reminder of best practice letters;
  - learning newsletter;
  - thematic reviews.

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- provide an assurance mechanism that learning from SAIs has been disseminated and appropriate action taken by all relevant organisations;

- review and consider learning from external/independent reports relating to quality/safety.

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

9.0 TRAINING AND SUPPORT

9.1 Training

Training will be provided to ensure that those involved in SAI reviews have the correct knowledge and skills to carry out their role, i.e:

- Chair and/or member of an SAI review team
- HSCB/PHA DRO.

This will be achieved through an educational process in collaboration with all organisations involved, and will include training on review processes, policy distribution and communication updates.

9.2 Support

9.2.1 Laypersons

The panel of lay persons, (already involved in the HSC Complaints Procedure), have availed of relevant SAI training including Root Cause Analysis. They are now available to be called upon to be a member of a SAI review team; particularly when a degree of independence to the team is required.

Profiles and relevant contact details for all available laypersons can be obtained by contacting seriousincidents@hscni.net

9.2.2 Clinical/Professional Advice

If a DRO requires a particular clinical view on the SAI review, the HSCB Governance Team will secure that input, under the direction of the DRO.

10.0 INFORMATION GOVERNANCE

The SAI process deals with a considerable amount of sensitive personal information. Appropriate measures must be put in place to ensure the safe and secure transfer of this information. All reporting organisations should adhere to their own Information Governance Policies and Procedures. However, as a minimum the HSCB would recommend the following measures be adopted when

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transferring patient/client identifiable information via e-mail or by standard hard copy mail:

- E-Mail - At present there is not a requirement to apply encryption to sensitive information transferred across the HSC network to other HSC organisations within Northern Ireland. Information transferred between the HSCB, Trusts and Northern Ireland Department of Health is not sent across the internet. If you are transferring information to any address that does not end in one of those listed below, it is essential that electronic measures to secure the data in transit, are employed, and it is advised that encryption is therefore applied at all times to transfers of sensitive / personal information.

  List of email addresses **within the Northern Ireland secure network:**
  '.hscni.net',
  'n-i.nhs.uk'
  'ni.gov.uk' or
  '.ni.gov.net'

  No sensitive or patient/service user data must be emailed to an address other than those listed above unless they have been protected by encryption mechanisms that have been approved by the BSO-ITS.

  Further advice on employing encryption software can be sought from the BSO ICT Security Team.

  Note: Although there is a degree of protection afforded to email traffic that contains sensitive information when transmitting within the Northern Ireland HSC network it is important that the information is sent to the correct recipient. With the amalgamation of many email systems, the chances of a name being the same or similar to the intended recipient has increased. It is therefore recommended that the following simple mechanism is employed when transmitting information to a new contact or to an officer you haven't emailed previously.

  Step 1 Contact the recipient and ask for their email address.
  Step 2 Send a test email to the address provided to ensure that you have inserted the correct email address.
  Step 3 Ask the recipient on receiving the test email to reply confirming receipt.
  Step 4 Attach the information to be sent with a subject line 'Private and Confidential, Addressee Only' to the confirmation receipt email and send.

- Standard Mail – It is recommended that any mail which is deemed valuable, confidential or sensitive in nature (such as patient/service user level information) should be sent using 'Special Delivery' Mail.

Further guidance is available from the HSCB Information Governance Team on: Tel 028 95 362912

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11.0 ROLE OF DESIGNATED REVIEW OFFICER (DRO)

A DRO is a senior professional/officer within the HSCB / PHA and has a key role in the implementation of the SAI process namely:

- liaising with reporting organisations:
  - on any immediate action to be taken following notification of a SAI
  - where a DRO believes the SAI review is not being undertaken at the appropriate level

- agreeing the Terms of Reference for Level 2 and 3 RCA reviews;

- reviewing completed SEA Learning Summary Reports for Level 1 SEA Reviews and full RCA reports for level 2 and 3 RCA Reviews; liaising with other professionals (where relevant);

- liaising with reporting organisations where there may be concerns regarding the robustness of the level 2 and 3 RCA reviews and providing assurance that an associated action plan has been developed and implemented;

- identification of regional learning, where relevant;

- surveillance of SAIs to identify patterns/clusters/trends.

Whilst the HSCB will not routinely receive Level 1 SEA reports these can be requested, on occasion, by a DRO.

An internal HSCB/PHA protocol provides further guidance for DROs regarding the nomination and role of a DRO.

12.0 PROCESS

12.1 Reporting Serious Adverse Incidents

Any adverse incident that meets the criteria of a SAI as indicated in section 4.2 should be reported within 72 hours of the incident being discovered using the SAI Notification Form (Appendix 1) and forwarded to seriousincidents@hscni.net

HSC Trusts to copy RQIA at seriousincidents@rqia.org.uk in line with notifications relevant to the functions, powers and duties of RQIA as detailed in section 3.6 of this procedure.

Any SAI reported by FPS or ICVS must be reported in line with 3.2 and 3.3 of this procedure.

Reporting managers must comply with the principles of confidentiality when reporting SAIs and must not refer to service users or staff by name or by any other identifiable information. A unique Incident Reference/Number should be utilised on all forms/reports and associated

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

12.2 Never Events

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

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

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

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

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

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

12.3 Reporting Interface Incidents

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

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

12.4 Acknowledging SAI Notification

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

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

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

Where relevant, RQIA will be copied into this receipt.

12.5 Designated Review Officer (DRO)

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

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

12.6 Review/Learning Summary Reports

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

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

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

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

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

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12.7 Closure of SAI

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

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

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

12.8 Regional Learning from SAIs

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

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

12.9 Communication

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

13 EQUALITY

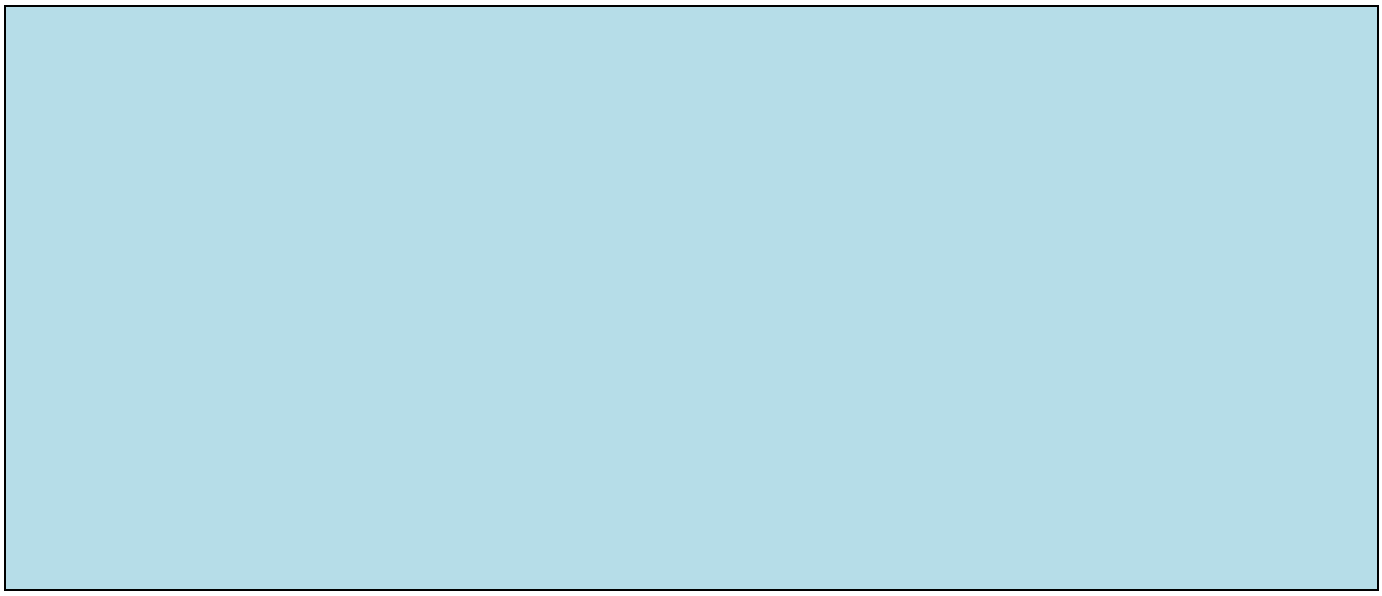
This procedure has been screened for equality implications as required by Section 75 and Schedule 9 of the Northern Ireland Act 1998. Equality Commission guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

SECTION TWO APPENDICES



APPENDIX 1

Revised November 2016 (Version 1.1)

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

8. DESCRIPTION OF INCIDENT:

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

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

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING

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

10. IMMEDIATE ACTION TAKEN TO PREVENT RECURRENCE:

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

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

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

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

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SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

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

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

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

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

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

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

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

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

Report submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

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

Additional information submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

Completed proforma should be sent to: Personal Information redacted by the USI
and (*where relevant*) Personal Information redacted by the USI

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 2

Revised November 2016 (Version 1.1)

Guidance Notes
SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

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

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

8. DESCRIPTION OF INCIDENT:

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

In addition include the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

OTHER – PLEASE SPECIFY BELOW

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

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

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

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

Report submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

21. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION:

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

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

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

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

Additional information submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

Completed proforma should be sent to: Personal Information redacted by the USI

and (*where relevant*) Personal Information redacted by the USI

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 3
Revised November 2016 (Version 1.1)

HSC INTERFACE INCIDENT NOTIFICATION FORM

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

5. DESCRIPTION OF INCIDENT:

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

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

7. PROVIDE DETAIL ON ISSUES/AREAS OF CONCERN:

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

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

10. OTHER COMMENTS:

REPORT SUBMITTED BY: _____ DESIGNATION: _____

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

Completed proforma should be sent to: [redacted]

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 4

Revised November 2016 (Version 1.1)

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

SECTION 1

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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

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

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

SECTION 6
26. DISTRIBUTION LIST:

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

Reporting Organisation SAI Ref Number:		HSCB Ref Number:	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

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

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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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

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

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

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

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

SECTION 2

INFORMING THE CORONERS OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*

1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 5

Revised November 2016 (Version 1.1)

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

SECTION 1 (To be submitted to the HSCB)

1. ORGANISATION: *Insert unique identifier number*	2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE: *Self- explanatory*
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE: *Self- explanatory*	4. DATE OF INCIDENT/EVENT: DD / MM / YYYY *Self- explanatory*
5. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: YES / NO ***Please select as appropriate***	6. IF 'YES' TO 5. PLEASE PROVDE DETAILS: *Self- explanatory*
7. DATE OF SEA MEETING / INCIDENT DEBRIEF: DD / MM / YYYY *Self- explanatory*	
8. SUMMARY OF EVENT: ***As per notification form. (If the notification form does not fully reflect the incident please provide further detail.)***	

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

SECTION 2

9. SEA FACILITATOR / LEAD OFFICER:	10. TEAM MEMBERS PRESENT:
Refer to guidance on Level 1 review team membership for significant event analysis – Appendix 10	*NAMES AND DESIGNATIONS*

11. SERVICE USER DETAILS:
Complete where applicable

DOB / GENDER / AGE

12. WHAT HAPPENED?

(Describe in detailed chronological order what actually happened. Consider, for instance, how it happened, where it happened, who was involved and what the impact was on the patient/service user[1], the team, organisation and/or others).

13. WHY DID IT HAPPEN?

(Describe the main and underlying reasons contributing to why the event happened. Consider for instance, the professionalism of the team, the lack of a system or failing in a system, the lack of knowledge or the complexity and uncertainty associated with the event)

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

All sections below be submitted to the HSCB

SECTION 3 - LEARNING SUMMARY

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

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

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

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

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

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

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

Self- explanatory

18. FURTHER REVIEW REQUIRED? YES / NO

Please select as appropriate

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

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

19. PLEASE INDICATE LEVEL OF REVIEW:
LEVEL 2 / LEVEL 3
Please select as appropriate

20. PROPOSED TIMESCALE FOR COMPLETION:
DD / MM / YYYY

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

Refer to section 2 of appendix 7.

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

Refer to section 3 of appendix 7.

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

APPROVAL BY RELEVANT PROFESSIONAL DIRECTOR AND/OR OPERATIONAL DIRECTOR

23. NAME: *Self- explanatory*

24. DATE APPROVED: *Self- explanatory*

25. DESIGANTION: *Self- explanatory*

SECTION 6

26. DISTRIBUTION LIST:

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 5

To be submitted to the HSCB

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

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

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

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER ***(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)***				
5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:			

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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

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

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

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

			NO	

SECTION 2

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

(complete this section for all death related SAIs)

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

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 6

Revised November 2016 (Version 1.1)

Insert organisation Logo

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

Organisation's Unique Case Identifier:

Date of Incident/Event:

HSCB Unique Case Identifier:

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

Responsible Lead Officer:

Designation:

Report Author:

Date report signed off:

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

1.0 EXECUTIVE SUMMARY

2.0 THE REVIEW TEAM

3.0 SAI REVIEW TERMS OF REFERENCE

4.0 REVIEW METHODOLOGY

5.0 DESCRIPTION OF INCIDENT/CASE

6.0 FINDINGS

7.0 CONCLUSIONS

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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

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

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

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

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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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

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

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

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 7
Revised November 2016 (Version 1.1)

Health and Social Care Regional Guidance

for

Level 2 and 3 RCA Incident Review Reports

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

INTRODUCTION

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

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

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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Insert organisation Logo

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

Organisation's Unique Case Identifier:

Date of Incident/Event:

HSCB Unique Case Identifier:

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

Responsible Lead Officer:

Designation:

Report Author:

Date report signed off:

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

1.0 EXECUTIVE SUMMARY

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

2.0 THE REVIEW TEAM

Refer to Guidance on Review Team Membership

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

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

3.0 SAI REVIEW TERMS OF REFERENCE

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

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

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

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

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

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3.0 SAI REVIEW TERMS OF REFERENCE

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

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

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

This list is not exhaustive

4.0 REVIEW METHODOLOGY

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

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

This list is not exhaustive

5.0 DESCRIPTION OF INCIDENT/CASE

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

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

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

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

5.0 DESCRIPTION OF INCIDENT/CASE

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

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

This list is not exhaustive

6.0 FINDINGS

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

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

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

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

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

(ii) Contributory Factors

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

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

This list is not exhaustive

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

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

7.0 CONCLUSIONS

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

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

8.0 LESSONS LEARNED

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

9.0 RECOMMENDATIONS AND ACTION PLANNING

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

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

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

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

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

10.0 DISTRIBUTION LIST

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

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

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

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

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

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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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

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

SECTION 2 **INFORMING THE CORONERS OFFICE** **(under section 7 of the Coroners Act (Northern Ireland) 1959)** *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 8

GUIDANCE ON MINIMUM STANDARDS FOR ACTION PLANS

The action plan must define:

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

The action plan **MUST** contain the following

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 9

GUIDANCE ON INCIDENT DEBRIEF

• Level 1 - SEA Reviews

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

The review should:

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

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

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

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

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

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

• Level 2 and 3 RCA Reviews

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 10

LEVEL 1 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

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

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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 11

LEVEL 2 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

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

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

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

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

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

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

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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 12

LEVEL 3 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 13

GUIDANCE ON JOINT REVIEWS/INVESTIGATIONS

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

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

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

Points to consider:

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

This guidance should be read in conjunction with:

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 14

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

1. INTRODUCTION AND PURPOSE

1.1. INTRODUCTION

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

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

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

1.2. PURPOSE

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

2. THE PROCESS

2.1. REPORTING SERIOUS ADVERSE INCIDENTS

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

2.2. MULTI-DISCIPLINARY REVIEW

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

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

2.3. ESTABLISHING AN INDEPENDENT REVIEW TEAM

2.3.1 CHAIR

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

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

2.3.2 MEMBERSHIP

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

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

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

3. TERMS OF REFERENCE

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

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

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

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

4. TIMESCALES

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

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

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

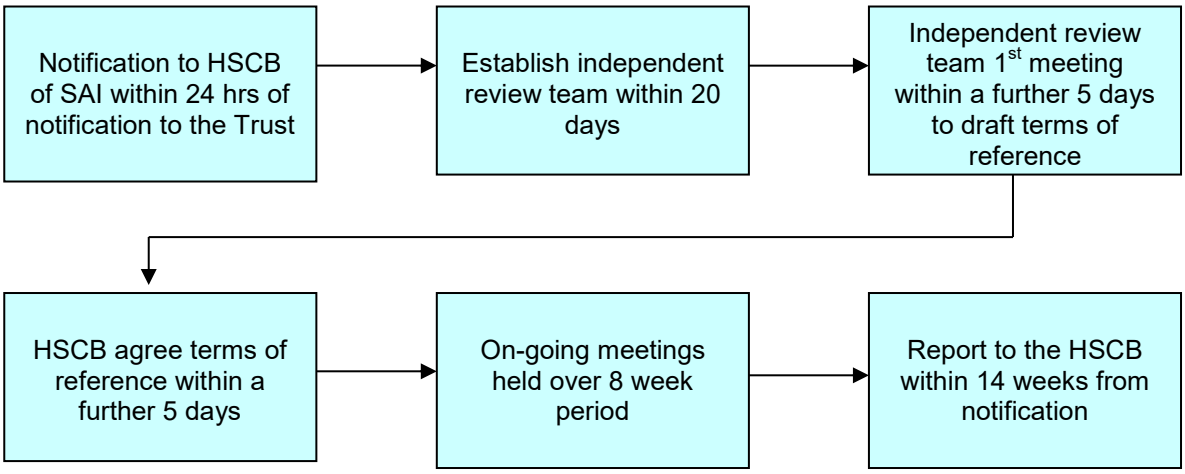
The team should meet to draft the terms of reference within a further five working days (i.e. twenty five days from notification of the incident to the Trust).

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

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

FLOWCHART OF PROCESS WITH TIMESCALES

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



5. THE HEALTH AND SOCIAL CARE BOARD RESPONSIBILITY

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

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

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APPENDIX 15

ADMINISTRATIVE PROTOCOL

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

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

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

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

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

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

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

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

All communications to be sent or copied via:

HSCB Governance Team: Personal Information redacted by the USI

and RQIA: Personal Information redacted by the USI

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 16

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

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

HSC Regional Risk Matrix – April 2013 (updated June 2016)

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

APPENDIX 17

CHILD AND ADULT SAFEGUARDING AND SAI PROCESSES

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

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

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

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

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

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

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

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

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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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

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

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

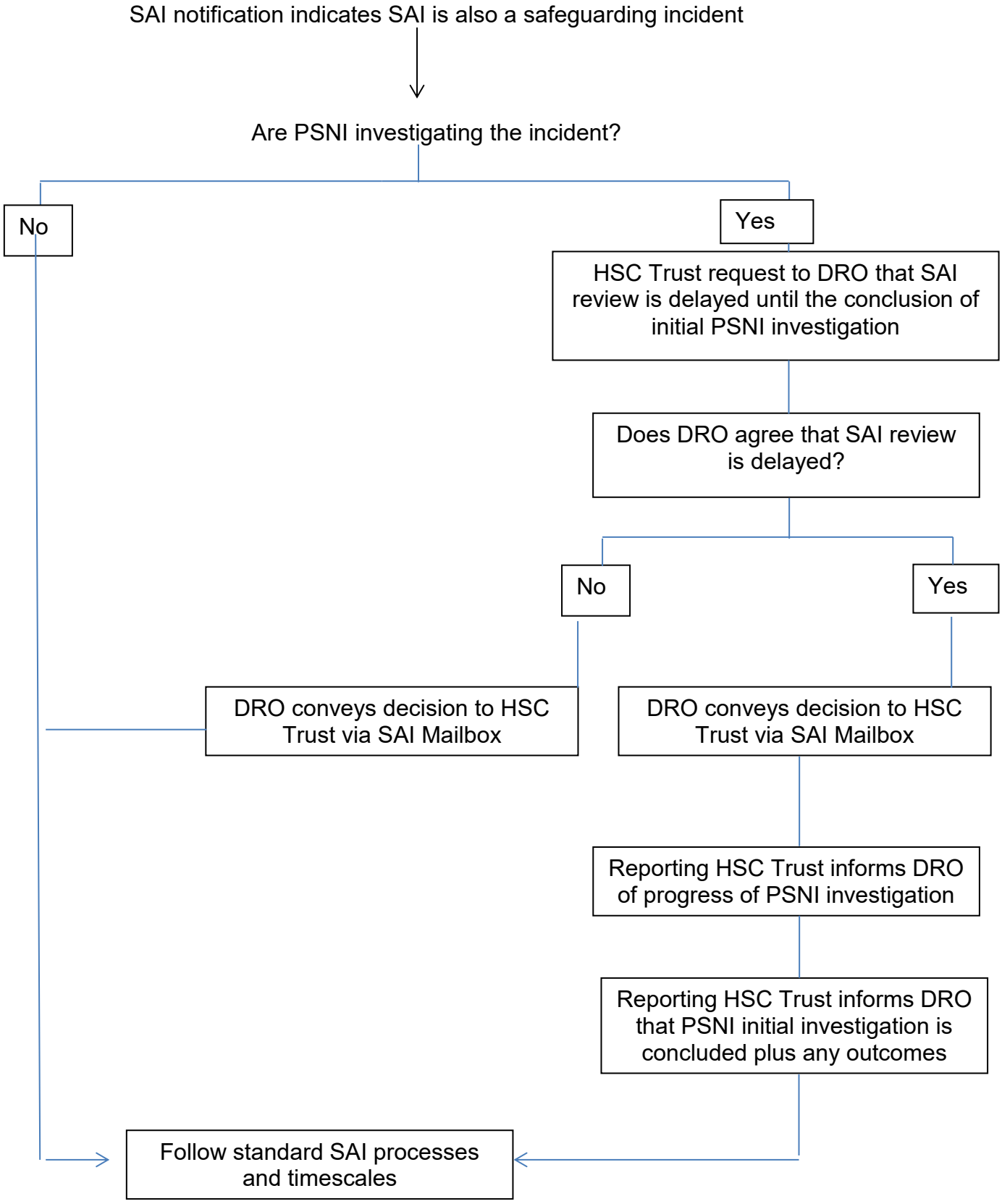
In addition "Achieving Best Evidence: Guidance on interviewing victims and witnesses, the use of special measures and the provision of pre-trial therapy" (revised in 2012), sets out clear protocols for interviewing vulnerable witnesses or victims, whether they are children or adults. This guidance ensures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

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

In such circumstances, the following process should be used:

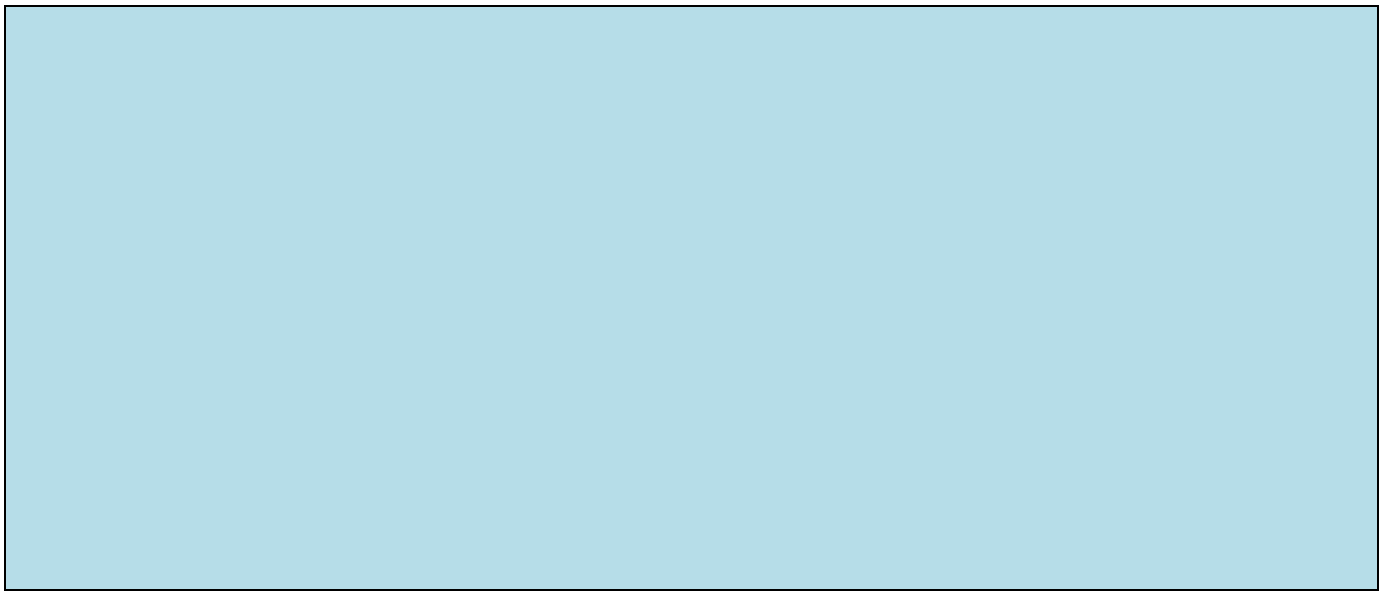
- Trust report SAI to HSCB using the SAI Notification Form;
- The SAI Notification Form or section 22 of the notification form i.e. 'additional information following initial notification, should indicate the following:
  - The SAI is also a Safeguarding incident
  - PSNI are conducting an investigation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

CHILD AND ADULT SAFEGUARDING AND SAI PROCESSES



Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

SECTION THREE ADDENDUM



ADDENDUM 1

A Guide for Health and Social Care Staff

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

November 2016
Version 1.1

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Notes on the Development of this Guidance

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

This guidance has been informed by:

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

Please note the following points:

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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

1.0 Introduction

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

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

It is therefore essential that there is:

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

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

2.0 Purpose

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

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

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

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

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

3.0 Principles of Being Open with the Service User / Family

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

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

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

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

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

3.1 Acknowledgement

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

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

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

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

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3.2 Truthfulness, timeliness and clarity of communication

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

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

3.3 Apology / Expression of Regret

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

3.4 Recognising the expectations of the Service User / Family

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

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

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

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

3.5 Professional Support

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

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

3.6 Confidentiality

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

3.7 Continuity of Care

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

4.0 Process

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

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

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- Stage 5 – Process Completion

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

4.1 Stage 1 - Recognition

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

4.1.1 Preliminary Discussion with the Service User / Family

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

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

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

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4.2 Stage 2 – Communication

4.2.1 Timing of Initial Communication with the Service User / Family

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

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

4.2.2 Choosing the individual to communicate

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

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

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

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

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

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

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

4.3.1 Preparation Prior to the Initial Meeting

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

4.3.2 During the Initial Meeting

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

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

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

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

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

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

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

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

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4.4 Stage 4 – Follow-up Discussions

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

The following guidelines will assist in making the communication effective:

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

4.5 Stage 5 – Process Completion

4.5.1 Communicating findings of review / sharing review report

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

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

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

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

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

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

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

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

4.5.2 Communicating Changes to Staff

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

4.6 Documentation

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

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

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

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

5.0 Supporting Information and Tools

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

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

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

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

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List of Acronyms and Abbreviations

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

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Particular Service user Circumstances

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

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

1.1 When a service user dies

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

1.2 Children

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

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

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

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1.3 Service users with mental health issues

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

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

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

1.4 Service users with cognitive impairment

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

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

1.5 Service users with learning disabilities

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

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1.6 Service users with different language or cultural considerations

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

1.7 Service users with different communication needs

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

1.8 Service users who do not agree with the information provided

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

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

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

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

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

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

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Health and Social Care Board

Public Health Agency

What I need to know about a Serious Adverse Incident

Information for Service Users, Family Members and Carers

Insert Name of Organisation

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

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

Introduction

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

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

What is a Serious Adverse Incident?

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

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

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

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

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

Can a complaint become a SAI?

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

How is a SAI reviewed?

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

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

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

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

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

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

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

What happens once the review is complete?

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

How will learning be used to improve safety?

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

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

For each completed review:

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

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

Do families get a copy of the report?

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

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

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Who else gets a copy of the report?

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

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

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

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

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

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

Further Information

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

Your link person is ……..…….

Your link person's job title is……..…..

Contact number …….

Hours of work……..……

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

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

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

You could also:

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

Patient and Client Council

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

Contact details:
Free phone number: 0800 917 0222

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Appendix 3

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

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

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

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Appendix 4

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

Before, During and After Communication / Engagement Documentation Checklist

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

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

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

Signature: _____

***Date*:** _____

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

Signature: _____

***Date*:** _____

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AFTER

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

Signature: _____

***Date*:** _____

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Southern Health and Social Care Trust

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Incident Management Procedure

October 2014

Received from Mairead McAlinden on 20/06/2022. Annotated by the Urology Services Inquiry.

Procedure Checklist

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

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1.0 Introduction:

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

1.1 Purpose:

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

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

1.2 Scope of the Procedure:

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

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2.0 The Roles and Responsibilities:

2.1 Chief Executive:

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

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

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

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

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

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

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

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

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

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

2.3 Directors:

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

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

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

The Assistant Director / AMDs must also:

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

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

2.5 Head of Service/ Team Manager:

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

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

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2.6 Incident Review Team:

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

The Review Teams should also consider and review the following:

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

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

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

2.7 The Directorate CSCG Coordinator:

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

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

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

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

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

2.8 All SHSCT Staff:

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

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

3.1 Incident Identification:

A useful definition of an incident is:

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

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

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

3.1.1 Other Systems for Reporting:

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

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

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

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

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

3.1.3 Immediate Action Checklist Following Identification of an Incident:

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

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

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

3.2 Reporting an Incident:

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

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

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

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

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

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

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

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

4.0 Procedure for Reviewing, Monitoring and Learning from Incidents:

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

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

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- Close all incidents following completion of the review process

4.1 Incident Review:

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

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

4.1.1 The person reporting the incident should undertake this stage of the assessment, entering it on the IR1 form (DIF1). Based on the actual impact of the incident at the time of occurrence (taking into account psychological as well as physical harm) a judgment is made as to the incident"s severity in the range Insignificant to Catastrophic.

4.1.2 Incidents assessed as causing actual **major** or **catastrophic** harm at the time of the incident must be given immediate consideration for further in depth analysis.

4.1.3 For incidents causing lesser levels of actual harm further questions need to be asked to decide on the level of investigation required.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

See Hyperlink:
http://www.hscboard.hscni.net/publications/Policies/102%20Procedure_for_the_reporting_and_followup_of_Serious_Adverse_Incidents-Oct2013.pdf

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

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

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

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

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

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

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

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

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

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

(subject to service users consent)

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APPENDIX 1:

KEY DEFINTIONS

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

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

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APPENDIX 2:

When and How an Incident Should Also Be Reported To Other Sources

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

TYPE OF INCIDENT	WHERE ELSE IT SHOULD BE REPORTED TO	USEFUL CONTACTS AND LINKS ON HOW TO REPORT IT
Potential Adult Safeguarding Incident	Definition available on the link opposite	Info available from Trust Intranet: http://vsrintranet.southerntrust.local/SHSCT/HTML/PandP/documents/SAFEGUARDINGVULNERABLEADULTSPROCEDUREGUIDANCEVERSION4.pdf Report form available on: http://vsrintranet/SHSCT/HTML/PandP/documents/PVA1BLANK.pdf
Health and Safety Incident	Via the Datix Web form Incidents should be automatically reviewed by Health and Safety	Contact: (Internal) Health & Safety Dept Number: 028 3741 2671 Email: http://vsrintranet.southerntrust.local/SHSCT/HTML/HR/documents/ReportableDiseases.pdf
MHRA	Should be notified (although voluntary) when an Adverse Drug Reaction occurs (ADR)	A paper form can be found in the back of every BNF or alternatively can be completed online at www.mhra.gov.uk/yellowcard
RIDDOR	An Incident is RIDDOR reportable if: **1)**The injury sustained is major, **2)** If a member of the public on Trust premises is killed or taken to hospital **3)** If the injury is sustained is an „Over 3 day injury" **4)** If there has been a Dangerous occurrence	Appropriate information should be completed on the Datix Web IR1 form which alerts the Trust"s Internal Health and Safety Dept. The above department is also contactable on **028 3741 2645** or **028 3741 2671**

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

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

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Appendix 3

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

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

Risk Likelihood Scoring Table

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

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

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APPENDIX 4:

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

- Any incident involving a service user should be discussed with this individual as soon as is appropriate by a senior member of the service team and preferably the lead professional. If the service user is a child or is unable to give consent due to their physical condition or mental capacity the incident should be discussed with their named next of kin contact. If the service user is able to provide consent and wishes the incident to be discussed with another carer or relative, the service team should facilitate this request.

- Specifically those incidents graded moderate, major and catastrophic should be discussed immediately with the service user and/or their relatives / carers, with consent. Those incidents of an insignificant and minor nature which occur out of hours can be discussed with those required at the most appropriate time within the next 24 hours.

- When discussing an incident with a service user and / or designated relatives / carers, the lead professional should outline the facts of the incident as known, the actual and potential consequences for the service user and how the team will review the incident for future learning. If the service user and/or designated carers / relatives wish to have the outcome of the incident review fed back to them the service team should consider this as good practice and should be conducted with consent of the service user if applicable. These interactions should be documented and attached to the incident report on Datix.

- If an incident meets the criteria for notification as an SAI or internal RCA, (**refer to Section 5**) the service user and / or designated relatives / carers must be informed of this decision before the SAI / RCA review begins. Where possible this should be undertaken by the Lead professional involved in the service user"s care. Where this is not possible to due relations being strained or it is judged to be inappropriate the Chair of the SAI /RCA review group supported by the Directorate CSCG Coordinator will undertake this role. This

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

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

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APPENDIX 5:

Guidance on Support for Staff following an Incident

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

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

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

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APPENDIX 6:

Major / Catastrophic Incident Checklist

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

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

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

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APPENDIX 7:

Incident Review Guidance

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

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

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

The above can be expanded to include where appropriate:

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

  (a) provide the care/service required, and

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(b) manage the incident when it occurred?

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

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

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APPENDIX 8

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

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

The main responsibilities of the review Chairperson are:

1.0 Prior to the Review

1.1 Reviewing all relevant case notes, statements, synopsis of care reports and relevant sections of policies and procedures related to the incident to enable them to lead the initial meeting of the Review Team.

1.2 In conjunction with the Governance Coordinator, prepare a draft Terms of Reference for consideration by the Review Team at the initial meeting.

2.0 During the Review

2.1 Ensuring that all attendees at the review are introduced to each other and are aware of their role.

2.2 Facilitating a process that is conducive to learning and analysis without interference from personal disagreements, criticisms, perceptions or dissatisfaction.

2.3 Ensuring that the review is open, fair and participative. That if required appropriate members of the Review Team are delegated to meet members of the service team involved in the incident to obtain clarity on events.

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2.4 Chairing the Review in a manner which ensures that: all salient facts, a clear chronology of events and interventions, areas of strength/weakness of policy or practice are identified and clear action plans are formulated and agreed.

2.5 Ensuring that Review Team members, service teams and patients / clients and /or relatives and carers are kept informed with respect to the review and its progress as required. See **Appendix 4** and **section 5.**

3.0 Following the Review

3.1 Liaising with the Governance Coordinator to ensure that a comprehensive report with recommendations / action points and timescales (where relevant) is produced and agreed ensuring that the service team involved in the incident are given an opportunity to check the information they have contributed to the report for factual accuracy. The Chairperson should sign off/approve the report prior to it being sent to the AMD /Assistant Director / Director.

3.2 If there are queries / comments raised by the AMD / Assistant Director/ Director following their review of the draft report, the Chair should consider these and reconvene the Review Team if necessary to address same.

3.3 Report practices, systems or other issues which the Review Team feel require immediate attention to the relevant Assistant Director, Head of Service and AMD, where appropriate.

3.4 If the Chairperson is the nominated contact with the patient/client and or family/ carers, they will be responsible for sharing the facts/ recommendations and action plan with them as outlined in **Appendix 4.**

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Southern Health and Social Care Trust

SAI RECOMMENDATIONS IMPLEMENTATION PLAN

1	Implemented
10	Ongoing Audit

RECOMMENDATION 1

The Southern Health and Social Care Trust must provide high quality Urological Cancer Care for all patients.

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

ii. Assurance from 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.

Action Required to Deliver Recommendation (s)	Responsible Officer[1]	Update	Status Rag	Evidence of Completion
i. Baseline assessment of all Cancer Multidisciplinary Team Meetings	• MDT Chairs • AMD • Cancer Services Improvement Lead	• All MDT completed baseline assessment using NICAN guidance. • Individual action plans devised for each MDT. Monthly review completed supported by Cancer Services Improvement Lead. • Principals document created based on NCAT Framework to support function of MDT. • Task & Finish Group sat monthly to provide update and assurance from each MDT on progress. • MDT Proformas devised for each MDT reflecting the expectations of function and responsibility of the MDT. Urology and Gynae fully operational. Respiratory proforma signed off, challenge with placing onto Sharepoint to facilitate accessibility. This is current being resolved. • GI and Breast Profromas are under review. Regional profroma is being amended for local use. This process is in consultation at present. • All remaining MDT will implement a proforma and audit schedule following further recruitment into the Audit Team. • Audit will be the next phase, which will be ongoing and developed further. Recruitment into Audit Team is also required to maximise this. • **<u>Feedback from Service Jan 2023</u>** o Wont deliver on the Cancer Access Standard due to ongoing workforce pressures		• Principals Document created, accepted and operationalised by MDT Chairs. • MDT Proforma created for Urology MDT. Audit schedule in place for monthly reporting. • Task & Finish group stood down as above elements operational. Audit cycle ongoing with services.
ii. Feedback from Patients from a variety of sources	• Head Of Service for Cancer Services • Governance Team • Patient Experience Team • CNS	• Review of historical complaints, Datix, Care Opinion, 10,000 Voices and Patient Surveys to establish issues/ themes and what measures were taken to address. • Utilising representation on the Service User Group to support New Patient Feedback Survey. Support from Quality Improvement Team within the Trust. • Peer Support Facilitator role through Macmillan introduced to provide support to patients receiving Cancer treatment. This role also supports gathering of Patient Experience feedback. • Targeted Care Opinion in Urology Outpatients. Set up of self serve kiosk in the waiting area to allow easy accessibility. CNS and Medical staff in Urology Outpatients received Care Opinion training to be able to review, respond and disseminate feedback amongst the team. Link made with the electronic Health and Needs Assessment (eHNA) to enable access for patients at key journey points. • **<u>Feedback from Service Nov 2022</u>** o <u>Questionnaire has been paused due to CNS having Section 21 notices and sickness within the small team. Priority on maintaining clinical activity for patients. Will be kept as a piece of work when capacity allows.</u>		• Macmillan Peer Support Report available. Excellent feedback. Presented at Departmental Urology Meeting. • Care Opinion Feedback provided to service. • Pilot Questionnaire for Patient Survey devised

[1] The Responsible Officer for ongoing audit and assurance is the individual teams/ services as stipulated in this column.

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iii. Data Mapping Exercise	• Trust Quality Improvement Team • MSD Pharmaceuticals • Cancer Services Improvement Lead	• A number of Cancer pathways were being data mapped to allow comparison and standardisation across tumour sites. • GI Pathway completed in conjunction with Belfast Trust. This was a regional piece of work to again strengthen the pathway and standardise in the region. This is being presented regionally on 19.1.2023. • Renal Pathway in Trust has been mapped. Key stakeholders currently reviewing, finalising and will be shared with the wider team for division of targeted Quality Improvement action plan. • **<u>Feedback from Service Jan 2023</u>** ○ **There has been proposed changes to the mapping. This is not yet complete.**		• Copy of the Data Maps with services for QI planning
			Overall RAG Rating	

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Received from SHSCT on 04/03/2024. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

RECOMMENDATION 2				
All patients receiving care from the Southern Health and Social Care Trust 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 expectations of Cancer Peer Review. *i. This will be achieved by ensuring all patient 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.* *ii. Assurance from comprehensive Cancer Pathway Audit and Patient Experience.*				
Action Required to Deliver Recommendation (s)	**Responsible Officer**	**Update**	**Status Rag**	**Evidence of Completion**
i. Information Pathway Review	• Cancer Services Improvement Lead • Head Of Service for Cancer Services • CNS	• NICAN Policy reviewed detailing information that must be given to patients. Newly created "Principals Document" includes these and the requirement to complete the Information Tracking Form. • Information Tracker Form review. Currently in paper format. The Trust raised regionally that the CaPPS system needs to allow electronic recording. Standardised in Trust whilst waiting on the regional update that paper form must be used. All CNS across all tumour sites received training on completion of the Information Tracker form. This was also raised regionally and all Trusts now reviewing the completion of this form whilst awaiting CaPPS update. • Once electronic recording is feasible, Trust will proceed with audit on recording of Information. An audit cycle will also be established. • Patient survey including assessment of information given to patients is also ready for pilot. • **<u>Feedback from Service Jan 2023</u>** o The audit of recording of information is now in place.		• A random audit identified gaps in completion of the paper tracker form. • Education of CNS completed. • A snapshot audit is pending shortly by Cancer Team. • Pilot Questionnaire for Patient Survey
ii. Advanced Communication Skills	• Cancer Services Improvement Lead • Heads of Service for Specialities with Cancer Site • MDT Attendees	• Raised with PHA regarding the lack or resource for training. Virtual Training model being assessed as used in England to implement in NI. • Trust facilitated a training package in interim from private company. • **<u>Feedback from Service Jan 2023</u>** o This is now a regional piece of work. A workshop was held to review and propose a new regional approach to this training as opposed to each Trust doing their own. This is still to be confirmed but early discussion indicates a preferred outsourcing approach with a very clear scope and for a defined group of staff.		• Not yet complete. • Regional Discussion and planning ongoing.
iii. Allocation of Key Worker at Diagnosis	• Cancer Services Improvement Lead • Head Of Service for Cancer Services • CNS	• CaPPS records the Keyworker name, which must be allocated at MDM. The CaPPS system required an update to allow a specific audit function to run reports of Keyworker allocation. This did not exist previously. The Trust raised this regionally and work is currently ongoing to update the system to allow Keyworker and other aspects to be audited. • Recognition that diagnosis is often made as a result of an ED attendance/ In patient stay. Gap recognised from acute ward care to specialist cancer care and link with CNS support. This requires further assessment when structure and process strengthened in Outpatient Cancer care. • In interim awaiting these updates, all CNS teams across all Cancer Sites have received training on completion of the Keyworker record. The Trust has standardised this requirement and will audit across all tumour sites once function is available. Default Keyworker is the CNS attending that MDM. This can be amended and reallocated after. • Breaking Bad News clinics. In accordance with guidance, which Trust acknowledged was out of date and raised regionally, noted that there was no standard practice for allocation of patients who are receiving a		• A random audit identified gaps in completion of the Keyworker. • Education of CNS completed. • a snapshot audit of Keyworker allocation now • CNS attendance at Consultant "Breaking Bad News" clinics audit results. • All CNS have had HNA training. • Electronic HNA training and process functional.

