Review Outpatients clinic	DCC	Tuesday	13:30 - 17:00	0:00	Core	Weekly timetabled	No	1, 3, 5	25.20	0.525	2:06	88:12
Admin other (please specify)	DCC	Tuesday	13:30 - 17:00	0:00	Core	Weekly timetabled	No	2, 4	16.80	0.350	1:24	58:48
Planned in-patient operating sessions	DCC	Wednesday	08:30 - 13:00	0:00	Core	Weekly timetabled	No	5	8.40	0.225	0:54	37:48
Inclusive of preop ward round												
Planned in-patient operating sessions	DCC	Wednesday	13:00 - 18:00	0:00	Core	Weekly timetabled	No	1, 2, 3, 4, 5	42.00	1.250	5:00	210:00
Inclusive of pre and post op ward round.												
Core SPA	SPA	Thursday	09:00 - 13:30	0:00	Core	Weekly timetabled	No	1, 2, 3, 4, 5	42.00	1.125	4:30	189:00
This makes up total allocation of SPA time and is flexible.												
Admin other (please specify)	DCC	Thursday	14:30 - 16:30	0:00	Core	Weekly timetabled	No	1, 2, 3, 4, 5	42.00	0.500	2:00	84:00
This admin time is to make up total allocation and is flexible.												
Urodynamics	DCC	Friday	09:00 - 13:00	0:00	Core	Weekly timetabled	No	1, 2, 3, 4, 5	42.00	1.000	4:00	168:00
Sub Specialty clinic	DCC	Friday	13:00 - 17:00	0:00	Core	Weekly timetabled	No	1, 2, 3, 4, 5	42.00	1.000	4:00	168:00
The all day Friday is a mix of urodynamics and Oncology reviews.												
									Core	**7.850**	**31:24**	**1318:48**

APA	0.000	0:00	0:00	

Flexible Activities

Activity	Category	Normal time	Premium time	Travel time	Property	Activity location	Num/Yr	PA	Hrs/Wk	Hrs/Yr
Day surgery	DCC	4:30	0:00	0:00	Additional		3.00	0.080	0:19	13:30
Daisy Hill Paediatric Day surgery X3 /year										
Planned in-patient operating sessions	DCC	3:00	0:00	0:00	Concurrent		14.00	(0.250)	(1:00)	(42:00)
additional operating lists during the year based on previous years activity										
							Core	**0.080**	**0:19**	**13:30**
							APA	**0.000**	**0:00**	**0:00**

On-call

Rota Name	Activity location	Weekday frequency	Weekend frequency	Category	Availability supplement:	PA	Hours
On-call Rota	Craigavon Area Hospital	6	6	A	5%	1.000	4:00

The total PA arising from your on-call work 1.000
The total hours arising from your on-call work: 4:00

Availability supplement: 5%

Comments

Additional Comments

Hi Aidan, This is our draft of your future job plan based on your emails and your present activity. Have a look and we can discuss/ sign of on Thursday. Ted

Summary

Category	Core PAs	APAs	Total PAs	Core Hrs	APA Hrs	Total Hrs
Direct Clinical Care	7.405	0.000	7.405	29:37	0:00	29:37
Admin other (please specify)	1.050	0.000	1.050	4:12	0:00	4:12
Day surgery	0.680	0.000	0.680	2:43	0:00	2:43
New patient Clinic	0.400	0.000	0.400	1:36	0:00	1:36
Planned in-patient operating sessions	1.475	0.000	1.475	5:54	0:00	5:54
Pre-op ward round	0.075	0.000	0.075	0:18	0:00	0:18
Predictable Emergency Work	0.000	0.000	0.000	0:00	0:00	0:00
Review Outpatients clinic	0.725	0.000	0.725	2:54	0:00	2:54
Sub Specialty clinic	1.000	0.000	1.000	4:00	0:00	4:00
Unpredictable Emergency Work	1.000	0.000	1.000	4:00	0:00	4:00
Urodynamics	1.000	0.000	1.000	4:00	0:00	4:00
Supporting Professional Activities	1.525	0.000	1.525	6:06	0:00	6:06
Core SPA	1.525	0.000	1.525	6:06	0:00	6:06
Additional NHS Responsibilities	0.000	0.000	0.000	0:00	0:00	0:00

External Duties	0.000	0.000	0.000	0:00	0:00	0:00
Fee Paying Services	0.000	0.000	0.000	0:00	0:00	0:00
Private Professional Services	0.000	0.000	0.000	0:00	0:00	0:00
Medical School	0.000	0.000	0.000	0:00	0:00	0:00
Total	8.930	0.000	8.930	35:43	0:00	35:43

Lookback Review "Corrections & Update" Letter

Update 18.7.22

Summary

As of 18 July the "Correction & Update" process has concluded with **1846** letter forwarded to patients in the LBR cohort. These letters corrected the situation regarding the USI which had been wrongly reflected in a letter from the previous CX and also updated progress of the Lookback Review for each individual patient.

The process commenced at start of June 2022 and concluded on 18 July 2022.