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		diagnosis. The use of "red flag" clinics, protected review slots or reviews in the Consultant Office or Ward Attendance were all methods that this practice occurred. This did not allow for 'coding' of this, to allow data reporting, or to secure and consistently have CNS in attendance. Discussions with Booking Centre and all Trusts identified that there wasn't a standardised process for this and this would need to be reviewed and addressed regionally. • At this time the Urology Team is auditing the Consultants clinics to establish was a CNS present in situation of breaking bad news. An audit completed in November 22 is available to provide baseline data. • Trust piloted a CNS Lead Post Diagnosis Clinic in the GI team. Consultants referred the patient to this clinic following diagnosis. • Patients with a diagnosis have access to an Holistic Needs Assessment (HNA). All CNS across all tumour sites received HNA training. This is now in electronic format, this has been rolled out across all CNS teams. The CNS now are completing a survey on HNA and holding a workshop, including the Support Workers, to review feedback and further develop and improve this. HNA is now part of all CNS job plans across all Cancer sites. • Chief Nursing Officer has raised support of recruitment to Band 4 Support Workers, to support the role of the CNS in their Keyworker interface with the patient. This would be to reflect and match the Band 4 roles that currently exist in Macmillan and would allow career progression with Band 3 staff. The benefit to patients would allow a more proactive supportive approach and allow for signposting for example to allow the CNS to maximise their skill set in cancer care. A regional meeting is pending to discuss this and hopefully progress to recruitment. • **<u>Feedback from Service Jan 2023</u>** o Cancer Positive Pathology report is now operational and is cross checked against CaPPs report. Safety net to ensure all patients tracked. o With regards to the Band 4 Support Workers, there was some developments regionally and advised that there is further discussion required due to complexity.		• Job planned session for HNA.
iv. Key Performance Indicator Audit Framework for CNS	• Cancer Services Improvement Lead • Head Of Service for Cancer Services • CNS	• There was no KPI Framework for CNS as there was for acute wards and nursing care. Recognised this is a significant gap in audit and assurance. • Trust raised this regionally and requires all Trusts and all Cancer Nurse Specialists to feed into this development. Trust held a KPI development workshop in March 2022 including all Cancer sites to begin the assessment of what needed to be included and how this would be implemented into the services. • The region has now progressed to establish a KPI working group and is now considering the inclusion of KPI auditing as part of the CaPPS system. • Review of the NIPEC Job Planning Guidance for Cancer Nurse Specialists. This supports the KPI's that need to be considered for auditing. • **<u>Feedback from Service Jan 2023</u>** o The KPI's have been locally agreed within the Trust to allow progress whilst regional direction is given. Roll out across the CNS teams across all tumour sites.		• Urology CNS completed Job Planning in accordance with the NIPEC guidance. • Nurse Lead Clinics and Nurse Lead Procedures all had Policies and Procedures completed and signed off to support this activity.
v. Staffing complement within CNS and Support Workers across all Tumour sites	• Cancer Services Improvement Lead • Head Of Service for Cancer Services • Trust • Region	• In supporting the Cancer Strategy, a regional census was completed by each Trust to establish the demand for CNS to support the actions within the Cancer Strategy. This census highlighted the gaps now and what will be required in the next 10 years to meet demand. The Trust then compiled a 5 Year CNS plan to support the Cancer Strategy to develop nurses into CNS roles and succession planning.		• CNS 5 Year Plan • Demand Paper for CNS
		Overall RAG Rating		

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Southern Health and Social Care Trust

RECOMMENDATION 3				
The Southern Health and Social Care Trust must promote and encourage a culture that allows all staff to raise concerns openly and safely. *i. This will be achieved by ensuring a culture primarily focused on patient safety and respect for the opinions of all members in a collaborative and equal culture. 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 monthly agenda. There must be action on issues escalated.* *ii. Assurance form the number of issues raised through Cancer Services, Datix incidents identified, numbers of issues resolved, number of issues outstanding.*				
Action Required to Deliver Recommendation (s)	**Responsible Officer**	**Update**	**Status Rag**	**Evidence of Completion**
i. Review of Trust and Regional Guidelines and Policies • Whistle Blowing Policy • DOH Your Right to Raise a Concern Guide • Nursing & Midwifery Accountability & Assurance Framework • Working Well Together Policy	• Director of HR • AD's of Directorates • HOS of Directorates • All Line Managers	• Review of all current Trust & Regional Policies to support this: o Whistle Blowing Policy o DOH Your Right to Raise a Concern o Nursing and Midwifery Accountability and Assurance Framework o Working Well Together Policy • Focus on Induction Pathway. Support and encourage raising of concerns/ potential concerns. • Review of historical reporting of concerns completed. Recognised that theme of concerns raised was based on working conditions associated with staffing levels. • Leadership "walkabouts" from Operational and Corporate Senior Staff across all directorates established. Allows staff to become familiar with management and be comfortable in potentially raising concerns. • Identifying learning from other Inquiries for example Muckamore. • Cyclical emails on Global to all staff highlighting Whistle Blowing and individual responsibility, support and encouragement. • CNS Forum now operational for all tumour site CNS. Support to raise issues/ concerns and opportunity to collectively discuss and agree standardised approach to Cancer care. • **<u>Feedback from Service Jan 2023</u>** o This is also now considered to include the systems and processes associated with the MDT. As such the Cancer Performance Monthly Meeting has MDT as a standard agenda item. This includes the monitoring of the MDT, the pathology reporting, quoracy of the MDT/ issues with attendance, issues and risk register review. Any issues with Non-Compliance is raised and addressed through Divisional Meetings. o Medical Directors Learning and Development Group established to allow sharing of issues/concerns/ shared learning.		• CNS Forum established to encourage peer support and forum for raising issues/concerns within cancer care in a safe space with support from senior managers. • Induction of all new staff includes the Whistle Blowing Policy.
ii. NMC & GMC Registration and requirements to Revalidate & provide assurance of Safety to Practice, Duty of Candour as stipulated in the Code of Conduct.	• Revalidation Team • All Line Managers • Individual Staff on a Professional Register • HR	• All registrants of both medical and nursing professions Revalidate in line with the professional body they are aligned to. • Revalidation process encompasses the 4 fundamental aspects of a nurses responsibilities within their Code of Conduct - Prioritise People -Promote Professionalism -Practice Effectively -Preserve Safety • Staff aware of the Duty of Candour (Nursing and Medical)		• Communication strategy already in place to ensure Revalidation requirements are met in time. • NMC has process of validation where records can be asked for to assess evidence and assure standard met.

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		• Revalidation team for nursing staff. Monthly emails to staff and line managers to ensure prompt submission of documents/ fees to ensure no lapse in status on register. Revalidation every 3 years which is signed off by a line manager whereby the Nurse must demonstrate how they meet the 4 principals of he code. Uploaded to NMC personal record and NMC validate. • Escalation Process for staff who have lapsed on Revalidation • Medical staff follow the same process within the Trust. Medical Revalidation Oversight Group established to address issues identified also in the 2016 SAI recommendations. • HR processes and supporting Policies for guidance to address poor practice, non compliance and performance issues. Encourage and support effective proactive management of issues early to protect patient safety.		• Sharepoint resource for support for the Revalidation process and access to Code of Conduct. • Terms of Reference for Medical Revalidation Group
iii. Available & Accessible Information that supports the raising of concerns and management of concerns with the Organisation.	• Governance Team	• Review of incidents within the Trust raised regarding concerns of Treatment. Currently the National Incident Reporting system (DATIX) does not allow for categorising "concern". Of the report run from Jan 2019 to Dec 2021 themes that could include a concern were: -Diagnosis-Wrong (8 reports) -Failure to Note Relevant Info In A Patients Record (61 reports) -Failure to Discontinue Treatment (10 reports) -Failure/ Delay to Order Correct Tests/ Images (125 reports) -Inadequate Investigation/ Inadequate Assessment (7 reports) - Treatment/ Procedure Not Clinically Indicated (13 reports) -Treatment/ Procedure Inappropriate/ Wrong (38 reports) • Of note there has been more reporting since 2019 and steady increase year on year. Reflective of staffs awareness to raise concerns and confidence to report. Discussed with Governance Team. Datix can code concerns but staff awareness of this is limited. Shared with Lead Nurses for sharing at Sisters Meeting to disseminate to teams regarding use of Datix for reporting concerns.		• Datix System accessibility and coding being reviewed regionally as does not allow ease of coding of issues/ raising concerns
		Overall RAG Rating		

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Southern Health and Social Care Trust

RECOMMENDATION 4				
The Southern Health and Social Care Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals. *i. This will be achieved by all MDM's 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 (eg. Oncology, Palliative Care, Community Services)* *ii. Assurance from quorate meetings, sufficient Radiology input to facilitate pre MDM Quality Assurance of images. Cancer Patient pathway audit, Audit of recurrent MDM discussion and onward referral audit of patients to Oncology/ Palliative Care etc.*				
Action Required to Deliver Recommendation (s)	**Responsible Officer**	**Update**	**Status Rag**	**Evidence of Completion**
i. All MDM meetings follow the Guidance from National Cancer Action Team (NCAT) and meetings formatted in accordance with this framework as recognised as best practice regionally.	• MDT Leads • Cancer Leads • Regional MDT	• MDT meetings are structured in accordance to the NCAT tool. Meeting agendas follow the essential elements detailed within the NCAT Tool and supported by the Principals Document. All MDM Chairs have accepted and support the use of this document in the function of the MDM. • Commenced with baseline audit of all tumour site MDM, identification of areas of improvement, gaps in process and non-compliance noted into an individualised action plan which was reviewed and actioned monthly. Supported by the Cancer Service Improvement Lead. • Recruitment of an MDM Coordinator to support the MDM Chair in conducting the MDM in accordance with the guidance. • Quoracy at MDT for specialities is not recorded in Policy and is not agreed regionally at a set %. Audit of Urology MDM commenced and back dated to March 2022. This will roll out to all MDM following further recruitment into Audit Team. • Clear recording of MDM recommendations and the responsible person to implement MDT recommendations. Audit undertaken now by DMD monthly on Urology MDM. Back dated to January 2022. 5 records audited per week of the month. Determines was the recommended outcome completed, and if not this goes back to the MDM and the named responsible person is held to account. If an action has not been completed this is recorded in a Datix and escalated through the Governance Structure. • Focus on recording of variances in actions from the recommendation of the MDT is clear and demonstrates rationale and decision making associated with this. • Moving towards all patients discussed at Urology MDM being subject to audit. Requires further recruitment into the Audit Team. • Detailed completion of the MDM Proforma and submission for audit and assurance purposes. This is operational in Urology and Gynae at this time. Resource to be boosted to support further implementation and audit. • Cancer Service Improvement Lead & Head of Service for Clinical Assurance met with each MDT Lead to review the outstanding actions and ensure all fully appraised of the requirements & timescales. • Task & Finish Supergroup meetings well represented across all tumour sites and lots of participation and engagement. • All CNS across all tumour sites are fully appraised of the SAI recommendations. • Training conducted with Cancer Trackers and Consultant Secretaries to enhance knowledge and awareness of MDM process and escalation processes if an issue/ concern is identified. • Recruitment of further Band 5 Cancer Information and Audit Tracker IN November 2022 further boosted this audit resource with a further pending recruitment to a Band 4 Support to this Band 5. The enhancement of the audit processes will follow this. • **<u>Feedback from Service Jan 2023</u>**		• Principals Document • Urology MDM Proforma • Urology MDM Proforma Audit • Urology MDM Quoracy Audit

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		○ Quoracy is not being met regionally. Regional Oncology resource is limited therefore there is gaps in representation. This is highlighted clearly in the MDT quoracy reports and has enabled this to be escalated regionally in a timely manner.		
ii. MDM Chairs and essential representation eg CNS will have Job Planned sessions for the MDM role. This should also be reflected in the Job Description.	• MDT Leads • Cancer Leads • Regional MDT • Medical Director • DMD'S • AD'S • Service Improvement Leads	• Job plans of MDT chairs and CNS reflect the required attendance at MDT • Job description clearly details roles and responsibilities for the Chair in keeping with the Effective MDT principals. • JD for Urology MDT had been finalised and agreed with the Chair and the Div MD. JD explains very clearly who is responsible for the operational element and who is responsible for the clinical elements of the particular Cancer MDT. • Audit support is now essential in providing assurance that the performance of the MDM is as expected and supported by the JD of the MDM Chair. • Job planning for MDT Chairs completed across all tumour sites. • Monthly quoracy audit is completed of all MDM. This report is fed through the Senior Management structure for escalation monthly as opposed to the quarterly reporting that was completed previously. • MDT to have 95% attendance at each meeting (across all those representing from all specialities). Previous issue with Radiology and Pathology representation has been addressed within Urology MDM with a consistent secure attendance from both. • Regional pathway of escalation strengthened. In particular with Oncology attendance issues for cross cover as this is supplied from region. The Trust has no control over this, and there remains a deficit in the compliment of Oncologists across cancer sites to consistently represent at all MDM's. • All CNS have been job planned for attendance at the MDM across all tumour sites. • Highlighted concerns over recruitment and retention of MDT Leads for future. • **<u>Feedback from Service Jan 2023</u>** ○ Job planning for all MDT Chairs now includes a PA. ○ This recommendation has moved back to amber as there is a Clinical Director gap in Cancer Services. Raised that there is potential for 3 further CD's to stand down. ○ Resources will be a significant impact to be able to meet this recommendation going forward.		• JD for Urology MDM Chair • Monthly Quoracy reports
Overall RAG Rating				

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Southern Health and Social Care Trust

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 . *i. 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 a safety mechanism 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.* *ii. Assurance from comprehensive cancer care pathway audit, exception reporting and escalation.*				
Action Required to Deliver Recommendation (s)	**Responsible Officer**	**Update**	**Status Rag**	**Evidence of Completion**

i. Compliance with Regional Tracking Requirements. Currently 31 & 62 day tracking is the only requirement in accordance with CaPPS.	• Operational Service Leads
	• Cancer Service Leads
		• All patients with Cancer diagnosis are recorded in CaPPS system
		• Patients are tracked 31 & 62 days
		• Regionally no Trust tracks beyond 62 days. If this changes this will be a collaborative regional piece of work and will require:
		-funding
		-resources including staff, training and IT system update to support.
		• X2 additional trackers now in post which has resulted in a fully resourced team.
		• Recognition if region decides to track beyond the 31 & 62 days there will be need for additional resources and needs to be a regional policy/ procedure change
		• Discussion with Lead Cancer Commissioner regarding the ask of the Trust to track beyond the regional requirements. Advised this must be a regional position and not only within one Trust. Identified there needs to be 100% increase in resource in all Trusts to meet the demand for enhanced tracking. It will be phased approach across the region looking at treatment tracking and tracking of secondary cancer diagnosis. Commissioner has escalated to HSCB that this request for the Trust alone is not appropriate or feasible. Noted that the process would need to begin with extending the 62 day tracking to the end of treatment and will lead to subsequent diagnosis tracking.
		• Trust has submitted as part of the Staffing Census what we require for now and projections for tracking in 10 years.
		• Re-establishment of regional Waiting Time Guidance Review Group. These guidelines are from 2008 and need work to update in line with England current guidance. This will look at subsequent treatment for 2nd diagnosis and onward pathway tracking beyond 62 days.
		
		• **<u>Feedback from Service Jan 2023</u>**
		  ○ Recommendation moved back to amber as resource is an issue. There is full resourcing of the 31 and 62 day pathway tracking. There is further recruitment pending to provide auditing function of the tracking process.
		  ○ The Trust would like to move to tracking any further MDT recommendation, to ensure it is actioned, thus extending beyond the 1st definitive treatment.
				• Tracking Report
				• Staffing Census for Trackers

ii. All patients with positive pathology results are identified and referred to MDT promptly.	• MDT Leads, Clinicians, CNS & MDT Coordinator	• Established within the Trust a weekly Pathology Report to support the MDM. This highlights all patients with a positive Pathology on a weekly basis. • Currently the DMD for Urology filters this data, and cross checks with the Tracker that this patient is on the MDM agenda.		• Pathology Report • SOP for Pathology Report filtering and actions.

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Southern Health and Social Care Trust

iii. Robust systems to enable alerts/ cross checking and sign off of pathology results for patients on tracking		• An audit was completed back dated to March 2022 and remains ongoing monthly. • DMD now on cross checking of positive pathology results, forwards the patient details to the CNS team to ensure they are added flagged as requiring a Keyworker allocation. This also allows the CNS to plan the allocation of patient load, and plan their attendance at their MDM, to provide consistent oversight of the patient journey. • Strengthens the CNS and MDM Chair relationship to ensure no patient is missed and raising issues promptly. • This will require implementation across all tumour sites and is subject to further resources being secured.		
			Overall RAG Rating	

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Received from SHSCT on 04/03/2024. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

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 patient outcomes. *i. 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.* *ii. Assurance form the Cancer Pathway Audit outcomes with exception discussion and escalation. Date should be declared externally to Cancer Peer Review.*				
Action Required to Deliver Recommendation (s)	**Responsible Officer**	**Update**	**Status Rag**	**Evidence of Completion**
i. Feedback from Patients from a variety of sources	• Cancer Services Improvement Lead • Head Of Service for Cancer Services CNS	• NICAN Policy reviewed detailing information that must be given to patients. Newly created "Principals Document" includes these and the requirement to complete the Information Tracking Form. • Information Tracker Form review. Currently in paper format. The Trust raised regionally that the CaPPS system needs to allow electronic recording. Standardised in Trust whilst waiting on the regional update that paper form must be used. All CNS across all tumour sites received training on completion of the Information Tracker form. This was also raised regionally and all Trusts now reviewing the completion of this form whilst awaiting CaPPS update. • Once electronic recording is feasible, Trust will proceed with audit on recording of Information. An audit cycle will also be established. • Patient survey including assessment of information given to patients is also ready for pilot.		• A random audit identified gaps in completion of the paper tracker form. • Education of CNS completed. • A snapshot audit is pending shortly by Cancer Team. • Pilot Questionnaire for Patient Survey
ii. Allocation of Key Worker at Diagnosis	• Cancer Services Improvement Lead • Head Of Service for Cancer Services CNS	• CaPPS records the Keyworker name, which must be allocated at MDM. The CaPPS system required an update to allow a specific audit function to run reports of Keyworker allocation. This did not exist previously. The Trust raised this regionally and work is currently ongoing to update the system to allow Keyworker and other aspects to be audited. • Recognition that diagnosis is often made as a result of an ED attendance/ In patient stay. Gap recognised from acute ward care to specialist cancer care and link with CNS support. This requires further assessment when structure and process strengthened in Outpatient Cancer care. • In interim awaiting these updates, all CNS teams across all Cancer Sites have received training on completion of the Keyworker record. The Trust has standardised this requirement and will audit across all tumour sites once function is available. Default Keyworker is the CNS attending that MDM. This can be amended and reallocated after. • Breaking Bad News clinics. In accordance with guidance, which Trust acknowledged was out of date and raised regionally, noted that there was no standard practice for allocation of patients who are receiving a diagnosis. The use of "red flag" clinics, protected review slots or reviews in the Consultant Office or Ward Attendance were all methods that this practice occurred. This did not allow for 'coding' of this, to allow data reporting, or to secure and consistently have CNS in attendance. Discussions with Booking Centre and all Trusts identified that there wasn't a standardised process for this and this would need to be reviewed and addressed regionally. • At this time the Urology Team is auditing the Consultants clinics to establish was a CNS present in situation of breaking bad news An audit completed in November 22 is available to provide baseline data.		• A random audit identified gaps in completion of the Keyworker. • Education of CNS completed. • snapshot audits pending of Keyworker allocation now • CNS attendance at Consultant "Breaking Bad News" clinics audit results • All CNS have had HNA Training

Received from SHSCT on 04/03/2024. Annotated by the Urology Services Inquiry.

		• Trust piloted a CNS Lead Post Diagnosis Clinic in the GI team. Consultants referred the patient to this clinic following diagnosis. • Patients with a diagnosis have access to an Holistic Needs Assessment (HNA). All CNS across all tumour sites received HNA training. This is now in electronic format, this has been rolled out across all CNS teams. The CNS now are completing a survey on HNA and holding a workshop, including the Support Workers, to review feedback and further develop and improve this. HNA is now part of all CNS job plans across all Cancer sites. • Chief Nursing Officer has raised support of recruitment to Band 4 Support Workers, to support the role of the CNS in their Keyworker interface with the patient. This would be to reflect and match the Band 4 roles that currently exist in Macmillan and would allow career progression with Band 3 staff. The benefit to patients would allow a more proactive supportive approach and allow for signposting for example to allow the CNS to maximise their skill set in cancer care. A regional meeting is pending to discuss this and hopefully progress to recruitment.		
			Overall RAG Rating	

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Received from SHSCT on 04/03/2024. Annotated by the Urology Services Inquiry.

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RECOMMENDATION 7				
The role of the Chair of the MDM should be described in a Job Description, funded appropriately and have an enhanced role in Multidisciplinary Care Governance.				
Action Required to Deliver Recommendation (s)	**Responsible Officer**	**Update**	**Status Rag**	**Evidence of Completion**

i. MDM Chairs will have Job Planned sessions for the MDM role. This should also be reflected in the Job Description.	• Medical Director
	• DMD'S
	• AD'S
	• Service Improvement Leads
		• Job plans of MDT chairs and CNS reflect the required attendance at MDT
		• Job description clearly details roles and responsibilities for the Chair in keeping with the Effective MDT principals.
		• JD for Urology MDT had been finalised and agreed with the Chair and the Div MD. JD explains very clearly who is responsible for the operational element and who is responsible for the clinical elements of the particular Cancer MDT.
		• Audit support is now essential in providing assurance that the performance of the MDM is as expected and supported by the JD of the MDM Chair.
		• Job planning for MDT Chairs completed across all tumour sites.
		• Monthly quoracy audit is completed of all MDM. This report is fed through the Senior Management structure for escalation monthly as opposed to the quarterly reporting that was completed previously.
		• MDT to have 95% attendance at each meeting (across all those representing from all specialities). Previous issue with Radiology and Pathology representation has been addressed within Urology MDM with a consistent secure attendance from both.
		• Regional pathway of escalation strengthened. In particular with Oncology attendance issues for cross cover as this is supplied from region. The Trust has no control over this, and there remains a deficit in the compliment of Oncologists across cancer sites to consistently represent at all MDM's.
		• All CNS have been job planned for attendance at the MDM across all tumour sites.
		• Highlighted concerns over recruitment and retention of MDT Leads for future.
		
		• **<u>Feedback from Service Jan 2023</u>**
		  ○ Moved back to Amber as CD role for Cancer is vacant. This has been escalated to Director and Medical Director.
		  ○ Highlighted the challenges in securing post holder as recognised the additional times required and PA to be allocated.
				• JD for Urology MDM Chair
				• Monthly Quoracy reports

			Overall RAG Rating	

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Southern Health and Social Care Trust

RECOMMENDATION 8				
All patients should receive cancer care based on accepted best practice guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance). *i. This will be achieved by ensuring the Multidisciplinary Team meeting is the primary forum in which the patient merits of all appropriate treatment options for the management of their disease, can be discussed. As such, a clinician should either defer to the option of his/ her peers or justify any variation through the patients documented informed consent.* *ii. Assurance from the 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.*				
Action Required to Deliver Recommendation (s)	**Responsible Officer**	**Update**	**Status Rag**	**Evidence of Completion**
i. Feedback from Patients from a variety of sources	• Cancer Services Improvement Lead • Head Of Service for Cancer Services CNS	• NICAN Policy reviewed detailing information that must be given to patients. Newly created "Principals Document" includes these and the requirement to complete the Information Tracking Form. • Information Tracker Form review. Currently in paper format. The Trust raised regionally that the CaPPS system needs to allow electronic recording. Standardised in Trust whilst waiting on the regional update that paper form must be used. All CNS across all tumour sites received training on completion of the Information Tracker form. This was also raised regionally and all Trusts now reviewing the completion of this form whilst awaiting CaPPS update. • Once electronic recording is feasible, Trust will proceed with audit on recording of Information. An audit cycle will also be established. Patient survey including assessment of information given to patients is also ready for pilot.		• A random audit identified gaps in completion of the paper tracker form. • Education of CNS completed. • A snapshot audit is pending shortly by Cancer Team. • Pilot Questionnaire for Patient Survey
ii. Allocation of Key Worker at Diagnosis	• Cancer Services Improvement Lead • Head Of Service for Cancer Services CNS	• CaPPS records the Keyworker name, which must be allocated at MDM. The CaPPS system required an update to allow a specific audit function to run reports of Keyworker allocation. This did not exist previously. The Trust raised this regionally and work is currently ongoing to update the system to allow Keyworker and other aspects to be audited. • Recognition that diagnosis is often made as a result of an ED attendance/ In patient stay. Gap recognised from acute ward care to specialist cancer care and link with CNS support. This requires further assessment when structure and process strengthened in Outpatient Cancer care. • In interim awaiting these updates, all CNS teams across all Cancer Sites have received training on completion of the Keyworker record. The Trust has standardised this requirement and will audit across all tumour sites once function is available. Default Keyworker is the CNS attending that MDM. This can be amended and reallocated after. • Breaking Bad News clinics. In accordance with guidance, which Trust acknowledged was out of date and raised regionally, noted that there was no standard practice for allocation of patients who are receiving a diagnosis. The use of "red flag" clinics, protected review slots or reviews in the Consultant Office or Ward Attendance were all methods that this practice occurred. This did not allow for 'coding' of this, to allow data reporting, or to secure and consistently have CNS in attendance. Discussions with Booking Centre and all Trusts identified that there wasn't a standardised process for this and this would need to be reviewed and addressed regionally.		• A random audit identified gaps in completion of the Keyworker. • Education of CNS completed. • snapshot audit pending of Keyworker allocation now • CNS attendance at Consultant "Breaking Bad News" clinics audit results • All CNS Have had HNA Training.

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		• At this time the Urology Team is auditing the Consultants clinics to establish was a CNS present in situation of breaking bad news. An audit completed in November 22 is available to provide baseline data. • Trust piloted a CNS Lead Post Diagnosis Clinic in the GI team. Consultants referred the patient to this clinic following diagnosis. • Patients with a diagnosis have access to an Holistic Needs Assessment (HNA). All CNS across all tumour sites received HNA training. This is now in electronic format, this has been rolled out across all CNS teams. The CNS now are completing a survey on HNA and holding a workshop, including the Support Workers, to review feedback and further develop and improve this. HNA is now part of all CNS job plans across all Cancer sites. • Chief Nursing Officer has raised support of recruitment to Band 4 Support Workers, to support the role of the CNS in their Keyworker interface with the patient. This would be to reflect and match the Band 4 roles that currently exist in Macmillan and would allow career progression with Band 3 staff. The benefit to patients would allow a more proactive supportive approach and allow for signposting for example to allow the CNS to maximise their skill set in cancer care. A regional meeting is pending to discuss this and hopefully progress to recruitment. • **<u>Feedback from Service Jan 2023</u>** o Audit process ongoing in Urology only for MDT performance. 5 patients discusses at MDM in previous month are reviewed. Escalation process is in final draft for how non-compliance with MDT recommendations is managed. o Trust would like to roll out further number of audits and across all tumour sites however the resource required to do this is not available and the risk needs to be balanced.		
			Overall RAG Rating	

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Southern Health and Social Care Trust

RECOMMENDATION 9				
The roles of the Clinical Lead of Cancer Services and Associate Medical Director Cancer Services should be reviewed. The Southern Health and Social Care Trust must consider how these roles				
Action Required to Deliver Recommendation (s)	**Responsible Officer**	**Update**	**Status Rag**	**Evidence of Completion**

i. Job Descriptions must reflect the requirements for robust Governance and Quality Assurance processes for Cancer Service Leads, AMD's and Divisional Medical Directors.	• Medical Directors Office (AMD'S/ DMD'S)
	• MDT Leads
		• Consistent and Standardised requirement within Job Descriptions across Leads, Directors and Associate Medical Directors. Specific Job Descriptions required review for:
		  ○ Clinical Director Job Description
		  ○ Divisional Directorate Medical Director
		• Review of Attendance/ Representation at Interface Meetings.
		• Communication channels between Divisional director and Cancer Lead when there are clinical concerns.
		• This will be a regional piece of work also as all Trusts need to reflect the same. Raised at Trust board in Jan 2022.
		• Job descriptions reviewed and "signed off".
		
		• **<u>Feedback from Service Jan 2023</u>**
		  ○ Advised this needs to go back to red as the CD Post for Cancer is currently vacant. As detailed previously this has been raised with Director and Medical Dircetor.
				• Copies of the Job Descriptions

ii. Each of the above will have full oversight of the requirements with the SAI Implementation Action Plan.	• Medical Directors Office (AMD'S/ DMD'S) • MDT Leads	• Governance structures are clear, consistent and robust across Cancer and Non Cancer • All DMD's invited to the Monthly Task and Finish Group Meetings and all fully appraised that the recommendations extend across all tumour sites therefore support from each is essential. • Updated action plan for each MDT is reviewed monthly with Cancer Service Improvement Leads. Feedback provided by each tumour site at the Task and Finish Group. • Associate Medical Director presented in February 2022 detailing the work completed in Medical Leadership, Appraisal, Revalidation and Governance including management of Private Patients.		• Update from Medical Directors Office • Copies of MDT Action Plan for each Tumour Site.
		Overall RAG Rating		

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Received from SHSCT on 04/03/2024. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

RECOMMENDATION 10				
The families working as "Experts by Experience" have agreed to support implementation of the recommendations by receiving updates on assurances at 3, 6 and 12 monthly intervals.				
				Evidence of Completion
i. The contribution of patients and/ or carers or relatives to the implementation of the recommendations. Evidencing their contribution throughout, in supporting and maximising the patient centred focus.	• Task and Finish Group	• Patients involved in the SAI's are provided with written updates on the progression of the action plan and meeting the requirements of the recommendations at regular intervals. A Task and Finish Group was established, terms of reference agreed and regular meetings held to provide update, oversight and input into the decision making and implementation of the recommendations. • Action plan clearly identifies the contribution from the service user representatives. • Letter 1 was completed and sent in September 21. Second letter sent January 22. This included an update of the work so far on the SAI recommendation actions. Following feedback from the service users on Letter 2 Update, the Trust has decided to re-issue this incorporating the feedback further into the process to be able to provide more information. • Sub Group established with service users to devise a Quality Improvement plan based on a Patient Experience Survey. • Final letter of update required for circulation to the SAI patients and families.		• Terms of Reference for SAI Task and Finish Group • Copy of the SAI update letters. • Pilot Patient Experience Survey.
			Overall RAG Rating	

DRAFT

Southern Health and Social Care Trust

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.				
				Evidence of Completion
i. Following implementation of the recommendations the Trust should assess if aspects of Quality improvement can be applied to any service/ team/ speciality outside of Cancer Care	• Medical Director • DMD'S • AD'S • Service Improvement Leads	• Generating Quality improvement opportunities across the Trust and Regionally to improve standards and patient care and experience • Based on outcomes of current QI work specific to Cancer Care. SPPG request of Outcomes Report for Phase 1. • **<u>Feedback from Service Jan 2023</u>** o This would include any learning potentially coming out of the Lookback Review (shared via the Learning and Development Group) o Extension of the Lookback Review o Quality Improvement links		• Trust proceeded to implement recommendations across all tumour sites and did not isolate to Urology Cancer only. • Trust is sharing implementation work at Regional Cancer Forum. • Trust Board will be appraised of the Quality Improvement Work. • Outcomes Report in final stages for SPPG. This will highlight the learning opportunities, strategies to implement improvement and regional sharing.
ii. The Trust is to consider if there is a requirement to extend the review of patients records beyond the current time period, based on the findings of the current review, and if additional opportunities for improvement can be availed of.	• Royal College of Surgeons (RCS) • RQIA Report • Medical Director • DMD for Urology • Lookback Review Team • Public Inquiry.	• Recognition that theme emerging that patients with a cancer diagnosis have been most subject to "sub optimal" care. • SCRR screening has identified the themes in Lookback Review Phase 1. Completed SCRR reports has established learning opportunities. Recognition that "new themes" will create an opportunity for new learning to be identified. • RQIA completed independent review of the SCRR process and recommendations made. Action Plan completed and implemented to meet recommendations. • RCS report based on review of 96 patient records extending back to Urological care delivered back to 2015 identified issues and supported the need for an extension of the Lookback and consideration of options for Phase 2. • Options paper drafted and considered with SPPG. Phase 2 has been confirmed with Phase 3 to follow. The requirement for further Phases will be based on the findings of Phase 2 and 3. • Phase 2 Project Plan completed to support and detail the requirements.		• RCS Report and subsequent actions. • RQIA Report and subsequent actions. • Options Paper • Phase 2 Paper
			Overall RAG Rating	

DRAFT

numbered paragraphs and in chronological order.

1.21 I commenced post as Acute Governance Coordinator on 4th April 2016 *(please see 2. Job Roles*).

1.22 My appointment was to be one of a number of appointments to improve the clinical governance structures within the Acute Directorate. The roles and responsibilities included:

a) Corporate liaison
b) Level 3 investigations
c) Level 2 investigations
d) Lessons learnt implementation
e) Allocation of SAIs
f) Development of report the Directorate and individual Divisions…
g) Preparation of Agendas for AD and AMD governance meeting
h) Quality assurance of SAI reports
i) SAI screening process

1.23 From commencement of my role I highlighted that the resources available within the governance team did not allow for development of robust governance systems and processes and did not allow for timely screening, reviews or report writing. Limited staffing resource prevented proactive work streams to support changes required to reduce risk or monitor implementation of actions from learning. This risk was consistently escalated during my tenure.

1.24 In September 2016 I note from email with information of incidents relating to delays to Dr Boyce, Mrs Trouton and Mr Conway the commencement of work in relation to delays in treatment and care: I refer to *9a.-9b. Delays in appointments diagnosis or treatment data Tracey 09 30 2016, A1*. In relation to the administrative issues, administrative teams produced and circulation of reports to escalate risks including triage reports, dictation reports, typing backlog reports: I refer to email *11. Delays meeting checking re triage with KR 02 10 2017.* To help address some of the risks relating to delays I progressed a number of meetings including meetings

Received from Trudy Reid on 16/05/2023. Annotated by the Urology Services Inquiry.

From: Carroll, Ronan Personal Information redacted by USI
Sent: 28 August 2017 14:11
To: Gishkori, Esther; Boyce, Tracey; Walker, Helen; McVey, Anne; Trouton, Heather
Subject: Governance Structure within ACute Services
Importance: High

Please find attached three (there are possibly more) SAIs where there is no evidence that the recommendations have been actioned.
We agreed to have 3 governance managers working to each MUSC (2) and SEC/ATICs (1). These staff were Connie, Sharon & Edel all B7 (Paula can work across all 3 clinical divisions)
So can I ask for an update on the above subject.
Ronan

Ronan Carroll
Assistant Director Acute Services
Anaesthetics & Surgery
Mob Personal Information redacted by USI

Received from SHSCT on 16/05/22. Annotated by the Urology Services Inquiry.

proactive governance, and that was staffing and staffing resource and the problems that came with that. One of the other issues you have touched on and I'll deal with in a bit more detail now was technology and data management and that kind of thing. One of the issues that you point up in your statement at 1.7 was that the Datix system at the time was a number of versions behind the other Trusts in Northern Ireland. It has recently been upgraded from version 12.2 to 14.12/, obviously these things get improvements and add-ons over the period of time. I suppose the thrust of the point, ignoring the fine detail of that, is that the Datix facility available to you made for difficulties. The way in which, as you said earlier, standards and guidance was documented made it difficult for you. Could you tell us more about that, was that simply again resourcing issues that you, if you like, complained about but it remained unchanged? 12:50 12:50 12:51 12:51

A. Within the Trust the Datix system was, that we used for incidents, was behind. But within Datix there is a number of modules. So you have complaints, you have incidents, you have litigation, and they were all on slightly different systems so it made triangulating that information between all of those systems a challenge. The Datix system that we had at the time also made it challenging to report and set up dashboards for the wards, departments and the Assistant Directors a challenge, so that they could see trends and be able to triangulate the information between, for 12:51 12:52

example, the litigation, complaint and an incident.

The M&M process sat on another system. The standards and guidelines was an Excel spreadsheet. The cancer tracking system was another system. And the PAS system that we used for recording patient appointments et cetera is again an old system. So the systems didn't speak to each other to allow us to triangulate that information.

154 Q. Yes. Did you have any analytics, data analytics support? I suppose you're shaking your head. No? 12:53

A. No. Within the team we had -- Mr. Cardwell was probably our expert on the Datix system and we worked together to see if we could develop some dashboards for the wards and departments and ADs to see if they could at least see their information on a graphical fashion. Because lots of reports, as you will have seen, are lines and lines and lines of information, names and detail. And it's only when you get a really expert in data analysts that actually the information tells you the story. Because information can be presented in many ways to tell different stories. So the expertise of a data analyst is really important to get the actual facts to the people that need them in a timely manner and in a manner that actually tells a story that people can identify the risks. 12:53 12:53 12:54

155 Q. Yes. You say in your statement, at paragraph 1.7, leaving aside the Datix issues you talk about "audit data and reports were mostly manually recorded"?

A. Yes.
156 Q. Ultimately it seems to come to this, you use this word which we're hearing a lot about, triangulation, "triangulation of risks was therefore challenging". You seem to put a lot of store by the need for good data access and good data analysis; why was that? Why is that? 12:54
A. Very simply, it's really challenging to identify risk when you can't see it from the different systems all aligned. So you may have a large amount of information but to identify from one system to another to another and pull that all together is really, really challenging and without being able to pull the information together you don't get the overall picture and, therefore, you can't see the overall risk. So some of the issues that had been identified, you know, with good data systems may have been easier to identify. But again it's as good as the information we put in so, therefore, making sure that your staff have the appropriate training to make sure that they know how to identify risk, how to fill in an information form so that you have got a clinician name to identify if it's a clinician or identify if it's a specific issue in relation to a medication or the sort of recording of the deteriorating patient, all of that is really, really vital to be able to really identify the risks that we have. 12:55 12:55 12:56
157 Q. Do you know whether - obviously long out of the job you were doing in Acute Directorate - do you know whether

23.1 I used Data Quality reports to check recording of information but there were no issues with my data quality reports in urology as per 10.1(a) and 10.2. *Please see 24. Validation Reports run by Head of Health Records and Team*

23.2 Health Records used the Casenote Tracking function on the Patient Administration System to record the location of charts. This did show a large volume of charts tracked to Mr O'Brien but we did not follow this up as no action was taken when we identified issues with Mr O'Brien's working practices, therefore I felt it was not practical to ask our very busy staff to carry out additional work which, in my opinion, and based on the fact that nothing had changed with our escalation and Datix reporting, would not change anything with regard to the charts being taken home.

24. Do you have any specific responsibility or input into any of the following areas within urology? If yes, please explain your role within that topic in full, including naming all others with whom you engaged:

(i) **Waiting times**

(ii) **Triage/GP referral letters**

(iii) **Letter and note dictation**

(iv) **Patient care scheduling/Booking**

(v) **Prescription of drugs**

(vi) **Administration of drugs**

(vii) **Private patient booking**

(viii) **Multi-disciplinary meetings (MDMs)/Attendance at MDMs**

(ix) **Following up on results/sign off of results**

(x) **Onward referral of patients for further care and treatment**

(xi) **Storage and management of health records**

a discussion about contemporaneous GP letters came up in one such meeting, Mr. O'Brien expressing an opinion that the only two people that needed to know the outcome of the consultation was him and the patient as his justification for why nothing else was needed. 10:59

43 Q. Does that suggest that, however frequently issues were raised with him and he rebuffed the challenge and nothing more was done, it was -- was it a group shrug of the shoulders, that's just Mr. O'Brien and we can't do much about it? 10:59

A. I think we had attempted to let him know our concerns, you know, even to the point of where if we were doing Clinics to see long waiting patients who had been seen by him before, we weren't able to see as many as we might see if we were doing a long waiting list of 11:00 patients in Clinic who had been under the care of someone else because we didn't have the documented decision-making processes leading up to that, that we could quickly review, and so the process of reviewing patients took longer. Did we collectively as a group 11:00 shrug our shoulders? I think I certainly continued -- well, I certainly had raised concerns and I did raise concerns where it impacted.

44 Q. You were, in raising concerns, looking to the systems and Management to take those concerns seriously and 11:00 make appropriate challenge and escalation if the challenge was rebuffed?