The breakdown is as follows:

- Corrections and Update letter – prioritised original B letter patients in Dec 2021 (see description below)
- Breakdown of Letter Types within "**Letter B**" Cohort

Letter B Cohort		
Letter Type	Details	Numbers Issued as of **1 July22**
Letter B (0) i.e. care being reviewed but had received no communication from Trust	Concerns	12
	No Concerns	22
	Awaiting Review	5
Letter B (1) i.e. got 1 letter to say care being reviewed. Had not received update	Concerns	40
	No Concerns	131
	Awaiting Review	178
Letter B (2) – got 2 letters - 1 to say care being reviewed and 2nd to say care is ok	Apology	49
Sub total		437
Letter following postal incident on 24 June 2022 (see below for details of incident)	Apology	463
TOTAL "B" SENT		**900**

- Action from 4th July 2022 was to review all patients within the original "No Concerns" cohort and ensure 10 Question Review Form completed and no further concerns identified.
- Breakdown of Letter Types within "Letter A " Cohort

"LETTER A" COHORT		
Letter Type	Details	Numbers Issued as of **18th July**
Group A (0) i.e. care being reviewed but received no communication from Trust.	A (0.1) Awaiting Review	0
	A (0.2) No Concerns	74
Group A (1) got 1 letter to say care was reviewed. Had not received update into further review.	A (1.1) Awaiting Further Review	0
	1 (1.2) No Concerns	657
Group A - other		215
TOTAL "A" SENT		946
GRAND TOTAL		**1846**

Outstanding Review Forms - these are for patients who currently have had no review completed or had a 4 question review and now require a complete 10 question review

- We received 247 completed Review Forms from Prof Sethia on **Thursday 30th June**
- Prof has committed to completion of the outstanding review forms by the end of July.
- As these continue to be returned the LBR team will actioned accordingly, advising patients of outcome and will be reported in more detail in future update reports

Update on Information Line Calls & Emails

- To date we have had a total of 15 calls to the info line and 7 emails.
- One call remains open as when HOS went to return call on the number provided on multiple attempts the mobile is turned off. The rest have all been addressed.
- One email relating to WL time has been forwarded to HOS and OSL team to review and advise patient.
- Detail capture more comprehensively in a spread sheet for record and USI discovery

Structured Clinical Record Review

Update 18.7.22

Summary to Date

- Original 77 screened
- 53 Confirmed 1st May for SCRR. The remaining 24 determined not to be SCRR
- 20 SCRRS allocated February 2022
- 20 Allocated May 2022
- 3 Allocated w/c 27 June 2022
- SCRR completion
- Further 29 cases screened in as SCRR – not allocated as no SCRR urologists can be secured
- 13 more cases waiting screening (10 identified in 2 weeks since last meeting from completion of Clinical review forms)

Confirmed SCRR	Number Sent to BAUS	Number Remaining to be Sent	Number Returned	Number Awaiting Return
First 53 (@ 1/5/22)	53	0	20	33
Further 29 (@1/7/22)	0	0	0	0

- 20 Returned SCRR Reports – Bespoke letters completed for 20 patients on return of completed SCRR.
- Forwarded to patients week of Monday 20 June.
- 1 Letter remains for Chief Executive oversight and family reviewed letter inviting them to meet with DMD – requested written feedback in the first instance
- All SCRR letters:
    - Summary of SCRR process including role of BAUS
    - Include a summary of the findings,
    - Offered face to face or telephone meeting with DMD and senior manager to discuss SCRR report
    - Patients offered opportunity to get a clinical consultation – with urologist and specialist nurse.
    - Correction of USI details
    - Updated SCRR Leaflet.

Next Steps

- Continue to liaise with BAUS regarding remaining returns
- Ongoing correspondence with patient when reports returned
- RQIA discussion re SCRR on Thursday 30th June – feedback not yet received following that meeting.

Update on correction letters 180722

Stinson, Emma M

From: Wallace, Stephen
Sent: 08 July 2020 15:41
To: Wallace, Stephen ([redacted])
Subject: Joanne Donnelly

Dr O'Kane gave background to AOB case including MHPS investigation. Advised Joanne of email from AOB 7th June 2020 re outstanding waits on patients and Mr Haynes. These patients had been assessed as elective / emergency patients who the Trust had not been aware of. AOB used a separate patient booking system, HoS did a review of patients (334 patients) 46% of patients concerns re being delayed / not being tested in a timely fashion. Vulnerability around MDM's, there are two patients who may have came to harm. A wider lookback is planned, a conversation with the RCS on scope and scale of lookback will be conducted. Dr O'Kane advised that NHS Resolutions had been contacted and advised that restrictions on practice should be considered. Joanne advised this should be shared with the GMC investigation team, restirctions will limit SHSCT but further reaching GMC sanction will be required to be considered.

Joanne agreed that this is a MHPS case – this should be handled separately to the existing process. Joanne to ask June Turkington regarding MHPS for no-employee. Decision can be re

Advise him on restriction and next steps – what happens with the GMC.

No clinical work - no private work assurance

Ref	Record name	Incident type	Incident date	Claim date	Description	Related inc/comp	Involvement	Report Requests	Current position
Personal Information redacted by the USI	Patient 108	Failure to carry out adequate post-operative observations	Personal Information redacted by the USI	05/01/2016	Allegations - The Plaintiff underwent surgery on Personal Information to remove a tumour and a small part of his kidney. The Plaintiff was discharged on Personal Information. On Personal Information the Plaintiff was re-admitted to hospital as he was feeling unwell and was losing consciousness. It is alleged that he collapsed in hospital due to organ failure and had to be resuscitated before emergency surgery to remove his kidney. The Plaintiff was discharged on Personal Information, and he alleged that he was unable to keep food down, he raised his concern with the Treating Dr who advised him that everything was ok. on Personal Information the Plaintiff was admitted to (South West Acute Hospital) SWAH where a CT scan was carried out which revealed a number of clots on the right side of his stomach, as a result of the toxic blood residue from organ failure and that these clots were pressing down on his bowels.	NO	Mr O'Brien performed the procedure on Personal Information and was the urologist in charge of the Plaintiff's care. Noted in the records is a letter in the patient's records from Mr O'Brien to the GP. This states that the patient had a reasonably uncomplicated postoperative recovery and was discharged on Personal Information redacted by the USI. He refers to the patient being admitted to SWAH on Personal Information following the onset of nausea and rigors, and that it was considered he had a wound abcess as indicated by abdominal USS. The wound was opened, drained and packed and the patient was discharged the following day. However was readmitted to SWAH on Personal Information redacted by the USI where all features were consistent with him having had a significant inter-abdominal haemorrhage, and then he was transferred to CAH that same day - found to have 2 litres of blood in his peritoneal cavity. Whilst no active bleeding from the left renal tumour resection site, a left mephrectomy was performed as there was no other detectable source of harmorrhage. Slow post-op recovery. Discharge on Personal Information redacted by the USI. Readmitted to SWAH on Personal Information. CT scan found to have a large, biloculaated collection, located anterior to the duodenal jejunal junction. Transferred again to CAH for treatment - discharged on Personal Information	23/05/17 - request for report 26/06/17 - reminder sent 09/10/17 - reminder sent 15/01/18: reminder sent 01/05/18 - T/C and reminder 29/10/18 - escalated to Ronan Carroll & Dr Haynes 19/11/18 - followed up with Ronan & Dr Haynes 25/01/2019 - followed up with Ronan & Dr Haynes Feb 19 - t/c to Mr O'Brien's secretary to follow up Mar 19 - raised again with Ronan Carroll, AD - report still outstanding	Pre-proceedings (not lodged with the Courts at present)
Personal Information redacted by the USI	Patient 109	Failure to diagnose/delay in diagnosis	Personal Information redacted by the USI	30/05/2012	The patient suffers from Personal Information redacted by the USI. He attended ED CAH on Personal Information with pain and swelling in his right testicle, which he was reported to have been suffering from for approx. 36 hours prior to attendance at ED. The parents were advised that because of time-frame elapsed, salvage of the testicle was unlikely. An ultrasound scan was carried out on Personal Information (highly suspicious of ischemia due to torsion). The patient and parents were advised of same and that surgery was required. A right	NO	Mr O'Brien performed the procedure and was the urologist in charge of the Plaintiff's care.	30/12/12 - report requested 20/01/14 - report received Difficulty obtaining further information to help assess liability Hearing vacated as unable to confirm Dr O'Brien's attendance	Case is now settling out of Court
Personal Information redacted by the USI	Personal Information redacted by the USI	Operator Error	Personal Information redacted by the USI	21/03/2014	Allegations relate to causing the 1/2cm hole in the Plaintiff's bladder, Causing patient to suffer a vesico-vaginal fistula, Failing to adequately perform a cystogram, Failing to carry out a vaginal repair of the fistula which resulted in a midline scar.	1I	Involved in repair surgery only	No issues recorded on file re involvement report	Settled
Personal Information redacted by the USI	Personal Information redacted by the USI	Lack of pre-operative evaluation	Personal Information redacted by the USI	08/01/2016	Plaintiff alleges that removal of bladder in late Personal Information at CAH was inappropriate and other more conservative treatment options were never offered to the Plaintiff and explored prior to the surgery and that had such alternative treatments been pursued, bladder removal would not have been necessary.	NO	Mr Young performed the surgery on Personal Information redacted by the USI. Mr O'Brien was involved in the care of the Plaintiff in Personal Information redacted by the USI (not required to be involved in case as the issue for the Trust relates to whether fully informed consent was obtained in relation to removal of bladder)	09/11/16: report requested 12/01/17: reminder Dr O'Brien on S/L 23/04/18: report requested again 30/04/18: reminder 02/05/18: report received	Personal Information redacted by the USI, the Trust have been notified that the case is listed for Personal. The case is against the Western Trust with the Southern Trust informally aligned. We are advised that it is likely the case will be adjourned due to the unavailability of witnessess
Personal Information redacted by the USI	Personal Information redacted by the USI	Failure to diagnose/delay in diagnosis	Personal Information redacted by the USI	23/08/2017	The Plaintiff attended Mr O'Brien on Personal Information for a Day Procedure to have a cyst removed from his scrotum. Following the procedure the Plaintiff suffered severe pain, incontinence and loss of function. The Plaintiff was subsequently diagnosed with prostate cancer (Personal Information redacted by the USI) with metastatic spread to the bone. The Plaintiff was advised by Information Governance by letter dated Personal Information that there is no histology or general lab tests held on his record for Personal Information. The Plaintiff sadly died in Personal	NO	Involved Clinician performed procedure on Personal Information (incident date) and has provided a history of the Pls' involvement with Belfast Trust Personal Information Personal Information redacted by the USI prior to his involvement. In his involvement report Mr O'Brien states that there was no suspicion of malignancy of or in the cyst and that it has never been his practice to submit a simple epididymal cyst for histopathological confirmation of its benign simplicity. Mr O'Brien advised that the in Personal Information, the PL had developed a rapidly aggressive cancer of recent onset. No evidence or suspicion of metatastic, prostatic carcinoma in Personal Information redacted.	16/11/17: initial report requested advising of urgency as the Plaintiff is terminally ill. 12/04/18 reminder sent. 15/06/18 reminder sent. 08/10/18 reminder sent. 05/11/18 reminder sent 03/12/18: escalated to Ronan Carroll 18/12/18: reminder sent 19/12/18: report received	Pre-proceedings file is under review as the Plaintiff's personal representative may want to advance the case.
Personal Information redacted by the USI	Personal Information redacted by the USI	Coroner's Investigation	Personal Information redacted by the USI	19/06/2017	The deceased underwent a left laparoscopic nephro-ureterectomy under GA on Personal Information Mr Glackin carried out the surgery and advises in his statement that it was completed without significant blood loss and no suspicion of injury to any other organ at the time of surgery. After the	Complaint NO IR2 or SAI	Not involved in initial surgery but carried out 2nd procedure.	Report received within timeframe	Coroner closed case