A. Yeah. We, as a group, had made an informal challenge of, you know, this is an issue for us.

45 Q. Yes.
A. And it was rebuffed.
46 Q. Just moving through your statement a little and go to 53948. Again, let me just step through this relatively quickly. At 69.7 on that page, you are reflecting upon the fact that Mr. O'Brien failed, from your perspective, to use the support services that were available to him, that he undertook many of the administrative tasks that otherwise would be performed by a secretarial bank. How were you able to observe that? 11:01 11:02
A. He would recount to us how long it took him to organise a planned theatre list because of the time taken to phone patients and check that they were available to come in, and the like. Where the process that others would use would be to identify the potential patients for a theatre list, and our secretaries would do the contacting of patients, the arrangements of times to come in, and the like, the arrangement for transport where required. He was spending time, to my observation, doing jobs that my secretary did for me. 11:02 11:02
47 Q. Moving down the page to 69.8, you make the point that he complained of the number of interactions or inquiries that he was having to deal with from the Primary Care Sector. Your response to that is that the absence of dictated letters to the General Practitioners to tell them about their patients would have addressed that kind of problem? 11:03
A. Yeah, and, as subsequently came to light with regards

ED Screening				
Department	**Type**	**Name and H&C**	**Background**	**Screening update**
ED	SAI	Personal Information redacted by the USI	Internal discussion ongoing ED discharged returned OD - ICU Antrim -	24th August 2017 Meeting - Email doctor. Meeting with doctor cancelled to be reorganised – further information required – email consultant involved again review Wednesday. Not discussed 20/11/17. Need final decision re SAI 6.8.18 Paula provided S Gibson with timeline in order for him to provide information to Chair. 03/09/2018 – awaiting a chair 12/09/2018- reminder sent to S Gibson 12/09/2018- Dr Hampton requests this case is prioritised as urgent. A McVey emailed Simon Gibson 19/09/2018- 24/09/2018- Reminder to Simon Gibson for external chair for ED. 01/09/2018 Awaiting a chair 24/10/2018 Dr Murphy to email Simon Gibson for external chair 26.10.18 Simon emailed Trudy asking if she wished Dr Ahmed to approach S O'Reilly 5.11.18 Trudy emailed Simon happy with this approach
ED	M&M	Personal Information redacted by the USI	ED attendance x3 out of hospital arrest Coroner's report received 18.6.18 Cause of death: Hypoxic Ischaemic Necrosis of Brain & pneumonia due to Cardiac Arrest.	03/01/2018 – Reviewed by Dr Hampton- for full screening with Dr Murphy. 10/1/2018 Reviewed by Dr Murphy care appropriate for M&M discussion and PM feedback. 24/01/2018 Discussed with Dr Hampton & M Burke – Await further discussion with Dr Murphy following family letter – Dr Moan to review. ED M&M findings available 15/02/2018 for discussion Dec M&M findings ED- Deceased in ICU. General discussion was held regarding recording peak flow. Peak flow should recorded when the patient is well to assist with discharge planning. There were no issues with the ED management of the patient. Case to be discussed at CAH medical and ICU M&M. Learning point Have an adequate discharge plan. Action Case to be discussed at CAH medical and ICU M&M. Dr Moan is reviewing clinical information- 1/08/2018- Dr Murphy to confirm his nomination for meeting. ? need for ED rep. 6.8.18 – Dr P Murphy agreed to meet with family & Trudy. Dr Murphy said no need for ED rep. 03/09/2018 Meeting to be organised 12/09/2018- as above 19/09/2018- 24/09/2018- Meeting being arranged. 01/09/2018 Meeting being arranged 24/10/2018 Dr Murphy & Trudy Reid to agree a date for meeting 5.11.18 Trudy to discuss meeting the family with Dr Murphy
ED	SAI	Personal Information redacted by the USI	Blood gas issues?	10/1/2018 - Reviewed Dr Hampton wants to review in-depth. 17/01/2018 Reviewed by Dr Murphy probably SAI – for final review – needs discussed with Dr Wright. Discussed with Anne McVey. 24/01/2018 Further discussion with Dr Hampton & M Burke – will check blood gas machine time and signature -Await Dr Murphy discussion with Medical Director- Need a Notification form. 14/02/2018 RS email discussed Dr Murphy to discuss with Medical director 03/09/2018 Awaiting a chair 12/09/2018- Reminder sent to S Gibson 19/09/2018- 24/09/2018- Reminder to Simon Gibson for external chair for ED. 01/09/2018 Awaiting a chair 24/10/2018 Dr Murphy to email Simon Gibson for external chair 26.10.18 Simon emailed Trudy asking if she wished Dr Ahmed to approach S O'Reilly 5.11.18 Trudy emailed Simon happy with this approach
ED	Internal	Personal Information redacted by the USI	Sedation post spinal injury Internal	Need 3rd meeting organised (Erskine Holmes & Paul Smith) next Meeting 26/1/2018 24/01/2018 - Dr Hampton & M Burke updated – need to draft report and organise meeting with EH and doctor involved – email sent 18/4/18- Email to Dr L Robinson to be followed up re what information she gave to family 01/08/2018- Dr Hampton suggested a draft letter to Erskine Holmes for him to send to Dr Robinson requesting her statement. 6.8.18 – Paula Emailed Dr Holmes to get statement from Dr L Robinson 20/08/2018- 05/09/2018- Discuss Dr Robinson's request for information- Chair to decide way forward. 12/09/2018- Dr Hampton to discuss case with Dr E Holmes. ? do report without Dr Robinson response. 19/09/2018- Discussed with Dr Hampton at screening.Dr Hampton to discuss case with Dr E McCormick. (Sedation performa in Resus) Dr Robinson request for information to be provided. 26/09/2018- Email to be sent to Dr Robinson 01/09/2018 Email sent to Dr Robinson on 26 09 2018 as per Dr Murphy - same opened by Dr Robinson 24/10/2018 Discussed at screening. It was agreed for information Governance Team to be contacted before sending encrypted email (NHS email) with information to Dr Robinson 5.11.18 Paula to discuss at screening meeting what should be sent to Dr Robinson
ED	SAI	Personal Information redacted by the USI	DHH deterioration from ED to Ward	15/08/2018- Case not presented on Friday. Acknowledgement letter to family approved, needs signed and posted. HSCB advised case will be presented in September at Acute Governance Meeting 21/08/2018 Report finalised for presentation at September meeting 03/09/2018 – To be presented to ACG 10/09/2018- Passed for circulation to family and HSCB 19/09/2018- Discussed at screening- Close. 24/09/2018- Questions from family being reviewed. Letter to be sent to family to advise report is ready and offer a meeting. 24/10/2018 Final report being prepared. 5.11.18 Letter with Esther for signature 7.11.2018-Letter posted
ED MUSC	SAI	Personal Information redacted by the USI	CVA	21/08/2018 Meeting to review report, Dr McCormick updating report 03/09/2018 - Dr McCormick updating report 12/09/2018- report with Dr McCormick 24/09/2018- Reminder to Dr McCormick. 08/10/2018- reminder to Dr McCormick re report 24/10/2018 Report being finalised
ED SEC	Internal	Personal Information redacted by the USI	M&M outcome	Personal Information patient undergoing chemotherapy for myeloma presented to DHH ED at 14:02 with history of being unwell for 3/52, diarrhoea 1/52 poor mobility. 06:15 Cardiac arrest, 18 min CPR- PEA/asystole. Resuscitation stopped. Passed away 06:15 06:45 Verbal report of Ct abdomen available from Dr 6: multiple grossly small bowel loops with dilated transverse colon. 18/07/2018 INTERNAL REVIEW as per SEC – Dr McKay surgical rep, Linda Magowan ED rep-need medicine rep 8.8.18 Meeting arranged for 15.8.18. 20/08/2018- report to be drafted and circulated 05/09/2018- report being drafted 24/10/2018 as above 5.11.18 - Report being drafted

ED MUSC	SAI	Personal Information redacted by the USI	Patient transferred to theatre from resus for insertion of lines and stabilization prior to transfer to ICU. Patient arrested and time of death was called at Person Patient had a DNR in place.	06/03/2018- Email from Dr L Martin who suggests case needs to be discussed with ED/Medics to review the management prior to the arrest. 4/4/2018 Level 1 SAI 03/09/2018 – Update requested from Dr Moore 10/09/2018- waiting update from Dr Moore 18/09/2018- Meeting with Dr Moore. Letters to be sent to the 2 doctors involved to invite to a formal meeting. 24/09/2018- 01/10/2018 awaiting feedback re 2nd doctor 24/10/2018 email reminder to Dr Moore 7/11/2018
ED Radiology		Personal Information redacted by the USI	On 04/06/18 I was working as SHO in CAH ED. I saw a patient Perso who presented with hip pain. On reviewing her clinical notes and previous investigations it became apparent that she had a CT scan of her chest / abdomen / pelvis on 27/4/18. The clinical history on the request for this scan did not match those of the patient in question. It appears that it was requested and subsequently carried out in error.	07/06/2018 -The wrong patient had radiology investigation- will need informed of unnecessary radiology exposure. Possible checking issues at radiology in relation to patient age Investigation needs to take place of the inpatient that should have been scanned. Need to check that the right patient has been scanned. When ward/specialty identified to be discussed at appropriate screening meeting 15/06/2018 CT has not taken place for patient we think should have been referred Personal 18/06/2018- chart obtained for patient scan was intended. 2.7.18 To be discussed with Medicine 01/08/2018- Need initial referral?from?indication. Email to Denise Newell 01/08/2018- Need initial referral?from?indication. Email to Denise Newell response from email dated 2.8.18 “I cannot see a CT chest for this patient on date in question However, she had a request for a CT chest, abdomen and pelvis with contrast requested on 27/2/18Referral source: Gynae ward, Craigavon Referring clinician: Isam Yousif Clinical details23FAdmitted with unilateral headache/ rt shoulder pain/ rt arm and leg paraesthesia.Reported 10kg weight loss over 4 months - unplanned. Vasculitis screen negative Queried lymphoma on rheumatological review. For OP scan - patient has since been discharged Referral status: NHS. Referrer name: Niall Gallagher. Referrer grade: FYI 1-2. Referrer contact bleep detail: 1173. This examination was performed on 27.4.18” 03/09/2018 still no follow up of other patient, Dr Murphy will review if needed 05/09/2018- Trudy to discuss with Dr Murphy. 24/09/2018- Trudy to discuss with Dr Murphy 01/10/2018 notes with Dr Murphy 24/10/2018 Dr Murphy to send letter to patient's GP. CLOSE 5.11.18 Check with Dr Murphy if he sent to letter to patient
ED MUSC		Personal Information redacted by the USI	On 8/8/18 at 12.50 patient Per in Ward 2 North was confirmed as having Mycobacterium tuberculosis in a sputum sample. This patient initially presented to Daisy Hill ED on 31/7/18 with cough, pyrexia and abdominal pain. He was treated for pneumonia and admitted to Male Medical Ward. He developed increasing scrotal swelling and following discussion with the Urology team was transferred to CAH Ward 3 South for incision and drainage of a potential scrotal abscess on 3/8/18. He developed worsening hypoxia, consolidation, sepsis and a pleural effusion over the next few days and was transferred to Ward 2 north side room.	For screening & timeline. Obtain ED record & notes DHH&CAH 03/08/2018 - Time line to be completed- review screening for starting infliximab. Awaiting medical notes. 10/09/2018- Notes received. Timeline to be completed 01/10/2018 Time line to be completed Medical notes had been requested for clinics and Consultant request. Received 08/10/2018. 24/10/2018 Timeline reviewed. For referral to Medical M&M for guidance on commencement of biologics prior to treatment . Email sent to Dr Rory Convery and Dr John Harty 5.11.18 Timeline complete, Dr Convery " need a trust group to develop guidance for biologic treatment" Back to screening. Discussed at screening. Team members suggested to include representatives from GI team, Dr S Bhatt and Specialist Nurse, Rheumatology, Dr N Maiden
ED MUSC	Complaint now SAI	Personal Information redacted by the USI	(Complaint.) Personal attended ED CAH 16/03/2018 with limb problems. Moderate pain. Fast VE SOB- Nebulizer & GTN & Furosemide. Breathing relieved at triage. Fall on 7/03/2018 ? NOF. Patient’s wife and daughter drew attention to staff that he could not weight bear on left leg and that left leg was markedly cold from calf down. The foot was turning in and he was unable to straighten it. Patient was transferred to Older People’s assessment Unit where his daughter drew attention to the doctor to the left leg and expressed concern regarding the coldness and lack of mobility in the foot. Family also expressed concern of coldness of left foot to nursing staff. Patient was transferred on 18/03/2018 to RVH Belfast for above Personal Information redacted by the USI left leg.	03/09/2018-Medical notes requested for timeline 10/09/2018- Timeline in progress 18/09/2018-TIMELINE COMPLETE- For screening 24/09/2018- Discussed at screening. Confirmed SAI. Issues: Missed in ED, handover and post take ward round. Nominations for review team: AMcVey to ask Dr David Craig, Dr Mumtaz Hussan, ? ED rep and Nurse. AMcVey to discuss with Sandra Burns. 24/09/2018- Email sent to AMcVey. Timeline to be reviewed. Meeting TBA. Charts copied for review team. Notification to be completed. 01/10/2018 To be completed as SAI- Datix required 08/10/2018 Dr Polley to complete Datix, medical notes provided. 24/10/2018 A McVey to provide names for review team. 5.11.18 Paula emailed AMcV re review team
ED		Personal Information redacted by the USI	Patient attended ED DHH following a fall. Diagnosed multiple rib fractures, lung contusions, pelvic fractures and delay in transfer to RVH	24/10/2018 Discussed at screening. Dr Hampton to review medical notes and discuss with his colleagues.
ED			ROI patient transfer issue	Correspondence to go to staff - hold to ensure action is complete 17/10/18 Discussed when more information available send to M&M chairs 18/10/2018 Discussed with Brigid Quin email sent to Anne etc. 24/10/2018 Non UK resident guidance discussed. A McVey asked Trudy to liaise with Anita Carroll. Email sent to A Carroll.
ED CAH	Screening	Personal Information redacted by the USI	patient admitted with unwitnessed fall + head injury- arrived at 14:00 and obs complete again at 19:15, CTB requested at 17:15 and completed at 21:30. On taking over care of the patient, I attempted to contact CT and radiographers multiple times as did the doctor who had seen the patient. eventually we were able to get in touch with them but patients CTB was delayed significantly with a significant result requesting neuro surgeon input	Medical notes requested. 7.11.2018- Notes received. For screening
ED/ATICS	Internal M&M	Personal Information redacted by the USI	Intubated and ventilated in ED	Discussed with Dr Scullion and at ED screening, consider an external chair. Dr Hampton will be ED rep waiting a ATICS rep 22.10.18 Dr Scullion nominated Dr Nidhi Gupta, Dr Scullion has suggested chair should be a senior doctor eg Dr Neta Chada, Dr Shahid Tariq. Trudy to discuss with Dr Murphy. 23/10/2018 Discussed with Mr Carroll and Dr Scullion who agreed Dr Tariq should be asked to chair the review team. Email to be sent. 24/10/2018 Discussed at ED screening and review team agreed. Email sent to Dr Tariq request to chair review team. 5.11.18 Meeting being arranged
NIAS	Intertrust		NIAS attended a call in Newry on the 20th November 2017. When the call was received from NIFRS Control at 18:27 the nearest available resources were S123 an S121 in Armagh some thirty-three minutes away with S327 and S325 in Craigavon estimated as thirty-seven minutes away. There had been only one crew on duty in Newry on the day shift which was allocated to AS1 Irrelevant in Crossmaglen and had arrived on scene at 18:28. In response to this request, the Area Control Officer allocated S123 at 18:31. When it became clear this was not the usual “persons reported” incident that normally requires one resource initially the Control Officer contacted Daisyhill Emergency Department at 18:38 attempting to secure the release of S520 which had been held at their department on AS1 Irrelevant since 16:55 due to the number of patients in their department. The staff stated they would release the crew in five minutes despite being told of the nature of the call. The crew of S520 contacted Emergency Ambulance Control at 18:57 to advise they were assisting the NIFRS staff who had just arrived at Daisyhill. There was little initial information received regarding this call, it built up in subsequent calls, while Daisyhill were not able to assist NIAS in permitting a crew to be released to a 999 call which was five minutes from their department. Attempts were made to secure the release of an ambulance crew from Daisyhill ED while other resources were travelling to the scene. Daisyhill ED failed to release the crew. The local Station Officer was deployed to Daisyhill ED to assist with casualty clearing and to establish the injuries suffered by each patient. The Station Officer arrived at Daisyhill at 19:04. As a result of media enquiries on 21 November 2017 the NIAS Communications Officer was given a complete report on the occurrence. He then liaised with the NIAS Director of Operations who advised me this incident would require a Serious Adverse Incident report.	19/09/2018 - Discuss with Dr Hampton – Email sent to Paul Smyth for review
ED	Screening	Personal Information redacted by the USI	40 minute delay in anaesthetist attending ED	24/10/2018 Discussed at screening. For referral to Anaesthetics. Datix sent to Mr R Carroll and Dr D Scullion 06/11/2018- Discussed with Dr Sculliona nd Mr Carroll. ED records sent to Dr Scullion to review.
ED	Screening		Enoxaparin	24/10/2018- Discussed at screening. For round table discussion between ED, Dr K Boyd, Sr Sharon Holmes, Mr Imran Yousif. Meeting to be arranged.
ED	Screening		Ng tube inserted by anaesthetic SHO, without consultantion to CT scan and no report was available at the time. Ct scan showed base of skull fracture	5.11.18 For screening
ED	Screening		Patient presented to ED CAH on 28/10/2018 following a fall and head injury- alcohol taken and fell whie walking home. GCS 15 ON ARRIVAL. Pateint was sitting outside Triage 4 waiting for blood tests and ECG. Apparently informaed another patient that he was leaving and walked outside ED. Witnessed fall by NIAS- Head Injury sustained.	5.11.18 For screening
ED	Screening		Complaint ref Irreleva Patient attended ED CAH 24th,25th and 27th 29th July 2018. Admitted 30th July Severe abdominal pain and distension. Diagnosed sigmoid volvulus with necrotic bowel and had left hemicolectomy end colostomy and subsequent revision and reclipping.	12/11/2018 For screening as per Dr McGarry following M&M

MUSC Screening				
Department	**Type**	**Name and H&C**	**Background**	**Screening update**
ED MUSC	SAI	Personal Information redacted by the USI	CVA	21/08/2018 Meeting to review report, Dr McCormick updating report 03/09/2018 - Dr McCormick updating report 12/09/2018- report with Dr McCormick 24/09/2018- Reminder to Dr McCormick. 08/10/2018- reminder to Dr McCormick re report 5.11.18 - Report being finalised by Trudy
ED MUSC	SAI	Personal Information redacted by the USI	Patient transferred to theatre from resus for insertion of lines and stabilization prior to transfer to IC	06/03/2018- Email from Dr L Martin who suggests case needs to be discussed with ED/Medics to review the management prior to the arrest. 4/4/2018 Level 1 SAI 03/09/2018 – Update requested from Dr Moore 10/09/2018- waiting update from Dr Moore 18/09/2018- Meeting with Dr Moore. Letters to be sent to the 2 doctors involved to invite to a formal meeting. 24/09/2018- 01/10/2018 awaiting feedback re 2nd doctor 5.11.18 Paula emailed Dr moore on 24.10.18 re 2 doctor. Dr Moore on leave until 5.11.18 12/11/2018 Meeting being arranged with Dr Moore and Trudy
MUSC Radiology	SAI	Personal Information redacted by the USI	Arrest post midazolam	03/09/2018 Family meeting fed back to screening, email doctor involved and present at ACG 05/09/2108- Coroner has indicated this will not go to formal hearing 10/09/2018- Passed at ACG. Report with Dr and Simon Gibson has a copy for Medical Director. 24/09/2018 – Further meeting to be arranged to discuss family questions 01/10/2018 meeting planned to address family questions 19/10/2018 Dr Polley, Dr Hull, T Reid, Dr McConville, Dr Yousif and Ms Redpath also need cardiology rep 5.11.18 Finalising response to family
MUSC	Intertrust	Personal Information redacted by the USI	VSD post infarct	Patient presented with anterior STEMI-not fit for primary PCI, stabilised in CCU and underwent triple vessel PCI in CAH LVEF 40-45% at the time. Went home thereafter. Readmitted following acute deterioration with reduced O2 saturation. M&M Learning Point - Case discussed at cardiology M&M and subsequently with cardiac surgeons MDT. Patient should not have been discussed at theatre team meeting. Post infarction VSD is a surgical emergency and correct management is to discuss with the emergency cardiac surgeon on call who will advise on management by current recommendations is surgical repair pending patient suitability for theatre 29/01/2018 Discussed – as there has been regional and local learning via M&M and MDT – SAI review not required M&M report – 4/4/2018 available in chart 03/09/2018 – Update requested from Dr Moore 10/09/2018- as above 18/09/2018- Meeting with Dr Moore. Difference of opinion between CAH Cardiology team and RVH Cardiology Team. As per email 18/9/18- "I have discussed this case again with Dr McEneaney, Clinical Lead for Cardiology, and we feel that it is not a SAI trigger but there should be an Interhospital Datix." 18/09/2018-Email to Kay Carroll who was Clinical Lead Feb 2017 for Datix to be done 24/09/2018 – Spoke to K Carroll requested datix to be completed, to be sent to Belfast as an intertrust 01/10/2018 Kay to complete datix 15/10/18 Notes left with Denise for datix completion 5.11.18 Paula emailed reminder to Denise Nelson- on leave until 13/11/18
MUSC SEC	Complaint	Personal Information redacted by the USI	Crohns and Colitis treatment (Complaint) Subtotal colectomy May 2018	For discussion as per Dr Murphy email. 18/06/2018- Medical notes requested for timeline – received. 2.7.18 – Paula to do timeline. 23/07/2018-timeline to be done 30.7.18 – Acknowledgment for approval. Check with Dr Murphy the timeframe for SAI review 01/08/2018- Dr Murphy advises SEC to approve acknowledgement. Timeline to commence from 1st admission. 6.8.18 Acknowledgment approved by RC 8.8.18 – Timeline to be complete 03/09/2018 -1st meeting with Mr Epanomeritakis, 2nd meeting to be organised with Mr Bhatt 10/09/2018- meeting being organised 19/09/2018- Meting 19/09/2018 with Dr Bhatt 24/09/2018 – Report being drafted
MUSC	SAI	Personal Information redacted by the USI		6.8.18 – Response to family to be discussed at M&M 6.8.18 Dr P Murphy & M Burke said signed off. Paula to check with Trudy on her return. 05/09/2018- response approved and to be sent to family. 10/09/2018- report with DLS for approval 24/09/2018 – Reminder to E O'Neill in litigation regarding DLS approval of response to family 01/10/2018 awating DLS response, extra questions from Litigation to Anne and Philip 5.11.18 - DLS had additional queries re inquest. Trudy to meet with litigation

MUSC Dermatology		Personal Information redacted by the USI	Patient/ Personal Information was seen at Dermatology Clinic on 11/05/2017. Review was planned for 2-3 months. Patient did not receive review appointment. He was being treated for actinic keratosis on his nose. Whilst awaiting review lesion progressed and presented today with a large tumour in keeping with a squamous cell carcinoma. Today's appointment 16/08/2018, took place as patient phoned requesting urgent review.	For screening. Email sent to K. Robinson for information. See emails 20/08/2018- Discussed at screening. How are we managing Risk? What systems are in place? Need clear guidelines. Lisa is clarifying what is routine for AMcVey. 03/09/2018 – Complaint received – Screening team updated- Dr Murphy and Anne McVey to review waiting lists. 10/09/2018- Discussed at screening. SEA has taken place within Trust. Anne McVey to discuss with Kay Carroll. Dermatology to review forms/urgent/routine reviews. How we manage risk with long waiting times. Need to inform staff (doctors) re waiting times. ? SEA/SAI? 24/09/2018- Anne McVey to discuss with Kay Carroll 01/10/2018 Meeting with Mrs McVey, Dr Murphy and Lisa McAreavey to look at waiting lists has taken place - actions letter to be sent to all consultants re triage category - hold on report until actions complete 5.11.18 Acute to review datix incidents re dermatology. Examples of incidents to be obtained
ED MUSC		Personal Information redacted by the USI	On 8/8/18 at 12.50 patient Pers appl in Ward 2 North was confirmed as having Mycobacterium tuberculosis in a sputum sample. This patient initially presented to Daisy Hill ED on 31/7/18 with cough, pyrexia and abdominal pain. He was treated for pneumonia and admitted to Male Medical Ward. He developed increasing scrotal swelling and following discussion with the Urology team was transferred to CAH Ward 3 South for incision and drainage of a potential scrotal abscess on 3/8/18. He developed worsening hypoxia, consolidation, sepsis and a pleural effusion over the next few days and was transferred to Ward 2 north side room.	For screening & timeline. Obtain ED record & notes DHH&CAH 03/08/2018 - Time line to be completed- review screening for starting infliximab. Awaiting medical notes. 10/09/2018- Notes received. Timeline to be completed 01/10/2018 Time line to be completed Medical notes had been requested for clinics and Consultant request. Received 08/10/2018. 5.11.18 Timeline complete, Dr Convery " need a trust group to develop guidance for biologic treatment" Back to screening. 05/11/2018- Discussed at screening who should be on the group. GI specialist Dr and Nurse, Rheumatology Dr and Nurse, TB nurse. ? Dr R Forbes for Neurology. Dr Murphy suggested Dr Bhatt and Dr Maiden.
MUSC	SAI	Personal Information redacted by the USI	Datix re Missed bowel tumour	03/00/2018 Discussed at MUSC screening - Internal review in first instance as per SEC – Review team in agreement 10/09/2018- Meeting arranged for 17/09/2018- Mr K McElvanna and Dr S Bhatt 19/09/2018- Mr McElvanna to discuss with Mr McArdle. Dr Bhatt to discuss with Dr Hillemand and Dr S Murphy. 08/10/2018- Email to Mr McElvanna and Dr Bhatt for update 5.11.18 Report being drafted
ED MUSC	Complaint	Personal Information redacted by the USI	(Complaint.) Personal Information attended ED CAH 16/03/2018 with limb problems. Moderate pain. Fast VE SOB- Nebulizer & GTN & Furosemide. Breathing relieved at triage. Fall on 7/03/2018 ? NOF. Patient's wife and daughter drew attention to staff that he could not weight bear on left leg and that left leg was markedly cold from calf down. The foot was turning in and he was unable to straighten it. Patient was transferred to Older People's assessment Unit where his daughter drew attention to the doctor to the left leg and expressed concern regarding the coldness and lack of mobility in the foot. Family also expressed concern of coldness of left foot to nursing staff. Patient was transferred on 18/03/2018 to RVH Belfast for above Personal Information redacted by the USI left leg.	03/09/2018-Medical notes requested for timeline 10/09/2018- Timeline in progress 18/09/2018-TIMELINE COMPLETE- For screening 24/09/2018- Discussed at screening. Confirmed SAI. Issues: Missed in ED, handover and post take ward round. Nominations for review team: AMcVey to ask Dr David Craig, Dr Mumtaz Hussan, ? ED rep and Nurse. AMcVey to discuss with Sandra Burns. 24/09/2018- Email sent to AMcVey. Timeline to be reviewed. Meeting TBA. Charts copied for review team. Notification to be completed. 01/10/2018 To be completed as SAI- Datix required 08/10/2018 Dr Polley to complete Datix, medical notes provided. 16.10.18 Datix completed 5.11.18 Paula emailed AMcV re review team
MUSC	SAI	Personal Information redacted by the USI	Arrest in DHH post cardiac cath - Anaes and transfer issues	Discuss at screening. See email from Dr Scullion. 01/10/2018 Request notes and prepare a time line. Time line to be completed 15/10/2018 Discussed Dr Scullion views- still needs time line 22/10/2018 DHH Medical notes requested as CAH notes do not contain relevant information. 30/10/2018- Contacted Medical records- await medical notes ? in BCH ICU. 5.11.18 Notes received from Belfast. Timeline to be completed
MUSC	SAI	Personal Information redacted by the USI	Endoscopy screening waiting times	08/10/2018-Discussed at screening. For timeline. Medical notes requested. 15/10/18 Identify delays from specialites with incidents 5.11.18 timeline to be completed by Jane Scott, notes with Jane
MUSC			Patient with metastatic melanoma and known brain secondaries and bone secondaries admitted with increasing left arm pain and arm weakness and back pain. Seen by a number of professionals an I feel opportunities missed to diagnose spinal cord compression - which the patient was subsequently diagnosed with on 06/09/2018 Emergency MRI and emergency radiotherapy arranged and family and ward staff informed. Notes clearly documented and Barry Conway informed.	Notes needed for time line 29/10/2018. Medical notes received. 5.11.18 Paula to complete timeline
MUSC		Personal Information redacted by the USI	Pacing issues M&M SOM4	12/11/2018 DHH notes requested from Villa 3.
MUSC	SAI		Endoscopy screening waiting times Male patient Personal Information redacted by the USI referred for colonoscopy for investigation of iron deficiency anemia. Colonoscopy revealed mass in ascending colon (likely malignancy). Investigated for same in 2016 with colonoscopy when a polyp was removed from ascending colon (not retrieved due to poor bowel preparation) At that time recommendation was made for follow up colonoscopy in 12/12 as a safety measure due to poor bowel prep. This appears not to have happened. There was a new GP referral to OPD in Sep 2018 with anemia which was followed by a colonoscopy request from OPD.	5.11.18 Jane Scott to complete timeline - For screening.

MUSC	Screen	Personal Information redacted by the USI	Late upgrade of Red Flag referral A referral from Respiratory to Gastroenterology dictated on 06.09.18. Date Typed was 22.10.18. The referral was date stamped with 30.10.18 - Date received in RBC. It appears that referral was triaged on 31.10.18 and was marked as RF. This referral was then received into the Red Flag booking office on 02.11.18. Appointment was booked on 02.11.18 for 06.11.18. (61 Day wait from date of registration on PAS) The delay on this occasion appears to be with the typing of clinic.	

SEC Screening

Department	Type	Name and H&C	Background	Screening update
SEC	M&M Internal	Personal Information redacted by the USI	Personal Information redacted by the USI patient undergoing chemotherapy for myeloma presented to DHH ED at 14:02 with history of being unwell for 3/52, diarrhoea 1/52 poor mobility. Seen by Dr 1. Loose green stools. Reduced oral intake. Occasional mild general abdominal pain. One loose stool today, did not take chemo med. Worsening shortness of breath. No chest pain, on examination he was noted to be cachexic, frail. Bi-basal creps. Marked bilateral lower leg oedema. ECG Sinus rhythm, 2 BBB. BP 86/51 with fluids and legs raised. Distended abdomen query ascetic. Mild generalised tenderness, no masses felt, bowel sounds present Diagnoses: diarrhoea query secondary to chemo meds, associated dehydration and ?acute LVF. Seen by Dr 4 at 23:00- Distention for 1/12. One episode of vomiting. Just completed 4 cycles of chemo for multiple myeloma. ATSP re abdominal distention. Abdomen tympanic with generalised tenderness with some guarding. Bowel sounds scant. PR: external haemorrhoids ++. Will discuss with senior and review plain films. Will add to handover list and query review in am. Fast, NGT if vomiting continues. Stool chart. IVF and anti-emetics 02:04 Seen by Dr 5. History as above. On examination: abdomen firmly distended, tympanic. Mild generalised tenderness. AXR: gross bowel dilation in keeping with obstruction. Imp: bowel obstruction query underlying cause. 06:15 Cardiac arrest, 18 min CPR- PEA/asystole. Resuscitation stopped. 06:15 Passed away. 06:45 Verbal report of Ct abdomen available from Dr 6: multiple grossly small bowel loops with dilated transverse colon.	26/06/2018 Discussed with Mr Carroll and Dr Scullion – M&M January 2018 - Statement of Management to be provided: Medicine Statement of management: 3 - contained aspects that SHOULD² be improved (learning identified); the patient's eventual outcome was NOT 21/08/2018- Report to be drafted. Management of abdominal pain ED DHH Version 1(17April 2015) sent to Dr McKay and Dr Magowan 11/09/2018- Report in draft
SEC	Internal	Personal Information redacted by the USI	Patient admitted with? Diverticular perforation. CT Shows likely perforated tumour. Not reported by radiology. Discharged home. Delay in diagnosis significant.	Discrepancy meeting outcome - Discrepancy, cognition and perception. Abnormality was felt to be solid and represented malignancy as opposed to a diverticular abscess. 01/02/2018 with Discussed Dr Yousaf The initial request highlighted abdominal pain, diarrhoea, tender LIF, previous unremarkable endoscopy, CRP 200, WCC 14.9,? Diverticular abscess,? localised perforation- the reported stated … Briefly collection/inflammatory exudate along descending colon – sigmoid in LIF likely to be cause of symptoms and signs. Gold standard for diagnosis is endoscopy not CT. This case has been discussed at the discrepancy meeting Follow up endoscopy – on 23/11/2017 – haemorrhoids – GI registrar 16/01/2018 CT CAP showed …suggestive of locally advanced, perforated tumour of the distal descending colon/proximal sigmoid colon….. From Radiology perspective does not meet the criteria for SAI 16/01/2018 CT CAP showed …suggestive of locally advanced, perforated tumour of the distal descending colon/proximal sigmoid colon….. From Radiology perspective does not meet the criteria for SAI 11/09/2018- Meeting being arranged. 13.9.18 Meeting arranged for Monday 12 November

SEC	Internal	Personal Information redacted by the USI	? Delay in Diagnosis of Recto-sigmoid adenocarcinoma. Issued raised by Mr Mc Kay. Patient had a US Abdomen 7/4/17 – Conclusion - Fatty Liver; CT Abdomen & Pelvis with Contrast 22/7/17 – Conclusion - Severe sigmoid colitis with evidence of localised perforation	24/07/2018- email to I Yousuf on 13/7/18 + 24/07/18 re discrepancy report. Mr Carroll updated 31.7.18 Wait discrepancy report from Dr Yousuf. 21/08/2018 reminder to Dr Yousef 11/09/2018-as above 25/09/2018- still to be discussed at radiology discrepancy meeting 22.10.18 Trudy emailed Dr Imran Yousuf re CT Abdomen and Pelvis dated 22/07/2017) has been discussed at discrepancy yet. Gail Lindsey replied not discussed but will expedite it. 5.11.18 To be discussed at coming audit day, Friday, 16th November at the next discrepancy meeting.
SEC	Internal	Personal Information redacted by the USI	Delay in tumour management . Emergency admission with abdominal pain- initial CT 19/11/2015 showed retrocaecal appendicitis with localised perforation……soft tissue thickening is present at the base of the appendix/tip of the caecum and evaluation of this region is advised in due course to exclude other pathology- managed conservatively- Discharge letter noted RIF pain Initial Diagnosis ?appendicitis ?walled-off appendix ?malignancy. Following subsequent admission CT 2/12/2105 comment At some stage colonoscopy of the cecal pole will be required in order to exclude cecal pole mass/tumour (if not already performed). Possible caecal pole mass may be contributing to the ongoing inflammatory process as the appendix does appear distended and may be obstructed at the base. A prominent ileocaecal valve area is considered and is possible but there is not much fat in this abnormal area. Colonoscopy 4/2/2016 with subsequent pathology report stating 'The appearances are those of an adenocarcinoma. 07/02/2016 discussed at MDM for consideration of right hemicolectomy. Surgery on 08/03/2016	INTERNAL SEA – Need chair – wait for meeting minutes to be circulated then approach GH again minutes circulated request chair again 2/1/2018 - email sent requesting GH to chair 09/01/2018 - awaiting date for meeting 14/3/18 – Dr Haynes advised that Mr Hewitt to again be asked for a date for meeting if this is not provided he should be advised that a meeting will be scheduled in place of one of his theatre lists (in next 6 weeks). 6/4/18 – R Farrell to contact Mr Hewitt's sec re dates re dates for meeting 6/4/18 – T Reid email Mr Hewitt re dates re dates for meeting 26/06/2018 Mr Carroll update regarding no response from Mr Hewitt 13/07/2018 Mr Haynes has agreed to cancel elective surgery to allow Mr Hewitt to Chair the SEA report 11/09/2018- as above. wait response from Mr Hewitt. Email sent to W Clayton 25/09/2018- meeting scheduled for 03/10/2018. 22 10 2018 reschedule meeting 5.11.18 Meeting being arranged
SEC	Internal	Personal Information redacted by the USI	Following review at OP where new iron deficiency anaemia was diagnosed Personal was referred to for OGD and colonoscopy and subsequently CT abdomen and pelvis which was performed on 2/08/2016 and reported on 7/08/2016, there was an incidental finding of sub- segmental and segmental emboli seen in the R lung. 2/08/2016 reported 7/08/2016. This result was emailed to the referring consultant and a specialty doctor wrote to the consultant highlight this finding on 23/08/2016, Personal was also reviewed at a number of OP clinics where there was no documentation of CT findings CT showed PE not actioned	INTERNAL SEA – Need chair- wait for meeting minutes to be circulated then approach GH again minutes circulated request chair again 2/1/2018 - email sent requesting GH to chair 09/01/2018 - awaiting date for meeting 14/3/18 - Dr Haynes advised that Mr Hewitt to again be asked for a date for meeting if this is not provided he should be advised that a meeting will be scheduled in place of one of his theatre lists (in next 6 weeks). 6/4/18 – R Farrell to contact Mr Hewitt's sec re dates for meeting 6/4/18 – T Reid email Mr Hewitt re dates re dates for meeting 26/06/2018 Mr Carroll update regarding no response from Mr Hewitt 13/07/2018 Mr Haynes has agreed to cancel elective surgery to allow Mr Hewitt to Chair the SEA report 11/09/2018- wait response from Mr Hewitt. Email sent to W Clayton 25/10/2018- Meeting scheduled for 03/10/2018 09/10/2018- Mr Carroll updated meeting had taken place and report was in progress. 5.11.18 - Report being drafted

SEC	Complaint	Personal Information redacted by the USI	On 19 January 2017 at 13:15 Personal Information redacted by the USI presented to CAH ED with RUQ Abdominal & Epigastric Pain/vomiting C/O SOB ongoing 1/52 Pallor poor at triage/clammy. ECG done at 13:52 Troponin 105 @13:45. Referred to Surgical team query cholecystitis, query Malignancy. Troponin repeated @ 22:00 122 and ECG repeated at 22:37 Transferred to 4S @ 00:45 on 20/01/17. At approx. 17:21 Persona l appeared to have seizure. Loss of consciousness- arrest team called. Persona l did not respond to resuscitation efforts. Most likely cause of death- massive cardiac event. Coroner contacted on Saturday 21/01/17- patient for post mortem. Clinical summary sent	11/09/2018- Meeting took place. Questions answered. Report to be amended. Notes of meeting to be approved. 25/09/2018- as above
SEC Radiology	SAI	Personal Information redacted by the USI	Missed diagnosis of Gallbladder CA	11/09/2018- Report was presented at ACG 7/9/18. AMD's/AD's suggest an Additional recommendation. Recommendation 2 The SHSCT should ensure that the WHO check list includes a question regarding all relevant results being signed off . Email to Mr Gudyma and Dr I Yousif for approval. 18/09/2018. Trudy Reid contacted Personal Information to discuss his requirements of SAI. 25/09/2018- Amendments made to report and sent back to Mr Gudyma and Dr I Yousif for approval 12/11/2018- Email on 22/10/18 to Dr Gudyma to check if he had a chance to share this report for factual accuracy with the staff involved. Mr Gudyma will discuss at Patient Safety meeting 16/11/18. 13/11/2018 Email to Mr Gudyma as a reminder report need to be shared with those involved.
SEC Paeds	SAI	Personal Information redacted by the USI	Child with fractured tibia admitted to Paeds ward (3N) against Trust policy for observation. Child given Oramorph overnight. T&O team not contacted. Child given breakfast against T&O admission policy. Child found to have compartment syndrome on ward round the following morning	11/09/2018- Meeting 12/09/2018 to finalise report 25/09/2018- Report in draft 09/10/2018- Report finalised and for Acute Governance Meeting this Friday. 22 10 2018 emailed Belfast for rep, reconsider recommendations following meeting and presentation to Acute Clinical Goverance Email to Dr V Roberts to advise re outcome of ACG meeting. 13/11/2018 reminder email to BHSCT for nomination for review team
SEC	SAI	Personal Information redacted by the USI	Person al was admitted with possible bowel obstruction on 30 April 2017, investigations included CT scan, IV access failed on route to the CT scanner. Person al aspirated in the CT scanner and developed respiratory failure, requiring intubation and ventilation. Person al had a subtotal colectomy and ileostomy, she was transferred to ICU post operatively but despite maximal treatment she continued to deteriorate and died on the Personal information redacted by USI Cause of death a) Multi-organ failure b) Small bowel obstruction. Datix reflected CT scan without IV access, NG tube or fluid resuscitation	11/09/2018- report approved by review team. 18/09/2018- Report to be finalised before sending to family 25/09/2018- Report being amended 22.10.18 To Mr Gilpin for sharing with the staff involved before I circulate to the family, HSCB and the coroner. I always like to ensure those in the SAI have had a chance to review prior to wider circulation. This was passed via acute clinical governance. 30/10/2018- Report out for sharing, still some team members to review. 13/11/2018 Checking re factural accuracy reminders sent. (W Clayton and Dr Gilpin, Dr Campbell)
SEC	SAI Urology	Patient 13 Patient 16 Patient 12 Patient 14 Patient 11	Delay in diagnosis and treatment of prostate cancer - Review commenced	14/3/18 – Not discussed Acknowledgement letter sent. 25/09/2018- Report sent to Julian Johnston (Chair) for approval.
SEC	SAI	Patient 15 Urology	GP routine referral to Urology 30/08/2015. Raised PSA. Seen bty Urology 8/2/2016. Appears a 6 month delay in diagnosis. Referral wasn't upgraded through triage process.	K R to – double check falls in urology SAI – Dr Wright and Dr Johnston have agreed to it can be included in original SAI 14/3/18 – Added to Urology Time Line Acknowledgement letter not sent yet. HSCB Notification to be completed. 25/09/2018- Report sent to Julian Johnston (Chair) for approval.

SEC ED	SAI	Personal Information redacted by the USI PEG tube	PEG tube insertion - perforation	11/09/2018- Report being final 25/09/218- Amendments of report with Dr R Thompson. Mr Gilpin feels case should be presented to the Coroner 01/10/2018 Report to be amended as per Mr Thompson 22 10 2018 Update sent to Dr Thompson 6.11.18 Trudy emailed Mr Thompson with report for final approval 13/11/2018 Approved by Mr Thompson. Trudy to discuss at screening re Coroner.
SEC ED	SAI	Personal Information redacted by the USI PEG tube	PEG tube insertion - perforation	11/09/2018- Report being finalised 25/09/2018- report finalised and being prepared for sending to HSCB. Mr Gilpin feels case should be presented to the Coroner. 01/09/2018 Report finalised
ED/Anaest	SAI	Personal Information redacted by the USI	Patient transferred to theatre from resus for insertion of lines and stabilization prior to transfer to ICU. Patient arrested and time of death was called at 05:21 Patient had a DNR in place. Personal Informatio attended Craigavon Area Hospital (CAH) Emergency Department (ED) on 19th February 2018 with chest pain, low oxygen saturations, shortness of breath and pyrexia. Personal Informatio had a cardiac history. Initial ECG was unremarkable; however repeat ECG showed ST elevation, at 23:06. Personal Informati condition deteriorated at approximately 02:15 Personal Informatio had a cardiac arrest, Cardiopulmonary Resuscitation was commenced, and Personal Informatio intubated and transferred to theatres for stabilisation. Do Not Attempt Cardiopulmonary Resuscitation was decided, Personal Informatio had a further period of cardiac arrest and died at 0Personal informati.	31.7.18 Report with Dr Moore 21/08/2018 Email Dr Moore re finalising report- on leave until 28 August 11/09/2018 18/09/2018- Meeting with Dr Moore. Letters to be sent to the 2 doctors to invite to a meeting. 24/10/2018 email to Dr Moore 30/10/2018- reminder to Dr Moore- On leave until 5/11/18 12/11/2018 Meeting to be arranged with Dr Moore. Names of doctors received and contact details being sought as they no longer work in SHSCT.
SEC ATICs	SAI	Patient 90 [redacted]	Patient admitted to ICU in extremis. Unexpected death after elective surgery. Preadmitted 03/05/2018 for 09/05/2018 care of Mr A O'Brien Urology. Patient transferred to ICU CAH and died. Post Mortem to be carried out. Case with Litigation.	31.7.18 Report being drafted 11/09/2018- as above 5.11.18 Report being drafted
SEC ATICs	SAI	Personal Information redacted by the USI [redacted]	Personal Information redacted by the USI who attended theatre in DHH for insertion of PEG tube on 15/05/2018. There are no traceability print outs for the scope and the scope used was potentially dirty. Possibly used on previous patient who had a flexible sigmoidoscopy? It was cleaned and rinsed with water but no detoxified.	31.7.18 With Dr Brown for final approval 21/08/2018 Further request to Dr Brown for approval 11/09/2018- email to Dr Brown 07/09/2018 for approval 25/09/2018- Further amendments to report sent to review team. 5.11.18 - For rediscussion
SEC ATICs	Internal	Patient 91 [redacted]	Patient admitted for ureterostomy on 18/05/18. Pyrexic and hypotensive following procedure. Transferred to ICU due to escalating inotropic support. Myocardial infarction. Despite aggressive intensive care management, patient's condition continued to deteriorate and death was confirmed on Personal information	31.7.18 Mr Carroll & Dr Scullion agree internal review. Meeting on 21.8.18- Initial meeting held. Report to be drafted 11/09/2018- report to be drafted 25/09/2018- 5.11.18 Report to be drafted
SEC	SAI	Personal Information redacted by the USI	Perso nal was admitted via ED on 6/11/2017 to the Trauma Ward at CAH following a fall at home. Perso nal was diagnosed with a fracture to her left neck of femur. Person al had a number of Co-morbidities which included COPD, Congestive cardiac failure, aortic stenosis, left bundle branch block, hypothyroidism and chronic kidney disease stage 4. Perso nal acutely deteriorated at 05:30hrs on 08/11/2017 with a reduced level of consciousness low blood pressure and had acute kidney injury. She was felt to be opioid toxic and was given reversal 3 times with naloxone which made some improvement. Perso nal was transferred to theatre for intubation and transfer to ICU. Person al died Personal information redacted by USI at 00:50hrs.	2.8.18 – Notification approved by R Carroll 21/08/2018 Meeting scheduled for 29th August. 11/09/2018- Report to be drafted 5.11.18 - Report being finalised

SEC	SAI	Personal Information redacted by the USI	Admitted perforated diverticular disease and small bowel obstruction. Delay to surgery needs reviewed and discussion. Subsequently never recovered and died. I believe there is a coroners inquest. Requesting urgent case review meeting and SAI will need to take place Died - 27/05/2018	Notes requested (with Litigation) 3.7.18 Timeline to be complete and notification to be completed. 13/07/018 – Discussed at screening Mr McKay to be contacted to review what the exact issue is- email sent to Mr McKay 17/07/2018 Reviewed by Mr McKay delay in getting to theatre in 1st 24 to 72 hours email to Mr Carroll & Mr Haynes 30.7.18 – Discuss with Ronan - Delay to surgery needs reviewed and discussion. Damian has confirmed our thoughts that the patient should have had early surgical intervention based on his original CT scan or review and surgery with 72 hours as per the NASBO report with recommendations are attached. There were also issues with the level of staff review etc. 31.7.18 Mr Carroll & Dr Scullion asked for incident to be referred to Surgical M&M, Paula to follow up 31.7.18 Paula referred incident to Dr Thompson for Surgical M&M 14.8.18 Confirm if SAI and if so nominations of review team 21/08/2018 Reviewed by Mr Haynes- SAI to be completed – Mr McIlvenna to chair. 11/09/2018- Timeline completed. Need review team for meeting. 26/09/2018- Email to screening team for nomination 09/10/2018- Discussed with Mr Carroll who suggested Mr MrArdle DHH for review team. Email to Mr Haynes to confirm he is in agreement. 23/10/2018 Meeting to be scheduled. 5.11.18 Meeting confirmed for 8.11.18 @ 9am 12/11/2018 Mr McArdle and Mr McElvanna to interview medical staff and further meeting to be scheduled in 3 weeks.
SEC	SAI	Personal Information redacted by the USI	Delay in investigation / management of a red flag cancer patient. For SAI. Protocols review	21/08/2018 Reviewed by Mr Haynes- SAI to be completed – Mr Epanomeritakis to chair. 11/09/2018- Need review team to arrange meeting 26/09/2018- Email to screening team for nomination. 09/10/2018- Discussed with Mr Carroll who suggested Mr M Yousaf for review team. Email to Mr Haynes to confirm he is in agreement. 23/10/2018 Meeting to be scheduled after timeline is done. 5.11.18 Sharon Glenny completing timeline

SEC	M&M	Personal Information redacted by the USI [redacted]	Clozpine levels and bowel obstruction Patient died from multiple organ failure on ICU on the Personal information as a result of chronic constipation and acute-on-chronic renal failure. The chronic constipation was contributed to by long-standing clozapine use, prescribed for schizophrenia. This is a known side effect and the patient had had previous hospital admissions with same. While still a patient on the medical ward (admitted with recurrent falls), clozapine levels were taken on the 23rd May following a review by psychiatry. As clozapine is a named medication, prescribed only by psychiatry, levels are monitored commercially by a lab in England and results communicated (as I understand it) directly to psychiatry. Following a second psychiatry review on 1/6, these levels were noted to be high indicating a possible 'clozapine toxicity'. Said levels were not communicated to medicine or ICU. We currently have no method of obtaining these ourselves – and I've checked with Richard, the ICU pharmacist and he is unaware of a current mechanism by which we can do this. I don't know if they were ever phoned through to psychiatry or whether checking the results requires contact to the company. Not knowing the clozapine levels did not affect this patient's care - clozapine continued to be with-held on ICU. There is no specific therapy for clozapine toxicity. Clozapine toxicity did not cause death.	Email from Jilly Clozapine has been associated with varying degrees of impairment of intestinal peristalsis, ranging from constipation to intestinal obstruction, faecal impaction and paralytic ileus. On rare occasions these cases have been fatal. Particular care is necessary in patients who are receiving concomitant medications known to cause constipation (especially those with anticholinergic properties such as some antipsychotics, antidepressants and antiparkinsonian treatments), have a history of colonic disease or a history of lower abdominal surgery as these may exacerbate the situation. It is vital that constipation is recognised and actively treated. Should this incident be screened as a SAI to determine if all appropriate action had been taken regarding the risk of constipation and gastrointestinal obstruction both with patient prior to attendance and with management while in hospital. Should it be shared with MHD? 26/06/2018 reviewed with Mr Carroll and Dr Scullion NOT SAI from and anaesthetics perspective- has been forwarded to MHD for review 3.7.18 Timeline to be completed 17/08/2018 Discussed 13/07/2018 SEC screening, suggested surgeon reviews. Mr McKay is reviewing and will discuss radiology finding with Radiology and respond with outcome 24/07/2018- awaiting feedback from Mr McKay, Mr Carroll updated re Mr McKays discussion and possible radiology findings 31.7.18 Email to Dr McKay on 27.7.18 request to review CT result. 21/08/2018. CT reviewed and medical notes left with Mr McKay today 11/09/2018- 25/09/2018- Dr D McKay has referred to Surgical M&M. 23/10/2018 Discussed at screening. For referral to Medical M&M. ? Round table discussion between Mental Health and Surgeons.
SEC	Internal	Personal Information redacted by the USI [redacted]	Complaint letter from patient and husband regarding her diagnosis, treatment and care. Patient treated for colitis subsequently had subtotal colectomy 14.5.18. (27.4.18 – 16.5.18)	26/06/2018 reviewed with Mr Carroll and Dr Scullion Probably not SAI as being taken through medical director process- email to be sent 26/6/2018 01/08/2018- Dr Murphy advises SEC to approve acknowledgement. Timeline to commence from 1st admission. 6.8.18 Acknowledgment approved by RC – Approved. 7.8.18 – Meeting confirmed for 3.9.18 10/09/2018- 2nd meeting being organised 11/09/2018- timeline complete. Internal review. Report to be drafted. 18/09/2018- Meeting with Dr Bhatt and Governance Team 19/09/2018. 25/09/2018- report to be drafted 5.11.18 report being drafted

SEC ED	Internal	Personal Information redacted by the USI	Personal Information redacted by the USI admitted to ED with catastrophic intracerebral bleed. GCS 3 on presentation. Anaesthetic SHO known to be on transfer so ED kindly intubated patient and transferred for scan. Once bleed confirmed, ICU contacted. ICU SHO (non airway competent attended) and contacted ICU consultant (myself). Patient accepted for ICU care but no beds in hospital so instructions given to search for regional bed and to arrange NICCATS transfer. ICU SHO remained with patient to provide care. Anaesthetic team - registrar, SHO, consultant failed to attend ED for five hours to care for ventilated patient despite knowing presence of patient in department and aware they were ventilated. No anaesthetic nurse involvement despite request from ED. Patient not transferred to theatres for ongoing care. Patient remained in ED (on portable ventilator) under care of ED/ICU SHO. Full monitoring according to AAGBI standards of a ventilated patient did not occur - potential harm with regard to cerebral perfusion in a head injured patient. Non-airway competent trainee left unsupervised. Patient was unprepared for transfer when NICCATS team arrived. Substantial additional burden placed on ED nursing and medical staff.	24/07/2018- screening Discussed with Mr Carrol and Dr Scullion, the patient outcome was likely not compromised; however there appear to initially be some internal process issues. Round table internal SEA to be arranged for next week. Time line re patient clinical documentation to be started, Dr Scullion and Dr Hampton to interview or get statements from medical staff in preparation for the meeting. 30.7.18 Meeting arranged for 31.7.18 with Dr Hampton & Dr Scullion. 31.7.18 Mr Carroll updated re meeting earlier today 31.7.18 - Agreed internal SEA at present. Has been discussed at ED M&M. For discussion at ICU M&M in September. Meeting of MDT to take place. To include ED, ICU Anaesthetics, Nursing, Bed management and medical team. 7.8.18 – Meeting took place on 31.7.18 7.8.18 - Mary Burke Advised at ED screening on 6.8.18 – No need for meeting she will discuss directly with Patient flow team. Presented at ED M&M on 25.7.18 for discussion and learning shared. Discussed at ED Screening on 1.8.18 - Mary Burke to advise head of patient flow that anaesthetic nurse is on call. Close from ED perspective. 21/08/2018- For discussion at ICU M&M in September 11/09/2018- Dr Scullion advises ICU M&M meeting will be 20/09/18 25/09/2018- Update from Dr Scullion- Further discussions to take place within Anaesthetic team. 09/10/2018- Dr Scullion advises a meeting is scheduled 15/10/18 to discuss the case. 23/10/2018 SAI. Meetings to be arranged. Dr G Hampton, Nidhi Gupta and Dr Tariq to be asked to chair. Email sent to Dr Tariq 24/10/18. 13/11/2108 Dates circulated for meeting
SEC MUSC	SAI	Personal Information redacted by the USI	Datix re missed bowel tumour	11/09/2018- Meeting scheduled 17/09/2018 with Mr S Bhatt and Mr K McElvanna 18/09/2018- Meeting held yesterday. Dr Bhatt to speak with Dr S Murphy and Dr C Hillemand. Dr McElvanna to speak with Mr G McArdle 09/10/2018- Meeting scheduled with Mr Bhatt and Dr Hillemand.Dr McElvanna has met Dr McArdle. 30/10/2018- Report in draft
SEC		Personal Information redacted by the USI	Patient Personal had ERCP in January 2016 for CBD stones but they could not be removed, a stent was inserted and he was referred for surgery. Lap chole and CBD exploration was performed in April 2016. Over past two months he has had 3 admissions with severe sepsis due to cholangitis. MRCP showed large stones in CBD. Personal attended for ERCP to clear these stones and at the time of the procedure it was noted he still had a stent in his CBD. This was why he developed the recurrent stones and episodes of cholangitis. It should have been taken out at the time of surgery in 2016.	23/10/2018- Timeline in progress. Medical notes received. 30/10/2018 - Timeline completed. For screening.
SEC/Urology		Patient 138	Patient had TURBT 22/12/17 was listed for MDM 28.12.17 (virtual MDM) patient was closed on cancer tracker system and not followed up until GP phoned to enquire 25/10/18. Histology report 28/12/17 showed Transitional cell carcinoma.	For screening. Red Flag team investigating for timeline

SEC	Interface	Personal Information redacted by the USI	Personal Information redacted by the USI attended the glaucoma service at the Wellbeing and Treatment Centre on 4 October 2018 and was seen at an additional clinic that had been set up to see long waiting new glaucoma referrals from the Southern Trust. At the appointment the patient stated that his vision had rediced in the left eye over the past year, vision was recorded as 6/48 on the Snellen Chart in the left eye. His left optic nerve showed early cupping with an early visual field defect. The patient was diagnosed with advanced glaucoma in the left eye and early glaucoma in the right eye. Personal Information redacted by the USI [redacted] The patient had been referred to ophthalmology outpatients in the Southern Trust in March 2017 by his community optometrist who queried glaucoma in his left eye. The referral letter stated that he had been previously referred in April 2015 but he had not been provided with an appointment. The delay in this patient being seen and treated has impacted on his overall outcome.	6.11.18 Email from Ronan Carroll "We need to follow our processes ie screen and a determination made as to the level of investigation required".

O&G Radiology Labs Screening

Department	Type	Name and H&C	Background	Screening update
Radiology	SAI	Personal Information redacted by the USI [redacted]	Patient seen in ED following RTC and CT carried out. CT report stated fractures of cervical spine but omitted to report multiple rib fractures and flail segment of chest. Patient referred to and transferred to RVH fracture clinic for admission. Patient later returned to CAH ED with no communication from RVH to advise of this. Multiple fractures only picked up on return from RVH as nursing staff were concerned regarding patient condition and asked ED consultant to review. As a result there was a significant delay in the appropriate management of this lady. Patient assessed by anaesthetics and transferred to theatre.	Timeline to be done. For screening 9/5/18- discharged home –discussed at ED screening - for screening by RADIOLOGY 07/06/2018 Flail chest is a clinical diagnosis not just radiological. The report was amended by outsourced company. The radiology report was incorrect and the medical director of the out sourced company has been informed. The clinical picture of significant bruising was not highlighted. When the patient returned to CAH further examination identified bruising and radiology were contacted and the report reviewed an amended. The radiology report was then amended. The patient outcome was not affected by the radiology discrepancy. Recommendation is that the case to be reviewed by Emergency Department again 11.10.18 Email from HSCB *I refer to the attached Interface Incident reported by the Southern Trust. This incident was recently discussed by the Acute SAI Review Team where it was agreed this should be reported as a SAI by Southern Trust, who will take the lead, with input from Belfast Trust. We would therefore expect to receive this by 24 October 2018.* Sent to Trudy to action
MUSC Radiology		Personal Information	Patient presented with headache and neck pain. Seen by neurology team who advised MRA. Attended for MR Angio at 1505 on 07/08/18. Noted at time of scan to be abnormal however medical staff told in MR that no one on to report scans that afternoon. Consultant escalated MRA report to be outsourced through bed management for report as if normal patient potentially for discharge. Informed turn around time would be 4hours. 25minutes post MRA patient developed left sided facial droop, slurred speech and left sided weakness. Thrombolysis call initiated and stroke team arrived. Felt not for lysis however concern about possible dissection. No consultant radiologist onsite available/ able to report MRA which was needed to guide management of patient. Stroke consultant present on ward. Significant effort expended by junior medical team seeking to obtain report of MRA. Consultant re-contacted bed management to escalate outsourced report. Ability to do this not widely known by junior staff and no available published protocols regarding its usage in or out of hours. Patient dropped GCS, anaesethetic team called and patient required intubation. MRA report back from Nighthawk showed multifocal ischaemic areas, lack of visualization of both vertebral arteries inc basilar artery. ?dissection ?thrombosis. Report time stamped 1650 however not visually available on PACS until 1730. Patient discussed with RVH Stroke and ICU, intubated and ventilated and transferred for out of hours clot retrieval. Significant difficulty in getting report of neuroimaging in emergency. No established protocols for accessing urgent or emergency report of otherwise unreported neuroimaging if necessary- would likely have been even greater issue if this had occurred during night shift.	Close from MUSC perspective – escalated to Radiology – (patient well) feedback requested to MUSC 19/09/2018- In review 24/09/2018- Dr McCaffrey advises she spoke with Dr Paul McGarry. Discussed at screening. Get formal feedback from Dr I Yousif. 01/10/2018- email to Radiology re review and ward re patient details

MUSC/Gynae		Personal Information	an you advise me if this lady's death was discussed at a gynae M+M given that she first presented to gynae and had problems identified on a CT scan that were not acted on and then referred to GI in Nov 17 but not seen by them either until admitted in Jan 18 terminal malignancy – so that I know whether she should be put down for discussion elsewhere. Was it recorded as an SAI?	Happy this lady is discussed at M+M but agree with David that the main learning will be through the radiology discrepancy process as the root cause problem was the initial CT report. She was referred to GI by gynae for management of her cirrhosis and ascites with a comment 'CT has shown no evidence of GI malignancy'. We get significant numbers of patients who are referred to initially to gynae with ascites who turn out to have cirrhosis. Patients with cirrhosis lose weight. The tumour markers inpatients with ascites can be elevated. She would have been urgent, not RF 5.11.18 Waiting on Radiology M&M
AHP		Personal Information redacted by the USI	Sight loss	Report in draft - Emailed Belfast re Dr George meeting to be arranged with Grandfather.
ATICS		Personal Information redacted by the USI	30/09/2018 Personal Information redacted by the USI was an acutely unwell child who presented to ED DHH. Anaesthetist was Fast bleeped on 4 occasions. Delay in reply and arrival to Resus for at least 40 minutes.	24/10/2018 Discussed at ED screening. For referral to Anaesthetics. Datix sent to Mr R Carroll and Dr D Scullion
Cancer team		Personal Information redacted by the USI	Staff member of Red Flag team emailed me, attaching the OC referral that had been upgraded at triage and advised that this was a late upgrade. I opened referral (06.11.18 due to annual leave) and could see that it was a referral from Respiratory to Gastroenterology. The date dictated on referral was 06.09.18. Date Typed was 22.10.18. The referral was date stamped with 30.10.18 - Date received in RBC. It appears that referral was triaged on 31.10.18 and was marked as RF. This referral was then received into the Red Flag booking office on 02.11.18. Appointment was booked on 02.11.18 for 06.11.18. (61 Day wait from date of registration on PAS) The delay on this occasion appears to be with the typing of clinic.	
ATICS	NIPCAS	Personal Information redacted by the USI	So far we have identified about 200 exams that need an official report - until these have been reported we will not know if any harm has come to the patients	For screening.

Update on M&M						
Patient name	Hospital number/HCN	Datix number	Date of incident	Division	Date to M&M	UPDATE
Personal Information redacted by the USI	Personal Information redacted by the USI	Personal Information	3.4.15	SEC		HSCB was notified of incident. To be presented at M&M Surgical Specialty specific M&M May 2017
Personal Information redacted by the USI	Personal Information redacted by the USI	Personal Information	22.6.16	MUC		Presented to ED M&M on 31.8.16
	Personal Information redacted by the USI	Personal informatio Complaint	19.1.17	MUC		4.9.18 Meeting held with sister and PCC.
Personal Information redacted by the USI	Personal Information redacted by the USI	Personal Information	21/12/2016	MUC		
Personal Information redacted by the USI	Personal Information redacted by the USI					No record to date case has been discussed at M&M
Personal Information redacted by the USI	Personal Information redacted by the USI		7.1.17	MUC	Feb 17 Cardiology M&M	There were areas of concern which may have contributed to this patients death SOM 4 – Just recently signed off by Dr McNeilly on IMMIX following receipt of Cardiology Sub-Speciality M&M minutes
Personal Information redacted by the USI	Personal Information redacted by the USI			MUC		This has been recorded as SOM 4 on IMMIX but is awaiting sign-off by ICU who completed IMMIX
Personal Information redacted by the USI	Personal Information redacted by the USI		6.4.17	MUC		Patient presented to ED DHH on 6/04/2017 with spontaneous pneumothorax – a Right sided chest tube in situ introduced via seventh intercostal space in anterior axillary line. From the insertion site the tube is directed cranially mildly compressing the base of the right lower lobe and impinging on the diaphragm. Personal was admitted to hospital and discharged on the 10/04/2017 with a referral to thoracic surgery given that he had 2 spontaneous pneumothoraces on the same side
Personal Information redacted by the USI	Personal Information redacted by the USI					Discussion Case was screened for SAI however was considered not an SAI. Case IRI. If there is uncertainty around reversing Warfarin then discuss with Haematology or senior colleagues. Octaplex was available however was not refilled from previous use. It is essential that this is restocked as soon as possible after use. Training and availability issues with the Point Of Care INR machine in Daisy Hill were raised. Point Of Care INR is a useful tool to have. This should be available to the Emergency Department on a 24 hour basis. Actions Point of care INR machine to be kept in the Emergency Department. When Octaplex has been used then this should be restocked. If there is uncertainty around reversing Warfarin then discuss with Haematology or senior colleagues. ACTIONS Mary to put on ED Newsletter emails sent last on 22 10 2018
Personal Information redacted by the USI	Personal Information redacted by the USI	Personal Information	8.6.18	CCS		28/06/2018-timeline complete. Response from Radiology "I was on the Saturday and ran all requests via Aaron who said confusion shouldn't be scanned at per guidelines. Ward never contacted me or him about it and covering Drs never mentioned – I always ask anything else for me! Not sure why wasn't scanned Sunday or the Friday" 01/08/2018- Screened. For Medical M&M to review examination process/System. Email sent to Connie Connolly. Wait outcome from Medical M&M. 6.8.18 Paula to Email Dr J Hardy re DHH M&M- email sent 7/08/18 03/09/2018 – Awaiting feedback –Dr Harty on leave until 10/9/18 10/09/2018- reminder email sent to Dr Harty 12/09/2018- Dr Harty advises "We have not presented this case at the m+m. My feeling is that this will lead to a blame culture around named junior and senior doctors. It will be discussed within the department and with our radiology colleagues"
Personal Information redacted by the USI	Personal Information redacted by the USI					SAH discuss at surgical M&M re anticoagulation

Personal Information redacted by the USI	Personal Information redacted by the USI			MUC		Kay to review as per AmcV 2/7/2018- Reminder to Kay Carroll- Medical notes requested (notes received) 23/07/2018- Email reminder to Kay Carroll 01/08/2018- wait update 03/09/2018 email reminder to Kay 12/09/2018- Medical notes receivedOut of hospital arrest – Coroners case- M&M (ICU). This Personal Information redacted by the USI was brought to hospital following a PEA cardiac arrest at home. Her family commenced bystander CPR and ROSC was achieved after 35 minutes with NIAS. This cardiac arrest occurred on the same day she was discharged from Craigavon Area Hospital where she had been an inpatient for 4 days receiving treatment for a Lower Respiratory Tract Infection, Acute kidney injury and electrolyte derangement. During this admission she had been on oxygen via nasal cannula- 3L SaO2 95% until the morning of her discharge. Her clinical observations as per the Nursing notes were SaO2 96% on room air immediately prior to discharge.
Personal Information redacted by the USI	Personal Information redacted by the USI			ED		Presented to ED with PV bleeding, pt had scheduled gynae appointment. Not checked in ED for PV loss. Large bleed. Etopic pregnancy.
Personal Information redacted by the USI	Personal Information redacted by the USI			ED		29/07/2018 - Pt attended ED after falling down flight of stairs, on initial assessment multiple spinal #S missed. Not picked up until reviewed by medical team in ED and CT 11 hrs later.
Personal Information redacted by the USI	Personal Information redacted by the USI	M&M referral		MUSC SEC		MUSC M&M SOM 1 SEC M&M waiting response from Mr Thompson
Personal Information redacted by the USI	Personal Information redacted by the USI			MUSC SEC		Presented to Surgical PSM 17/5/2017 outcome 2 recorded. Presented to ED PSM 25/1/2017 outcome 3. contained aspects that SHOULD² be improved (learning identified); the patient's eventual outcome was NOT affected i.e. Near Miss. Consider referring to Trust Incident Reporting System unless already considered or reported.
Personal Information redacted by the USI	Personal Information redacted by the USI	Personal Information	4.6.18	MUSC SEC MHD		26/06/2018 – Discussed with Mr Carroll and Dr Scullion – no SEC/ATICS issues referred to MHD 27/06/2018 Discussed with Dr Murphy and Dr Hampton – no ED issues referred to MHD 17/08/2018 Discussed 13/07/2018 SEC screening, suggested surgeon reviews. Mr McKay is reviewing and will discuss radiology finding with Radiology and respond with outcome 24/07/2018- awaiting feedback from Mr McKay, Mr Carroll updated re Mr McKays discussion and possible radiology findings 31.7.18 Email to Dr McKay on 27.7.18 request to review CT result. 21/08/2018 Mr McKay reviewing notes 03/09/2018 Mr McKay has reviewed chart- to go to Surgical M&M – screening meeting updated
Personal Information redacted by the USI	Personal Information redacted by the USI	Personal Information	8.7.19	MUSC SEC ICU		9.10.18 This case has been presented and discussed at the Anaesthetic Patient Safety Meeting on the 20/9/2018. Minutes with lessons learnt will be added when available. As pewr Laurie Martin ICU Has been discussed at ED M&M. For discussion at ICU M&M in September. Meeting of MDT to take place. To include ED, ICU Anaesthetics, Nursing, Bed management and medical team. 7.8.18 – Meeting took place on 31.7.18 7.8.18 - Mary Burke Advised at ED screening on 6.8.18 – No need for meeting she will discuss directly with Patient flow team. Presented at ED M&M on 25.7.18 for discussion and learning shared. Discussed at ED Screening on 1.8.18 - Mary Burke to advise head of patient flow that anaesthetic nurse is on call. Close from ED perspective. 21/08/2018- For discussion at ICU M&M in September 11/09/2018- Dr Scullion advises ICU M&M meeting will be 20/09/18

Personal Information redacted by the USI	Personal Information redacted by the USI	Personal Information	31.12.17	MUC		30.07.18 Meeting to be arranged with family, Dr Hampton attending need name of medical Dr to attend. 1/08/2018- Dr Murphy to confirm his nomination for meeting. ? need for ED rep.6.8.18 – Dr P Murphy agreed to meet with family & Trudy. Dr Murphy said no need for ED rep. 03/09/2018 Meeting to be organised 21/05/2018- email to litigation re PM report 2/05/2018 – Awaiting approval of report 6/4/18 – Report drafted by T Reid and share with MUSC 24.1.18 ED M&M findings sent to Dr Moan for review 10.1.18 Letter from family. For presentation at ED M&M.
Personal Information redacted by the USI	Personal Information redacted by the USI	Personal Information	2.10.18	MUC		Discussion at ED screening, it was requested that this incident is discussed at ED M&M Fall New Neurological deficit. Pt attended ED DHH head injury alcohol on board. CT head and neck NAD. Patient transferred to ward before surgical clerk in. CT spine ordered showed fracture T9 T10 T11
Personal Information redacted by the USI	Personal Information redacted by the USI			SEC		M&M referral DC conversions at ward level 18/12/2017 - DC conversion at ward level. Review -29/01/2018 – Discussed incident – also M&M findings – which state Complex co-morbidity – RCA undertaken – no change in outcome – SOM 1 was satisfactory. There were no particular Learning Lessons. Does not meet the criteria for SAI. 07/02/2018 - Review again following M&M M&M Issues: □ Interface between specialities □ DC cardioversion was carried out despite advice of medical SpR and Cardiology consultant against. □ Not appropriate to ask Junior Doctors to leave the wards to complete DC cardioversion □ Action: Forward to Surgical/ICU M&M with feedback to Medical M&M 30/04/2018 –being discussed at M&M – await formal sign off 18/06/2018- Close. (Keep on SEC) 31.7.18 – Wait formal signoff of surgical M&M. 21/08/2018-wait response from Dr Thompson re Surgical M&M 11/09/2018-as above 25/09/2018- No Surgical M&M report available
Personal Information redacted by the USI	Personal Information redacted by the USI			ED		09/02/2018 – Notes reviewed by Dr Hampton and Dr Murphy (no time line) no obvious lapse in care – surgery to review 12/04/2018 provisional M&M on ICU - ECR SOM1 was satisfactory there were no particular learning lesions .21/08/2018- as before. PM report sent to Dr R Thompson Mr Haynes aware 11/09/2018- wait surgical M&M 25/09/2018 No surgical M&M report available

Personal Information redacted by the USI	Personal Information redacted by the USI	Personal Information		SEC		Email from Jilly Clozapine has been associated with varying degrees of impairment of intestinal peristalsis, ranging from constipation to intestinal obstruction, faecal impaction and paralytic ileus. On rare occasions these cases have been fatal. Particular care is necessary in patients who are receiving concomitant medications known to cause constipation (especially those with anticholinergic properties such as some antipsychotics, antidepressants and antiparkinsonian treatments), have a history of colonic disease or a history of lower abdominal surgery as these may exacerbate the situation. It is vital that constipation is recognised and actively treated. Should this incident be screened as a SAI to determine if all appropriate action had been taken regarding the risk of constipation and gastrointestinal obstruction both with patient prior to attendance and with management while in hospital. Should it be shared with MHD? 26/06/2018 reviewed with Mr Carroll and Dr Scullion NOT SAI from and anaesthetics perspective- has been forwarded to MHD for review 3.7.18 Timeline to be completed 17/08/2018 Discussed 13/07/2018 SEC screening, suggested surgeon reviews. Mr McKay is reviewing and will discuss radiology finding with Radiology and respond with outcome 24/07/2018- awaiting feedback from Mr McKay, Mr Carroll updated re Mr McKays discussion and possible radiology findings 31.7.18 Email to Dr McKay on 27.7.18 request to review CT result. 21/08/2018. CT reviewed and medical notes left with Mr McKay today 11/09/2018- 25/09/2018- Dr D McKay has referred to Surgical M&M. 05/11/2018- Email to Dr Convery who advises for presentation at Medicine M&M November.
Personal Information redacted by the USI	Personal Information redacted by the USI	Personal Information		ED		
Personal Information redacted by the USI	Personal Information redacted by the USI	NONE	23.7.18	MUC		03/09/2018 Emailed Dr Murphy regarding presentation at M&M

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required a more in-depth review including SAI I or one of the governance team attempt to do a high level review of Datix reports.

3.25 Datix reports include everything from minor incidents to catastrophic incidents. The wording on reports does not always fully reflect the incident and thus I relied on further escalation by the services to identify some additional risks. The wording may have suggested a less significant issue when in fact there were significant risks.

3.26 While Governance Coordinator Datix system was an older version of Datix version 12.2.02 it has recently been upgraded to Datix 14.1.2 to bring the SHSCT into line with the region. It was challenging to run reports on the older version of the Datix system and make changes to the system. The litigation team used a separate version of the Datix system to record litigation cases. Staff feedback on the system was sought before I commenced post and some changes were made, although some staff continued to comment that the system made reporting challenging.

Screening meetings

3.27 Incident screening meetings usually include the Assistant Director (AD), Associate Medical Director (AMD) and/or the Clinical Directors (CD), and a member of the governance team. The AD and clinicians review the Datix report or complaint and where available the timeline and or clinical notes (governance team having reviewed clinical notes to extract a chronology of events). This is to see if an incident meets the criteria for an SAI and also to identify any early learning. I escalated incidents from the governance team's review of Datix at these meetings. I have also been notified by the operational teams at incident screening meetings of incidents or other governance concerns.

3.28 On occasion, meetings were cancelled but the screening information, which had been prepared to support the meetings, was forwarded to the screening team to remind them of the cases requiring screening and highlighting delays and allowing preparation should an additional meeting be facilitated.

3.29 I do not have details of all cancelled meetings however my recollection is that

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to close it.

Would you accept that an incident such as this - and I didn't bring you to the entry which suggests that the incident was categorised as "major" - that it should have been screened in for an SAI? 15:28

A. Yes, it should have been screened in for an SAI. It would have met the definition to be screened to identify learning.

254 Q. Would you agree that this Datix form should have been populated with some explanation as to why it wasn't screened or it should be documented elsewhere? 15:28

A. It should be -- if it wasn't screened it wouldn't be documented within the screening form. So there should have been something to indicate why it was closed. 15:28

255 Q. From a governance perspective was there anything in place that would have ensured that cases such as this were appropriately screened?

A. The cases like that should have been escalated from the operational teams up into the governance team or -- and I see some of the governance teams look as if they have been involved in it. So again we would have brought things to the screening meetings that, you know, looked unusual and had a discussion to see did it need to be progressed further. 15:29 15:29

256 Q. It's a little unfair to task you with these questions in the absence of direct knowledge, but can you see the problem, a major incident, not screened, and it would appear no mechanism by which the operational team were

challenged to explain why it wasn't screened? Was it possible in the environment in which you worked for incidents such as this to either be shuffled away by the operational team if it was, for example, too inconvenient or simply, to take a more benign view of it, forgotten about?

A. It would have been with the volume of Datixes that came through, sometimes with the quality of information on them, if they weren't escalated then there was a chance that they wouldn't have been screened, as in this case. 15:31

257 Q. Could we turn to the case of Patient 137. This was another case where the recommendation of the multidisciplinary meeting in urology had not been actioned, the practitioner concerned was Mr. Young, Mr. Michael Young and it was noted by you in the table that we looked at a few moments ago, indeed you were the facilitator, I think I called it coordinator earlier, but you were the facilitator for this matter. If we look at the Datix that was raised, WIT-100386, if we scroll down. It records that the patient was discussed at the multidisciplinary meeting 12th January 2017.

"The outcome was that the patient was to be referred to an endocrine MDM. Unfortunately this did not happen. A further GP referral came in five months later, 12th May 2017, and brought this to Mr. Haynes' attention, my attention, and a referral has now been done."

Now, if we go then to the incident checklist at WIT-100393, again the incident is summarised, the key point was that the referral wasn't made and the situation was only recovered by the GP's intervention. 15:33
Scroll down please. Plainly there were a number of discussions which you would have been party to, I assume. It said that, if we look at 21st September 2017, it records that:

15:34

"The patient has been reviewed by the endocrine team and is for discussion with radiology but likely outcome will be ongoing surveillance."

So although there was this five-month delay in the 15:34
referral, it would appear that the patient hadn't come to harm. So it says:

"Discussions concluded that while this is not an SAI there is learning regarding the processes in MDM. This 15:34
incident is to be shared with Mr. Glackin, Chair of the MDM for discussion regarding current processes."

Again, on 20th October 2017, outcome discussed at screening, not SAI. 9th January, not SEA. Could you 15:35
try to help us, Mrs. Reid, with the thinking there? An MDM decision hadn't been implemented, potentially catastrophic effects if it hadn't been picked up on by the GP. Happily, when he was ultimately referred he

was given a relatively clean bill of health, in other words no harm had been caused. Why, nevertheless, does that not enter the territory of an SAI review, having regard to the definition we looked at earlier?

A. Looking at the definition it should have been screened through as an SAI. I think in this case, and I think you can see from a number of, even after the decision that it wasn't, I have gone back on a number of occasions to see do we need to action anything, are they sure. And again, from memory, I would have escalated this through to meeting with Mrs. Gishkori as well. So, going by the letter of the definitions, it should have been screened through. 15:35 15:36

258 Q. The conclusion that appears to have brought an end to the process as such was that a letter would be given to Mr. Young, and we will look at that. But did you feel uncomfortable with how this was being talked through and the avoidance of an SAI or were you relatively content that in the absence of harm to the patient a letter to Mr. Young would address the mischief? 15:36 15:37

A. I probably, from memory, was uncomfortable. And I think, from what I can see here, I have gone back a number of times to ensure there was an action progressed in relation to the incident, even though it took quite a considerable time to get to that point. 15:37

259 Q. Hmm. Can you recall, because it's not clearly recorded here but it's maybe implied in the absence of harm to the patient, but can you recall the rationale for not pursuing an SAI?

A. Yes, I would say from 2019 the system has improved greatly in relation to being able to capture those particular incidents that need to be screened.

94 Q. You properly make the point that, even if incidents don't come with that label of major or catastrophic, there can be a cadre of cases that are nevertheless to be appropriately reviewed for the purposes of one of the levels of SAI. I suppose what you are pointing to is that, even if the case is not major or catastrophic, near misses, where perhaps no harm has resulted may nevertheless reflect underlying weaknesses in a clinical system? 10:46 10:47

A. Yes, that can do. We also would use complaints, clinical negligence cases, coroner's cases as well and other sources of feedback to inform the screening team as well. So, you know, if a complaint comes in it can be escalated to us asking does it need to be screened. Similarly in relation to clinical negligence cases, the litigation team would make us aware of those and then we would determine if it needed to be added on to the screening sheet as well. So we're not just using the Datix system for the purposes of identifying issues, we're taking a wider approach. 10:47 10:48

95 Q. Tell us a little more about that kind of conversation? Obviously the catastrophic and the major speak for themselves. 10:48

A. Yes.

96 Q. But you, wearing the responsibilities of the hat that you have, if you see something come your way, whether

4.24 The audit committee meetings commenced but Mrs Gishkori did not alwaysattend all the meetings and no additional administrative support was available for clinicians to facilitate audit and subsequently attendance at the acute meetings reduced meaning meeting were not quorate. The poor attendance led to meetings not continuing. However, clinical audit did continue with the support of the corporate clinical governance team and reports were presented to Acute Governance and Acute Clinical Governance Committees.

4.25 To progress key pieces of work I facilitated or was a member of a number of groups including conscious sedation committee, Sepsis 6 group, insulin QI group and othersto progress regional actions and recommendations from SAIs. Operationallythere appeared to be limited capacity to facilitate these meetings.

4.26 The resources available in the Acute Governance Team did not allow for regular review of action plans. Time was required to develop screen incidents, develop timelines to allow for review of complex cases and in preparation for SAI's, facilitate the SAI process and meetings, write SAI reports, and facilitate various meetings to progress some work streams.

(c) If these systems were introduced in response to SAIs, please explain why you think the risk and governance issues those systems were designed to address were not flagged before SAI stage? What was wrong with the systems existing at that time that the issues were not identified? If they were identified by existing systems, why were they not addressed?

4.27 The operational teams within the Acute Directorate were very busy managing services on a day to day basis with limited administrative support. The staffing resource within the divisions were focused on the

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directorate teams has been what we colloquially call the Scottish heat map, which is self-assessment governance assurance framework that is used in NHS Scotland, and we've found really helpful in terms of mapping across these systems to identify where the hotspots are so that we can draw attention to them. So I am beginning to see the workings out of all of this in terms of the shared learning and improvement.

172 Q. Yes. This could only be delivered on the basis of significant investment? 14:47

A. Yes.

173 Q. In different Human Resources?

A. Yes.

174 Q. Did that come as a struggle?

A. I have to say Shane Devlin was very supportive. Once - 14:47 I mean it was my job to persuade the system that this was the right thing to do. Once we got to that point he underwrote this by saying it should be funded.

175 Q. And we can see in the papers, and I'll not turn up all the job descriptions, but in Post-Clinical and Social 14:47 Care Governance Coordinator, a patient ahead of Patient Safety Data and Improvement, Family Liaison Officers.

A. Yes.

176 Q. A Corporate SAI Chair, is that right?

A. Yes, that's right. 14:48

177 Q. We'll come on to look at SAIs presently, but maybe it's convenient to explore this now. What is - is that one person sitting in the corporate structure ensuring that SAIs are essentially processing appropriately?

A. So the corporate SAI Chair is, some of our SAI Chairs are retired doctors who have come back to undertake this function, because one of the challenges that we had in this was finding SAI Chairs in the first place and then people having the time do it. So they have been employed to undertake this function - and some of them also have other roles. And that has been really important again in terms of taking a standardised approach to all of this and helping these SAIs through the system, because they can become incredibly laborious. So there's a weekly report on, you know, the progress of all of those that comes through the weekly governance report. But in addition to this, this is partly how the early learning template was developed that is now being seen as something that's really helpful to the SAI process in the Trust and which has been developed now in each of the other directorates. 14:48 14:49 14:49

178 Q. And if the ambition of this reform was to make stronger, make more robust the corporate model for clinical and social care governance, how, how in real terms is that achieved? Can you give us an example of how this new model makes a meaningful difference? 14:49

A. I can give you some examples. I mean there is obviously the followthrough in relation to the SAIs and the early learning template that has come out of that, and I think the fact that the clinical teams now who are involved with that process moved to adopt learning that they have generated themselves and have that 14:50

embedded almost before we have the SAI process completed, which was really helpful. And, again, you know, that particular example, we move to accreditation status for SAIs in mental health and disability, and the Royal College of Psychiatrists has commended that as good practice and has, you know, suggested that that is adopted more widely than just us. So that has been really helpful.

In relation to the Datix, which I mentioned yesterday. Again, when we've looked at that, we have put Datix staff in there again to make sure that the Datix are followed through on and that that Datix system has been enhanced since I think May 2022 in terms of the span of areas that it can include so that we can use that to triangulate the data and see patterns much more readily.

Another example built within...

179 Q. Can I just interrupt you... 14:51

A. Sorry.

180 Q. In fact, and just remembering that there is a document that perhaps conveniently speaks to some of this. It is TRU-306245, and it's a report from Clinical and Social Care Governance regarding improvements, and it's hot off the press, like many of these documents, March 2024. Would I be right to suggest that this was prepared for the Inquiry, this document? 14:51

A. It's been prepared for two things. It was - so, when I

A. That I think is really relevant to this process? It mentions training and support. Prior to me undertaking those SAIs, I did not have any training. So, I recall being asked by Eamon Mackle to Chair the first, chronologically whatever the first SAI was that I did. 10:20

47 Q. That was --

A. I can't recall which one it was.

48 Q. Yeah.

A. But I sat in the office reading the e-mail and I thought "Am I really ready to do this? Do I really know how to do this?", and I batted that back to Eamon in a conversation and it was kind of - the answer wasn't "you'll be grand", but it was to that effect. 10:21

49 Q. Yeah. I was going to ask you about the training, and maybe that was a convenient but accidental point to stop on. 10:21

A. I've subsequently had training.

50 Q. Yes. You outline in your statement, 19.4 for the panel's reference, that you completed training in structured clinical record reviews in 2021. 10:21

A. Yes.

51 Q. As well as root cause analysis training.

A. Yes.

52 Q. The Inquiry is very interested in the nuts and bolts that make up the aspects of the SAI process. Training in 2021, you did your first SAI, so far as this Inquiry's concerned, in 2015? 10:21

A. Yes.

53 Q. Moving on to - I forget the - I know the name of the

patient, but I can't find her...

A. Cipher.

54 Q. Cipher.

A. Yeah.

55 Q. But we'll come to that in due course. Patient 10, in 2016/2017. And then into another SEA, I think it was, in 2018/2019. Your training comes in 2021; Mr. Mackle, words to the effect of "You'll be grand", pressing on without training. Was training of value to you when you eventually got it? And would it have been better in advance? 10:22 10:22

A. Yeah. So as a trainee, I'd had experience of governance processes in at least two of the Trusts towards the end of my training. And that was useful, because it gave me an insight into how these processes worked. But I'd had no training in the Southern Trust as a consultant prior to undertaking those three SAIs. 10:22

When Dr. O'Kane came into post, she was very keen that training would be provided to consultants who would be undertaking these kinds of tasks, and it's my understanding that she was really the driving force behind getting the training organised. So, I participated in two different learning events, I can't remember how long they lasted, maybe one or two days each, for each of those, the RCA and the structured clinical review process. 10:23 10:23

56 Q. Yes. And --

A. And it was useful.

57 Q. Yes. And I suppose it's that old chestnut, you don't know what you don't know, but when you took on the SAI in 2015, did you feel something of an innocent abroad?

A. Yeah. I was, I was relying on the expertise of the governance team to keep me right. I'd obviously read the documents in terms of how these things would be conducted. But I was a novice. 10:23

58 Q. Back to the point I had lost, but have now found again, to start this off, at the bottom of the page there...

A. The learning of the SAIs? 10:24

59 Q. Yeah. And I suppose the key aim of the SAI procedure is to improve services and reduce the risk of incident recurrence, both within the reporting organisation and regionally.

10:24

"The dissemination of learning following an SAI is therefore core to achieving this. To ensure shared lessons are embedded in practice and the safety and quality of care provided."

10:24

An important statement of principle. You reflect in your statement, I suppose, a concern about the efficacy of the SAI process based on your experience of -- I just want to be sure to pick up on the precise wording you use. So if we can go to WIT-42313, and there you say that: 10:25

"Many concerns and complaints can be resolved informally. Complaints or concerns requiring a formal

44. ~~39.~~ **How did you ensure that you were appraised of any concerns generally within the unit?**

44.1 As a consultant within the urology service I was part of the team and therefore present at Departmental Meetings and Patient Safety Meetings. In addition, as AMD I regularly met with the HoS operationally, and attended regular meetings with the management team including regular SEC/ATTICS meetings, and Acute Clinical Governance Meetings (when they didn't clash with other commitments) where an overview of complaints / incidents was discussed.

45. ~~40.~~ **How did you ensure that governance systems, including clinical governance, within the unit were adequate? Did you have any concerns that governance issues were not being identified, addressed and escalated as necessary?**

45.1 The governance systems in the urology service were the same as those across the rest of the Acute Directorate. I have described, in my response to Question 38, the processes which were in place.

45.2 I believe the Trust is aware of the risk relating to the length of time an SAI process can take to investigate (*please see 44. 20180717 Datix* Irrelevant redacted by the USI*, 45. 20201113 Final Report* Irrelevant redacted by the USI *46. 20210719 Approved Action Plan to HSCB and 47. 20210719 Approved Action Plan to HSCB A1*) and believe there are a number of SAI recommendations over many years which have taken significant periods to implement, e.g. in the case of Mrs Patient 10 *(please see 48. 20160106 Datix Incident, 49. 20170315 Final Report* Irrelevant redacted by the USI *and 50. 20201204 Action Plan SAI* Patient 10*).* With regard to standards and guidelines, a weakness across NI is that regularly these are not able to be implemented in full due to staffing / infrastructure / finance issues, e.g., regional implementation of NICE NG12 *(please see 51. 20190208 59).*

Received from Mr Mark Haynes on 20/09/22. Annotated by the Urology Services Inquiry.

process can take months to complete, largely because the process relies on the availability of a panel to meet several times to finalise a report. The efficacy of the process is, in my view, questionable. Sharing learning from this activity is challenging. The volume of information cascading down the management structure means that most of it goes unread and therefore unactioned."

So, you are reflecting back out of your own experiences of Chairing or leading three SAIs, and more widely, is that fair?

A. Yes. So, my own experience is that they do take too long. And for the reasons I've outlined, I think that is not helpful. Because if there's quick learning needed then you're not getting that out there as it should be, you know, across the organisation. Secondly, when an SAI report comes down through the governance structure to the M&M patient safety meeting, for instance, what you get is basically a set of recommendations. It's often very difficult to contextualise those recommendations, to put them in a scenario where the people in the room understand, you know, this is what has happened and this is why we're making these recommendations.

And another problem that I think with the recommendations is that I may Chair an SAI, Mr. Haynes may Chair an SAI, Mr. O'Donoghue may Chair an SAI - and

Southern Health and Social Care Trust

Quality Care - for you, with you

Clinical and Social Care Governance Assurance Template – June 2018

Please consider the following when populating the assurance template

- *Effectiveness and robustness of present arrangements*
- *Clarity of roles & responsibilities*
- *Assurance mechanisms – operational/ corporate*
- *Cognisance of external reviews*

	Strengths •*What advantages does your does your current directorate processes and systems possess?* •*Given your existing assurance structures what do feel you do well?* •*What resources can your directorate draw upon that could be replicated in other service areas?*	**Weaknesses** • *What could be improved Trustwide?* •*What have staff in your directorate identified as weaknesses with current arrangements?* •*Could any identified weaknesses be*	**Opportunities** •*What opportunities can you identify to strengthen current systems and processes?*	**Threats** • *What factors are barriers to improvements?* •*When future challenges do you foresee?*
SAI investigations	• Operational Governance Teams • Ownership and oversight at directorate level	• Weak challenge function via approval process • No SMT role in oversight • Directors choose what they bring to SMT • There is no consistent approach to SAI training • There is no consistent approach to the appointment of SAI chairs • There is no dedicated time across all professions to undertake SAI investigations	• To create a baseline programme for SAI chair training • Governance review to strengthen challenge function via director of governance structures • Opportunity to clarify roles and responsibilities via governance review process	• Outputs of IHRD workstreams – potential changes to existing processes may impact on our opportunities to develop better local systems and processes

Received from SHSCT on 21/12/2021. Annotated by the Urology Services Inquiry

Ireland and Northern Ireland. I then became the Associate Medical Director and eventually became the Medical Director of the Trust for four years. I am a visiting professor of the Ulster University, at the newly established graduate entry medical school, and I currently am an Associate with the Leadership Centre. Some of my work that I currently do, I spend one day a week at the Independent Medical Examiner's Office, I have supported RQIA in the review of deceased patients who were previously seen by Dr. Watt, and I am the senior responsible owner for the Encompass Project for Northern Ireland, which is an Epic implementation to completely review the IT infrastructure on an Epic platform for Health and Social Care and providing a portal for patients. 10:21

13 Q. In terms, Dr. Hughes, of your SAI experience and know how, if I can put it in those terms, could I draw your attention to what you have said at WIT-84149. Just scroll down the page to paragraph 5. You have explained that you have formal training in SAI, that you have chaired SAIs and that, as Medical Director, you had a review and quality assurance role. You suggest that your experience, between 2015 and '19, shortly before doing this work for the Southern Trust, that quality assurance role brought 350 cases across your desk? 10:22

A. DR. HUGHES: Yes, all SAIs in the Trust would have been reviewed at Director level, and I chaired that process, and that was to assure immediate learning to quality

assure and make sure that the learning was embedded within the system. Subsequently to that, after leaving that role, I have done a range of SAIs, one -- as well as the Southern Trust, one I have done work for the Belfast Trust reviewing nine cancer-related cases in Thoracic Surgery. I have also done two nosocomial covid SAIs relating to outbreaks of Covid, both within the Western Trust. These would have involved patient engagement and chairing SAIs processes. I think it was about 22 patients in total. 10:23

14 Q. We will come on, in just a few moments, to look at the circumstances in which you became to be appointed to the role for the Southern Trust. Your role specifically, Dr. Hughes, was to be the external Independent Chair; isn't that correct? 10:24

A. DR. HUGHES: Yes, that's correct.

15 Q. Mr. Gilbert, again, external independent subject matter expert, I suppose, with responsibility for reviewing the clinical aspects, benchmarking, and providing an analysis of any deviation from benchmark? 10:24

A. MR. GILBERT: Exactly, yes.

16 Q. Dr. Hughes, in the last paragraph of your statement, I'm going to bring it up in front of you just to orientate you, it's WIT-84175, paragraph 24. You draw the Inquiry's attention to the General Medical Council's guidance called Leadership and Management For All Doctors, which was published in January 2012, and you go on to say: 10:25

development of the organisation, explained that you brought significant changes to reporting and practice with the outworking of the Champion Review, and she remarked upon the, for example, the kinds of information the Governance Committee now gets in relation to standards and guidelines, SAI process, complaints, just to name several examples.