Personal Information redacted by the USI

Barrister-at-Law

Bar Library
91 Chichester Street
Belfast
BT1 3JP

Telephone:
Mobile: Personal Information redacted by the USI
Bar Library:

Irrelevant information redacted by the USI **NR BELFAST**

email: Personal Information redacted by the USI

Business Services Organisation
Directorate of Legal Services
2 Franklin Street
Belfast
BT2 8DQ

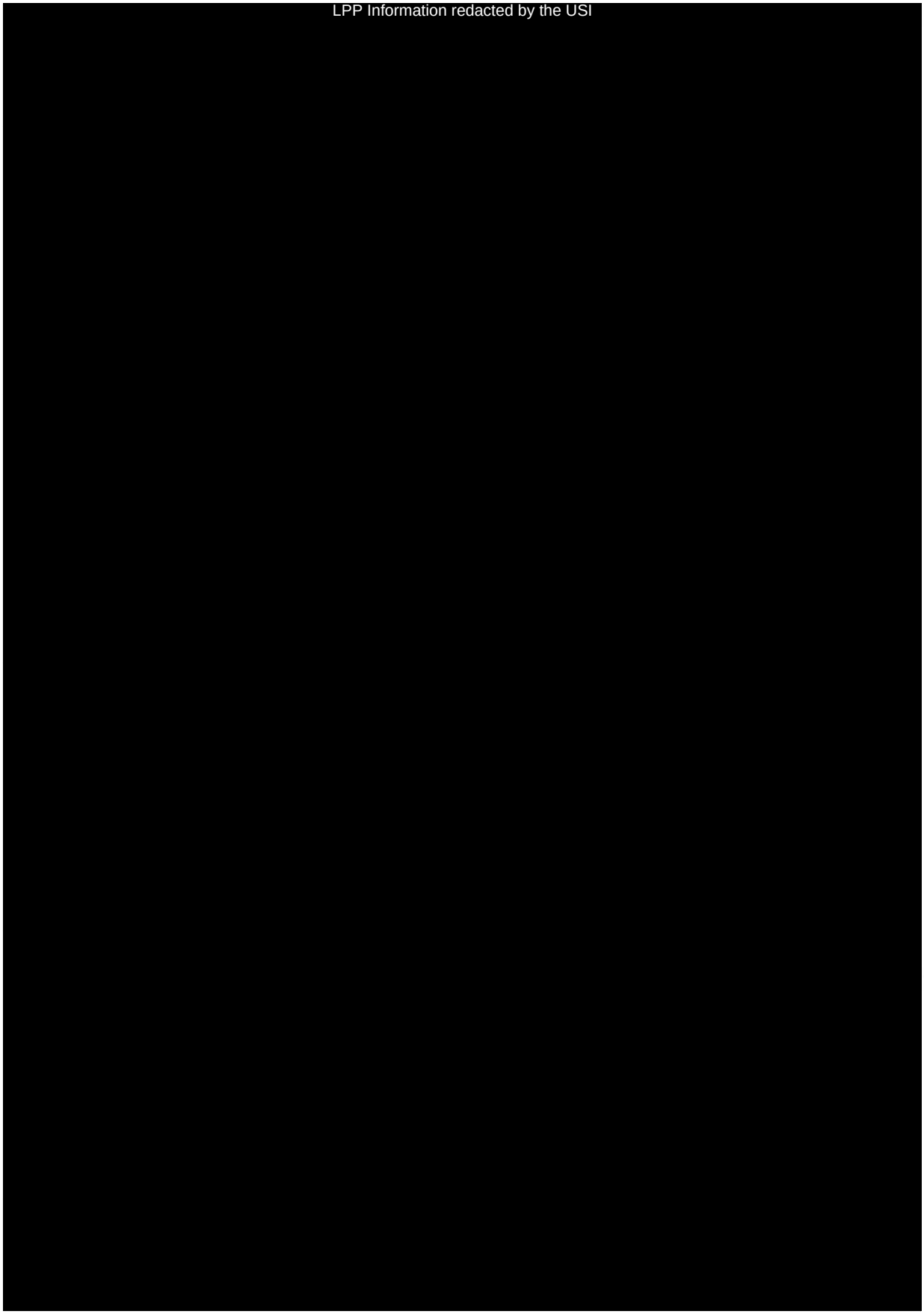
Irrelevant information redacted by the USI