Do you wish to, can you expand on that for us? What, from your perspective, have you and your colleagues added to the body of information received by your Non-Executive Directors on a regular basis and what has driven this improvement?

A. Well, I think that the drive towards improvement certainly started with the Champion Review in relation to what was included there, and I think gave us an indication that potentially the structures weren't supporting the function of the organisation. So working through those 48 recommendations has helped us, I think, you know, now have a more robust approach to governance, and then within all of that what we've worked really hard to do is to improve the reporting structure and the quality of the information that goes there, because I think our concern was, when we looked at some of our committees, that actually there was very little opportunity to triangulate information and to understand the connectivity across the organisation in terms of what this might mean. So the increasing emphasis in recent times has been in making sure that

they would support the Trust Board in its learning from others and in its development of the Board Team.

Concern	Raised with	When	What was done
Knowing our blind spots	Roberta Brownlee and Shane Devlin.	27 August 2020	Workshop -Muckamore Abbey Hospital – Report of the Independent Leadership and Governance Review.
Email and note sent to Chair and NEDs as I would not be in attendance at the meeting. NED Sub Committee Membership/Other interested areas/Roles and responsibility	Roberta Brownlee, all Non-Executive Directors, and copied in Shane Devlin.	20th May 2019	No reference in the minutes that this was discussed.
Chief Executive performance targets	Roberta Brownlee and Non-Executive Directors.	28 October 2018	I requested Culture be placed as part of the CEO performance targets.

46.4 As Chair of the Governance Committee, I also sought improvements to reporting, in particular in respect of clinical and social care governance. This was ongoing with each Committee meeting highlighting the need for additional/different information to support its work. Each of the three Medical Directors (2016 – 2019) had their own way of reporting. Dr Maria O'Kane brought significant changes to reporting and practice with the outworking's of the Champion Review. This included Standards and Guidelines, SAI Process, and Complaints.

Received from Eileen Mullan on 26/09/2023. Annotated by the Urology Services Inquiry.

was Dr. Hughes?

A. Yes. It really helped that the Chair was independent and the Chair was available to assist with the reviews because, if you can see from the meetings, we had meetings every two weeks to keep the momentum going. 12:12
Keeping a facilitator step down from this review would have been perfect. I had asked for it on numerous occasions but it wasn't possible, to be fair.

180 Q. Why was that not possible?

A. Because all the other work in governance still had to 12:12
be done, you know, so it wasn't possible for me to step down and then leave nobody to do the work. You would have needed to put somebody in place. That would have been brilliant if that had happened, but then you have to train that person. You need somebody in place who 12:13
knows what they are doing.

So, yes, an SAI Review with the timeframes. We were held to a very tight schedule to get these reports done, it was significant pressure. It would have been 12:13
ideal to be just doing that and nothing else.

181 Q. Given your commitment to that in relation to time and to the scope and the breadth of the work that had to be done for nine, did you have a sense of disappointment that you didn't see the recommendations implemented 12:13
before you left?

A. Yeah, very much so because I was really invested in this review. As I said in my statement, this is one of the best SAIs I have ever undertaken. To have the

level of communication with the families, I mean, I really -- I had bonded with so many of the families during that review, I wanted to see things come to fruition, I wanted to be able to work with some of them because some of them wanted to be involved in the recommendations as well, which was very admirable of them. But obviously retirement was beckoning.

182 Q. There was an introductory meeting for your team for the nine SAIs on 10th September 2020. That's at WIT-93794. We will see that the date is Thursday, 10th September 2020. Dr. Hughes, Fiona Reddick, Patricia Thompson and Patricia Kingsnorth. 12:14 12:15

Were you involved in any way with securing the services of any of the other team members? 12:15

A. That would have been a multidisciplinary decision with the ADs and the Directors. Whilst I was appointed as a facilitator, from memory there was a discussion about who the clinical nurse, would we go outside for that. But there was a new Clinical Nurse Specialist who had just started in the Trust, and Dr. Hughes was happy for her to come on board because she didn't know anybody in the Trust, she had no vested interest of it and yet, at the same time, she would have had feet on the ground to know where to access information should we ask. 12:15 12:16

The head of service would have been appointed by her line manager, Barry Conway. Again, a multidisciplinary decision of who was the best person to help with this,

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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

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APPENDIX 6

Revised November 2016 (Version 1.1)

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

Organisation's Unique Case Identifier: [redacted]

Date of Incident/Event: January 2016 – September 2016

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)

Responsible Lead Officer: Dr J R Johnston

Designation: Consultant Medical Advisor

Report Author: The Review Team

Date report signed off: 22 May 2020

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

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1.0 EXECUTIVE SUMMARY

During an internal review in 2016, following an Index Case, the Trust identified a number of GP Urology referrals who were not triaged by one particular Consultant Urologist; 30 patients should have been red-flag referrals and of these 4 had cancer. A fifth patient Patient 15, discovered during an outpatient clinic, was included as he was also not triaged and subsequently had a cancer confirmed.

Patient 15 – a 68-year-old male was referred to Urology Outpatients on 30 August 2015 for assessment and advice for an elevated Prostate specific antigen (PSA) (The blood level of PSA is often elevated in men with prostate cancer). The referral was marked Routine by the GP. The referral was not triaged on receipt. However, a second GP referral was received on 29 January 2016 marked Suspected Cancer Red Flag and had received a red flag appointment. Following this referral, he was seen in clinic on 8 February 2016 (D153). On day 166, Patient was diagnosed with a confirmed cancer; a resultant 6-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 14 – a 63-year-old male was referred to Urology Outpatients on 3 June 2016 for assessment and advice for an elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of the internal review, the referral was upgraded to Red Flag and was seen in clinic on day 246. On day 304, the patient had a confirmed cancer diagnosis. There has been a resultant 10-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 1 – a 68-year-old male was referred to Urology Outpatients on 28 July 2016 for assessment and advice for an elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of an internal review the referral was upgraded to Red Flag and seen in clinic on day 217. On day 258, Patient 11 was diagnosed with a confirmed cancer; a resultant 9-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 13 – a 51-year-old male referred to Urology following an episode of haematuria on 28 July 2016. The referral was marked Routine by the GP. The letter was not triaged and Patient 13 was placed on a routine waiting list on 30 September 2016. As part of an internal review this patient's referral letter was upgraded to a Red Flag referral. Patient 13 was reviewed at OPD on 31January 2017. Subsequent investigations diagnosed with bladder and prostate cancer. Patient 13 has locally advanced bladder cancer. There has been a resultant 6-month significant delay in obtaining a diagnosis and a recommendation of treatment for his bladder cancer.

Persona – a 73-year-old male was referred to Urology Outpatients on 8 Sept 2016 for assessment and advice on lower tract symptoms and elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of the internal review the referral was upgraded to Red Flag and was seen in clinic on day 152. On day 215, Patient 1 had a confirmed cancer diagnosis T3a with no nodal metastases. There has been a resultant 8-month delay in

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obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Causal Factors

1. Referral letters did not have their clinical priority accurately assigned by the GP. Referral letters were not triaged following receipt by the Hospital.

HSCB

Recommendation 1

HSCB should link with the electronic Clinical Communication Gateway (CCG) implementation group to ensure it is updated to include NICE/NICaN clinical referral criteria. These fields should be mandatory.

Recommendation 2

HSCB should consider GP's providing them with assurances that the NICE guidance has been implemented within GP practices.

Recommendation 3

HSCB should review the implementation of NICE NG12 and the processes surrounding occasions when there is failure to implement NICE guidance, to the detriment of patients.

HSCB, Trust and GPs

Recommendation 4

GPs should be encouraged to use the electronic CCG referral system which should be adapted to allow a triaging service to be performed to NICE NG12 and NICaN standards. This will also mean systems should be designed that ensure electronic referral reliably produces correct triaging e.g. use of mandatory entry fields.

TRUST

Recommendation 5

Work should begin in communicating with local GPs, perhaps by a senior clinician in Urology, to formulate decision aids which simplify the process of Red-flag, Urgent or Routine referral. The triage system works best when the initial GP referral is usually correct and the secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

Recommendation 6

The Trust should re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW.

Recommendation 7

The Trust will develop written policy and guidance for clinicians on the expectations and requirements of the triage process. This guidance will outline the systems and processes required to ensure that all referrals are triaged in an appropriate and timely

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manner.

Recommendation 8

The current Informal Default Triage (IDT) process should be abandoned. If replaced, this must be with an escalation process that performs within the triage guidance and does not allow Red-flag patients to wait on a routine waiting list.

Recommendation 9

Monthly audit reports by Service and Consultant will be provided to Assistant Directors on compliance with triage. These audits should be incorporated into Annual Consultant Appraisal programmes. Persistent issues with triage must be escalated as set out in recommendation 10.

Recommendation 10

The Trust must set in place a robust system within its medical management hierarchy for highlighting and dealing with 'difficult colleagues' and 'difficult issues', ensuring that patient safety problems uncovered anywhere in the organisation can make their way upwards to the Medical Director's and Chief Executive's tables. This needs to be open and transparent with patient safety issues taking precedence over seniority, reputation and influence.

CONSULTANT 1

Recommendation 11

Consultant 1 needs to review his chosen 'advanced' method and degree of triage, to align it more completely with that of his Consultant colleagues, thus ensuring all patients are triaged in a timely manner.

Recommendation 12

Consultant 1 needs to review and rationalise, along with his other duties, his Consultant obligation to triage GP referrals promptly and in a fashion that meets the agreed time targets, as agreed in guidance which he himself set out and signed off. As he does this, he should work with the Trust to aid compliance with recommendation 6.

2.0 THE REVIEW TEAM

Dr J R Johnston - Consultant Medical Adviser - Chair

Mr M Haynes - Consultant Urologist

Mrs K Robinson - Booking & Contact Centre Manager

Mrs T Reid - Acute Clinical & Social Care Governance Coordinator

3.0 SAI REVIEW TERMS OF REFERENCE

1. To undertake an initial investigation/review of the care and treatment of patients [redacted], in the period after referral to the SHSCT Urology service using

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3.0 SAI REVIEW TERMS OF REFERENCE

National Patient Safety Agency root cause analysis methodology.

2. To determine whether there were any factors in the health & social care services interventions delivered or omitted to Personal information redacted by the USI that resulted in an unnecessary delay in treatment and care.
3. The investigation / Review Team will provide a draft report for the Director of Acute Services. This report will include the outcome of the Team's investigation/review, identifying any lessons learned and setting out their agreed recommendations and actions to be considered by the Trust and others.
4. The Trust will share or disseminate the outcomes of the investigation/review with all relevant parties internally and externally including the service user and relevant family member(s) (where appropriate).

4.0 REVIEW METHODOLOGY

The Review Team will undertake an analysis of the information gathered using RCA tools and may make recommendations in order that sustainable solutions can minimise any recurrence of this type of incident. The Review Team will request, collate, analyse and make recommendations on such information as is relevant under its Terms of Reference in respect of the incident outlined above.

Gather and review all relevant information

- Inpatient notes Craigavon Hospital.
- Information from the Northern Ireland Emergency Care Record (NIECR) and Patient Administration System.
- Information from laboratory systems.
- Information obtained from relevant medical, nursing and management staff.
- Review of Relevant Reports, Procedures, Guidelines.

Information mapping

- Timeline analysis
- Change analysis for problem identification and prioritisation of care delivery problems and service delivery problems as well as identifying contributory factors.

5.0 DESCRIPTION OF INCIDENT/CASE

5.1 Triage of GP referrals - background

The general public expect that, when they engage with their GP complaining of symptoms that are potentially due to a cancer, they will be referred to the appropriate secondary care services promptly and that they will respond, also promptly, to confirm or exclude the diagnosis of cancer.

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5.0 DESCRIPTION OF INCIDENT/CASE

The DHSSPSNI **Service Framework for cancer prevention, treatment and care** (Standard 13) of 2011 indicates, "*All people with signs and symptoms that might suggest cancer should be appropriately assessed by their GP and referred promptly on to hospital for further tests if needed*".

Cancer specialists, working in networks, have formulated lists of symptom and sign triggers which can signify the development of a cancer. Using these lists, primary care doctors can refer patients into secondary care; triaging a large number of patients by assigning them to different degrees of urgency (Routine, Urgent and Red-flag). If these are used as designed, this can provide an efficient referral system.

NICE have been instrumental in ensuring uniformity and the validity of these cancer recognition and referral lists of symptoms and signs. They have also formulated guidance regarding how safety nets should be setup to ensure patients are not missed. Local programmes, using this type of guidance, have been established, under the auspices of NICaN and the HSCB, to set up these triage pathways and safety nets.

5.2 Triage of GP referrals – Northern Ireland

NI Referral Guidance for Suspected Cancer (2012)

The Northern Ireland Referral Guidance for Suspected Cancer 2012 is based on the NICE clinical guideline, CG 27 - *Referral guidelines for suspected cancer,* published in June 2005. This has a section on Urological Cancer. It was introduced to GPs by HSCB correspondence (30/12/2012), revealing the new red-flag process and indicating in appendix A that, "*triaging will take place in a timely manner, within 72 hours of receipt of referral or the referral should continue with the GP Prioritisation".*

This is still the only set of referral guidance for suspected urological cancer available online on the NICaN website (last accessed 18/11/2018).

However, the 2005 CG27 guidance has been replaced by NICE Guideline NG12 *Suspected cancer: recognition and referral* published in June 2015. This was endorsed by the Department of Health (NI) with HSC (SQSD) (NICE NG12) 29/15 on the 19th August 2015 which instructed the HSCB / PHA to send out the guidance to the appropriate Family Practitioners. This particular kind of guidance requires the HSCB to circulate regionally endorsed NICE guidelines to Trusts and GPs for implementation. Trusts are expected to review guidance against a base line assessment and provide HSCB with an assurance that the guidance has been implemented. If a Trust is unable to fully implement the guidance within the one-year period without regional co-ordination and/or additional resources, they should provide a formal assurance to HSCB, and this is to be managed as part of the risk management process. This assurance process does not however apply to primary care and GP's.

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5.0 DESCRIPTION OF INCIDENT/CASE

NICaN Urology Cancer Clinical Guideline (2016)

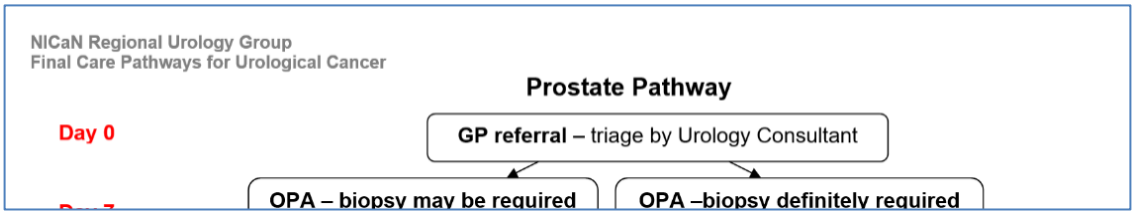
The NICaN Urology Cancer Clinical Guideline document, (version 1.3, March 2016), was produced regionally to support the diagnosis, treatment and management of urological cancer. This version included amendments, to replace the previous red flag guidelines, with those from NICE NG12; the document was signed off on behalf of the NICaN by Consultant Urologist, Cons1.

The Review Team's evaluation of the advantages of NICE NG12 (2015) over the CG27 (2005) guidelines reveals fewer cases would be red-flagged for Urology, as a result of,

- a reduction in number of non-visible haematuria patients; and
- increases in age criteria of 45 years and over.

However, rollout of NG12 by the HSCB does not appear to have happened. The Review Team understands that the reason NG12 has not been implemented lies with ongoing discussions between the HSCB and GPs.

Appendix 2 of the NICaN Urology Cancer Clinical Guideline guidelines highlights the Urology Care pathways. Cons1 was present at the workshop discussing those on 02/10/2008. It clearly indicates that, for the Prostate pathway, the GP referral would be triaged by the Urology Consultant.



5.3 Triage of GP referrals – SHSCT

The process of Urology triage in CAH is based upon the NI Referral Guidance for Suspected Cancer of 2012 as described above i.e. it is based on the 2005 NICE CG27 guidelines and not the more up to date 2012 NG12. In CAH, triage of referrals is performed by the Consultant Urologist of the week.

The SHSCT Urological Cancer multi-disciplinary team (MDT) was led at the time by Consultant 1 (Cons1), who was also a joint chair.

Over a period of decades, within the SHSCT and Craigavon AH, there were occasions when triage was not performed; and this varied between consultants and specialities. Acute Services had a particular problem with this issue. Preliminary discussions by the Review Team revealed that triaging within Acute Services was a, "*very haphazard process going back for approximately 25 years. There were many Consultants who would not triage but Consultant 1 was the most persistent and there were multiple attempts to tackle this issue*".

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5.0 DESCRIPTION OF INCIDENT/CASE

Interview with Associate Medical Director (AMD1)

AMD1 first became aware of waiting list problems with Cons1 in 1996–8 when AMD1 was the lead clinician in outpatients. Cons1's OPD letters were being kept in a ring binder and were not on any waiting list. Once challenged, Cons1 would stop this practice and improve but would then slip back. There were further non-triage meetings with Cons1 when AMD1 was the Clinical Director of Surgery.

Interview with Director of Acute Services (DAS2)

In 2007, DAS2 (while in previous post in CAH) found a waiting list which was 10 years long. They worked on this with the Consultant, Cons1, and cleaned it up; they found no serious patient related issues.

Interview with Director of Acute Services (DAS1)

DAS1 indicated that the Urology Services were under various kinds of pressure during her time as Director. There was a regional transformation project in place for Regional Urology Services under Mr M. Fordham; this generated an element of pressure to modernise and change. Along with this and other issues, including the triage problem, Consultant 1 struggled to adapt to these changes and to comply with the other issues and triaging. DAS1 paints a picture of many issues with Cons1, triaging being only one of many issues but, in her opinion, not the most important issue.

Nevertheless, in April 2010, Consultant 1 (Cons1) was put under pressure to complete his triage list. The surgical Associate Medical Director (AMD1) brought concerns to DAS1. The other Urologists had been 'covering' triaging for Cons1; the Head of Service Surgery had informed AMD1 of this. They met Cons1 the next day. The European Association of Urology meeting was in Spain the following day and Cons1 wished to attend. DAS1 and AMD1 informed Cons1 he would not be attending the meeting unless he triaged all his referrals immediately. Cons1 duly addressed the triage backlog, completing them that evening. From that time on, AMD1 and the Head of Service (HoS1) monitored that Cons 1 was triaging the GP referral letters. However, DAS1 commented that the HoS1 had a difficult job managing Cons1.

Following interview with Head of Service (HoS1)

The Head of Service for Urology (HoS1) indicated that she inherited the problem upon appointment although she was aware that it was a long running issue, going back perhaps 25 years. She highlighted this was an ongoing issue with Cons1. He had the longest backlog and took longest to triage. There were issues with other Consultants who, on occasion, did not triage but Cons1 was the only one, when asked to triage, didn't do it. This came to head in 2010 (referred to above) and again in 2014.

Informal Default Triage (IDT) process

In May 2014, after escalation to HoS1, an Informal Default Triage (IDT) process was put in place by the Trust's booking centre. This process allowed the booking office to allocate

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5.0 DESCRIPTION OF INCIDENT/CASE

patients, who had not been triaged in time, to be allocated to a 'waiting list' using the GP triage category. Therefore, this IDT process of putting patients on the waiting list without triage meant that they did not get missed. However, some patients, who should have been triaged as a red flag, waited on the waiting list with their 'incorrect' GP triage category. After much discussion, this detailed process was formally circulated to all specialties on the 6th November 2015 by the Assistant Director of Support Services (ADSS1).

When questioned about this IDT process, the DAS2 was not aware of it even though it started during her time in post i.e. May '14. When asked about its potential problem of leaving incorrectly triaged (by their GP) patients on a waiting list she stated, "*Completely ridiculous, because would allow a cancer patient who should have been red flagged by their GP to go unchallenged by a Consultant triage process i.e. could have to wait for 11 months*".

5.4 Index case

In 2016, the SHSC Trust investigated ([Personal information redacted by the USI] in what subsequently became an 'Index case' for the cases in this RCA, the treatment and care of Patient 10 was a patient who had had Ca Colon (2010), breast carcinoma (2013) and then developed renal carcinoma. During review for her Breast Ca in June 2014, a CT Scan revealed that, previously noted, renal cysts had increased in size. Further investigation by a MRI scan was reported in a limited and incomplete fashion; resulting in a 'routine' referral GP letter on 29/10/2014.

During the investigation, the Review Team identified that Patient 10 GP referral letter had not been triaged; the Consultant Urologist with responsibility that week for triage duties was Cons1. This referral therefore waited as a 'new routine' referral till January 2016 to be seen by a Consultant Urologist.

The index case Review Panel agreed 3 main contributing factors led directly to Patient 10 delay in diagnosis. Firstly, the content of the MRI report; secondly a letter following a CT scan did not mention important information and thirdly, 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.

The index case Review Panel concluded in March 2017 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 (*vide infra*) continues to be initiated secondary to the omission of Triage by individual members of the urology team and not the entire Urology Team*".

Of the 2 lessons learnt, one indicated that,

> "*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*."

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This led to a recommendation that,

> *"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 the Integrated Elective Access Protocol (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."*

The findings of this investigation, chaired by Consultant Urologist 2 (Cons2), were made available in December 2016 and formally signed off on the 15th March 2017. A letter highlighting a number of concerns was sent to the (then) lead for Acute Governance for Acute Services (AGAS1), on the 15th December 2016.

The letter pointed out that the IDT process implied that triage non-compliance was to be expected but that this process did not have a clear escalation plan to include the individual Consultant and, indeed, had not been effective in addressing triage non-compliance. Furthermore, the letter pointed out that, from July 2015 till October 2016, there were 318 non-triaged letters which the Trust could not provide assurance that patients were not being exposed to harm by waiting as a routine or urgent appointment i.e. when they should have been red-flagged.

It is not absolutely clear who wrote this letter as it has no signature, but it appears to have been written by, or on behalf of, Cons2. On the 10th January 2017, Cons2 was requested by the Medical Director (MD3) to share the report with the 2 key Consultants involved in the SAI. One of these was Cons1. Cons2 refused, stating that he was Cons1's colleague and not his manager.

This letter was escalated to the Director of Acute Services (DAS3) and the Assistant Director of Anaesthetics & Surgery. This was further escalated to the Chief Executive of the SHSCT.

Cons1 was written to by AMD1 on the 23rd March 2016, acknowledging his hard work as a Consultant Urologist but pointing out that there were governance and patient safety concerns with regard to untriaged letters dating back over 2 years, and other important issues. Cons1 was asked to respond with a commitment and immediate plan to address these issues.

The Review Panel also determined that there were 7 other patients who were not triaged that week along with Patient 10 They subsequently performed a 'look-back' exercise (number 1) of these referrals. Of the seven referrals, six charts were available and each patient had an appropriate

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management plan. One set of notes were missing and efforts were made to find them.

Cons1 provided his personal review, dated 25/01/2017, of the Index Case to the Chairman of this Review Team. It provides an argued retrospective rationale that a timely triage by himself would not have altered the referral grading. However, it does not provide a sound reason for his actual lack of triage. His report is consistent in arguing his view that he does not have time to perform both Consultant of the Week (CoW) duties and triaging of non-red flag referrals.

5.5 Look back exercise #2

Upon realisation that the 'look-back' exercise #1 had resulted from non-triage over the week beginning the 30/10/2014, further efforts were made to investigate the size of this non-triage issue and to find missing referral letters. Cons1 was contacted and the Head of Service for Urology (HoS1) obtained permission to look for missing GP referral letters in his filing cabinet. Cons1 stated that there were referral letters in a filing cabinet in his office. During interview, he stated that he kept the referrals to ensure they would not be missed or overlooked. The Head of Service for Urology retrieved these referral letters, which numbered over 700 along with the triage lists from the booking centre.

These referrals were then reviewed by the Urology Consultant Team revealing 30 patient referrals should have been red-flagged and four of these patients, following review, were diagnosed with cancer, becoming the subject of this review.

This ([Personal information redacted by the]) Review Team reviewed the clinical notes from these 4 patients and following discussion, under the Urological guidance of AMD1, detailed the clinical course and made the following conclusions.

Patient 14 03/06/2016 - 63-year-old male referred to Urology Outpatients by GP for assessment and advice with a raised PSA.
The referral was marked Urgent by the GP.
The referral was not triaged on receipt.
09/08/2016 - added to W/L Urgent.
27/01/2017, as part of the internal review #2, the referral was upgraded to R/F and was seen in clinic on day 246. Therefore, this was an incorrect GP referral.
05/04/2017 (D304), following U/S guided biopsy, the patient obtained a confirmed cancer diagnosis and there was a recommendation for treatment of a prostate cancer by surveillance protocol.

Conclusions

Resultant 10-month delay in obtaining diagnosis.
Following Review Team consideration, deemed not to be a clinically significant delay.

Patient 1 28/07/2016 - 68-year-old male referred to Urology Outpatients by GP for assessment and advice, concerning elevated PSA.
The referral was marked Urgent by the GP.

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The referral was not triaged on receipt.
30/09/2016 - added to W/L Urgent.
18/01/2017 - as part of an internal review #2, upgraded to R/F. Therefore, this was an incorrect GP referral.
20/02/2017 (D207) seen at R/F appointment. Sent for MRI and prostate biopsy.
11/04/2017 (D258) - diagnosed with a confirmed low risk prostate cancer and there was a recommendation for treatment of a prostate cancer by surveillance protocol.

Conclusions

Resultant 9-month delay in obtaining diagnosis.
Following Review Team consideration, deemed not to be a clinically significant delay.

Patient 13 28/07/2016 - 51-year-old male referred to Urology by GP following an episode of haematuria.
The referral was marked Routine by the GP.
The letter was not triaged.
30/09/2016 - Patient 13 was placed on a Routine waiting list.
19/01/2017 - As part of an internal review #2, upgraded to a R/F referral. Therefore, this was an incorrect GP referral.
31/01/2017 (188d) - reviewed at OPD and flexible cystoscopy.
22/02/2017 TURBT/TURP - diagnosed with bladder (locally advanced) and prostate cancer and there was a recommendation of treatment for his bladder cancer.

Conclusions

Resultant 6-month delay in obtaining diagnosis.
Following Review Team consideration, it is probable that the delay is clinically significant; time will tell*.

* The Review Team referred to an expert for advice.
Delay in definitive surgical treatment beyond 12 weeks conferred an increased risk of disease-specific and all-cause mortality among subjects with stage II bladder cancer. He remains disease free as of September 2018.

1. John L. Gore, Julie Lai, Claude M. Setodji, Mark S. Litwin, Christopher S. Saigal, and the Urologic Diseases in America Project. Mortality increases when radical cystectomy is delayed more than 12 weeks. Results from a surveillance, epidemiology, and end results–Medicare analysis. Cancer March 1, 2009.
2. Nader M. Fahmy, Salaheddin Mahmud, Armen G. Aprikian. Delay in the surgical treatment of bladder cancer and survival: Systematic Review of the Literature. *European Urology 50 (2006) 1176–1182.*

Patient 3 08/09/2016 - 73-year-old male was referred to Urology Outpatients on for assessment and advice on lower tract symptoms and elevated PSA.
The referral was marked Urgent by the GP.
The referral was not triaged on receipt.
27/01/2017 – further GP letter – please upgrade to R/F.
30/01/2017 - as part of the internal review #2, upgraded to R/F.

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06/02/2017 - seen in clinic on day 152.
11/04/2017 (D215) - confirmed cancer diagnosis T3a with no nodal metastases – high risk and there was a recommendation of treatment for a locally advanced non-metastatic prostate cancer.

Conclusions

Resultant 8-month delay in obtaining diagnosis.
Following Review Team consideration, it is probable that the delay is not clinically significant.

At a later date, towards the end of 2018, another patient came to the attention of the Review Team [redacted] Patient 15 This patient could also have been one of those found in Cons1 filing cabinet but appeared at an outpatient clinic before the outworking of the look back exercise #2. A Consultant Urologist realised in the clinic that this was also a Cons1 non-triaged patient who was incorrectly referred by their GP.

Patient 1 30/08/2015 - 63-year-old male referred to Urology Outpatients by GP for assessment and advice with a raised PSA.
The referral was marked Routine by the GP.
The referral was not triaged on receipt.
29/01/2016 2nd GP referral marked as Suspected Cancer – Red flag; Patient 1 was added to W/L R/F following this referral.
As part of the internal look back #2, the referral was noted.
Patient 1 had already received an appointment and was seen in clinic on day 153. Therefore, 1st GP referral was incorrect; the 2nd was a correct GP referral.
11/02/2016 (D166), following a prostate biopsy, the patient obtained a confirmed cancer diagnosis T3a and there was a recommendation for treatment of a prostate cancer.

Conclusions

Resultant 6-month delay in obtaining diagnosis.
Following Review Team consideration, it is felt that the delay is unlikely to be clinically significant.

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7.0 CONCLUSIONS

The Review Team interviewed a number of Trust staff including Directors (past and present), an Assistant Director, Head of Service and an Associate Medical Director as part of the review process. These interviews, along with clinical documents and health records systems, have helped inform the conclusions by providing the evidence and also corroboration where there appeared to be differences of opinion.

The Review Team and everybody interviewed, including Cons1, provided affirmation that a timely, efficient triage system which checked the initial GP referral was very important to patients. Comments made when interviewees were asked about the importance of triage and where the process of triaging a potential cancer patient ranked alongside other issues such as probity, patient experience and performance, were consistent,

"Very significant". Very high up the list in terms of importance".
"It is fundamental people are seen in the appropriate time".
"Very important" ... "Important for the patient".
"Vital" ... "Very significant .. patients are often anxious and depend on the system to work".

Cons1 replied,

"It is a serious issue, very important"..... "Number one ranking in overall scheme of things"

The Review Team established that there were factors in HSC service delivery to the 5 patients under examination that resulted in an unnecessary delay in treatment and care. In 4 patients the delay was thought not to be clinically significant but in 1 (Patient 13 [redacted]) there probably was a significant delay.

Consideration of the causative factors to the patients' delays reveal,

- Referral letters did not have the clinical priority accurately assigned by the GP; and
- Referral letters were not triaged following receipt by the Hospital.

7.1 Referral letters did not have the clinical priority accurately assigned by the GP.

Contributory factors

Task Factors (policy and guidelines)

The Review Team reviewed the GP referrals regarding the five patients listed above. They concluded, as judged from the Northern Ireland Cancer Network (NICaN) Referral Guidance for Suspected Cancer (December 2012), that all five patients should have been referred to Urology by the GP's as red flag referrals (suspected cancer) i.e. incorrect triage.

Task Factors (decision aids)

The current decision aid for GPs is the NI Referral Guidance for Suspected Cancer 2012 based on NICE CG 27 *Referral guidelines for suspected cancer* published in June 2005. It is clear that Secondary care, in the form of Consultant Urologists, should triage these GP referrals; by doing so, 11% of GP referrals are changed (from Review Team member). It is also clear that Cons1 would have been in no doubt as to his responsibilities; he was intimately

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involved in setting this standard and signed off the NICaN clinical guidelines.

However, it is clear this very important and critical triage safety net, work can be considered onerous and other electronic methods which GPs can use might be more efficient and help to reduce that load.

According the HoS1, most patient referrals by GPs to Trusts for outpatient appointments are now made through the electronic Clinical Communication Gateway (CCG). However, some paper referrals are still received. CCG is a digital referral system for Primary care which can contain referral criteria that meet NICE and NICaN guidance. This would enable appropriate clinical triaging of referrals to be performed as part of the selection of referral reasons and/or symptom description.

Using the electronic CCG pathway, some clinical specialties, such as gynaecology, have worked closely with the Public Health Authority to develop a better GP referral tool e.g. using 'banner guidance' (a specialty specific banner, listing symptoms and signs) which complies with NICE/NICaN guidance. This 'banner guidance' helps by directing clinicians to use the NICE/NICaN referral criteria which allow for timely and appropriate triage of patients to clinically appropriate appointment types. It is possible when red flag symptoms are chosen that an immediate alert could go to the Red Flag booking team, to allow the appointment booking process to begin immediately. However, currently, the referral criteria fields are optional i.e. not mandatory, so opening up the possibility that fields are not completed, leading to error and delay.

NICE NG12
The reference CG27 guidance has been replaced by NICE Guideline NG12 *Suspected cancer: recognition and referral* but, despite being endorsed by the DHSSPSNI and accepted by the Regional Urologists, it has yet to be implemented. Its use as a triage standard should result in fewer red-flagged cases which should ease some of the pressure on waiting lists. Its adoption would take place in primary care and should form the basis of the electronic CCG referral tool.

There was a consistent medical staff view from the Review Team, the AMD1, and indeed Cons1, that GP's have a crucial and important responsibility in getting the referral criteria/urgency category correct. If the GP does not provide enough, or the correct information, the NI Electronic Care Record (NIECR) needs to be checked and that slows the whole triage process down. It was clear that the triage system works best when the initial GP referral is usually correct and the Secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

7.2 Referral letters were not triaged following receipt by the hospital.

Contributory factor

Task Factors (policy and guidelines)

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The Integrated Elective Access Protocol (IEAP) (DHSSPS, April 2008) defines the roles and responsibilities of staff (in both primary and secondary care) when patients enter an elective care pathway. It states,

> '…*an Executive Director will take lead responsibility for ensuring all aspects of this Protocol are adhered to…. Patients will be treated on the basis of their clinical urgency with urgent patients seen and treated first*'.

The Principles for booking Cancer Pathway patients states,

> "Clinical *teams must ensure triage is undertaken daily, irrespective of leave, in order to initiate booking patients*".

and,

> "*Referrals will be received, registered within one working day and forwarded to Consultants for prioritisation*".

However, the IEAP states,

> *"…if clinical priority is not received from Consultants within 72 hours, processes should be in place to initiate booking of urgent patients according to the GP's classification of urgency".*

Following on from the IEAP of 2008, national and regional policies and guidelines, already referred to above, have been introduced which have outlined the detailed role of the Urology Consultant in triaging referrals that have come in from Primary care e.g.,

- Service Framework for cancer prevention, treatment and care (Standard 13) 2011;
- NI Referral Guidance for Suspected Cancer 2012; and
- NICaN Urology Cancer Clinical Guideline document, (version 1.3, March 2016).

These have provided agreed lists of the critical symptomatology of Urological cancers and the roles and responsibilities of Primary and Secondary care staff in ensuring patients receive prompt recognition and treatment of their cancer.

Review of Adult Urology Services in Northern Ireland

In March 2009, a *Review of Adult Urology Services in Northern Ireland - A modernisation and investment plan* was published. Its External Advisor was Mr Mark Fordham. SHSCT Consultant Urologists were represented on the committee.

Recommendation 4 states, "*Trusts must review the process for internal Consultant to Consultant referrals to Urology to ensure that there are no undue delays in the system".* Consultants indicated that they would routinely upgrade a significant number of routine and urgent referrals (GP) to urgent or red flag. It was noted that the development of agreed referral guidelines/criteria for suspected Urological cancers was a priority piece of work for the recently formed NICaN Group. That work was led by Cons1; see page 6.

Section 3.31 of the report indicates that, "*Consultant Urologists unanimously consider that referral triage should be led by Consultants. With over 40% of referrals being cancer related*

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(and with many not red flagged or marked urgent) they believe that they are best placed and skilled to undertake the triage process. They also believe that despite the volume of referrals, this is not a particularly time consuming process."

Contributory factor

Staff factor

It is obvious from reading the documents referred to above that Cons1 has been aware of developments in this field and, indeed has been party to the discussions and signed some of them off. Cons1 was chair of NICaN (Urology) and was involved in drafting the NICaN regional Urology guidance, and therefore was very familiar with the requirement to triage GP referrals.

Despite all of this, and even though Cons1 agreed that this triaging role was, "*very important*", …. it was, "*a very serious matter not to be minimised, very serious"* he stated he would not triage non-red flag referrals.

When asked, *"Does triage still need done?"* Cons1 answered*, "a procedure is needed to highlight when it needs done and who does it".* When further asked, *"Who was involved in SHSCT Urology service in setting up triage"?* Cons1 answered for urological cancer, "*I was the Lead"*.

He felt triage of referral letters was too time consuming and the amount of time spent on triage, in his opinion, rendered inpatient care unsafe. He highlighted that he had previously escalated his concerns about work load to management teams and medical directors.

In relation to triage, Cons1 stated, '*I would love if we had a Trust Urology agreement on the type of triage to be conducted*'. When it was pointed out that, "*Consultant colleagues did triage for you. How did they do it?"* He stated, "*It depends on how you do it"* ..... "*Not all do advanced / enhanced triage, they compromise. It is a spectrum"... "They have not done it in the detail I felt it needed for routine/urgent non-red flag case".*

When questioned further, regarding his way of organising his own work load, Cons1 stated, '*....yes I did it my way – I wasn't cognisant of being unbending, I am very particular*'.

Cons1 highlighted to the Review Team that he currently takes annual leave each Friday and spends the weekend triaging. He stated that it is impossible to be Urologist of the Week and triage referrals appropriately. He stated he still can't do triage and everything else. He stated, '*I do triage entirely in my own time to allow me to do it properly'*.

When asked about using the NIECR - Electronic Referral using the Clinical Communication Gateway (CCG) method, Cons1 stated found the new CCG triage system*, "Very, very good, I wish all information was available on ECR. It is less time consuming. ECR makes it easier to check information".*

The Review Team concluded that there was a serious inconsistency between the guideline

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standard that a Consultant should triage GP referrals (which Cons1 helped to construct) along with his stated view of the crucial importance of triage and Cons1's actual practice.

Cons1's chosen method of triage was beyond what is required. His triage is the equivalent of a virtual clinic where he reviews NIECR and books investigations for patients. While the Review Team recognised this was a detailed triage process, they concluded that his prioritisation of work and attention to detail meant that some patients got a higher standard of triage/care, while, crucially, others were not triaged, leading to a potentially critical delay in assessment and treatment for those patients. Cons1 is aware of this.

The Review Team concluded that Cons1's prioritisation of work and attention to detail led to some patients receiving a high standard of care, while others ran the real risk of having a cancer diagnosis delayed till it was dangerously late.

Contributory factor

Work load/scheduling

In 2008, when the IEAP was published, there was a maximum waiting time of 9 weeks for a first Outpatient appointment. On 30th September 2016, there were 2012 patients on the routine Urology outpatient waiting list, with 597 patients showing as waiting 52 weeks and over. The longest waiting time was 554 days (80 weeks). Therefore, if patient referrals are incorrectly referred, or not triaged and continue to use the GP's classification of urgency, there will be a significant wait. Cons1 is aware of this reality.

The Review Team considered the Consultant of the Week (CoW) work load, including ward rounds, clinics, emergency theatre sessions as a contributory factor. Cons1 has consistently argued that he cannot triage non-red flag referrals and carry out the duties of the CoW. He has not indicated who else should carry out the triage duties. However, the Review Team note that the other Consultant Urologists were able to manage this work load and triage referral letters in a timely fashion, with other members of the consultant team also ordering investigations, providing treatment recommendations and adding patients directly to waiting lists, similar to outcomes achieved from Cons1's 'advanced triage'.

Contributory factor

Organisational

The Review Team concluded that the non-triage of Urology referrals by Cons1 has been an ongoing problem in the Trust for many years, possibly decades. While there were pockets of non-compliance by other Consultants, when escalated, compliance improved. However, the Review Team note that Cons1 consistently did not return triage information on referrals thus not allowing the appropriate prioritisation of appointments by clinical need.

Interviews with 2 previous and the current Director of Acute Services, AMD1 and the Head of Surgery Service have highlighted that on many occasions, over a prolonged period, attempts had been made by the Trust's officers to address Cons1's non-compliance with triage. These

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attempts encompassed both direct face to face conversations which were often heated, correspondence and, as in 2010, study leave refusal until there was compliance. These interventions all resulted in a familiar pattern of response; temporary improvement in compliance with triage, followed by a return to non-compliance.

In 2014, due to continuing non-compliance, the Trust implemented an 'Informal' Default Triage Process to manage the referrals which were not being triaged and returned to the Booking Centre. The Review Team considered the intention of this process was to prevent any delay in patients being added to the waiting list. However, this meant the 'non-return of triage' was not individually addressed with the non-compliant clinicians. Furthermore, and most importantly, it allowed patients, who should have been red-flagged, to remain on a waiting list until review.

In 2014, the Director of Acute Service 2 (DAS2) discussed non-compliance with Cons1 and agreed that Cons1 would no longer triage referral letters. Cons1 was heavily involved with formulating the NICaN Urology guidelines at the time and was grateful to the extent that he thanked DAS2.This task was delegated to other Urology Consultants for a time. However, Cons1 does not recollect having to formally stop triage. At interview, DAS2 was not aware that he had resumed those duties; she remembered that their Cancer performance figures improved when Cons1 was not triaging.

Escalation within Organisation

At every interview, questions were asked whether Cons1's consistent and prolonged non-compliance with triaging was referred upwards to executive level i.e. the Medical Director and Chief Executive.

Director DAS1 considered that the problem was being managed at Service level, although as it was only one of a series of issues and considered to be a 'minor' one, it did not predominate at higher level meetings with the Medical Director (MD1); to the extent that he may not have been aware of it.

Director DAS2 considered that the problem was dealt with by agreeing with Cons1 to stop triaging. There were other issues that were flagged up to MD2, but she was not able to remember whether MD2 was made aware of the triage problem.

During DAS3's current tenure Executive members certainly knew; at CAH Oversight meeting level and at the time of the look back exercise #2 which ultimately led onto this SAI and RCA process. The Medical Director (MD3) was directly involved in the RCA process and the CEO was aware. At Trust Board level, it is thought that a non-Executive member was asked to examine the situation which would indicate that it had also reached that level.

Overall, the Review Team in considering whether there was a satisfactory escalation of this 'non-triage' issue have concluded that there was no evidence of consistent and proactive escalation of 'non-return of triage' either to the Medical Director or the Chief Executive until the look back exercise #2 basically forced the seriousness of the issue out into the open. Indeed,

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they do not appear to have appreciated the importance of triage, certainly from the patient's perspective. The Trust's officers made efforts to address Cons1's non-triage over time but were consistently thwarted by Cons1's refusal to comply. The Trust failed to put systems, processes and fail safes in place to ensure Cons1's consistently triaged patient referrals until 2017.

Systems and processes have now been put in place so that the Head of Service for Urology reviews Cons1's compliance with triage. HoS1 will check all Urology triage on an adhoc basis but, with Cons1, she will check daily when he is the Consultant of the Week. Any non-compliance with returning referrals without triage is addressed immediately. However, this process is heavily dependent on HoS1 who, when she is on leave, often has to recover non-triaged cases upon her return.

8.0 LESSONS LEARNED

1. The clinical urgency category allocated by GPs to 30 patients referred to Urology were incorrect. The referrals using NICaN guidance should have been referred as a Red Flag. Four (plus 1) of these patients were subsequently shown to have cancer.

2. The process of triaging Urology cancer referrals from Primary Care to Secondary Care, under the direction of the HSCB, appears to be less efficient than it could be, bearing in mind that NICE NG12 guidance has not been adopted and electronic referral using CCG is not being used as efficiently as it could.

3. GP's are not mandated to provide HSCB with an assurance that they comply with the most up to date NICE or other guidelines. Therefore, HSCB are unaware of any risks consequent upon the non-compliance with NICE and other guidance within GP practices.

4. GP's are not mandated to refer patients using CCG clinical criteria banners; this can lead to error and delay.

5. There is no Regional or Trust guidance or policy on what is expected of clinicians when triaging referral letters. Triage of patient referrals is obviously viewed as extremely important but does not seem to be at an equivalent level of importance when ranked alongside other clinical governance issues. Despite being an evident problem for decades and requiring considerable time and effort to find a solution, it only really surfaced within the Trust after an Index case forced the situation out into the open.

6. Despite it being absolutely clear to Consultant 1 (based upon his close proximity to the development and signing off of regional guidance) of the consequences of non-triage, he did not routinely triage referral letters. The Review Team consider that Cons1's refusal to triage to a level similar to other clinicians, led to patients not being triaged,

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and this resulted in delays in assessment and treatment. This may have harmed one patient.

7. Cons1 confirmed that despite the Trust reminding him of the requirement to triage, he did not consistently triage referrals. He argued that, due to time pressures, he felt he was unable to perform the duties of the Consultant of the Week and his triaging duties. He has highlighted those views to Trust operational and management teams over a number of years.

8. The Trust made efforts to address Cons1's non-triage over time. However, the Trust failed to put systems, processes and fail safes in place to ensure Cons1 consistently triaged patient referrals until 2017. However, this safeguarding process is heavily dependent on the Head of Service checking triage is completed when Cons1 is Consultant of the Week.