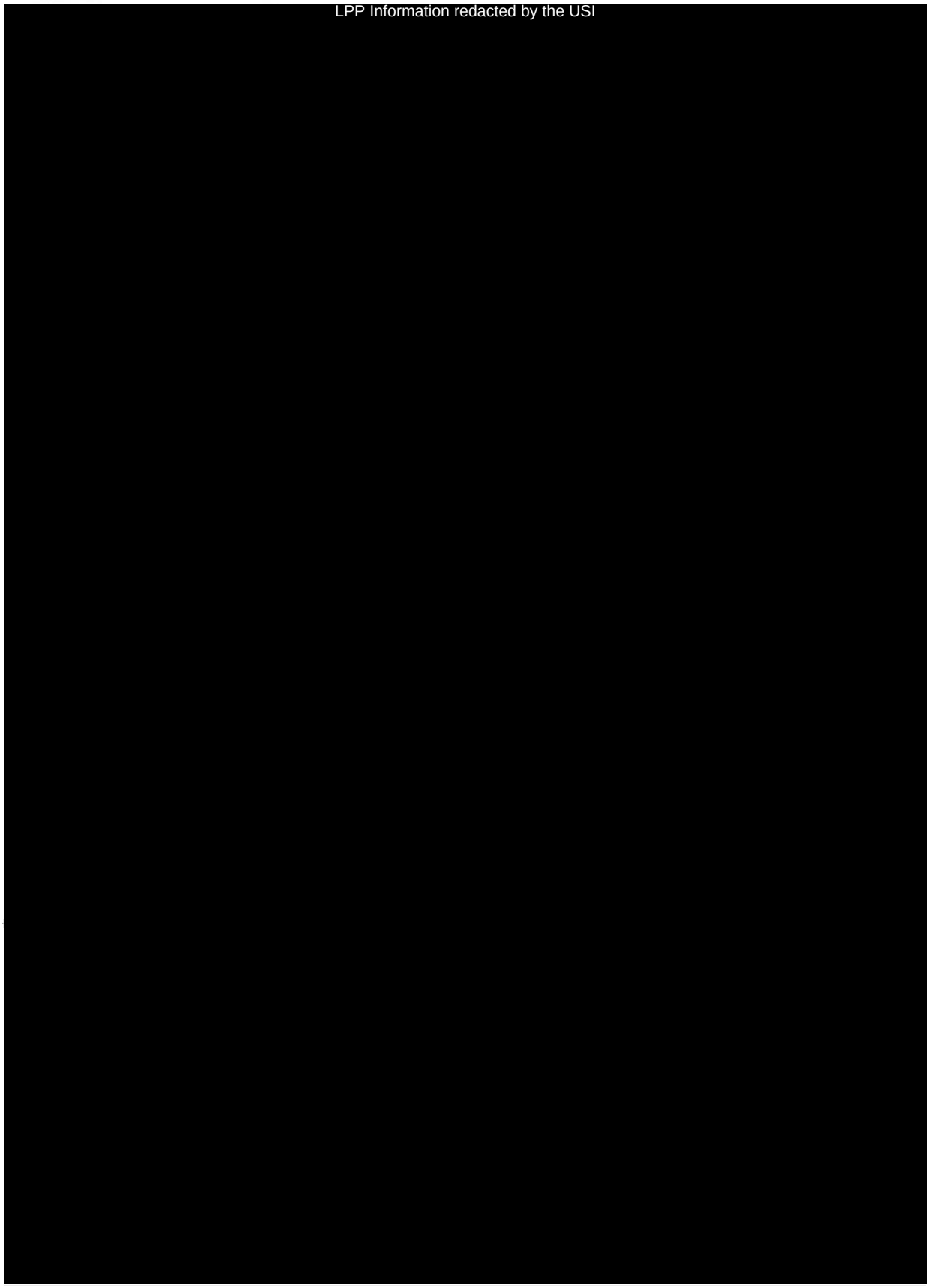
Your Ref: Personal Information redacted by the USI

Dear Avril

Re: Patient 109 **(a Person under a Disability) by** Patient 109's mother **his Mother and Next Friend -v- Southern Health and Social Care Trust and Northern Health and Social Care Trust**

LPP Information redacted by the USI


LPP Information redacted by the USI


LPP Information redacted by the USI

LPP Information redacted by the USI

Yours sincerely

Personal Information redacted by the USI BL

Bar Library

Stinson, Emma M

From: Scullion, Damian
Sent: 06 September 2019 13:59
To: OKane, Maria
Subject: AOB appraisal/revalidation

Importance: High

Dear Maria,

I am currently arranging Aidan O'Brien's appraisal and he has informed me that the GMC has informed him that his deferred revalidation date is 04/11/2019. I asked him to inform you of this.

I will continue with his 2018 appraisal in the near future.

Regards

Damian

Southern Health and Social Care Trust.

This job plan started 01 February 2017.

Job plan for Mr O'Brien, Aidan in Urology

Basic Information

Job plan status	In 'Discussion' stage
Appointment	Full Time
Cycle	Rolling cycle - 12 weeks
Start Week	1
Report date	05 Apr 2018
Expected number of weeks in attendance	42 weeks
Usual place of work	Craigavon Area Hospital
Alternate employer	None Specified
Contract	New
Private practice	Yes

Job plan stages

Job plan stages	Comment	Date stage achieved	Who by
In 'Discussion' stage		16 Apr 2015	Mr Malcolm Clegg
In 'Discussion' stage - awaiting doctor agreement		10 Oct 2016	Mr Colin Weir
In 'Discussion' stage - request cancelled		10 Oct 2016	Mr Colin Weir
In 'Discussion' stage - awaiting doctor agreement		7 Nov 2016	Mr Colin Weir
In 'Discussion' stage - request cancelled		13 Feb 2017	Mr Colin Weir
In 'Discussion' stage - awaiting doctor agreement		19 Apr 2017	Mr Colin Weir
In 'Discussion' stage - request cancelled		16 Aug 2017	Mr Colin Weir

PA Breakdown

	Main Employer PAs	Total PAs	Core hours	ATC hours	Total hours
Direct Clinical Care (DCC)	9.422	9.422	37:17	0:00	37:17
Supporting Professional Activities (SPA)	1.587	1.587	6:20	0:00	6:20
Total	11.009	11.009	43:37	0:00	43:37

On-call summary

Rota Name	Location	Weekday Freq	Weekend Freq	Category	Supplement	PAs
On-call Rota	Craigavon Area Hospital	6	6	A	5%	1.000

Type	Normal	Premium	Cat.	PA
			Total:	1.000
Predictable	n/a	n/a	DCC	0.000
Unpredictable	n/a	n/a	DCC	1.000

The total PAs arising from your on-call work is:	1.000
Your availability supplement is:	5% (based on the highest supplement from all your rotas)

On-call rota details

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Case review structured reflective template

Name of doctor: Aidan O'Brien	GMC No: 1394911
Date of clinical event: Personal Information redacted by the USI	Patient Identifier: Personal Information redacted by the USI

Description of clinical event:

Hint: You may choose a single consultation at random, or you may prefer to choose a case in which you were involved over time. Either way, your involvement should have been significant. You should write from your personal perspective, and reflect on how your own professional behaviour can improve, not that of the organisation, or of others.

This Personal Information redacted by the USI man had a history of atrial fibrillation, hypertension and heart failure prior to the onset of retroperitoneal fibrosis resulting in bilateral ureteric obstruction and acute renal failure and severe anaemia in Personal Information redacted by the USI. He initially required bilateral ureteric stenting and nephrostomy drainage to obtain optimal recovery of renal function. He was transfused six units of packed red cells. He was prescribed Prednisolone which enabled removal of the nephrostomy drains. He continued to have indwelling ureteric stents during Personal Information redacted by during which time he remained anaemic, requiring repeated transfusion. Bone marrow biopsy confirmed a myelodysplasia.

The indwelling ureteric stents caused increasingly severe urinary symptoms and bilateral flank pain during Personal Information redacted by the USI. He required acute admission Personal Information redacted by the USI for intravenous hydration and antiobiotic therapy. He remained anaemic. He was discharged to be readmitted electively for bilateral ureterolysis.

He attended for preoperative assessment on Personal Information redacted by the USI, when his Hb was 87 g/L. He had two units of packed cells transfused on Personal Information redacted by the USI, and was admitted on Personal Information redacted by the USI for bilateral ureterolysis. On admission, his Hb remained unchanged at 86 g/L. After endoscopic replacement of the ureteric stents, bilateral ureterolysis and omental wrapping was performed by way of a midline incision. Tube drains were placed in both flanks. He had two units of packed cells transfused intraoperatively for a total blood loss of 500 ml.

He became acutely unwell postoperatively. He was distressed, hypotensive and severely acidotic. He drained a further 300 ml from the drain in the left flank. His abdomen remained soft and was not tender. He was transferred to the Intensive Care Unit. Despite ventilation, inotropic support and correction of acidosis, he died some hours later.

His death was referred to the Coroner. He was found to have both significant cardiomegaly and retroperitoneal bleeding at autopsy. The Coroner concluded that an inquest was not required.

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It was only after his death that I appreciated that he had been reported to have left atrial dilatation and left main stem coronary arterial calcification on CT scanning in [redacted] when admitted with a right inguinoscrotal hernia. He had not been referred for cardiological review. Its significance had not been appreciated at preoperative assessment.

The reason for the failure of preoperative transfusion to result in an increased Haemoglobin remains unknown.

Reflections relating to **Good Clinical Care**:
Hints: This refers to the systems allowing effective care, and your place within them. Was all information to hand? Was there enough time for the consultation? Was the environment conducive to patient privacy and dignity? Were all required clinical facilities available? Were local guidelines available? What can I do to improve these factors?

I believe that it is the overarching responsibility of the primary clinician to ensure that the patient has been adequately assessed and prepared for any operative procedure. Even though I had known this patient for one year prior to his surgery, I had not reviewed the report of a CT scan done months previously when under the care of another specialty. I believe that the primary clinician cannot be completely absolved of that responsibility by the presence and input of a preoperative assessment service. However, a complete cardiac assessment and even coronary arterial intervention may not have prevented his perioperative death.

However, I believe that the fact that it was known that his anaemia had not been relieved by preoperative transfusion could have caused me to consider deferring his surgery. If it had been appreciated that he had not had a cardiac reassessment, his persistent anaemia should have caused his surgery to be deferred.

Reflections relating to **Maintaining Good Medical Practice**
Hints: This refers to your level of knowledge. How do I judge my level of knowledge, or skill around this clinical topic? What unmet learning needs can I identify? How can I address them?

I first performed this operation in [redacted]. Though not a common operation, it does not require complex surgical skill. I was very happy with the surgery at completion of the operation.

I believe that the failures were those of failing to ensure cardiac assessment, having the findings of cardiac assessment inform the operative decision making, and failing to appreciate the significance of his anaemia remaining unchanged by preoperative assessment.