9. The Informal Default Triage process allows patients who should be red flagged to remain on a waiting list of routine or urgent cases.

10. From examining the triaging issue over the length of time it has existed, it is obvious that there is an unwillingness or inability within the medical hierarchy to tackle its 'difficult colleague' problem. The reasons behind this probably include not taking ownership of its own problems and poor support from senior medical management perhaps resulting in issues not being referred upwards.

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9.0 RECOMMENDATIONS AND ACTION PLANNING

HSCB

Recommendation 1

HSCB should link with the electronic Clinical Communication Gateway (CCG) implementation group to ensure it is updated to include NICE/NICaN clinical referral criteria. These fields should be mandatory.

Recommendation 2

HSCB should consider GP's providing them with assurances that the NICE guidance has been implemented within GP practices.

Recommendation 3

HSCB should review the implementation of NICE NG12 and the processes surrounding occasions when there is failure to implement NICE guidance, to the detriment of patients.

HSCB, Trust and GPs

Recommendation 4

GPs should be encouraged to use the electronic CCG referral system which should be adapted to allow a triaging service to be performed to NICE NG12 and NICaN standards. This will also mean systems should be designed that ensure electronic referral reliably produces correct triaging e.g. use of mandatory entry fields.

TRUST

Recommendation 5

Work should begin in communicating with local GPs, perhaps by a senior clinician in Urology, to formulate decision aids which simplify the process of Red-flag, Urgent or Routine referral. The triage system works best when the initial GP referral is usually correct and the secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

Recommendation 6

The Trust should re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW.

Recommendation 7

The Trust will develop written policy and guidance for clinicians on the expectations and requirements of the triage process. This guidance will outline the systems and processes required to ensure that all referrals are triaged in an appropriate and timely manner.

Recommendation 8

The current Informal Default Triage (IDT) process should be abandoned. If replaced, this must be with an escalation process that performs within the triage guidance and does not allow Red-flag patients to wait on a routine waiting list.

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Recommendation 9

Monthly audit reports by Service and Consultant will be provided to Assistant Directors on compliance with triage. These audits should be incorporated into Annual Consultant Appraisal programmes. Persistent issues with triage must be escalated as set out in recommendation 10.

Recommendation 10

The Trust must set in place a robust system within its medical management hierarchy for highlighting and dealing with 'difficult colleagues' and 'difficult issues', ensuring that patient safety problems uncovered anywhere in the organisation can make their way upwards to the Medical Director's and Chief Executive's tables. This needs to be open and transparent with patient safety issues taking precedence over seniority, reputation and influence.

CONSULTANT 1

Recommendation 11

Consultant 1 needs to review his chosen 'advanced' method and degree of triage, to align it more completely with that of his Consultant colleagues, thus ensuring all patients are triaged in a timely manner.

Recommendation 12

Consultant 1 needs to review and rationalise, along with his other duties, his Consultant obligation to triage GP referrals promptly and in a fashion that meets the agreed time targets, as agreed in guidance which he himself set out and signed off. As he does this, he should work with the Trust to aid compliance with recommendation 6.

10.0 DISTRIBUTION LIST

In addition to the Review Team, the following.

Mr S Devlin, Chief Executive SHSCT.

Dr Maria O'Kane, Medical Director, SHSCT.

Mrs Melanie McClements Interim Director of Acute Services.

Health & Social Care Board (HSCB).

Chairs of Morbidity & Mortality Groups SHSCT.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

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

Reporting Organisation SAI Ref Number:	Personal informa	**HSCB Ref Number:**	S Personal informa

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	✓	
	Comment: 5 ***If multiple service users are involved please indicate the number involved***				
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**	✓	**NO**		
	If **YES**, insert **date informed**:19.2.18				
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI				
	a) No contact or Next of Kin details or Unable to contact				
	b) Not applicable as this SAI is not 'patient/service user' related				
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user				
	d) Case involved suspected or actual abuse by family				
	e) Case identified as a result of review exercise				
	f) Case is environmental or infrastructure related with no harm to patient/service user				
	g) Other rationale				
	If you selected c), d), e), f) or g) above please provide further details:				
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**		
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY			
	NO	If **NO**, provide details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**					
Content with rationale?	**YES**		**NO**		

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

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

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

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

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

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

DATE CHECKLIST COMPLETED	**22.5.2020**

[1] *Service User or their nominated representative*

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Script for Lookback Exercise – Urology – Sept 2020

Urology Helpline

Helpline Telephone Number: xxxxxxxxxxxxxxx

Welcome to the Urology helpline .

To help us deal with your query can I take some details.

First of all are you phoning for yourself or another member of your family?

Does your ? know that you are contacting us?

I will take your details and they will be passed on to xxxxxx who will contact you xxxxxxxxxxx in relation to your query.

Could I have your / the patient's :

Name

DOB

Address

What is your concern?

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

King, Dawn

From: Kingsnorth, Patricia
Sent: 19 May 2021 10:24
To: Connolly, Carly; Cardwell, David
Cc: Farrell, Roisin; Haynes, Mark; Carroll, Ronan
Subject: Patient 15

Dear Carly and David
I can confirm that Mr Haynes has telephoned Patient 15's wife this morning and advised her that her husband was part of the original SAI into urology services.
He firstly apologised and then advised her about the original review into the triage of GP referral letters.
He advised her that the review looked at two aspects.

1. What can be done about the process and the consultant
2. What impact the delay in referral letters had on the patients overall care.

He advised that we would follow up with the learning to the family. We will agree a letter for Melanie to send but I do believe all the patients involved in these cases new and old urology reviews should have an formal apology from the Trust.
I will discuss at my one to one with Melanie this afternoon.

Kind regards
Patricia

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



Received from SHSCT on 02/02/22. annotated by the Urology Services Inquiry.

and scroll down quickly. Thank you. We can see it there. Tell us about that principle and how important it is in terms of the, I suppose the modern climate of dealing with incidents that are perhaps harmful, but you need to know about them and you need to learn from them.

A. Mm-hmm.

203 Q. And there may well be a reluctance to communicate adverse incidents if there is a belief perhaps that there might be a punishment for the perceived wrongdoer. So does the principle or the concept of a just learning culture come in there?

A. Yes. I think I mentioned earlier, you know, the evidence base for this comes from the Drucker work in relation to just an open culture and, again, it is nested very firmly in the idea that, particularly in safety organisations - and, you know, the NHS is like the airline industry, it is a safety organisation - that incidents rarely happen because of, you know, a bad actor in the middle of it all, it's very often to do with a system not functioning in the way that actually yields the best result. So part of the approach that we take in relation to this and, you know, what we've tried do is inculcate a lot of this through simulation training.

15:14 15:14 15:15 15:15 15:16

So to give you an example. When our foundation Year 1 doctors are new into the Trust, as part of their induction in July/August, what we now do is take, you

e-mail until 11th June, and when I interrogated that e-mail I had concerns. At that time I would have looked at the needs for the breast surgical team, the colorectal team, the gynaecology team, the ENT team and the Urology team, and then put them together in terms of the time need and what we had available and the urgency, and looked to meet as many patients as we could, demand, and looked to see where patients could be managed, including what was available to us in the independent sector.

149 Q. When you wrote to Mrs. O'Kane on 11th June, that was to trigger a process which, administratively, was led by Mrs. Corrigan. She carried out some initial work at looking back at certain cases, and we will look at that in a moment. Did you know at this time, that is around 11th June, that Mr. O'Brien was not prepared to take the decision to refuse his return to work. He wasn't prepared to take that lying down. He was going to fight that?

A. I don't recall being aware of that. The decision to look into things further was really, as in the concern in my e-mail, if there are patients who haven't been added to the waiting list, and specifically with the group of patients that both were, which was patients who had had ureteric stents inserted as first step in their management of stones, then we needed to identify if there were any others because they needed to have their needs addressed, so that was the reason for that work. Initially one of the groups Martina Corrigan

482 Q. Astounded?
A. Yeah.
483 Q. And when you got that report, I know you had a meeting with Dr. Hughes in February '21, we'll come on to that, when you saw the report in March 2021 - 15:06
A. Yes.
484 Q. - was that the first time that you saw it altogether?
A. Absolutely. When we met Dr. Hughes at the end of February my astonishment came from the background that this process had been going on for three or four months 15:06 in terms of investigating the SAIs. And on reflection I would think that after one, if not two, but definitely if three people were identified as having no key worker, perhaps there was an opportunity there to engage with the CNS team or say to the CNS team, "this 15:06 is becoming a feature here, is this widespread? Is this something you know about? Can you do anything about this?"

So, I was a bit taken aback that we didn't hear 15:06 anything of that until the outcome of the SAIs were ready to be signed off as such.
485 Q. Just so the Panel is clear about the chronology, you first saw the report and we'll go to the meeting of that, that you had, you first saw the report in March 15:07 2021?
A. Yes.
486 Q. Prior to that you had been at the MDT meeting -
A. Yes.

Southern Health and Social Care Trust

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

Organisation's Unique Case Identifier:

Personal Information redacted by the USI

[redacted]

Date of Incident/Event: Multiple dates

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: Male Age:

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN)

Report Author: The Review Team

Date report signed off: 26 February 2021

Date submitted to HSCB: 1 March 2021

Received from SHSCT on 28/09/2022. Annotated by the Urology Services Inquiry.

1.0 EXECUTIVE SUMMARY

The purpose of the review is to consider the quality of treatment and the care provided by Doctor 1 to the patients identified 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. Nine patients have been identified as potentially suffering harm. This review will examine the timelines of each individual case and analyse if any deficits in treatment or care has occurred. As part of the review the cancer pathways will be used to determine where learning can be extracted.

The SHSCT recognise the life changing and devastating consequences to the 9 families. It wishes to offer an unequivocal apology to all the patients and their families involved in this review. This was not the cancer care they expected and should not have been the cancer care they received.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair former Chair of the NICAN. Former Medical Director Western Health and Social Care Trust.
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (Formally from SET / recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

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

Received from SHSCT on 28/09/2022. Annotated by the Urology Services Inquiry.

3.0 SAI REVIEW TERMS OF REFERENCE

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.

4.0 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.

DRAFT

Received from SHSCT on 28/09/2022. Annotated by the Urology Services Inquiry.

5.0 DESCRIPTION OF INCIDENT/CASE

The review team conducted individual reviews on 9 patients on their treatment and care. A summary of each case is discussed within this report.

Causal deficits in their care and contributory factors were identified.

Service User A

Service User A was diagnosed with prostate cancer and was started on an anti-androgen therapy as opposed to Androgen Deprivation Therapy (ADT). This did not adhere to the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016). These Guidelines had been signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-Disciplinary Meeting (MDM), as their protocols for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. Following discussion with the families, the review team noted that there was no discussion with Service User A that the treatment given was at variance with regionally recommended practice. There was no evidence of informed consent to this alternative care pathway.

The review team have identified that during the MDM that a quorum had not been met. This was due to the absence of an oncologist from these meetings. Even so, the recommendations made by the MDM were not actioned by Dr 1. Members of the MDT may not have been aware of this, but similar practice in prescribing an anti-androgen had been challenged. Any challenges made regarding the appropriateness of treatment options were not minuted nor was the issue escalated.

The Review Team suggested that the initial assessment of Service User A was satisfactory although rather prolonged, the subsequent management with unlicensed anti-androgenic treatment (Bicalutamide) at best delayed definitive treatment. Bicalutamide (50mg) is currently only indicated before (as an anti-flare agent) or in combination with a LHRH analogue (Complete Androgen Blockade) Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer (reference is EAU guidelines), and further it decreases overall survival. Treatment for prostate cancer is based on achieving biochemical castration (Testosterone <1.7 nmol/l), which is best accomplished by the use of a LHRH analogue, by an LHRH antagonist or by bilateral subcapsular orchidectomy.

Service User A did not have Urology Cancer Nurse Specialist allocated to his care. The review team questioned this and it was established that whilst there were no resources for a Urology Cancer Nurse Specialist to attend any outreach clinics, their contact numbers should have been provided to the patient.

The Review Team conclude that Service User A received unconventional and inadequate treatment. The expected multi-professional involvement in his care was omitted. Service User A's disease progressed whilst being inadequately treated. The opportunity to offer him radical treatment with curative intent was lost.

Received from SHSCT on 28/09/2022. Annotated by the Urology Services Inquiry.

5.0 DESCRIPTION OF INCIDENT/CASE

Service User B

Service User B was diagnosed clinically and biochemically with prostate cancer, and was commenced on bicalutamide 50mgs. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent (or in combination with a LHRH analogue) and is only prescribed before definitive hormonal (LHRH analogue) treatment. The review team note that this treatment was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016), which was signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their protocols for Cancer Peer Review (2017). This guidance was issued when Doctor 1 was the chair of this group and had full knowledge of its contents. The review team note that, following discussion with Service User B, he was unaware that his care given was at variance with regionally recommended best practice. There was no evidence of informed consent to this alternative care pathway.

A biopsy result taken at the time of transurethral resection of prostate (TURP) showed benign disease (low volume sample 2g from central area of prostate). There were no further investigations to explore the clinical suspicion of prostate cancer.

The possibility of localised prostate cancer was considered from the time of presentation because the PSA was elevated; however, there was no record in the medical notes of any digital rectal examination (DRE) findings. During the operation further signs might have been elicited and appropriate biopsies could have been performed. TURP is not an adequate way to biopsy the prostate gland for suspected prostate cancer. The Review Team conclude that sufficient evidence of localised prostate cancer was apparent from the time of presentation. A correct course of action would have been to arrange appropriate staging scans and biopsies. Service User B should have undergone investigation with a MRI scan of the prostate and pelvis and a bone scan should have been considered. A transrectal biopsy performed either at the time of the TURP or separately, would have secured the diagnosis.

Arrangement could then have been made to start conventional Androgen Deprivation Therapy (a LHRH analogue) with referral on to an oncologist for consideration of external beam radiotherapy (EBRT) potentially with radical intent. However, the patient was apparently lost to follow up after his appointment in July 2019.

Service User C

Service User C was referred to urology service following a visit to ED in December 2018. He was reviewed promptly by Dr 1 in January 2019. Investigations were arranged and a diagnosis of a large right-sided renal carcinoma was made. He was counselled regarding the risks and benefits of surgical intervention and chose to proceed with the high-risk surgery.

On 6 March 2019 Service User C was admitted for an elective radical nephrectomy. The procedure was undertaken as planned and he was transferred to the intensive care unit (ICU) to support his blood pressure. He was later transferred to the ward. He developed a bacteraemia (infection) which was successfully managed with the advice of the microbiology team. Follow up CT scans were performed in June with a planned follow up in July 2019. This did not happen. Service User C was admitted to Ward 3 North following an ED admission. He was reviewed again via telephone in November

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5.0 DESCRIPTION OF INCIDENT/CASE

2019 by Dr 1 who arranged for a repeat CT scan to be performed on 17 December 2019 with a plan for review in January 2020. This did not happen.

The CT scan report was available on 11 January 2020 which showed a possible sclerotic metastasis in a vertebral body which had not been present on the previous CT scans. This report was not actioned until July 2020 when a new consultant reviewed the care. Service User C was subsequently diagnosed with prostate cancer.

The Review Team find that the treatment and care in relation to management of the renal tumour was of a high standard. High-risk surgery was performed successfully following informed consent as to the risks and benefits of the surgery. A urology review was planned for July 2019 following the CT scan report in June but this didn't happen. Service User C appeared to be lost to review. The scan performed in December 2019 with a plan to review in January was not actioned and the plan for review did not happen. This resulted in a delay of 6 months in diagnosis of a prostate cancer from the scan result. This would be approximately a delay of 18 months from his first presentation in ED in November 2018.

Service User D

Service User D attended ED on 24 December 2018 with retention of urine. A urinary catheter was inserted, and a urology consultant review was planned to coincide with a trial removal of catheter with a specialist nurse. Service User D was placed on the waiting list for a TURP. A normal PSA result (2.79 ng/l) was noted.

On 19 June 2019 Service User D underwent a TURP. The procedure notes describe the prostate tissue as having "endoscopic appearances of prostatic carcinoma". Histology confirmed adenocarcinoma (Gleason score 5+5) in 90% of the resected tissue. His case was discussed at MDM on 25 July 2019 who noted there was no evidence of metastases on a CT abdomen and pelvis. It recommended a CT scan of chest and a bone scan to check for spread outside the prostate. Further, a LHRH agonist as ADT should be commenced. In August 2019 a bone scan and CT scan were requested together with an ultrasound scan of the urinary tract to assess bladder emptying. Doctor 1 prescribed Bicalutamide (50mgs once daily), in order to 'assess its tolerability in a generally frail man' and in the 'light of the low presenting PSA'.

The Review Team could not locate any record in the medical notes of a digital rectal examination being performed at any point during this patient's medical treatment. This may well have provided evidence to support the malignant nature of the prostate gland prompting a swifter biopsy.

The patient was discussed at MDM on 25 July 2019 when the recommendation for ADT (a LHRH analogue) was made. He should have been started on this hormonal therapy to achieve "castration testosterone levels" as soon as the diagnosis of poorly differentiated prostate cancer was made. Instead he was started on an inadequate dose of a drug (bicalutamide) which was not licensed for the treatment of prostate cancer and was contrary to the recommendations at MDM. This therapy was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines (2016) which were signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Team, as their standard of care for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional

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5.0 DESCRIPTION OF INCIDENT/CASE

chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. There was no evidence in the medical notes or from speaking with Service User D's family of informed consent to this alternative care pathway.

Service User D should have been referred to an oncologist to at least allow consideration of other treatment options. His care was not coordinated with the palliative care team. The diagnosis of possible metastasis which would not have changed best practice was nevertheless pursued in a dilatory fashion. The Review Team suggested that when the patient developed anaemia consideration should have been given to the possibility of this being due to malignant involvement of the bone marrow, rather than an effect of severe chronic disease.

The Review Team noted that Service User D's case was not brought back to MDM for rediscussion and multi-disciplinary input despite disease progression.

Service User E

Service User E was diagnosed with testicular cancer. His case was discussed at MDM.He attended for CT chest, abdomen and pelvis on 9 July 2019 which indicated no evidence of metastases (cancer spread). The following day the patient had a left inguinal orchidectomy (removal of left testicle and full spermatic cord) carried out. Pathology of the resection specimen found that the tumour was a classical seminoma measuring 2.6cm across. Although the tumour was confined to the testes, it did involve the rete testis (exit tubules from the testis) and , in addition, intratubular germ cell neoplasia was seen. These findings indicate an increased risk of spread. Service User E's case was discussed at the Urology MDM on 25 July 2019. The plan was for Doctor 1 to review the patient in outpatients and refer him to oncology.

The patient was reviewed on 23 August 2019 and it was noted that Servicer User E had an uncomplicated recovery and his operative wound had healed satisfactorily. It was agreed that he would be reviewed in SWAH again in February 2020 by Doctor 1 to determine if the patient wished to have a testicular prosthesis implanted. The referral to oncology was made on 25 September 2019.

Although, this presentation was unusual, the progress of the patient's investigation and treatment up to the orchidectomy was of a high standard. However, the 2 month delay in his referral to a Medical Oncologist complicated treatment choices. Whether this will compromise the long-term outcome is uncertain as this treatment is recommended to be given within 6 weeks as per the designated protocol.[1,2,3]

The Review Team acknowledge that there is limited oncology presence within the Urology MDT and the date when the patient's case was discussed there was no oncologist present.

The vast majority of the Urology MDMs within the Southern Trust are non-quorate due to the absence of an oncologist and does not meet the existing guidelines. (0% quorate for 2019).

Whilst it was the primary responsibility for the consultant in charge to make the referral to oncology a failsafe mechanism to ensure agreed actions took place, such

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5.0 DESCRIPTION OF INCIDENT/CASE

as an MDM administration tracker, was not in place.

Alternatively, the allocation of a Urology Cancer Specialist Nurse as a Key Worker would have supported the patient on his journey as well as having ensured key actions had taken place. Service User E was not referred to a Urology Cancer Nurse Specialist nor was any contact details provided to him. The MDM guidelines indicate "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner"[(4)]. This did not happen. A Key Worker/ Urology Cancer Nurse Specialist would have prompted the oncology referral sooner.

Service User F

Service User F presented with possible prostate cancer and was commenced on bicalutamide 50mgs indefinitely or until biopsy results were available. The diagnosis of prostate cancer was confirmed by biopsy in July 2019. The patient was discussed at the MDM on 8 August 2020. The diagnosis of intermediate-risk organ confined prostate cancer was agreed. The plan was that Doctor 1 should review the patient and discuss management by surveillance or by active treatment with curative intent.

When Service User F was reviewed by a locum consultant in October 2020 the patient did not recall any conversation about the options of external beam radiotherapy (EBRT) as a radical treatment and Active Surveillance. A Urology Cancer Nurse Specialist was appointed as the Key Worker at this review, not having one at time of diagnosis.

Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment. Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer.

The presence of a Urology Cancer Nurse Specialist would support the patient on his journey as well as working collaboratively with the multidisaplinary team to ensure key actions had taken place. Service User F was not referred to a Cancer Nurse Specialist. This is in contrast to declaration for Cancer Peer Review 2017 "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner" [(4)]. This did not happen.

Service User G

Service User G was diagnosed in June 2016 with a renal mass measuring 2.5 cms in diameter on the anteromedial cortex of the lower pole of the left kidney. The case was presented to MDM in July 2016, and the recommendation was for active surveillance with interval CT scans. These were carried out at the scheduled times.

On 23 August 2018 his case was discussed at MDM. The July 2018 scan was reviewed and now showed the lesion to measure 3.0cm. The MDM recommended to review and discuss with the patient the options of continuing active surveillance or

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5.0 DESCRIPTION OF INCIDENT/CASE

open partial nephrectomy. The case was to be discussed at the Regional Small Masses MDM.

On 28 March 2019 at MDM the renal mass was noted to be enlarging. A further recommendation for Dr 1 to discuss the options of laparoscopic radical nephrectomy versus continued surveillance with its attendant risks was made.

On 29 March 2019 the patient was reviewed by a Locum Consultant Urologist. It was noted that the patient had a 3.1cms left sided kidney mass since July 2018 and this mass was increasing slowly in size. It was noted that the CT would be repeated in November 2019.

On 13 November 2019 a CT scan was performed which showed a further increase in size of lesion to 3.5 cms. No action was taken.

The overall progress of this patient's management was, on balance, acceptable even though the result of the November 2019 CT scan was not acted on.

The Regional Small Renal Mass MDM was developed to oversee the management of this group of patients. An appropriate referral to this group was omitted, despite the MDM's recommendation on at least two occasions.

The patient was reviewed in 29 March 2019 by locum consultant who appears not to have had an update from the MDM held on 28 March 2019.

The patient underwent laparoscopic radical nephrectomy on 25 November 2020 and was discharged on 27 November 2020 with a planned follow up. On 15 January 2021 Dr. 5 reviewed Service User G. He was noted to be doing well. Histopathology confirmed the left kidney mass was pT1a grade 3 papillary carcinoma (mixed oncocytic and type 2) kidney cancer. A plan for CT chest abdomen and pelvis in 12 month was agreed.

Service User H

Service User H was diagnosed with penile cancer. The pathology confirmed squamous cell carcinoma of the prepuce. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease, at presentation and subsequently.

The MDM was a virtual meeting conducted by a single urologist. Its plan was that Doctor 2 would review the patient and arrange for a CT scan of the Service User's chest, abdomen and pelvis to complete staging. The CT scan (26 July 2019) showed a single enlarged, left inguinal lymph node measuring 1.3cms in its short axis. Otherwise, there was no evidence of metastatic disease.

At the MDM of 12 September 2019 it was agreed that the Service User H should undergo a left inguinal lymphadenectomy. There does not appear to have been any discussion regarding the referral of Service User H to a supra-regional penile cancer MDT.

The Review Team found that the MDM recommendations did not follow NICE

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5.0 DESCRIPTION OF INCIDENT/CASE

guidance for the management of penile cancer [6,7,8] and that there was an opportunity at each meeting to intervene and question Service User H's management.

The treatment provided to this patient was contrary to the NICAN Urology Cancer Clinical Guidelines (2016) for Penile Cancer where it states that local care is restricted to diagnosis. This Guidance was adopted by the SHSCT Urology MDT and evidenced by them as their protocols for cancer peer review 2017. Dr 1 was chair of the NICAN Urology Tumour Speciality Group when the guidance was issued.

The initial clinical assessment of Service User H would have benefited from staging imaging either before or immediately after the original circumcision. All cases of penile cancer should be discussed by the supra-network MDT as soon as the diagnosis is confirmed by biopsy.

The clinical stage G2 pT1 should have led to a consideration of surgical staging with either a bilateral inguinal lymph node dissection (ILND) or sentinel node biopsy (SNB). This omission reduced the likelihood of Service User H's 5 year survival from 90% to less than 40%. The left ILND yielded only 5 nodes, which might be considered at the lower limit of that expected in experienced hands.

The consent form signed by the surgeon and patient is inadequate as it does not state the rationale for the procedure nor the potential complications. The timings between the steps in treatment and management were unduly long and failed to the show the urgency needed to manage penile cancer.

Service User I

Service User I was seen on 27 October 2014 with lower urinary tract symptoms that continued despite medical treatment. Doctor 1 discussed options with Service User I and he decided to proceed to surgery (TURP).

A letter dated 11 November 2016 Service User I's General Practitioner asked for Service User I TURP to be expedited.

The Patient underwent TURP on 29 January 20 and histology confirmed prostatic adenocarcinoma.

Collation of Multidisciplinary meetings should have a fail-safe whereby lists of all urological cancers by site and SNOMED code are generated weekly. This system was not in place.

Although Doctor 1 planned to review the patient in April 2020, he was not seen until August 2020 at an appointment arranged by another doctor who has continued care. The patient had done well following his TURP. The histology was explained as an incidental finding that required continuing surveillance with an up to date serum PSA level and a prostate MRI scan.

Service User I was informed on 9 September 2020 that the serum PSA level was within the normal range and that the MRI scan did not show any features of prostate cancer. The prostate cancer was considered unlikely to represent a threat during the patient's life expectancy and would not be anticipated to require any treatment other

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5.0 DESCRIPTION OF INCIDENT/CASE

than surveillance with PSA monitoring.

6.0 FINDINGS

Diagnosis and Staging

- 5 of the 9 patients in this review experienced significant delay in diagnosis of their cancer. This was related to patients with prostate cancer and reflected variable adherence to regionally agreed prostate cancer diagnostic pathways, NIACN Urology Cancer Clinical Guidelines (2016).
- Service User B had a delay of over 15 months from presentation.
- The review team could not find evidence of a Digital Rectal Examination in the notes of Service User D - potentially missing an opportunity to detect his high grade cancer earlier in his pathway.
- Service User F had a slow initial diagnostic pathway which was outside expected cancer care time-frames.
- Service User C had a delayed diagnosis of a metastatic prostate cancer following successful treatment of Renal Cancer. This was due to non-action on a follow-up CT scan report.
- Patient I had a delayed diagnosis of Prostate cancer due to non-action on a histopathology report at TURP.
- Patient H with penile cancer had a 5 week wait between referral and first appointment. Subsequent time to diagnosis and MDM were appropriate. He had a 17 week wait for a CT scan for staging.
- Service User G was on a renal mass surveillance programme - a recommendation at MDM to discuss his case with the regional small renal lesion team was not actioned and it is not known if they would have suggested earlier intervention.

Targets

- Three of the nine patients were said to have met one of their 31 / 62 day targets.
- Service User I was said to have met his diagnostic target for 31 days despite his tissue cancer diagnosis being missed and the patient suffering an 8 month delay.
- Service User H was said to have met his 62 day (1st treatment) target but had been referred down a pathway that did not meet the NICAN Urology Cancer Guidelines 2016. A regional Penile Cancer Pathway was agreed in January 2020.
- Service User B was said to have met his diagnostic target of 31 days despite having a delay from initial presentation of 15 months.

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6.0 FINDINGS

Multidisciplinary Meeting

- The MDM made appropriate recommendations for 8 of the 9 patients but there was no mechanism to check actions were implemented - this included, further investigations, staging, treatment and appropriate onward referral.
- Dr 1 was present for the discussions and party to the recommendations, 8 of which were compliant with National and Regional Guidelines.
- In the case of the 5 patients with Prostate cancer, 5 patients were referred to the Multidisciplinary Meeting and had appropriate MDM recommendations.
- Service User A and Service User D to start Androgen Deprivation Therapy with LHRHa while Service User F was advised to have active surveillance or curative intent radiotherapy. None of these recommendations were implemented.
- NICAN Regional Hormone Therapy Guidelines for Prostate cancer 2016 were not followed.
- Service User B had a delayed diagnosis of prostate cancer and was belatedly seen at the Urology MDM 15 months after his first presentation. The recommendations from this MDM were correct but not implemented. Regional NICAN Hormone Therapy Guidelines for Prostate Cancer 2016 were not followed
- Service User I had an unexpected diagnosis of cancer at TURP. His diagnosis on pathology report was not actioned and he was discussed at MDM 8 months after his surgery and pathological diagnosis of cancer. His subsequent MDM recommendations were correct.
- Two patients had renal cancer. Service User C was initially appropriately discussed at MDM with action on recommendations. However a routine CT scan in December 2019 was not actioned, leading to a delayed re-presentation to MDM with a second primary diagnosis of metastatic prostate cancer.
- Service User G was on a surveillance pathway for a small renal lesion he was appropriately discussed at MDM. The meetings were not always quorate but a radiologist was present on 4 out of 5 occasions. An MDM recommendation to seek input from the regional small lesion group was not actioned.
- Service User E had a testicular tumour and was appropriately discussed at MDM with the recommendation onward referral to the regional testicular oncology team. This recommendation was time critical but did not happen.
- Service User H was appropriately discussed at the local MDM at diagnostic stage. Unfortunately his treatments and further discussions were restricted to local level and did not meet the NICAN Urology Cancer Guidelines 2016. Service User H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 and, although a Regional Penile Cancer Pathway was only agreed in January 2020, referral to a specialist with appropriate experience should have been pursued.
- Collation of MDM lists did not include a fail-safe list from histopathology. This would ensure all tissue diagnoses of cancer were cross checked against clinician declared cases. This would capture unexpected cases of cancer as in

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6.0 FINDINGS

case I or as in case B where a delayed diagnosis presented to the GI surgeons for initial biopsy.

- The patient's care was through a Multidisciplinary Team process but unfortunately they did not benefit from it. The Multidisciplinary Meeting failed in its primary purpose to ensure patients received best care as defined by Regional and National Guidelines.
- The Urology MDM was under resourced and frequently non quorate due to lack of professionals. The MDM had quorate rates of 11% in 2017, 22% in 2018 0% in 2019 and 5% in 2020. This was usually due to lack of clinical oncology and medical oncology. Radiology had only one Urology Cancer Specialist Radiologist impacting on attendance but critically meaning there was no independent Quality Assurance of images by a second radiologist prior to MDM.
- The Urology MDM was under resourced for appropriate patient pathway tracking. The Review Team found that patient tracking related only to diagnosis and first treatment (that is 31 and 62 day targets). It did not function as a whole system and whole pathway tacking process. This resulted in preventable delays and deficits in care.
- Safe cancer patient care and pathway tracking is usually delivered by a three pronged approach of MDT tracking, Consultants and their Secretaries and Urology Specialist Nurses, in a Key Worker role. The Review found that these 9 patients were not referred to Specialist Nurses and contact telephone numbers were not given. Therefore the CNS were not given the opportunity to provide support and discharge duties to the 9 patients who suffered as as consequence. The MDM tracking system was limited. The consultant / secretary led process was variable and resulted in deficits. The weakness of the latter component was known from previous review.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non implementation of these MDM recommendations was unknown to others in the MDM. One patient D presented as an emergency and his care was changed to the MDM recommendation by another consultant.

Multidisciplinary working and referral

- The review team noted repeated failure to appropriately refer patients
- Service User A should have been referred to oncology initially and then to palliative care as his disease progressed.
- Service User B should have had an earlier diagnosis and referral to oncology.
- Service User D should have been referred to oncology and palliative care.
- Service User E should have been referred to oncology for time critical care.
- Service User F should have been referred to oncology.
- Service User G should have been referred to the Small Renal Mass Team.
- Service User H should have been referred to the Regional / Supra-

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Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 but a Regnional Penile Cancer Pathway was only agreed in January 2020. Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 and, although a Regional Penile Cancer Pathway was only agreed in January 2020, referral to a specialist with appropriate experience should have been pursued.

- Patients were not aware that the care given varied from Regional Standards and MDM recommendations. They could not have given informed consent to this.
- All patients were not referred to Urology Cancer Nurse Specialists despite this resource being increased by the Southern Health and Social Care Trust. Peer Review 2017 was informed that this resource was available to all. Their contact numbers were not made available.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non referral was an unknown to others within the MDM.

Patient Support and Experience

All patients or families reported a positive experience with their treating consultant initially.

All patients and families were unaware of the additional support available to other patients.

Where patients had disease progression, they expressed concern at the disjointed nature of service provision and the inability to access supportive care. As they were unaware of the normal support mechanisms they believed this to be the normal standard of care or a standard that had been compromised by Covid 19 Pandemic.

All patients and their families were shocked by the fact that their care was not supported and that the care did not follow MDM recommendations. This was especially true when appropriate care should have entailed onward referral to oncology or palliative care.

Affects of Covid

- Some patient's planned review appointments did not go ahead but were rescheduled virtually. Some of the patients did not have their planned review in March / April 2020.

- The review team after speaking with the families and hearing their stories learned that for many of these patients they could not access services in their locality due to the covid restrictions. At the time two families described having difficulty accessing district nursing services for intravenous antibiotics in the community as services were stood down. One family expressed dismay at having difficulties visiting their loved one prior to his passing in hospital due to

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the covid restrictions and the emotional impact this has had on their grieving process. Others described how when catheters blocked they could not access support from their GP and where hence referred to the Emergency Department which the review team agree was not the best place for them. The review team are of the opinion that access to a specialist nurse could have offered support for these families and provide direction to the appropriate services.

Governance / Leadership

- The review team considered the treatment and care of 9 patients who were treated under the care of Dr 1 Consultant Urologist. Individual reviews were conducted on each patient. The review team identified a number of recurrent themes following each review.
- The treatment provided to 8 out of 9 patients was contrary to the NICAN Urology Cancer Clinical Guidelines (2016). This Guidance was adopted by the Southern Health and Social Care Trust Urology Multidisciplinary Team and evidenced by them as their protocols for Cancer Peer review (2017). The Guidance was issued following Dr.1 & Chairmanship of the Northern Ireland Cancer Network Urology Cancer Clinical Reference Group.
- The Urology MDM made recommendations that were deemed appropriate in 8 of 9 cases and were made with contribution and knowledge of Dr.1. Many of the recommendations were not actioned or alternative therapies given. There was no system to track if recommendations were appropriately completed.
- The MDT guidelines indicate “all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner”. None of the 9 patients had access to a Key Worker or Cancer Nurse Specialist. The use of a CNS is common for all other urologists in the SHSCT urology multidisciplinary team allowing any questions or concerns that patients’ have to be addressed. This did not happen.
- The review team considered if this was endemic within the Multidisciplinary Team and concluded that it was not. Patients booked under other consultant urologists had access to a specialist nurse to assist them with their cancer journey.
- Statements to Urology Cancer Peer Review (2017) indicated that all patients had access to a Key worker / Urology Cancer Nurse Specialist. This was not the case and was known to be so.
- The Urology Cancer Nurse Specialist play an integral role of the MDT and should be facilitated on all the MDM to advocate on patient’s best interest throughout the patient’s journey. This should include independently referring and discussing patients at MDT.
- The Review Team regard absence of Specialist Nurse from care to be a clinical risk which was not fully understood by Senior Service Managers and the Professional Leads. The Review team have heard differing reports around escalation of this issue but are clear that patients suffered significant deficit because of non inclusion of nurses in their care. While this is the primary

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responsibility of the referring consultant, there is a responsibility on the SHSCT to know about the issue and address it.

- Assurance audits of patient pathways within the Urology Cancer Services were limited between 2017 and 2020. They could not have provided assurance about the care delivered.
- Because of resource, the MDM was very focused on first presentation at MDM and did not have a role in tracking subsequent actions if it lay outside 31 and 62 day targets. Tracking of patients was flawed by limitations within the MDM systems and the lack of Specialist Urology Nurses from their Key Worked role. Two of the three normal safety nets for patient pathway completion were,in essence absent. A collaborative approach did not appear to be actively encouraged within the MDT.
- Annual business meetings had an expressed role in identifying service deficits and drawing up an annual work plan to address them. Cancer Patient Pathway compliance audits were limited and did not identify the issues within this report.
- Governance of professionals within the MDT ran through their own directorates but there was no functioning process within Cancer Services to at least be aware of concerns - even if the responsibility for action lay elsewhere within the Southern Health and Social Care Trust. There was disconnect between the Urology MDT and Cancer Services Management. The MDT highlighted inaction by Cancer Services on Oncology and radiology attendance at MDM, but did not escalate other issues.
- The Review team found that issues around prescribing and the use of Clinical Nurse Specialists were of long standing. They were known internally and in the case of prescribing externally (Regional Oncology Services). The Northern Ireland Cancer Network drew up specific Guidance on Hormonal Therapy in Prostate Cancer in 2016 following concerns about this issue. The Guidance was not subject to audit within the Southern Health and Social Care Trust.
- The Review team were concerned that the leadership roles focused on service delivery while having a limited process to benchmark quality, identify deficiencies and escalate concerns as appropriate. Senior managers and clinical leaders in medicine and nursing were unaware of the issues detailed in this report.
- There had been a previous SAI signed off in May 2020 regarding adherence to Cancer Red Flag referral Pathways. The SAI process started in July 2016. The review team is concerned that, as part of early learning, assurances regarding other aspects of the cancer pathway were not sought. Clinical Leadership within Cancer Services were unaware of issues leading to the SAI in 2016.
- Patients in this review were not referred back appropriately to MDM as their diseased progressed. This meant there was no access to oncology and palliative care for many patients, when needed. Care needs within the community were unmet and patients left isolated.

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7.0 CONCLUSIONS

The Review Team would like to thank the patients and their families for their contribution to the report and their willingness to share their experiences. The process was difficult and at times traumatic for them.The review team acknowledge that this report may cause distress to the patient and their families, however the team has endeavoured to produce a complete and transparent account of each patient's journey.

The Review of nine patients has detailed significant healthcare deficits while under the care of one individual in a system. The learning and recommendations are focused on improving systems of multidisciplinary care and it's governance. It is designed to deliver what was asked of the Review Team by patients and families -" *to ensure that this does not happen again or that another patient suffers".*

The Patients in this review received uni-professional care despite a multidisciplinary resource being available to all others. Best Practice Guidance was not followed and recommendations from MDM were frequently not implemented or alternative treatments chosen. There was knowledge of that prescribing practice varied from regional and national guidelines in the Southern Health and Social care Trust, as well as more widely across the Cancer Network. This was challenged locally and regionally, but not effectively, to provide safe care for all patients. Inappropriate non referral of patients to oncology and palliative care was unknown.

The primary duty of all doctors, nurses and healthcare professionals is for the care and safety of patients. Whatever their role, they must raise and act on concerns about patient safety. This did not happen over a period of years resulting in MDM recommendations not being actioned, off guidance therapy being given and patients not being appropriately referred to specialists for care. Patients were unaware that their care varied form recommendations and guidance. They could not and did not give informed consent to this.

The systems of governance within the Urology SHSCT Cancer Services were ineffective and did not provide assurance regarding the care and experience of the nine patients in the review. Assurance audits were limited, did not represent whole patient journey and did not focus on areas of known concern. Assurances given to Peer review were not based on systematic audit of care given by all.

While it is of little solace to the patients and families in this review, The Review team sought and received assurances that care provided to others adhered to recommendations on MDM and Regional / National Guidance.

Four of the nine patients suffered serious and significant deficits in their care. All patients had sub-optimal care that varied from regional and national guidelines.

As part of the Serious Adverse Incident process, the Review Team had requested input fromDr 1. This related to the timelines of care, for the nine patients involved in the SAI reviews and specifically formed part of the root cause analysis. This fell under professional requirements to contribute to and comply with systems to protect patients and to respond to risks to safety. To date a response has not been received.

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8.0 LESSONS LEARNED

The review identified Cancer Care given by Dr 1 that did not follow agreed MDM recommendations nor follow regional or national best practice guidance. It was care given without other input from Cancer Specialist Nurses, Oncology and palliative care. It was inappropriate, did not meet patient need and was the antithesis of quality multidisciplinary cancer care.

Ensure all patients receive appropriately supported high quality cancer care irrespective of the professional delivering care.

Ensure all cancer care is multidisciplinary and centred on patients physical and emotional need.

Have processes in place to provide assurances to patients and public that care meets these requirements.

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

9.0 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 and ongoing

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

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9.0 RECOMMENDATIONS AND ACTION PLANNING

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 and ongoing

Assurance - Comprehensive Cancer Pathway audit and Patient experience.

Recommendation 3.

TheSHSCT 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 in a collatorative and equal culture.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 monthly agenda. There must be action on issues escalated.

Timescale – Immediate and ongoing

Assurance - Numbers of issues raised through Cancer Services, Datix Incidents identified, numbers of issues resolved, 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 and ongoing

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

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9.0 RECOMMENDATIONS AND ACTION PLANNING

pathway assurance. This should be supported by a safety 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 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, 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 and ongoing

Assurance - Variance from accepted Care Guidelines and MDM recommendations

should form part of Cancer Pathway audit. Exception reporting and escalation would

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9.0 RECOMMENDATIONS AND ACTION PLANNING

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.

Timescale - 3 months

Recommendation 10.

The families working as "Experts by Experience" have agreed to support implementation of the recommendations by receiving updates on assurances at 3, 6 and 12 monthly intervals.

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.

References:

1. Hoffmann, R., et al. Innovations in health care and mortality trends from five cancers in seven European countries between 1970 and 2005. Int J Public Health, 2014. 59: 341.
2. Oliver, R.T., et al. Radiotherapy versus single-dose carboplatin in adjuvant treatment of stage I seminoma: a randomised trial. Lancet, 2005. 366: 293.
3. Laguna M.P., et al EAU Guidelines: testicular cancer. https://uroweb.org/guideline/testicular-cancer/note_127-129 (accessed 26/02/2021)
4. Peer review Self-Assessment report for NICaN 2017
5. Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016)
6. EAU guidelines for penile cancer: section 6.2.1 (2019)
7. NICE improving outcomes in urological cancer (2002)
8. NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 (3).

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9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

Mr Shane Devlin – Chief Executive SHSCT

Mrs Melanie McClements – Director of Acute Services SHSCT

Dr Maria O'Kane – Medical Director SHSCT

Mrs Heather Trouton Executive Director of Nursing, Midwifery and AMPs

PHA

HSCB

DRAFT

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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:	Personal Information redacted by the USI	**HSCB ref Number:**	Personal Information redacted by the USI

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**		**Multiple Service Users***	x	**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**		**NO**			
	If **YES**, insert **date informed**:					
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being 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**	x	**NO**	
	If **YES**, insert date informed: **all informed 26 October 2020**			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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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)

Continued overleaf	**d)** No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

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

SECTION 2

INFORMING THE 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**	
	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**	
	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**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Received from SHSCT on 28/09/2022. Annotated by the Urology Services Inquiry.

A. Well, obviously we've got additional tracking resource. We have highlighted the gaps in tracking for a number of years, again to the Health and Social Care Board. We put in bids for additional resource because our numbers had significantly increased from when cancer trackers were first appointed. So, we now have got recurrent funding, and the numbers have expanded of trackers, which is good, and tracking is more often up-to-date than not, which is positive. 11:55

146 Q. Is there anything else you'd like to add at this point to your evidence that perhaps I have not covered, I have not taken you to, or is there a point you'd like to make or any evidence you've heard that you do not agree with? 11:56

A. Well, I suppose we did do a lot of work across the region and developed a cancer strategy for the first time in many years, and the report came out in 2022. That does highlight a lot of the inefficiencies and things that we've talked about throughout this process, and obviously a lot of the improvements that we need to make across Cancer Services in the future, right from, you know, sending out health promotion messages right through when patients are diagnosed, their treatment and life after cancer. I think there's a lot of need for resources -- you know, for services to be properly resourced to fully meet the needs of cancer patients going forward. 11:56 11:56

147 Q. Just finally, does Urology still sit outside your remit?

SAIs about a result known to the pathology lab that there was a confirmed cancer, but not then known to the MDT, but was known to the clinician, that is Mr. O'Brien, but not actioned, so that the case sat with a positive cancer result and there was delay in follow-up. Is that the mischief that this arrangement, a cross-check mechanism with the laboratory, is designed to address? 15:15

A. Yes. So the MDT process requires someone to initiate the addition of the patient to the MDT. For Urology, there's an electronic form for that MDT addition. That cross-check is so that if there is a patient with a cancer on biopsy who has not been added to the MDT by the clinician, that patient will be brought to the MDT. 15:16

133 Q. Thank you for that. 15:16

Overall, taking into account your experience of working within this MDT before 2020 and knowing the environment now in light of these changes, how would you characterise the improvements? Has there been meaningful progress and is it a safer environment for your patients? 15:17

A. I think there has been significant progress. It's a safer environment for patients. It's also an environment where we as clinicians feel safe. We know that there are processes to make sure that everything is happening as it should be. 15:17

134 Q. Can I turn to some other clinical aspects that captured the attention of the Panel through the evidence. There

units.

318 Q. It's come out of this, hasn't it?

A. It's really good work from the teams.

319 Q. Presumably looking at that now as you look back on those nine SAIs, those recommendations, everything that's happened, and you reflect on the general issue of action plans and SAIs, you perhaps realise a bit more that there's a huge problem in actually embedding this. 15:31

A. Yeah. 15:31

320 Q. Do you think the Trust has made progress on that in a general way, because this isn't really just about Urology governance, is it, it's about learning from error?

A. I think it unnerved a lot of people at the start when they knew we picked up a range of issues aligned to one consultant, thinking over the sort of initial stages. Then there was a realisation, no, this isn't about one person -- 15:32

321 Q. No. 15:32

A. -- this is about a system --

322 Q. Yes.

A. -- and this is about how we govern. I think that whetted their appetite because they knew as Divisional Medical Directors or Clinical Directors or Assistant Directors, they needed to be part. That Task and Finish group, for example, had every division, every specialist practice built in in that, which was really good. It moved then from that place of being unnerved, 15:32

Southern Health and Social Care Trust

Lessons Learned Forum – Terms of Reference

Date: 13th November 2017

Background:

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

The Trust is committed to quality improvement, and will continue its strong focus on delivering high quality, safe and effective services. The Trust Lessons Learned forum will assist in the identification, sharing and appropriate risk mitigation of areas of concern

Purpose / Role of the Group:

- To provide a formal corporate cross directorate interface for the identification and sharing lessons learned from **adverse incidents, complaints** and **litigation cases**, internal to the Trust, regional and national.
- To identify areas for improvement regarding Trust adverse incident and complaints management and if appropriate, propose system changes
- To provide challenge and scrutiny to Trust adverse incident processes

Membership:

Trust Members

- Medical Director (Chair)
- Assistant Director Clinical and Social Care Governance
- Associate Medical Directors
- Directorate Governance Coordinators
- Assistant Director Professional Lead Social Work and Care
- Assistant Director Professional Lead Nursing Governance
- Operational Assistant Directors as nominated by Directors
- Project Manager Clinical and Social Care Governance
- Governance Officer, Clinical and Social Care Governance

External Members

- Patient and Public Involvement Representative
- Public Health Agency Representative

Accountability:

- Forum members will be responsible for presenting potential sharing lessons learned from their service areas
- Forum members will assist in sharing information on Lessons Learned from the Forum with their respective service areas

Review:

- Terms of reference for the group will be reviewed annually

Meeting Format:

- Meetings held on a quarterly basis (3 meetings per year)
- Chaired by Medical Director
- Initial Standard format agenda (See appendix A)
- Papers will be circulated 5 working days prior to meeting date via email
- Additional members or presenters will be invited as dictated by the Forum Chair

Confidentiality:

- Lessons Learned will be anonymised and confidential information removed.

DRAFT

Southern Health and Social Care Trust

Lessons Learned Forum
16th January 2018

Meeting Room, Trust Headquarters CAH videolinked Clanrye House Meeting Room DHH

Present: Dr Richard Wright, Margaret Marshall, Tony Black, Marita Magennis, Claire McNally, Dr Jeffrey Brown, Trudy Reid, Dr Ahmed Khan, Dr S Tariq, Dr David McCaul, Stephen Wallace

Apologies: Dr Lauren Megahey

ITEM	NOTE	*ACTION*
1.0	**WELCOME** Margaret Marshall welcomed attendees to the meeting explaining the purpose of the meeting and the proposed frequency of meetings.	
2.0	**MEMO FROM DR WRIGHT** Dr Wright explained that the Trust Senior Management Team has given approval for the Trust Adverse Incident Groups terms of reference to be reviewed and repurposed as the Trust Lessons Learning Forum. Dr Wright referenced that the Trust currently operates several cross-directorate forums and groups that either deal with specific areas for learning (e.g. falls prevention) or more general learning at directorate level(e.g. Morbidity and Mortality meetings) and he wishes to strengthen the corporate lessons learned arrangements.	
3.0	**TERMS OF REFERENCE** Dr Wright asked forum members to review the terms of reference and provide any comments for the next forum meeting	***Forum members to review Forum Terms of Reference***

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

4.0	**TEAM MEMBERSHIP** Dr Wright asked those present to review the list of forum members and consider if other staff from their directorates / areas of responsibility should be considered to join the forum	***Forum members to review membership list***
5.0	**LESSONS LEARNED AGENDA** The group discussed the format of the agenda and felt there may be merit in having a 'themed' approach each quarter to Lessons Learned could assist in focusing the forum approach to distilling lessons learned for wider circulation The group agreed that in the first instance a Non-Executive Director should be invited to attend to provide external input and views to the forum	***NED to be invited to join Forum membership***
6.0	**COMMUNICATION OF LESSONS LEARNED** The group considered approaches to communication of lessons learned and agreed that sample lessons should be discussed at the next meeting to consider methods for targeting specific groups who will benefit most.	***Sample Lessons Learned to be presented at next meeting***
7.0	**ANY OTHER BUSINESS** None declared	
8.0	**DATE AND TIME OF NEXT MEETING** Friday 27th April 2018 10:30, Old Staff Room, College of Nursing, Ground Floor Trust HQ	

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

PROPOSAL FOR STRUCTURED CLINICAL RECORD REVIEW
DRAFT V1 - 17th February 2021

Background

1. On the 23rd November 2021 the Minister for Health gave direction for the initiation of a Public Inquiry regarding the Clinical Practice of Mr Aidan O'Brien, Consultant Urologist.

2. Although yet to be developed, the terms of reference for Public Inquiry will consider Mr O'Brien's practice across all of his clinical activity. This will likely include reviews involving individual patient cases where a potential adverse outcome was identified.

3. While ensuring that the work of the Public Inquiry is not disrupted or delayed, in the interests of maintaining patient safety it remains incumbent on the Trust to ensure that where potential patient safety incidents are identified, a proportionate patient safety review should take place to inform learning and develop safer systems in a timely manner.

4. Remaining cognisant of regional parameters and requirements for the identification, review and learning from Adverse and Serious Adverse Incidents (SAI) as set out in the HSCB *Procedure for the Reporting and Follow up of Serious Adverse Incidents (November 2016)* the Trust has sought to provide an alternative, proportionate and robust review structure that can be utilised to review SAI's in a timely manner.

5. Any patient safety review process will function and report within the existing clinical governance arrangements for the Trust and as such be subject to quality assurance processes and an appropriate level of scrutiny.

Title of Review Structure

6. The Trust is mindful that any proposed alternative review structure should be demarcated clearly as different to the SAI process. It is therefore important that for clarity for service users, staff and the public that the title should articulate this clearly.

Proposal 1 – The name of the review mechanism will be titled STRUCTURED CLINICAL RECORD REVIEW (SCRR)

Underpinning Review Methodology

7. To ensure confidence in the SCRR process an adoption of a robust and validated method will be required. To this end, the Trust has spoken to the Royal College of Physicians with a view to adapting the underpinning principles and methodology found in the Structured Judgement Review (SJR) Process.

8. The Royal College of Physicians SJR combines clinical-judgement based review methods with a standard format. The format requires reviewers to make safety and

quality judgements over phases of care, to make explicit written comments about care for each phase, and to score care for each phase.

9. As an outcome of the SJR the result is a short but rich set of information about each case in a form that can also be aggregated to produce knowledge about clinical services and systems of care.

10. The objective of the SJR method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about the hospital systems where care goes well, and to identify points where there may be gaps, problems or difficulty in the care process.

11. In order to answer these questions, there is a need to look at: the whole range of care provided to an individual; holistic care approaches and the nuances of case management and the outcomes of interventions.

12. The Trust proposes developing an adapted form from the base Royal College of Physicians SJR template and seeking Royal College of Surgeons agreement. The Trust envisages that the tool will be developed in two sections to consider both inpatient and outpatient care provided.

Proposal 2 – The underpinning methodology will be based on the Royal College of Physicians Structured Judgement Review tool

Identification of Cases for Structured Clinical Record Reviews

13. The inclusion criteria and thresholds for cases in the SCRR process will remain in keeping with those set out in the HSCB *Procedure for the Reporting and Follow up of Serious Adverse Incidents (November 2016)* with particular reference to section 4.2 of the document which outlines the following specific criteria:
    - Serious injury to, or the unexpected/unexplained death of a service user
    - 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

14. Where appropriate the Trust will continue to screen adverse incidents, complaints and returns from patient record reviews for consideration of inclusion in the SCRR process.

Proposal 3 – The Trust will maintain the same screening criteria, thresholds and processes for SCRR as is currently in place for SAIs

Conducting Structured Clinical Record Reviews

15. The Trust recognises the requirement to conduct SCRR in a timely manner to identify and action learning and system changes as appropriate. In this regard the Trust

proposes engaging the services of an independent Consultant Urologist via the Royal College of Surgeons to conduct the SCRR process who has training, knowledge and experience in applying Structured Judgement Review methodology.

16. To support the process for conducting the SCRR the Trust clinical governance teams will source and share records electronically and support the development of 'timelines' that will support the reviewer in their task completing the SCRR.

Proposal 4 – The Trust will seek to engage an Independent Consultant Urologist Subject Matter Expert to conduct SCRR's and ensure that appropriate clinical governance support is available to facilitate each review

Engaging Patients and Families in Structured Clinical Record Reviews

17. The Trust places paramount importance on the need to fully involve patients and families are engagement in the SCRR process. The Trust recognises that the communication of the SCRR process to patients and families is crucial in terms of setting expectations of outcomes and how this will relate to the work of the Public Inquiry.

18. To support this work the Trust has appointed a dedicated Urology Service User Liaison Officer to communicate and support patients and families who are part of the SCRR process.

19. The outline proposed family engagement strategy is as follows:

    a. Once the requirement for an SCRR is identified, the patient or family is notified via phone-call and then follow up letter informing of the decision to conduct a SCRR. Communication will include details of what the review process is, what the expected outcomes will be and how this process links to the Public Inquiry. The communication will also contain the contact details of the Service User Liaison Officer who can offer individual patient and family support.
    b. The review will be conducted by the independent Consultant Urologist and the judgement and outcomes recorded.
    c. The Service User Liaison Officer will share the report's findings with the patient and family for their review and comment.
    d. The Service User Liaison Officer will return feedback to the Consultant Urologist from the family if received.
    e. A final copy of the SCRR will be shared with the family and arrange any required further follow-up or discussions required with the Trust Urology service.

Proposal 5 – The Trust will utilise the Service User Liaison Model to engage patients and families with set milestones as outlined

Timescales for Completion of Structured Clinical Record Reviews

20. Although to be formally agreed it is expected that each SCRR should be completed within 8 weeks in line with the regional timescales for Level 1 Significant Event Audits..

Proposal 6 – The timescale for completion of each SCRR should be a maximum of 8 weeks

Initiating Learning and Change from the SRCC

21. The Trust will incorporate the learning and findings from SCRR's into existing clinical governance streams. This includes ensuring that:
    a. Where actionable outcomes are identified, these are taken forward to improve services
    b. learning for regional bodies is shared via HSCB
    c. assurance on action closure is provided to the UAG
    d. Where a SRCC identifies the requirement for a more in-depth review, this is flagged for consideration at the Trust and HSCB weekly meeting.

Proposal 7 – The process of learning and change from SRCC will be embedded in Trust clinical governance structures and appropriate escalations for learning and if required further review is considered

DRAFT

TRU-157737

The Regulation and Quality Improvement Authority

RQIA Review of the Urology Structured Case Record Review Southern Health and Social Care Trust

September 2022

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is the independent body responsible for regulating, inspecting and reviewing the quality and availability of health and social care services in Northern Ireland. RQIA's reviews identify best practice, highlight gaps or shortfalls in services requiring improvement and protect the public interest. Reviews are supported by a core team of staff and by independent assessors, who are either experienced practitioners or experts by experience. Our reports are submitted to the Minister for Health and are available on our website at www.rqia.org.uk.

RQIA is committed to conducting inspections and reviews, taking into consideration our four key domains:

- Is care safe?
- Is care effective?
- Is care compassionate?
- Is the service well-led?

Membership of the Expert Review Team

Professor Aneez Esmail	Professor of General Practice (Emeritus), Centre for Primary Care and Health Services Research, University of Manchester
Mr Hall Graham	Professional Advisor, Regulation and Quality Improvement Authority
Dr Leanne Morgan	Clinical Lead, Regulation and Quality Improvement Authority
Mr Brian O'Hagan	Lay Representative and Independent Expert Advisor to the review

Membership of the Project Team

Mr Hall Graham	Professional Advisor, Regulation and Quality Improvement Authority
Helen Hamilton	Project Manager, RQIA
Emer Hopkins	Interim Director of Improvement, RQIA
Dr Leanne Morgan	Clinical Lead, RQIA

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

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Appendix 1: Terms of Reference for the Statutory Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust

Appendix 2: Structured Judgement Review

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Section 1 Introduction

1.1 Background and Context

On 31 July 2020, the Southern Health and Social Care Trust (SHSCT) contacted the Department of Health (DoH) to report an early alert concerning the clinical practice of a Urology Consultant (referred to in this report as Consultant A).

An initial review, which considered cases over an 18-month period of the consultant's work in SHSCT from 1 January 2019 to 30 June 2020, focussed on whether patients had had a stent inserted during a particular procedure and if the stent had been removed within the clinically recommended time frame. The initial review identified concerns with 46 cases out of a total of 147 patients who had the procedure and were listed as being under the care of the consultant during the period addressed by the initial look-back exercise[i]. The findings were significant and led the Minister for Health, Robin Swann MLA, to announce on 24 November 2020 that a statutory public inquiry would be established under the Inquiries Act 2005. The Urology Services Inquiry, which is currently ongoing, is chaired by Ms Christine Smith QC.

In parallel, yet separate, to the work of the public inquiry, SHSCT subsequently established a review group to assess the further findings of the initial review exercise and to explore the need for a further look-back review in the context of additional concerns.

Areas of concern were identified relating to:

- Elective and emergency activity;
- Radiology;
- Pathology and cytology results;
- Patients whose cases were considered in multidisciplinary team meetings;
- Oncology; and
- The safe prescribing of an anti-androgen drug outside established NICE guidance in the management of prostate cancer.

Nine cases were identified that met the threshold for a Serious Adverse Incident (SAI) review. Following the completion of these initial nine SAI reviews in 2021, the Trust was advised by DoH that the SAI process should not be used to review subsequent potential issues in care identified by the lookback process.

As a result, SHSCT developed a Structured Case Record Review (SCRR) process based on the Structured Judgement Review methodology as developed by the Royal College of Physicians. The aim of the SCRR process was to identify any areas of learning where patient safety could be improved.

In March 2022 SHSCT asked RQIA to undertake:

[i] Ministerial Statement by Health Minister to the Northern Ireland Assembly, 24th November 2020

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

- A review of the choice of Structured Judgement Review methodology to underpin their SCRR process.
- A review of the Trust SCRR process in relation to its effectiveness in identifying learning.

It was further agreed that, in the event that the SCRR process was not considered to be appropriate the Trust would like RQIA to suggest an alternative approach.

1.2 Terms of Reference

Although RQIA was requested to review the suitability of the Trust's SCRR process, we considered that the scope of the review should be wider. It would not be appropriate to only assess the tools involved but we should also assess the surrounding process within which the SCRR operates. Therefore the following Terms of Reference were agreed with SHSCT.

1. To assess the suitability of the Structured Judgement Review methodology as the basis for the Trust SCRR process.

2. To assess the specific Trust SCRR methodology in relation to its effectiveness in identifying learning.

3. To assess the overall trust process/framework for conduct of its record review.

4. To make recommendations in relation to the overall process and if the SCRR process is not considered to be appropriate suggest an alternative approach.

1.3 Review Methodology

RQIA used a PRINCE project management approach to underpin this review. The review utilised a range of methodologies to obtain supporting information to inform our assessment:

- We undertook a review of the literature around the use of the Structured Judgement Review Method to help identify key themes and areas of focus.
- We designed and issued structured questionnaires to the Southern Health and Social Care Trust.
- We analysed information returned to us and used this to develop Key Lines of Enquiry for meetings with the Trust.
- Our Expert Review Team (ERT) conducted focus groups and meetings with the independent panel of reviewers, senior staff and other relevant staff from the Trust.
- We analysed the information gathered through our structured pre review questionnaires, meetings, focus groups and staff questionnaire responses in order to determine our key findings and recommendations.

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Section 2 Findings

In assessing the effectiveness of all aspects of the SCRR process we considered the overall process in respect of a number of component parts.

2.1 OVERALL TRUST PROCESS AND FRAMEWORK FOR SCRR

2.1.1 Background to the Structured Case Record Review

The provision of background and contextual information is vital to the understanding of the rationale and purpose of the Structured Clinical Records Review process. This information was provided by SHSCT, in conjunction with a Structured Case Review proposal document and was explored further by the Expert Review Team during fieldwork sessions with Trust representatives.

During fieldwork, the Expert Review Team heard how the Inquiry was announced unexpectedly in November 2020 during what was a difficult time for SHSCT, when it was grappling not just with the emerging issues within Urology Services but also with the COVID-19 pandemic and its associated pressures for service; this contextual information provided the Expert Review Team with a valuable insight into the challenges faced. At the point of announcement of the Inquiry Terms of Reference (see Appendix 1) SHSCT had already commenced a Lookback Review and through this had identified a significant number of patients meeting the threshold for an SAI review under the regional SAI procedure[1].

Due to the volume of patients identified, the time and resource required to progress SAI reviews, and the limited additional value of repeatedly reviewing the same type of incident via the SAI process, it was suggested that an alternative methodology is used to derive learning from these cases. The decision to use the SCRR approach, as an alternative to SAI methodology, was taken in conjunction with SPPG and DoH's Urology Assurance Group. The Expert Review Team considers that this decision was the correct one, and that Structured Judgement Reviews methodology, such as that developed by the Royal College of Physicians, is a robust method of assessing the quality of care and treatment of individual cases, when applied as intended. As such, the Expert Review Team endorses the decision to adopt an alternative approach to undertaking repeated SAI reviews in such circumstances.

Although the decision to proceed with the SCRR was taken prior to the announcement of the Public Inquiry, the Expert Review Team noted that SHSCT continually referenced the SCRR process within the context of their broader work to meet the requirements of the Inquiry. However, the Expert Review Team considers that the Inquiry and the SCRR are separate processes.

The Inquiry is an independent statutory process, supported by underpinning legislation, to deliver on its Terms of Reference; whereas the SCRR is a Trust and DoH-initiated process to establish themes of learning with a view to improving Trust systems to reduce the likelihood of similar incidents happening in the future. Whilst running in parallel to the Inquiry, the SCRR should not be influenced by the Inquiry's agenda or timescales, but instead should be focused on the need to derive learning and implement the necessary improvement.

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

During fieldwork, Trust representatives accurately described this distinction between the differing roles and purposes of the Inquiry and SCRR, the relationship between the differing processes and the arrangements for sharing information with the Inquiry Team. However, upon reviewing Trust documentation, although the rationale for the SCRR is clearly stated, the Expert Review Team identified a lack of clear documentation explaining the role, purpose and remit of the SCRR and, in particular, that it is an entirely separate process to the Inquiry.

Similarly, SHSCT SCRR documentation does not make clear whether the cases selected for SCRR are being reviewed on behalf of the Inquiry, or whether all or some of these cases could be subject to a second review by the Inquiry team, and whether patients and families are aware of the potential for conflicting findings. This is likely to cause confusion since the Inquiry Terms of Reference (ToR) include:

> (c) To examine the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate, in order to provide a comprehensive report of findings related to the governance of patient care and safety within SHSCT's urology specialty.

The Expert Review Team considered that, although Trust representatives demonstrated a good understanding of the distinction between these two processes, which is further mitigated by the fact that at the time of drafting this report, the Inquiry methodology for ToR (c) has not yet been announced, and the patient / family information materials and Trust documentation require improvement. In the current format, the versions provided to the Expert Review Team do not fully and accurately inform patients and families and, thus, have the potential to inadvertently cause confusion and compound anxiety and distress.

We were informed that SHSCT, in light of recent criticism regarding factually inaccurate information contained in patient letters, regarding the Inquiry's purpose, has sought to improve the clarity and accuracy of documentation. The Expert Review Team was provided with a copy of a "Patient Letters Investigation" report which outline a thorough investigation undertaken by an experienced Director independent from the SHSCT and is accompanied by a number of sensible recommendations. The Expert Review Team commends this report and welcomes these improvement efforts. In addition to these, the Expert Review Team is of the view that SHSCT would benefit from improving their systems for developing and quality assuring patient / family information or indeed any documentation that is publicly accessible or likely to enter the public domain. Such arrangements should include the involvement of a lay person / service user representative and those with communications expertise within SHSCT. Where there is a pending or ongoing Public Inquiry, legal input should also be considered.

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Recommendation 1

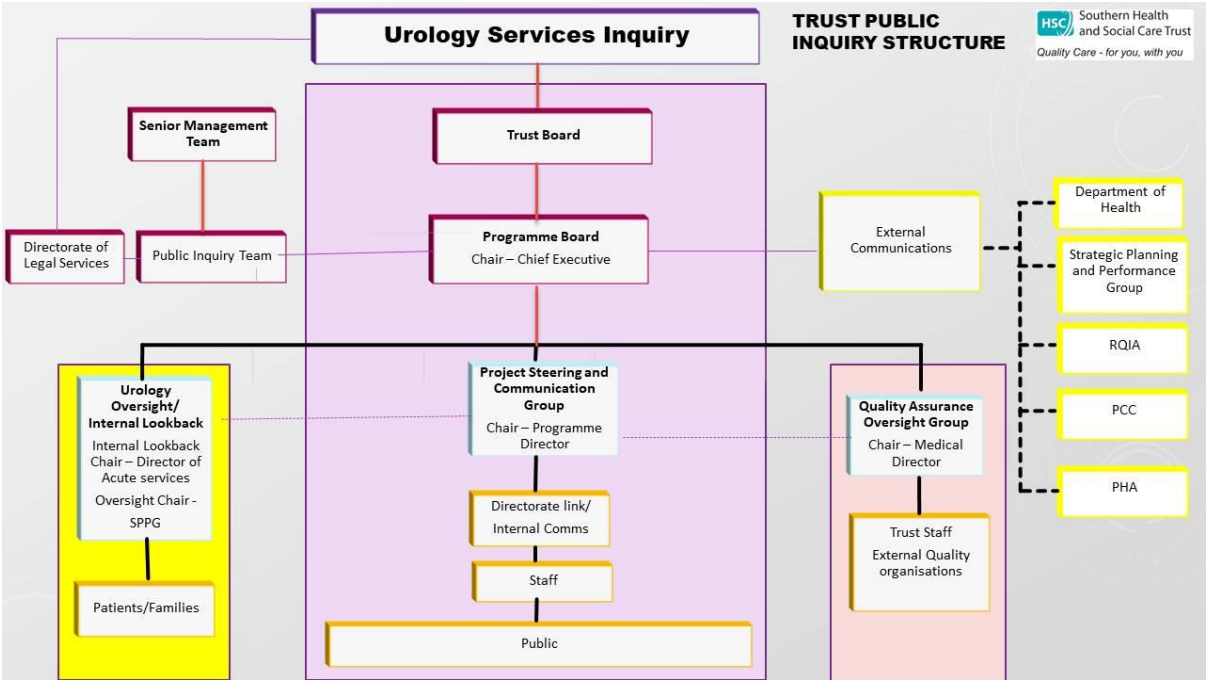
SHSCT should urgently update all relevant documentation to ensure that there is clarity regarding the SCRR including a description of the SCRR purpose, remit and process; explicitly stating that it is a separate process to any parallel Inquiries or investigations.

SHSCT should review their arrangements for developing and quality assuring patient / family information materials and publicly accessible information to ensure there is adequate lay / service user involvement, communications expertise and, where beneficial, legal input.

2.1.2 Review Structure

Robust structures are essential for ensuring effective delivery, assurance and accountability. SHSCT provided details of the Review Structure and advised that the SCRR process sits within its current Trust governance structures.

Figure 1. Current Review Structure



We were informed that the Review Structure is presently overseen by SHSCT Internal Urology Lookback Group. SHSCT Public Inquiry Programme Board is chaired by the Chief Executive. The Programme Board members act on behalf of SHSCT Board to oversee the work of the:

- Public Inquiry Response and Communications Group;
- Public Inquiry Urology Oversight / Lookback Steering Group; and
- Quality Assurance and Improvement Oversight Group

The Lookback Review is included on the Corporate and Acute Services Risk Registers. External oversight of the process is provided by the fortnightly Service

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Planning and Performance Group (SPPG) Meeting and Department of Health led Urology Oversight Group.

ToR were provided for the Public Inquiry Programme Board, Trust Internal Urology Lookback Group and Health and Social Care Board[ii] (HSCB) Urology Group. The Expert Review Team noted the broad remit of oversight and co-ordination groups and considered that some of the committees were very large, with overlapping membership. The Expert Review Team noted that the composition of the Lookback Review Steering Group (referred to as the Urology Oversight / Internal Lookback Group) does not reflect the Regional Guidance for Implementing a Lookback Review Process (July 2021)[2] which suggests inclusion of:

> "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 Public Health Agency (PHA) representative and an Health and Social Care Board (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."

The Expert Review Team acknowledged the challenges and sensitivities of including a service user / advocacy representative who has been impacted by or has a vested interest in the matter of concern. However the inclusion of a lay member, not impacted by SHSCT Urology concerns, but nonetheless with previous experience of representing the interests of service users / the public on similar pieces of work, can be hugely valuable and should be considered by SHSCT. The benefits include enhanced public confidence in the process, improved adherence to the statutory duty of Personal Public Involvement (PPI), provision of advice on patient / family / public messaging and on the fulfilment of a duty of candour.

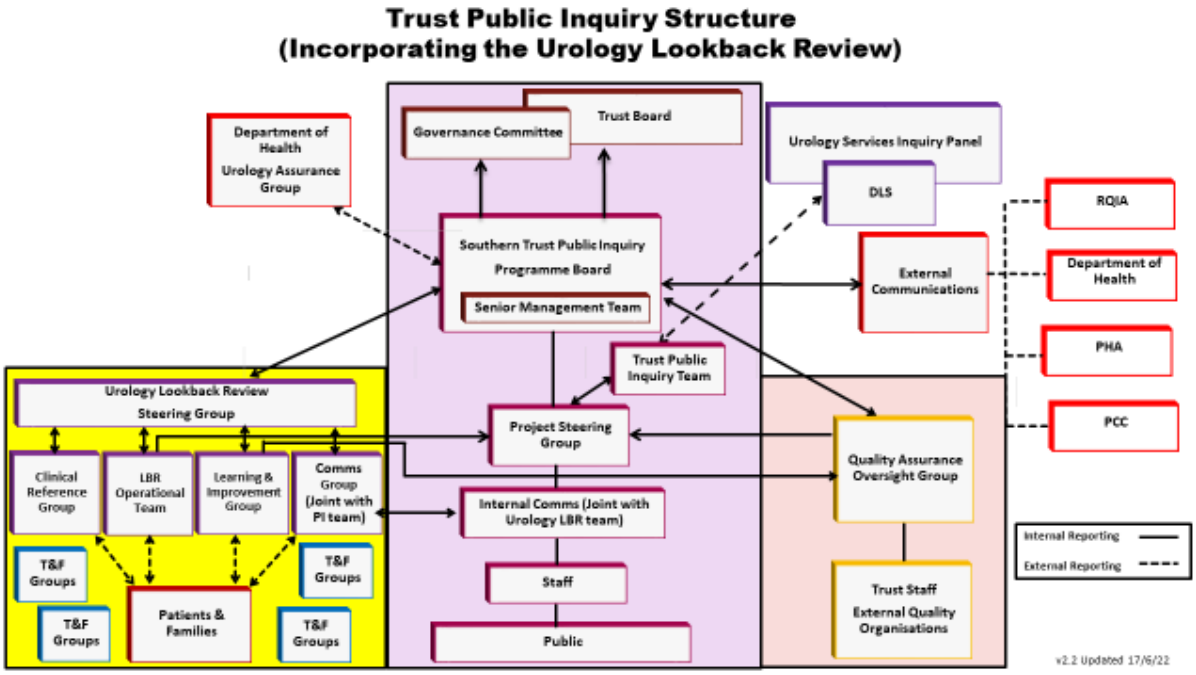
The Expert Review Team considered that there was a lack of clarity surrounding leadership / responsibility and arrangements for accountability and reporting. During fieldwork, we were advised that the Chief Executive has ultimate accountability for the SCRR and that recent work had been undertaken to improve oversight, reporting and ensure clear lines of accountability. This resulted in a proposed new structure for oversight of the SCRR process. The Expert Review Team is of the view that any new structure should also be designed to support SHSCT to fulfil its responsibilities in respect of all Urology work, to deliver on SCRR objectives and should avoid creating unnecessary duplication or complexity.

The Expert Review Team was informed that the new structure exists in shadow form at present with the Operational Team being chaired by the seconded Director in a holding position until the new Director responsible for surgery takes up post.

[ii]The Health and Social Care Board was replaced by the Service Planning and Performance Group (SPPG) April 2022.

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Figure 2. Proposed New Review Structure (draft document at the time of the Review)



Although the Expert Review Team welcomes improvements to the overarching review structure, it is of the view that, given the sizeable undertaking and complexity of the work, the operational arrangements for management and co-ordination of the SCRR and potentially the Lookback Review itself, would benefit from the establishment of a dedicated project team. It was noted that one individual was seconded from another Trust to support SHSCT with its work and this was a welcome development; however, no other Trust representative attending the fieldwork sessions reported having experience of conducting Lookback Reviews. This represents a considerable lack of skill and experience, which can occur when there has been recent turnover or change within the management structures of an organisation. In light of this shortfall, the dedicated project team should include people with previous experience in undertaking similar work, who can draw upon a wide network of 'critical friends' to provide support, advice and guidance.

Recommendation 2

SHSCT should consider reviewing the composition of Lookback Review steering group to reflect that which is stated within Regional Guidance for Implementing a Lookback Review Process; in particular, consideration should be given to the inclusion of a lay representative.

SHSCT should establish a dedicated project team for the management and co-ordination of SCRR. SHSCT should recruit people with the skills and experience who, if required, can seek the advice and guidance of experts from across the region.

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2.1.3 Project Management

Effective project management is crucial in ensuring a well-co-ordinated delivery of objectives within acceptable timescales; this is best implemented with the support of a project manager accredited in using validated project management methodology such as PRINCE / PRINCE 2.

SHSCT SCRR project is currently managed as a sub-workstream of SHSCT corporate lookback process rather than by an individual with project management expertise supported by dedicated project team. Furthermore, the process does not use a specific project management methodology and has followed an iterative approach in terms of its design, signoff and deployment.

To ensure identified project actions are undertaken, minutes are kept of screening and lookback meetings and these are carried forward into future meetings. Individual case records for SCRR are tracked to the relevant Expert Reviewer; ensuring updates can be sought on progress.

The Expert Review Team considered that, whilst these arrangements might suffice for small numbers of cases, they are not sufficiently robust for managing a large volume of work. The Expert Review Team is of the view that a dedicated project team for the co-ordination and management of the Lookback Review and SCRR process, should include a Project Manager; ideally such an individual should have previous experience in managing a Lookback Review or, in the absence of previous experience, should have an understanding of the process and should be supported by a network of people who have the requisite skills and expertise.

The Expert Review Team was advised that a proposal paper outlining an updated Lookback Review structure, process and accountability has been submitted to SHSCT Programme Board. In this paper it states that the Urology Lookback Review is a project and should be constructed as such in terms of purpose, ToRs, reporting lines, risk register etc., including the identification of / clarity on who is the Senior Reporting Officer (SRO) for the project; suggesting this should sit at Director level.

SHSCT further advised that this includes a review of the associated Project Management arrangements in order to ensure that the project progresses swiftly and with clear accountability. The Expert Review Team welcomes this approach.

Recommendation 3

Considering the need for dedicated co-ordination and management of the Lookback Review and the SCRR process; SHSCT should prioritise the appointment of a suitably qualified Project Manager.

2.1.4 Terms of Reference / Objectives of the SCRR

A clear Terms of Reference (ToR) or, in lieu of a ToR, a set of specific objectives serves to focus the minds of those undertaking the Structured Clinical Record Review process on the purpose, remit and what needs to be achieved during the

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course of the process. Providing a framework for monitoring progress and accountability for delivery, it is also helpful in communicating the scope of work in a clear, open and transparent way; a Terms of Reference can also assist in conveying information about the process to interested parties, such as DoH, SPPG / PHA, Health and Social Care (HSC) Trusts, patients / families / carers and the public.

Unfortunately, there were no ToR / Objectives provided by SHSCT relating to the SCRR process itself. The Expert Review Team considers that a ToR should be drafted and agreed as soon as possible. Trust representatives were keen that this should adequately convey the clinical elements of the SCRR.

In light of this, a possible ToR could include:

1. To assess the quality of care and treatment provided by Consultant A, using Structured Judgement Review methodology which gives specific consideration to the following:

- Triage;
- Initial assessment;
- Diagnostic investigations;
- Outpatient care;
- Inpatient care;
- Perioperative care;
- Care during any medical or surgical procedure (excluding IV cannulation);
- Communication with colleagues, MDT and primary care;
- Communication with patient and families; and
- Discharge plan and follow-up arrangements.

2. To review the findings of the individual Structured Judgement Reviews and produce a thematic analysis report.

3. To identify learning and make recommendations for improvement.

The Expert Review Team also considered that it would helpful for SHSCT to explicitly state the purpose of the SCRR. It is referenced within the Review Methodology Section of the proposal document provided by SHSCT that “the objective of the SJR method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about the hospital systems where care goes well and to identify points where there may be gaps, problems or difficulty in the care process”. This is closely aligned to the purpose of the SCRR, which is ultimately for SHSCT to define, but may best be described as serving “to assess the quality of care and treatment, in order to identify learning and implement improvement”. Clearly setting out the purpose in this way would also help to differentiate the SCRR from the Inquiry.

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Recommendation 4

SHSCT should define and explicitly state the purpose of the SCRR process. Furthermore, a clear Terms of Reference / set of objectives should be agreed and referenced within the relevant Trust documentation.

2.1.5 Time period for inclusion of cases for SCRR

All cases reviewed as part of the current Lookback Review undergo screening for consideration for inclusion in the SCRR process; those meeting the SAI threshold are 'screened in'. The scope of the Lookback Review pertains to all patients that were under the care of Consultant A during the time period 1 January 2019 – 30 June 2020. The Expert Review Team explored the rationale for this time period with Trust representatives. When concerns first came to light, this period was chosen as it was believed that this was when patients were most at risk from aberrant clinical practice.

The Expert Review Team acknowledges that no lookback exercise can review all cases at once, that there has to be a starting point, and that a phased approach is preferable in order to expedite learning and facilitate reflection; furthermore, to start with those patients identified as being most at risk is sensible, justified and in keeping with regional guidance. However, the Expert Review Team was informed that since then, it has been identified, by examination of historical care through the Patient Casenote Review process, that patients treated by Consultant A prior to 2019 may also have received substandard care. This is unsurprising; it is the Expert Review Team's experience that problems with a clinician's practice tend to be longstanding and not restricted to a particular period of time. We were advised that in light of this finding, the Royal College of Surgeons (RCS) is currently undertaking a review of a sample of 100 cases from 2015 in order to identify whether there were problems present at this stage

The Expert Review Team is of the view that if there is already enough evidence to inform a risk assessment that patient groups receiving treatment prior to 2019 are at risk of harm, SHSCT should not wait for the RCS work to conclude and should proceed as a matter of urgency to extend their Lookback Review to identify and recall at risk patients under the care of Consultant A prior to 2019. This can be done using a phased, risk-stratified approach based on the learning gathered to date. It can then be extended and scaled up further, following receipt of the RCS findings, should this be required. However, regardless of the approach adopted, given the risk posed to live patients, it is imperative that a further phase of the Lookback is commenced as a matter of priority.

Since this is likely to be a considerable undertaking, requiring suitable expertise to offer advice and guidance, it is vital that SHSCT is adequately supported by its partners across the HSC system, including DoH/ Urology Assurance Group / SPPG and PHA. As this work is scaled up, an independent assessment of the current Urology Lookback Review arrangements would serve to provide assurance regarding its effectiveness and identify any areas that need strengthened; this assessment could be undertaken by RQIA as a 'Part 2' to this review of the SCRR. Assurance of the current lookback arrangements would serve to strengthen the

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foundations in place for extending the time period and scaling up to include additional patient subgroups.

Recommendation 5

SHSCT should give urgent consideration to extending their Lookback Review to identify and recall further groups of patients. DoH / Urology Assurance Group / SPPG, PHA and RQIA should work together to support SHSCT with the Lookback Review.

RQIA should consider undertaking an independent assessment of Trust arrangements for the Urology Lookback Review in order to provide assurance on its effectiveness and identify any areas for improvement.

As there is a need to prioritise the Lookback Review, to ensure that patients at risk are promptly reviewed and that ongoing care and treatment is arranged, it may be preferable for an external body, such as the Royal College of Physicians, to undertake the SCRR on behalf of SHSCT. Not only would this allow Trust teams to focus on the Lookback Review whilst maintaining a safe level of care provision for its current and new patients, it would mean that the SCRR is conducted by an independent organisation that has the requisite expertise, governance structures, well tested processes and quality assurance mechanisms in place to support this type of work; consequently, the output may be more expedient and performed to a higher standard. However, the Expert Review Team acknowledges that commissioning an independent body may not be possible either due to a lack of agreement, resources or time, in which case the recommendations outlined in this report should support SHSCT itself to facilitate the SCRR.

Recommendation 6

SHSCT should consider commissioning an independent body to undertake the SCRR process on its behalf.

2.1.6 Case selection

Appropriate case selection is important to ensure effective use of time and resources, which should be prioritised towards cases where there is likely to be learning.

During fieldwork, Trust representatives outlined the process for case selection. All service users who were under the care of Consultant A between January 2019 and June 2020 were reviewed using a 10-question Patient Review form either internally by SHSCT or an external consultant urologist commissioned for this purpose. This 10-question Patient Review Form explored current as well as historical care. At a point in time, this list of questions was shortened to 4 questions which explored current care, following discussions with SPPG (formerly HSCB) who were keen that it mirror the approach used by the Belfast HSC Trust Neurology recall. It reverted back to 10 questions at the request of the Trust (and with agreement by SPPG) with all relevant case notes being assessed retrospectively to ensure consistency.

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Where concerns regarding the quality of care are identified, these cases are then considered at a screening meeting, attended by the Trust's acute directorate governance and clinical staff, to establish if the concerns meet the threshold set out in the regional SAI procedure. Where the case meets the criteria for an SAI, it is progressed as an SCRR.

The Expert Review Team considered that if the aim is to identify all cases where there is likely to be learning, the use of SAI thresholds may not be the most effective method. This was explored with Trust representatives who were in agreement. We were advised that cases considered for inclusion in the SCRR included the following:

1. SAI threshold met; concerns around the care and treatment in keeping with a theme already identified
2. SAI threshold met; concerns around the care and treatment in keeping with an emerging theme, not previously identified
3. SAI threshold not met; nonetheless, learning identified
4. SAI threshold not met; care and treatment "reasonable"

The Expert Review Team is of the view that it is acceptable to include cases from Group 3. Although a case may not meet the criteria for an SAI review, it may still contain valuable learning from a patient experience or service quality perspective.

To date, 53 cases have been identified that meet the criteria for SCRR. This number is likely to increase further, particularly if the care and treatment of additional patient groups is going to be subject to an extension of the Lookback Review; a total in excess of 90 cases is expected to be identified from this phase alone.

During fieldwork the Expert Review Team heard that of the 53 SCRRs passed to the external SCRR urologists between February and May this year only 20 have been returned to date. This prolonged process poses challenges for the Trust as they are keen to establish the full extent of learning in relation to these cases.

Given time constraints and limited availability of expert reviewers, the Expert Review Team was keen to explore whether a sampling approach had been considered by SHSCT. Such an approach would seek to maximise learning within the constraints of available resources and may lead to improvements being implemented at an earlier stage.

During fieldwork, Trust representatives remarked on the similarity of themes across the cases that have already been reviewed. We were informed that there was very similar learning arising from 19 out of 20 cases reviewed to date. This supports an argument that a point of saturation might be reached and there may be limited additional benefit to reviewing all cases, as was initially intended.

The Expert Review Team recognises that a pragmatic approach to sampling would mark a departure from the original intention and direction of the SCRR. It would be the Expert Review Team's view that such a departure requires a clear rationale to be agreed by the DoH; this would require the purpose, scope and Terms of Reference for the SCRR review to be clearly articulated and defined. DoH should ensure that such an approach is justified when taking into consideration the wider context,

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including the planned work and emergent findings of the Public Inquiry. The Expert Review Team's view is that a sampling approach would expedite learning and would allow an opportunity for earlier improvement to be implemented. However, there are ethical considerations and SHSCT should take steps to ensure that the sampling framework is robust and should be open and honest with patients and families about the approach and its rationale.

Understanding that some patients and families may be disappointed that their case is no longer going to be reviewed, SHSCT may wish to include an option for patients and families to request inclusion in the SCRR. If it is not feasible or reasonable to grant such a request, then the patient or family should be informed of the alternatives available to them, such as submitting a concern to the Urology Public Inquiry, SHSCT Complaints Department, GMC, PSNI or any redress scheme. It would be helpful at this stage for DoH / Urology Assurance Group / SHSCT to liaise with the Urology Public Inquiry to ascertain their intended approach to case identification and proposed methodology for delivering on Inquiry ToR (c). Should the inquiry intend to review all cases for those patients / families approaching the Inquiry Team, this would lessen the expectations on SHSCT, enabling the SCRR work stream to focus on applying a sampling framework with a view to deriving system learning and implementing improvement.

Recommendation 7

SHSCT should consider implementing a sampling approach to case selection for SCRR. Such an approach should be agreed with DoH / Urology Assurance Group / SPPG. SHSCT should be clear on the rationale, its benefits and limitations and ensure that there is openness and transparency in communication with patients, families and the public. SHSCT should engage the Clinical Ethics Committee to consider any ethical issues arising from such an approach which can then be addressed and mitigated by SHSCT.

2.1.7 Ethical Considerations

The application of ethical principles when conducting reviews of a complex and sensitive nature is invaluable to guide decision-making and ensure that the review is conducted in an open, transparent, fair and sensitive way. It can be helpful in ensuring a rigorous approach, adherence to a duty of candour, respect for confidentiality but also autonomy (i.e. right not to know) and in ensuring that specific patient groups are not inadvertently disadvantaged. It is also helpful when considering specific ethical issues that may arise from the process of reviewing patient cases, such as circumstances where previously undiagnosed or undisclosed hereditary conditions are identified.

SHSCT advised that no Clinical Ethics issues were identified for discussion with SHSCT Clinical Ethics Committee. The Expert Review Team is of the firm view that given the scale and sensitivity of the work involved, and the potential for inadvertent harm to be caused by the process, SHSCT would benefit from giving due consideration to the application of Ethical Principles. Advice from SHSCT Clinical Ethics Committee should be urgently sought and, if deemed necessary, this could be assisted by the HSC Regional Clinical Ethics Committee.

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We refer SHSCT to a recently issued Ethical Framework[3], developed specifically for RQIA's Expert Review of Deceased Patients of Dr Watt, which contains overarching themes that are applicable to any lookback or review of this nature:

1. Respect for Persons (which includes Privacy, Confidentiality and Data Protection, and the Right to Know and the Right Not to Know)
2. Transparency and Candour
3. Fairness
4. Responsibility

It was RQIA's experience that the process of discussing ethical principles and deliberating the potential for ethical issues is as valuable as the end product of any framework or ethical paper. In the context of the Expert Review of Deceased Patients of Dr Watt, it had wider benefits beyond ensuring that the methodology and the approach were ethically rigorous, and greatly assisted with the drafting of correspondence to families, and in the interactions with families by the RQIA Family Liaison Team.