Reflections relating to **Relationships with Patients**
Hints: How well did I communicate with the patient? Did the patient feel respected? Did the patient have sufficient opportunity to tell their story? Did the patient feel a partner to the outcome of the consultation? How do I gauge these? What skills can I identify which will enhance these?

Southern Health and Social Care Trust

Quality Care - for you, with you

I believe that my relationship with the patient was very good. I had provided him with my telephone number, enabling him to contact me frequently in the months prior to his surgery.

Reflections relating to **Relationships with Colleagues**

Hints: Did I take account of notes made by others prior to this event? Did I gather information appropriately from others? Did I make comprehensive, legible records for others who may see the patient subsequently? Did I appropriately respect the clinical approach of others, even if it differs from my own? What can I do to improve this area in the future?

I do believe that my relationship with my colleagues, particularly anaesthetic, recovery and intensive care staff were very good.

Outcome: For completion at your appraisal:

Agreed potential learning needs for consideration for inclusion in your personal development plan, considering how your outcome will improve patient care.

Stinson, Emma M

From: OKane, Maria
Sent: 08 July 2020 12:38
To: Wallace, Stephen
Subject: FW: SHSCT - Dr O'Brien – GMC No. 1394911

From: Joanne Donnelly (Personal Information redacted by the USI) [mailto: Personal Information redacted by the USI]
Sent: 24 October 2019 14:39
To: OKane, Maria
Cc: Shields, Katie; Scullion, Damian; Support TeamELS
Subject: RE: SHSCT - Dr O'Brien – GMC No. 1394911

Dear Maria,

Just to confirm our telephone conversation on Tues 22 Oct 19- and to provide further advice.

When we spoke on Tuesday, you advised that Dr O'Brien's revalidation date is 4 Nov 19. You advised that Dr O'Brien is engaging in local revalidation processes appraisal.

You asked whether a decision has been made yet in relation to your referral of Dr O'Brien – as this is potentially relevant to your consideration as to whether a deferral recommendation is necessary. I advised that a decision has not as yet been made.

I referred you to the "RO Protocol" – see link - https://www.gmc-uk.org/-/media/documents/responsible-officer-protocol_pdf-56096180.pdf

You will see that at para 2.2 (page 14 onwards) it is stated:

"*You must use all of the information available to make your recommendation. This includes:*

- *outputs from the doctor's annual appraisals, including their reflections on supporting information (if the doctor is in training the assessments and other curriculum requirements of their training programme)*
- *intelligence from other sources, such as clinical and corporate governance systems from all settings where the doctor works*
- *information about the doctor's compliance with any GMC conditions or undertakings that have applied to their registration during the current revalidation period*
- *information about the doctor's compliance with any locally agreed restrictions on their practice.*

The information must, as far as possible, cover all aspects of the doctor's practice, in all settings and the entire time period under consideration. You should be assured that a doctor is fit to practise and that there are no unaddressed concerns about them.

If you have insufficient or incomplete information on which to base a recommendation to revalidate, you must decide whether it is appropriate to recommend a deferral, or to recommend that the doctor has not sufficiently engaged in revalidation (see section 5 and section 6)."

And at para 5.1 it is stated:

"*Recommendations to defer can be made when a doctor is engaged in the systems and processes that support revalidation but:*

- *there is incomplete information on which to base a recommendation to revalidate*
- *they are participating in an ongoing local governance process, the outcome of which is material to your evaluation of the doctor's fitness to practise and your ability to make an informed recommendation*."

You will also see that at para 2.47 it is stated:

"*If the doctor has raised public interest concerns and you need to make a subsequent consecutive deferral recommendation (see section 5.3), you should discuss the situation with your ELA. We may seek further information from you about any on-going local process before processing the recommendation*."

I see that Dr O'Brien was previously deferred on 14 May 19 – so this would be a second deferral – so if you were to make a 2nd deferral recommendation I expect that our Revalidation Team may wish to seek further information from you, in line with the above, on the public interest concerns you mentioned in connection with your referral of Dr O'Brien.

You will of course have to make your recommendation decision based on the information you currently have available to you (for example including information from the SHSCT local investigation), however I appreciate that your consideration of this matter is rendered more complex because you are waiting to hear from GMC Triage Team as to whether the referral you made to GMC FTP meets the threshold for a GMC investigation – and by the fact that, as you are aware, one of the factors being considered by GMC Triage is the information you have already provided in relation to the "systems" issues raised by Dr O'Brien.

In light of this, I will forward this e-mail to my colleagues in Triage Team and Revalidation Team.

I assume that the Trust has been engaging with Dr O'Brien throughout this process – and that he is aware of the concerns, aware of the stage of the local investigation, aware that he has been referred to the GMC and that is aware of the factors you need to consider when making a revalidation recommendation decision – and that he will in due course be made aware of the recommendation that is to be made and the rationale for this (precisely how SHSCT engages with SHSCT doctors is, of course, a matter for local determination – however GMC would recommended openness and transparency (in so far as such an approach is not prohibited by any legislation/guidelines e.g. re safeguarding)

I tried to call you a short time ago to discuss this, as the above goes further than the conversation we had on Tuesday - please do give me a ring as I expect you may have further questions.