Recommendation 8

SHSCT should request SHSCT Clinical Ethics Committee to review both current and proposed arrangements for the Lookback Review and SCRR. Where ethical issues are identified, SHSCT should give this due consideration and, where required, adapt the methodology and approach for the review.

2.1.8 Legal Considerations

A legal perspective on review proposals and arrangements is prudent when undertaking work of this nature.

The Expert Review Team's experience is that it can be helpful across a number of areas including:

- Identifying previously unconsidered pitfalls in relation to correspondence with interested parties, proposed review methodology and approach;
- Ensuring there is appropriate indemnity for reviewers undertaking the SCRR;
- Managing data protection issues;
- Managing legal challenges from solicitors acting on behalf of patients / relatives;
- Managing legal challenges from Consultant A's legal team; and
- Requesting clinical records of patients reviewed by Consultant A in a private a capacity

Trust representatives advised that the Directorate of Legal Services (DLS) is supporting SHSCT with the Inquiry and that an opinion could be sought if required. However, SHSCT advised that legal advice had not been sought as the SCRR is being utilised as an alternative of SAI to establish learning from the situation. The Expert Review Team considered that legal input would be required in order to make this determination and also to consider the potential for future legal ramifications.

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It is the Expert Review Team's view that given the significance and scale of concerns, the likelihood of negligence and that this is a departure from the regional SAI process, a legal perspective should be sought in relation to the arrangements for SCRR.

Recommendation 9

SHSCT should engage with Trust legal representation to obtain a legal perspective on the arrangements for the SCRR.

2.2 METHODOLOGY AND IDENTIFICATION OF LEARNING

2.2.1 Patient and Family Engagement

There is a statutory duty of Personal Public Involvement as set out in the Health and Social Care (Reform) Act (Northern Ireland) 2009[4]. Best practice in involvement is to seek the input of service users and families to help shape the review process, particularly around sensitive person-centred communication, the provision of support and a mechanism for sharing concerns. There may be additional valuable information from affected service users / families that will not be evident in the clinical documentation of the clinician under investigation; information from families and carers is particularly vital in those cases where a patient has sadly deceased. Importantly, effective patient and family engagement is crucial in order to adhere to the principles of candour and 'being open'.

The regional SAI procedure stipulates the requirements for patient and family engagement. On 7 July 2022, the report of the RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland[5] was published; this has relevant findings on effective engagement and involvement of families and recommendations for strengthening the regional approach and procedure. Furthermore, a draft 'Statement of Rights' as an output of the O'Hara Inquiry may be helpful in focussing HSC Trusts on the importance of appropriate and sensitive interaction with patients and their families.

Although the SCRR is not an SAI process, the Expert Review Team is of the view that, as a minimum, patients and families should be informed of the purpose of the SCRR, and that those affected should have an opportunity to provide additional information about their care and treatment. SHSCT outlined their process for engaging and involving families. The Expert Review Team is impressed with and commends the significant efforts SHSCT has made in contacting all impacted families, which, given the scale, is a huge undertaking. However, we note recent issues arising regarding the quality of patient information and consider that the arrangements for patient and family involvement in both shaping the process and sharing concerns require improvement.

The Expert Review Team considers that SHSCT PPI team and those external to SHSCT, such as the PHA and Patient Client Council, have been underutilised in ensuring that there are robust arrangements for PPI as part of the Lookback Review and SCRR.

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Recommendation 10

SHSCT should review their arrangements for the involvement of patients and families to ensure that it fulfils its statutory duty of Personal Public Involvement. SHSCT should consider engaging those with Personal Public Involvement expertise and external partners such as the PHA who have PPI training resources for staff and the PCC who could provide advice and support in the involvement of patients and families as part of the Lookback Review and SCRR.

SHSCT outlined its arrangements for following up and sharing the findings of the SCRR with patients and family members. Although there is a Family Liaison Officer (FLO) available to support patients and families, the findings are primarily shared through postal correspondence. Whilst this may be the preference of a large number of families, many may require additional support to understand and emotionally cope with the findings.

The Expert Review Team consider the following to represent good practice[6,7,8]:

- As far as possible, reports should be quality assured, checked for factual accuracy, and should be written in easy to understand lay language;
- Patients / families should be provided with a range of options on how they wish to receive the report; one option should be a face to face meeting. They also have a right “not to know” the findings;
- The Family Liaison Officer should be accompanied by a medical doctor in relaying the findings of the report;
- Psychological support should be made available to those impacted by the process and findings of the SCRR;
- If further medical follow-up is required by patients or relatives, there should be Trust arrangements in place to facilitate this in a timely manner; and
- There should be opportunities for the FLO to debrief with colleagues and timely access to psychological support for the FLO and any others involved in family engagement.
- Independent advocacy should be considered for patients or families, particularly when cases are complex. The PCC have extensive experience in this area through previous work on SAIs and other Inquiries.

During fieldwork, the Expert Review Team explored the support available for those staff members involved in the review and, in particular, the patient and family engagement. SHSCT described effective provision of support including: senior and peer support, psychological support and access to Inspire Wellbeing Counselling service. The Expert Review Team is content that the arrangements for support appear sufficient but cautions that a substantial proportion of the work appears to be undertaken by one FLO. Given the large number of cases identified, it may be beneficial to increase the capacity of the Family Liaison Team to provide support to those impacted by the Lookback Review and SCRR.

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Recommendation 11

SHSCT should review their arrangements for sharing SCRR findings with patients and families giving consideration to good practice as outlined by the Expert Review Team in this report.

2.2.2 Methodology & Tool

Structured Judgement Review methodology is a reliable, well validated tool that has been developed by the Royal College of Physicians. It allows for the blending of traditional, clinical-judgement based, review methods with a standard format. The approach requires reviewers to make safety and quality judgements on particulars of care, to make explicit written comments, and to assign a score for the quality of care at each phase. This produces a rich set of information about each case in a form that can be aggregated to produce knowledge about clinical services and systems. SHSCT discussed the use of this tool with the Royal College of Physicians and opted for this methodology to underpin the SCRR process.

The Structured Judgement Review methodology was adapted for the SCRR in order to take into consideration the relevant phases of care. The phases of care assessed are:

- Triage;
- Initial assessment or review;
- Review of Diagnostics;
- Ongoing Outpatient Care;
- Admission and Initial Management;
- Ongoing Inpatient Care;
- Care during a procedure (excluding IV cannulation);
- Perioperative care; and
- Discharge plan of care.

The Expert Review Team is not privy to all the specific clinical concerns therefore cannot be certain that the tool adequately scrutinises all relevant aspects of care. With this caveat in mind, the SCRR tool generally appears reasonable. However, the Expert Review Team did note some areas that SHSCT may wish to address. There is some divergence from the RCP methodology in terms of the data collection instrument. There is no section to assess:

- Quality of documentation in the records;
- Communication between Consultant A and the patient / carer / family; and
- Communication between colleagues, MDT and primary care.

Whilst we were advised that deceased patients are included in the review, there are no sections outlining a review of the death certification or whether a referral to the coroner's service was required.

Of particular value in relation to deceased patients, but of great value for all cases, is the consideration of patient and family concerns. In general, there is a lack of patient

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and family input into the SCRR process. Patients and families were not engaged with in order to shape the review. Equally, there is no consistent mechanism to proactively seek the concerns of patients and families for consideration as part of the individual SCRR. This marks a considerable deficit in the information available to formulate findings. The experience of the Expert Review Team is that, where concerns from patients and families are taken into account, this greatly enhances the learning process and provides information and context that is often not present in the notes. RCP has successfully incorporated patient / family concerns into its review process by asking expert reviewers to review the notes firstly without knowledge of the patient / family concerns and then a second time taking the patient / family concerns into consideration. The complaint can then be judged to be 'upheld', 'partially upheld' or 'not upheld'.

RQIA's experience from the Expert Review of Deceased Patients of Dr Watt is that there is a close correlation between the views of family members and the judgement of the structured judgement tool (SJR), strengthening the argument that there is great benefit in attaining patient and family input. Where there is little or no correlation between the patient / family story and the clinical picture documented in the records, the Review Panel may determine that the family concern is 'not upheld'; of note, this only occurred for two (out of 44) patients included in Phase 2 of the Expert Review of Deceased Patients of Dr Watt.

Recommendation 12

SHSCT should liaise with RCP and consider amending the Structured Clinical Record Review tool to include an assessment of the quality of documentation and an assessment of the documented communication with patients and families; the clinical team, MDT and primary care. SHSCT should consider facilitating the consideration of patient / family concerns as part of the SCRR to mirror the approach undertaken by RCP.

Whilst Structured Judgement Tools provide an objective assessment of the care and treatment documented within the clinical records, it can only allow for a partial systems perspective. For example, it may tell a story of care and treatment according to the national standards of the time, of the standard and quality of documentation, multidisciplinary involvement, communication between colleagues and communication with family members. Of direct relevance, it will not examine factors such as caseload, working relationships and peer review.

Furthermore, it will not tell us about the governance systems within Urology Services or within SHSCT as a whole. It will not examine the role of external bodies and the wider system in providing oversight and assurance of quality and safety of care.
With this in mind, DoH or SHSCT Board may wish to commission RQIA to undertake a Review of Governance within Urology in Southern Health and Social Care Trust. This would provide an opportunity to identify and remedy any deficits, and to share learning within SHSCT and across the system so that governance systems may be strengthened and future harm prevented.

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Recommendation 13

DoH should commission RQIA to undertake a Review of Governance Arrangements within Urology Services in Southern HSC Trust.

2.2.3 Expert Reviewers

Each case is reviewed independently by a 'Subject Matter Expert' (or Expert Reviewer) utilising the SCRR methodology. SHSCT provided details of Expert Reviewers, including a description of the job role and a copy of the guidance provided to reviewers at the outset of the work. The Expert Reviewers are nominated via the British Association of Urological Surgeons (BAUS) for their subject matter expertise. SHSCT ensures that each reviewer is appropriately registered and of good standing with their professional regulator, the General Medical Council (GMC). The Expert Review Team is content that reviewers appeared suitably independent and qualified.

In total, SHSCT approached 13 reviewers of which four Expert Reviewers have been recruited to support this work. Given the difficulty recruiting Consultant Urologists and the time consuming nature of the SCRR process, the Expert Review Team considered whether specialist nurse reviewers or urologists in training could be used instead. A clearly defined protocol with consultant oversight of the process would facilitate this. It was considered that a hierarchical culture within HSC, associated with perceptions amongst the Northern Ireland public that attaches particular significance to reviews undertaken by a consultant, may be a barrier to implementing a non-consultant review process. Therefore, if the work cannot supported by specialist nurses or trainee urologists, consideration should be given to the use of doctors working outside the specialty of urology.

The Expert Review Team noted that no training was provided to Expert Reviewers, who instead were stated to be familiar with SJR tool methodology. In addition, there was no specific manual provided to reviewers; albeit the following guidance was provided:

- Using the Structured Judgement Review method - A guide for reviewers; National Mortality Case Record Review Programme 2019[9]; and
- Structured Judgement Review - Frequently Asked Questions 2019.

Additionally, the process had not been piloted and there was no method of calibration between reviewers to ensure inter-reviewer reliability and consistency. Importantly there is no mechanism for quality assuring the work of reviewers, either by assigning two reviewers to each case or by second-reviewing a sample of the cases.

The Expert Review Team notes that 20 SCRRs had been completed at the time of fieldwork; and while we understand the challenges in delivering quality assurance of reviews within the current limited pool of reviewers it may be beneficial to conduct an independent review by a second expert reviewer to ascertain the degree of reliability and consistency in assessing the quality of care. A panel should then be convened

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to discuss any significant discrepancies in judgement, to gain consensus and provide expert reviewers with an opportunity to standardise their approach.

Even in the absence of discrepancies, it can be helpful for clinical reviewers to have a forum to discuss cases, debrief and avail of emotional or psychological support. Although it was reported that each reviewer can contact SHSCT Deputy Medical Director for Quality and Safety if issues arise, the Expert Review Team is of the view that SHSCT is missing an opportunity to proactively support reviewers, seek feedback on the process and seek reviewers' views on the learning arising.

Recommendation 14

SHSCT should not be limited to consultant urologists when recruiting clinical reviewers to undertake the SCRR process. All Expert Reviewers should be provided with guidance and support, including an opportunity to debrief, feed back and avail of emotional / psychological support if required.

A document should be drafted specific to this particular piece of work to guide reviewers through the process of conducting the SCRR; this should include a defined protocol for the assessment of the quality of care and treatment.

A sample of cases already reviewed using the SCRR methodology should undergo a second review to ensure inter-reviewer reliability and consistency. Consideration should be given to quality assurance of a defined sample of cases for the remainder of the SCRR.

2.2.4 Review Panel

Good practice dictates that in undertaking a review, an expert panel to deliberate findings and attain consensus on recommendations is preferable to the judgement of one individual expert. A forum for discussion between panel members allows for a sharing of expertise and perspective, brings a deeper and broader understanding of issues, mitigates bias and derives learning more effectively.

SHSCT stated that there is no specific review panel for the SCRR; however, the Trust Lookback Group oversees the overall lookback process that includes the SCRR. On completion of the initial batch of SCRRs, an independent Consultant Urologist will develop a thematic report on the findings.

The Expert Review Team considered that, as SHSCT has rightly identified that a key outcome of the SCRR is a thematic analysis in order to identify learning and inform system improvements, the process would benefit from a dedicated review panel rather than relying on the professional judgement of one individual to collate findings, identify themes and make recommendations. This was explored with Trust representatives during fieldwork, who advised that the RCS and BAUS had both been approached to undertake an independent quality assurance of the SCRR but SHSCT had not been able to secure agreement from either of these bodies. Subsequently SHSCT considered convening a multidisciplinary panel comprising eight individuals but due to limited resource and availability of staff this had not progressed. The Expert Review Team considers that a smaller panel, including

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urology, governance and lay expertise would suffice; encouragingly, Trust representatives were amenable to this model.

The Expert Review Team is of the view that any learning and evidence-based recommendations made by the review panel would require a commitment from SHSCT to implement a clear prioritised action plan within acceptable timescales.

Recommendation 15

A review panel should be constituted, for the specific purposes of identifying learning and determining recommendations arising from the SCRR process. This panel should include individuals with expertise in urology and governance, and include a lay member.

2.2.5 Identification and Dissemination of Learning

Dissemination of learning is crucial in order to improve systems for delivery of care both within SHSCT and across the region. Any strategy for the dissemination of lessons learned should be supported by DoH / SPPG / PHA and should incorporate an action log of the system improvements required, along with timescales for follow up and review.

SHSCT stated that each SCRR report will be reviewed by a Trust clinician who will identify if there is any previously unidentified learning. The thematic analysis report will also be considered by SHSCT in respect of broader system issues.

SHSCT advised that returned SCRRs are reviewed by a Trust clinician who will decide on the appropriateness of sharing learning more widely; this includes learning that should be shared beyond Trust boundaries. Mechanisms for sharing learning were stated to include:

- Using SHSCT local shared learning template;
- Regional shared learning template;
- Morbidity and Mortality Meetings (Patient Safety Meetings);
- Acute Governance Meetings (Directorate wide); and
- Urology and Cancer Services team meetings.

The Expert Review Team considered that the arrangements for identifying, implementing and disseminating learning required strengthening. The reliance on the professional judgement of one clinician to undertake a thematic analysis, in the absence of a mechanism for the reviewers to discuss and feedback, compounded by the lack of quality assurance of individual reports, risks that important system issues may go unidentified. Similarly, the reliance on a Trust clinician to determine whether learning should be shared wider, lacks independence, and runs the risk that one person acts as a gatekeeper to the implementation of improvement and dissemination of lessons learned.

As stated previously, a review panel with representation from urology, governance and a lay member would serve to ensure that there is a robust mechanism for deriving, implementing and making determinations on the dissemination of learning.

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Where learning is derived, the Expert Review Team would expect that recommendations are made and clear prioritised time-specific action plans are put in place with arrangements for monitoring and accountability. A follow-up review, with defined parameters for assessment around implementation, would provide assurance around the implementation of sustainable improvements.

The information provided by SHSCT indicates that the consideration of dissemination of learning is confined to within Trust boundaries; although a regional shared learning template is referenced, it is not clear whether this in itself would be sufficiently robust to disseminate learning to the relevant stakeholders across the system. SHSCT representatives were of the view that the previous HSCB process for sharing learning from SAIs needs to be adapted or replicated for the SCRR process but that this had not yet commenced. The Expert Review Team is of the view that the mechanisms for sharing learning should be discussed urgently with DoH / SPPG / Urology Assurance Group. Recipients should include Public Inquiry, SHSCT Board, Urology Assurance Group, DoH / SPPG, PHA, and RQIA; under duty of candour principles, it should be considered whether there is an onus to share learning with the public. In any case, an effective strategy for communication with stakeholders would serve to underpin arrangements for the effective dissemination of learning.

Recommendation 16

SHSCT should work with DoH / SPPG / PHA to develop an effective dissemination strategy for the Lookback Review and SCRR so that learning is shared regionally with all relevant stakeholders and the public is effectively informed under duty of candour principles.

2.3 GOVERNANCE OF THE SCRR

2.3.1 Risk Management

Effective risk management relies on the identification, assessment, mitigation and monitoring of risk. All projects incur risks, such as risks associated with timescales, available expertise, budgetary constraints and data protection vulnerabilities. However, projects of this nature can carry considerable additional risk, such as the risk of causing harm to patients / families / public and reputational risk to the health service. It is vital that the structures, systems and processes in place support effective recognition and management of such risk.

The Expert Review Team was advised that the project does not keep a formal risk log; however, risks are recorded and discussed through meetings. At the time of review, there were three risks identified with mitigation actions identified for each.

When the Expert Review Team explored the issue of risk it was advised that the risks associated with the SCRR had progressed to both the directorate risk register for Acute Services and to the Corporate Risk Register.

The Regional Guidance for Implementing a Lookback Review Process (July 2021) states that:

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> "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 Expert Review Team was further advised that SHSCT is currently transitioning to a revised organisational structure, designed to fully support SHSCT to fulfil its function in respect of the SCRR objectives; this is currently operating in in shadow form. As a consequence, the project will operate under more robust governance structures with a live risk register maintained specifically for the Lookback Review. Issues of risk will also be included in the ToR for the new Urology Lookback Review Steering Group and SHSCT Public Inquiry Programme Board (note these are working titles which may change when the new structure is finalised). The Expert Review Team welcomed these improvements which will serve to strengthen the current arrangements for risk management.

2.3.2 Records Management

Effective management of clinical records requires protocols for retrieving, scanning and sharing records, underpinned by strong governance arrangements. SHSCT described robust arrangements for accessing and sharing of clinical records, which was in keeping with good information governance.

A list of patient names and health and care numbers of those cases identified for SCRR is shared with a dedicated administrator. When a decision is made to proceed with SCRR, the relevant patient records are obtained through normal hospital processes by request of hardcopy notes via the medical records team. Notes in patient charts which are not available on NIECR are copied, scanned and uploaded to Egress Secure Workspace, an electronic platform, for sharing with expert reviewers. Expert reviewers also have secure access to NIECR.

There is a dedicated member of the clinical governance team assigned to support the SCRR process, who is responsible for obtaining the charts, extracting the records for scanning and who also uploads to Egress Secure workplace and notifies and liaises with the external expert reviewers. The Expert Review Team considered this approach to be acceptable.

2.3.3 Data Considerations

SHSCT outlined their arrangements for data protection. Document transfer is managed via SHSCT Egress document sharing platform and also via secure VPN access to NIECR records. Each Expert Reviewer is required to complete a Trust confidentiality agreement and Data protection agreement prior to accessing records.

The Expert Review Team identified a potential General Data Protection Regulation (GDPR) issue with the arrangements for contacting families. SHSCT would benefit

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from further consideration of information governance, and in particular, data protection issues in relation to SCRR.

Given the sizeable number of patients involved, a database is beneficial to track progress of the Lookback Review / SCRR, to analyse demographic and clinical information, and to monitor outcomes. SHSCT is presently developing a new database to store and analyse information in relation to the selected cases. Unlike the previous database which relied on manual population, the new database allows for automatic population, reducing the risk of input error. The Expert Review Team welcomes this development and advises that a statement of purpose should be drafted for the new database, outlining the rationale for transferring data; a copy of the old redundant file should be retained in case it needs to be examined at a later stage. If deemed to be helpful, SHSCT could be signposted to regional experts who recently developed a database as part of the neurology live patient recall.

Recommendation 17

SHSCT should draft a statement of purpose for the new database, outlining the rationale for transferring data and should retain a copy of the redundant file on record.

2.3.4 Communication with Stakeholders

Effective communication with stakeholders ensures that there is clear, consistent messaging on the purpose, remit, progress and findings of any review. It also facilitates liaison and co-operation regarding specific aspects of the work where external input is required in order to achieve a particular outcome. The need for robust stakeholder communication is referenced within the Regional Guidance for Implementation of a Lookback Review which highlights that the principle of 'no surprises' should be adopted and outlines that there should be:

- An agreed communication plan/liaison plan for other HSC organisations or independent/private providers which might be affected;
- An agreed media/communications management plan if required, that aims to be proactive in disclosure to the general public and considers responses to media enquiries; and
- Engagement with PSNI and coroner's service in line with standard procedures.

In addition to the above stakeholders, there should also be a channel of communication established with the GMC via the HSC Trust's Responsible Officer. All these elements are best considered as part of a comprehensive Communications Strategy developed for the specific Lookback Review.

SHSCT advised that when completed, the SCRRs are planned to be shared with the Urology Public Inquiry along with the thematic review of cases. Additionally, DoH will be provided with updates on the process via the Urology Assurance Group. SHSCT advised that the Coroner will be notified if there is a potential issue identified via the SCRR processes which has not previously been identified via Trust processes.

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The Expert Review Team considers that there is an absence of an overall communication and stakeholder engagement strategy. It is also noted that there is no channel of communication established between SHSCT and PSNI or GMC. The GMC is likely to be interested in the findings, which will be relevant to the Fitness to Practice (FTP) investigation of the consultant concerned. In addition, there is a possibility that the harm found could be of PSNI interest in terms of possible assault, gross negligence, or in extreme cases, manslaughter. The Expert Review Team considers that a Communications Strategy should be developed and examples from recent lookback exercises or similar review work across the region may assist SHSCT in expediting this.

Recommendation 18

SHSCT should urgently develop and implement a communication strategy specific to the Lookback Review and including the SCRR process.

A channel of communication specific to Urology work streams should be established between SHSCT, PSNI, GMC and Coroner's office; SHSCT should ascertain the thresholds for referral in respect of specific concerns arising out of cases reviewed as part of the SCRR.

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Section 3 Conclusion and Recommendations

3.1 Conclusion

RQIA acknowledges the commitment of SHSCT to ensuring that this work is undertaken a manner that is robust and effective in deriving learning and informing improvements. This was evident, not only by the fact that SHSCT approached RQIA to request this review, with the aim of providing assurance, but also in the Expert Review Team's engagement with Trust representatives and staff during fieldwork. We acknowledge the amount of time and effort that SHSCT staff have given to this piece of work and commend their openness, candour and willingness to learn from the expertise of the Expert Review Team. This positive engagement and 'buy in' will assist SHSCT in implementing the necessary improvements.

RQIA was initially approached to provide independent assurance of the SCRR methodology. During preliminary discussions with SHSCT, we determined that this assurance should be broadened to include the wider process, governance and framework surrounding the SCRR process. This was felt to be particularly important given that the SCRR arose as a result of a significant number of SAIs which were identified through SHSCT Lookback Review, at which point the decision was made to adopt alternative methodology to the SAI process. The Expert Review Team endorses this decision. Structured Judgement Methodology, when applied appropriately, is a reliable, validated methodology which offers an effective means of deriving learning and implementing improvements.

However, when examining the SCRR process within the context of the Lookback Review, it was apparent to the Expert Review Team, that the Lookback in itself is not only a significant undertaking for SHSCT but its progression is a matter of urgent priority. An assessment of the historical care of patients, whose cases had undergone the screening process for SCRR, identified deficits in care and treatment prior to 2019. SHSCT is presently conducting a risk assessment and has commissioned RCS to undertake a review of cases relating to 2015 which should assist SHSCT in determining the future scope and scale of their Lookback. The Expert Review Team is of the firm view that SHSCT should not wait until this work concludes, and based on the evidence SHSCT has gathered to date should proceed to review and recall further groups of patients which it has identified to be at risk of harm.

Understanding that this is a considerable undertaking and that issues have already been identified regarding the availability of expertise and resource to support the Lookback Review, SHSCT will require significant support from the wider HSC system: DoH, SPPG, PHA and RQIA. A dedicated, appropriately resourced and experienced project team should be established as soon as possible to support this work. This may require secondment of additional individuals with the relevant skills and experience to SHSCT. RQIA recognises the efforts SHSCT has already undertaken to improve its lookback arrangements and is keen to support SHSCT with further improvements. As RQIA is best placed to provide assurance on the current arrangements to ensure strong foundations for scaling up and extending the Lookback time period, we recommend that RQIA undertakes a follow-up piece of assurance work looking specifically at the Lookback Review. Going forward, in order

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to allow SHSCT to focus on the Lookback Review, ideally the SCRR should be undertaken by an independent body. The Expert Review Team understands that SHSCT may not be able to secure the support of an external organisation; therefore, we make a number of recommendations to strengthen the existing SCRR process and arrangements.

SHSCT should explicitly state the purpose of the SCRR and draft a Terms of Reference as soon as possible. Caveated with the fact the Expert Review Team is not privy to all specific clinical concerns, the tool itself appears reasonable, but it does deviate from the tool used by RCP and leaves a number of areas unexamined such as quality of documentation. In addition, given that a proportion of patients are deceased, it would be judicious to update the tool to take into consideration death certification and the need for coronial referral. The Expert Review Team advises that SHSCT liaise with RCP to ensure the tool is appropriately aligned and that SHSCT mirrors RCP's approach to considering patient and family concerns as part of the SCRR process.

The arrangements for patient and family involvement require significant strengthening. Inclusion of lay membership on the relevant project groups would ensure SHSCT meets its statutory duty of patient and public involvement. The Expert Review Team also provides advice on best practice in involving, listening to and supporting patients and families through processes such as these in a way that reduces the potential for further harm and serves to restore faith in the health service. Given the scale, complexity and sensitivity of the work involved, due consideration should be given to seeking an ethical perspective on arrangements through SHSCT Clinical Ethics Committee.

RQIA notes the large number of cases that have been identified for SCRR and the difficulty this poses in terms of conducting SCRRs within reasonable timescales, compounded by the limited number of expert reviewers. A sampling approach is pragmatic and effective in deriving learning within the constraints of time and resource. However, this requires a clear purpose; ToR; agreement with DoH / Urology Assurance Group; due consideration of ethical considerations; and considered and sensitive engagement with patients and families. Importantly, where cases are selected for review, this should be done to a high standard.

A document should be developed to guide reviewers through the SCRR process and there should be a mechanism for calibration between reviewers to ensure consistency and inter-reviewer reliability. Additionally, a sample of the cases should be subject to second review for quality assurance. Understanding that this is challenging to achieve within reasonable timescales with a limited number of reviewers, the Expert Review Team recommends that SHSCT considers recruiting non-urology consultants to review the cases, guided by a defined protocol and with appropriate expert oversight.

Whilst the outcome of individual case reviews will be valuable to patients and families in terms of understanding what went wrong and why, it is the overall learning derived from the SCRR process that will assist SHSCT and the region in improving its systems. Therefore, it is vitally important that SHSCT strengthens its arrangements for identification and dissemination of learning. A review panel

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comprising members with expertise in urology and governance, and a lay representative should be established to deliberate findings, derive learning and make evidence-based recommendations. Equally, the mechanisms for sharing learning require an effective dissemination strategy to be agreed with DoH / SPPG and PHA. Underpinning this, communication with stakeholders including GMC, Coroner's Service and PSNI requires to be underpinned by a Communication Strategy and established channels of communication. Furthermore, the arrangements for sharing information with the public under a duty of candour and for developing patient and family information require considerable strengthening. Encouragingly this is already being explored by SHSCT in light of concerns surrounding factual accuracy of previously issued patient correspondence.

On the whole, the challenges facing SHSCT are considerable, complex and require a concerted effort with appropriate involvement of a number of organisations; DoH / SPPG, PHA and RQIA. Retaining the focus on patient safety, the Lookback Review requires urgent support and upscaling. Whilst SCRR will be valuable in establishing deficits within the care and treatment of this patient population, it is limited in terms of deriving systems and governance learning. As such, RQIA advises that a Review of Governance of Urology Services would be crucial in terms of providing assurance around the current service. RQIA is committed to providing both independent assurance and improvement support to SHSCT as it continues its efforts to urgently address deficits in care whilst improving the quality and safety of SHSCT urology services.

3.2 Summary of Recommendations

Recommendation 1

SHSCT should urgently update all relevant documentation to ensure that there is clarity regarding the SCRR including a description of the SCRR purpose, remit and process; explicitly stating that it is a separate process to any parallel Inquiries or investigations.

SHSCT should review their arrangements for developing and quality assuring patient / family information materials and publicly accessible information to ensure there is adequate lay / service user involvement, communications expertise and, where beneficial, legal input.

Recommendation 2

SHSCT should consider reviewing the composition of Lookback Review steering group to reflect that which is stated within Regional Guidance for Implementing a Lookback Review Process; in particular, consideration should be given to the inclusion of a lay representative.

SHSCT should establish a dedicated project team for the management and co-ordination of SCRR. SHSCT should recruit people with the skills and experience who, if required, can seek the advice and guidance of experts from across the region.

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Recommendation 3

Considering the need for dedicated co-ordination and management of the Lookback Review and the SCRR process; SHSCT should prioritise the appointment of a suitably qualified Project Manager.

Recommendation 4

SHSCT should define and explicitly state the purpose of the SCRR process. Furthermore, a clear Terms of Reference / set of objectives should be agreed and referenced within the relevant Trust documentation.

Recommendation 5

SHSCT should give urgent consideration to extending their Lookback Review to identify and recall further groups of patients. DoH / Urology Assurance Group / SPPG, PHA and RQIA should work together to support SHSCT with the Lookback Review.

RQIA should consider undertaking an independent assessment of Trust arrangements for the Urology Lookback Review in order to provide assurance on its effectiveness and identify any areas for improvement.

Recommendation 6

SHSCT should consider commissioning an independent body to undertake the SCRR process on its behalf.

Recommendation 7

SHSCT should consider implementing a sampling approach to case selection for SCRR. Such an approach should be agreed with DoH / Urology Assurance Group / SPPG. SHSCT should be clear on the rationale, its benefits and limitations and ensure that there is openness and transparency in communication with patients, families and the public. SHSCT should engage the Clinical Ethics Committee to consider any ethical issues arising from such an approach which can then be addressed and mitigated by SHSCT.

Recommendation 8

SHSCT should request SHSCT Clinical Ethics Committee to review both current and proposed arrangements for the Lookback Review and SCRR. Where ethical issues are identified, SHSCT should give this due consideration and, where required, adapt the methodology and approach for the review.

Recommendation 9

SHSCT should engage with Trust legal representation to obtain a legal perspective on the arrangements for the SCRR.

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Recommendation 10

SHSCT should review their arrangements for the involvement of patients and families to ensure that it fulfils its statutory duty of Personal Public Involvement. SHSCT should consider engaging those with Personal Public Involvement expertise and external partners such as the PHA who have PPI training resources for staff and the PCC who could provide advice and support in the involvement of patients and families as part of the Lookback Review and SCRR.

Recommendation 11

SHSCT should review their arrangements for sharing SCRR findings with patients and families giving consideration to good practice as outlined by the Expert Review Team in this report.

Recommendation 12

SHSCT should liaise with RCP and consider amending the Structured Clinical Record Review tool to include an assessment of the quality of documentation and an assessment of the documented communication with patients and families; the clinical team, MDT and primary care. SHSCT should consider facilitating the consideration of patient / family concerns as part of the SCRR to mirror the approach undertaken by RCP.

Recommendation 13

DoH should commission RQIA to undertake a Review of Governance Arrangements within Urology Services in Southern HSC Trust.

Recommendation 14

SHSCT should not be limited to consultant urologists when recruiting clinical reviewers to undertake the SCRR process. All Expert Reviewers should be provided with guidance and support, including an opportunity to debrief, feedback and avail of emotional / psychological support if required.

A document should be drafted specific to this particular piece of work to guide reviewers through the process of conducting the SCRR; this should include a defined protocol for the assessment of the quality of care and treatment.

A sample of cases already reviewed using the SCRR methodology should undergo a second review to ensure inter-reviewer reliability and consistency. Consideration should be given to quality assurance of a defined sample of cases for the remainder of the SCRR.

Recommendation 15

A review panel should be constituted, for the specific purposes of identifying learning and determining recommendations arising from the SCRR process. This panel

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should include individuals with expertise in urology and governance, and include a lay member.

Recommendation 16

SHSCT should work with DoH / SPPG / PHA to develop an effective dissemination strategy for the Lookback Review and SCRR so that learning is shared regionally with all relevant stakeholders and the public is effectively informed under duty of candour principles.

Recommendation 17

SHSCT should draft a statement of purpose for the new database, outlining the rationale for transferring data and should retain a copy of the redundant file on record.

Recommendation 18

SHSCT should urgently develop and implement a communication strategy specific to the Lookback Review and including the SCRR process.

A channel of communication specific to Urology work streams should be established between SHSCT, PSNI, GMC and Coroner's office; SHSCT should ascertain the thresholds for referral in respect of specific concerns arising out of cases reviewed as part of the SCRR.

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Appendix 1: Terms of Reference for the Statutory Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust

(a) To review the Southern Health and Social Care Trust's (the Trust) handling of relevant complaints or concerns identified or received prior to May 2020 and its participation in processes to maintain standards of professional practice. The Inquiry shall determine whether there were any related concerns or circumstances which should have alerted the Southern Trust to instigate an earlier and more thorough investigation over and above the extant arrangements for raising concerns and making complaints.

(b) To evaluate the corporate and clinical governance procedures and arrangements within the Trust in relation to the circumstances which led to the Trust conducting a "lookback review" of patients seen by the urology consultant Mr Aidan O'Brien (for the period from January 2019 until May 2020). This includes the communication and escalation of the reporting of issues related to potential concerns about patient care and safety within and between the Trust, the Health and Social Care Board, Public Health Agency and the Department. It also includes any other areas which directly bear on patient care and safety and an assessment of the role of the Board of the Trust.

(c) To examine the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate, in order to provide a comprehensive report of findings related to the governance of patient care and safety within the Trust's urology specialty.

(d) To afford those patients affected, and/or their immediate families, an opportunity to report their experiences to the Inquiry.

(e) To review the implementation of the Department of Health's "Maintaining High Professional Standards Policy" by the Trust in relation to the investigation related to Mr O'Brien. The Inquiry is asked to determine whether the application of this Policy by the Trust was effective and to make recommendations, if required, to strengthen the Policy.

(f) To identify any learning points and make appropriate recommendations as to whether the framework for clinical and social care governance and its application are fit for purpose.

(g) To examine and report on any other matters which the Chairman considers arise in connection with the Inquiry's investigations in fulfilment of these Terms of Reference.

The clinical practice of Mr O'Brien is being investigated by the General Medical Council (GMC) and it would, therefore, be inappropriate for the Inquiry to encroach on the GMC's remit. The Inquiry shall submit a report as soon as practicable to the Minister for Health. Should the Inquiry as part of its investigation establish any issue of concern which it believes needs to be brought to the Minister's immediate attention, then this will be done.

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Appendix 2: Structured Judgement Review[10]

Case note review remains a prime means of retrospectively assessing quality of patient care. Implicit review is based on clinical judgement and is judged to be effective in identifying and recording the detail and nuance of care (both unsatisfactory and good).

Unstructured implicit review was criticised for low inter-rater reliability (high variability) and for potential reviewer bias. Structured implicit review methods require reviewers to use a judgement based structured explicit scale to rate quality of care from very poor to excellent. However, this form of review only provides a scale based quantitative result giving no indication of why a reviewer made a particular judgement. This means that it is useful for large scale monitoring or epidemiological studies of adverse events but is less effective for more detailed review at ward or hospital level of why an event occurred.

To increase the value of structured review in reviewing the whole spectrum of care quality, rather than focussing only on adverse event rates, a methodology was developed where reviewers were required to provide implicit clinical judgements and to write explicit comments to support judgement based quality of care scores: this forms the basis of Structured Judgement Review.

Structured Judgement Review requires reviewers to make safety and quality judgements over phases of care, to make written comments about care for each phase and to score care for each phase.

The objective of this review method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about hospital systems where care goes well and to identify areas where there may be gaps, problems or difficulties with the care process. It can be used for a wide range of hospital based safety and quality reviews across services and specialties and not only for those cases where patients die in hospital. The quality and safety of care may be judged and recorded whatever the outcome of the case and good care is judged and recorded in the same detail as care that may have been problematic.

There are two stages to the review process.

Stage One

Carried out by ‘front line’ reviewers who are trained in the method and who undertake reviews within their own services, for example in Morbidity and Mortality Reviews.

Phases of care – the ‘structure’ part of the process.

Phases of care are shown below but may be varied depending on the type of care or service being reviewed:

- Admission and initial care – first 24 hours
- Ongoing care

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- Care during a procedure
- Perioperative/procedure care
- End of life care (or discharge care)
- Overall assessment of care

Explicit Judgement Comments

Explicit judgement commentaries provide:

- The means for the reviewer to concisely describe how and why they assess the safety and quality of care provided.
- A commentary that other health professionals can really understand if they subsequently look at the completed review.

Phase of Care Scores

Care scores are recorded after judgement comments have been written and the score is itself an overall judgement of the reviewer. Scores range from excellent to very poor.

1. Very poor care
2. Poor care
3. Adequate care
4. Good care
5. Excellent care

Judging the quality of recording in the case notes.

As part of the overall assessment, the reviewer is also asked to record their judgement on the quality and legibility of the records again using a score of 1-5.

Second Stage Review

A score of 1 or 2 is given when the reviewer assesses that care has been poor or very poor. A score at this level should trigger a second stage review through the hospital governance process.

A second stage review also uses the structured judgement method and takes place if a patient has died. If the second stage reviewer broadly agrees with the initial case review a decision may be taken to carry out a further assessment concerning the potential avoidability of the patient's death.

The judgement is framed by a 6 point scale. A score of 1,2 or 3 on the avoidability scale would indicate a governance 'cause for concern'.

1. Definitely avoidable
2. Strong evidence of avoidability
3. Probably avoidable (more then 50:50)
4. Possibly avoidable, but not very likely (less than 50:50)
5. Slight evidence of avoidability

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6. Definitely not avoidable.

Structured Judgement Review can produce learning at two levels:

- The detail captured can identify both poor practice and good practice of individual clinicians.
- When multiple reviews are undertaken within a clinical area or a hospital, a thematic analysis can be performed that may highlight systemic issues in a system.

Quantitative data identify very poor to excellent care in a number of care phases. Qualitative data from explicit judgements may be analysed, for example using word detection software, to identify recurrent themes.

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

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Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

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Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

Quality care – for you, with you

REPORT SUMMARY SHEET

Meeting: Date:	**Governance Committee** **6th December 2018**
Title:	The RQIA base line review of Trust Governance arrangements around services commissioned from the Independent Sector.
Lead Director:	Melanie McClements Director of Older People Primary Care
Corporate Objective:	Provide Safe, High Quality and Effective Care
Purpose:	For Information

Summary of Key Issues for Governance Committee

High level context:

The Department has commenced work on reviewing the 2003 Quality Improvement and Regulation Order. This legislation is one of the key components of arrangements to ensure that the HSC provides and commissions quality and safe services.

The Department has directed the RQIA to undertake a baseline review of Trust Governance arrangements around services commissioned from the Independent Sector focusing on nursing and residential homes, domiciliary care (including supported living), adult day care, adult placements and independent hospitals/clinic.

RQIA have been commissioned to undertake this review which has not yet commenced.

In preparation the Trust has arranged three workshops for December 18 / January 19 with key cross-directorate personnel to review each of the areas identified including the range of assurances provided regarding governance, compliance and validation in responses to recent correspondence to both Mr Pengelly and Deborah McNeilly (DOH).

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

RQIA SCRR REVIEW RECOMMENDATIONS

IMPLEMENTATION PLAN

RECOMMENDATION 1				
1 (a) SHSCT should urgently update all relevant documentation to ensure that there is clarity regarding the SCRR including a description of the SCRR purpose, remit and process; explicitly stating that it is a separate process to any parallel Inquiries or investigations.				
Action Required to Deliver Recommendation(s)	**Responsible Officer[1]?**	**Update**	**Status RAG**	**Evidence pf Completion**
Update PID – with detail and purpose of SCRR,	LBR Project Manager (LE)	**20/10/22** – work commenced on this	Ongoing	
Draft a "stand-alone" summary of the background, purpose, objectives and process of SCRR	LBR Project Manager (LE)	**20/10/22** – work commenced	Ongoing	
1(b) SHSCT should review their arrangements for developing and quality assuring patient / family information materials and publicly accessible information to ensure there is adequate lay / service user involvement, communications expertise and, where beneficial, legal input.				
Add lay representation to the Urology Lookback Review steering and operational group.	Head of the Lookback Review (SW)	**20/10/22** – Lay representation sought via PPI team in Trust	Ongoing	
Patient / family information materials required for Phase 2 to be activity considered by Lay representatives and tested within other PPI forums either internal or external to Trust.	This is an action for the future – will be addressed and evidenced in phase 2			

[1] Responsibility for delivery this action plan sits with the SRO for the LBR who is chair of the LBR Steering Group (MOH)

Received from SHSCT on 12/01/2023. Annotated by the Urology Services Inquiry

d. assisted, through the provision of documents, a number of former Trust servants or agents who are not represented by the Trust legal team (such as Mrs Brownlee and Mrs Gishkori);

e. assisted other staff who have been amongst the 200-plus nurses and registrars who received questionnaires[4] from the Inquiry.

1.7 Looking beyond the headline statistics of cooperation to an even more important issue, the Trust has sought to adopt a positive approach to the issues raised by this Public Inquiry; a positive approach that has extended both before and beyond the parameters of the Inquiry.

1.8 What this means is that the Trust has actively approached both the issues examined by the Inquiry and the Inquiry process itself as opportunities rather than as challenges. In particular, the Trust has viewed the Inquiry and the events giving rise to it as:

a. an opportunity to identify, reflect upon, and be candid about its failings;

b. an opportunity to learn from its failings and improve; and

c. an opportunity to change culture.

1.9 Examples of this include, but are not limited to, the following:

a. Before any Public Inquiry was ever anticipated, indeed before all of the shortcomings related to or revealed through Mr O'Brien were even apparent, the Trust had recognised that there were shortcomings in its systems and had taken steps to address these. An exemplar of this is the commissioning of the Champion *'Clinical and Social Care Governance Review'*[5]

[4] TRA-00322, Day 6, p49, lines 11-13
[5] WIT-46954 to WIT-47014.

Received from SHSCT on 31/05/2024. Annotated by the Urology Services Inquiry.

31. Following an intensive stakeholder engagement phase between August and December 2023, the Panel are currently preparing a draft report of their key findings and recommendations which they intend to formally present to the Department by June 2024. The Department undertakes to share a copy of the report with the Inquiry once published to allow it to inform the Inquiry's own deliberations on MHPS.

Redesign of SAIs and Review of Early Alerts

32. It has been highlighted in the evidence before the Inquiry, and the Department recognises, that often the current SAI procedure does not work well for those involved. There is a need for speedier learning reviews for both families and staff, along with meaningful engagement, involvement and support with patients and families early and ongoing throughout the process.

33. To that end, the Department has made a redesign of the SAI procedure a priority task. Proposals for a new Framework are progressing with further engagement and involvement ongoing with stakeholders. The Department is working towards a consultation on the new Framework in Autumn 2024.

34. It is anticipated by the Department that the new Framework will see a fundamental change in how health and social care can deliver learning and continuous improvement following patient safety incidents. When things go wrong, as the Inquiry has seen, there are many contributing factors within a complex healthcare system. Key aims of the new process are to identify and then embed learning quickly, while helping families to understand events.

35. The intention is that all those involved in such events will be engaged with on a compassionate basis, including patients, families and staff, whilst streamlining and simplifying the process. The Department sees this change as an essential tool in supporting an open, just and learning culture.

36. The new Framework will support and encourage compassionate engagement with all those involved in a health and social care safety incident – including patients, families, carers and staff - ensuring an approach that respects the contribution of everyone in the review process.

37. The Permanent Secretary committed to a review of the Early Alert system when giving evidence in November 2022. Due to resourcing pressures, this work has not

Received from Department of Health on 30/05/2024. Annotated by the Urology Services Inquiry.