Best wishes

Joanne

Joanne Donnelly Personal Information redacted by the USI
GMC ELA for NI

From: Joanne Donnelly (Personal Information redacted by the USI)
Sent: 17 October 2019 17:25
To: 'OKane, Maria' < Personal Information redacted by the USI >
Cc: Shields, Katie < Personal Information redacted by the USI >; Scullion, Damian < Personal Information redacted by the USI >; STeamELS Personal Information redacted by the USI
Subject: SHSCT - Dr O'Brien – GMC No. 1394911

Dear Maria,

It would be useful to discuss this further – grateful if you would give me a call – on either Personal Information redacted by the USI or Personal Information redacted by the USI

Best wishes

Joanne Donnelly (Personal Information redacted by the USI)
GMC ELA for NI

Revalidation – recommendation - SHSCT - Dr O'Brien – GMC No. 1394911 – GMC request for further information (17.10.19)

From: OKane, Maria [Personal Information redacted by the USI]
Sent: 17 October 2019 16:37
To: Joanne Donnelly (Personal Information redacted by the USI) < Personal Information redacted by the USI >
Cc: Shields, Katie < Personal Information redacted by the USI >; Scullion, Damian < Personal Information redacted by the USI >
Subject: FW: AOB revalidation status
Importance: High

Dear Joanne -

Mr Aidan O'Brien's appraisal was completed yesterday evening and am awaiting 2nd sign off(Robin Brown)

He asked his appraiser about his revalidation status who wasn't able to provide an accurate answer. His deferred revalidation date is 4/11/2019.

Can you advise please if we can proceed to revalidate while the concerns are being investigated through GMC?

Many thanks Maria

The General Medical Council helps to protect patients and improve medical education and practice in the UK by setting standards for students and doctors. We support them in achieving (and exceeding) those standards, and take action when they are not met.

General Medical Council

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

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

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

Stinson, Emma M

From: Wallace, Stephen
Sent: 17 August 2020 16:09
To: Chris Brammall ([redacted]) ([redacted])
Cc: Joanne Donnelly ([redacted]) ([redacted]); OKane, Maria
Subject: RE: General Medical Council - Mr O'Brien Encryption
Attachments: 2020817_LtrGENERAL MEDICAL COUNCIL - MR AIDAN O'BRIEN GMC NO. 1394911.pdf; Appendix 3 (i) The Northern Ireland Cancer Network.pdf; Appendix 3 (ii) Revised Prostate Diagnostic Pathway December 2019.pdf; Appendix 4 (i) Service User A Notes.pdf; Appendix 4 (ii) Service User B Notes.pdf; Appendix 1 (i) Job_Plan_View_-_Mr_O'Brien,_Aidan_-_01_Apr_2018.pdf; Appendix 1 (ii) Job_Plan_View_-_Mr_O'Brien,_Aidan_-_01_Apr_2013.pdf; Appendix 2 Report to HSCB 29.5.2020.pdf

Dear Chris,

Please find attached letter from Dr Maria O'Kane re below request, this has been issued with encryption protection. Please let me know if you have any difficult in accessing.

Please do not hesitate to contact me directly if you have any queries.

Best regards
Stephen

[redacted]

From: "Chris Brammall ([redacted])" <[redacted]>
Date: Jul 27, 2020 2:45 PM
Subject: General Medical Council - Mr O'Brien
To: "OKane, Maria" <[redacted]>
Cc: "Joanne Donnelly ([redacted])" <[redacted]>,"David Horkin ([redacted])" <[redacted]>,"Syed Ahmed ([redacted])" <[redacted]>

Dear Dr O'Kane, after some discussions about Mr O'Brien and the information that you have already sent to us I have been asked to contact you again to obtain some additional information. I do appreciate that this is a lot of information that we are requesting and can confirm that we would be happy to receive this 'piecemeal' if this makes it easier to collate the information.

Please would it be possible for you to send me:

- A copy of Mr O'Brien's job plan
- Any update that you may have about contacting the RCS for advice on the parameters of a possible lookback / patient recall exercise and information that may have arisen out of any review
- An update about the new MHPS investigation that was being considered due to the additional concerns about Mr O'Brien that arose recently
- Any updates concerning the SAI reviews for the following patients identified in the information originally sent to the GMC (if SAIs have been completed, please could you provide copies of these?):
  [redacted] (CAHE[redacted])
  [redacted] (CAHE[redacted])
  [redacted] (CAHE[redacted])
  [redacted] (CAH[redacted])
- Any updates concerning the SAI reviews for service user A and service user B as identified in the new concerns that were recently sent to the GMC

- Any data that you may hold for comparison purposes regarding the triage process and Mr O'Brien's peers (for example, any audit data / data gathered in relation to other urology consultants) in relation to patients who may have been mistriaged
- The outcome (or a copy of) the independent review into the administrative procedures that is due to be concluded by September 2020 (when this becomes available)
- Any guidance or protocols that were put in place for the urology department in terms of triaging incoming referrals using the three tier system and how this was shared with the urology consultants including Mr O'Brien
- The relevant medical records for service user A and service user B as identified in the more recent concerns. I do understand that these are currently subject to screening for advancement as potential Serious Adverse Incidents but, please would it be possible to provide copies of the records to me by **17 August**?
- The relevant medical records for the following patients as identified in the concerns originally sent to the GMC. Please could these be sent to me by **17 August**?

Patient 10
Patient 14 (CAHE Personal Information redacted by the)
Patient 11 (CAHE Personal Information redacted by the)
Patient 13 (CAHE Personal Information redacted by the)
Patient 12 (CAH Personal Information redacted by the)

- Please could you provide details of the circumstances of the cancellation of the meeting in September 2018 and the lack of senior management availability in December 2018 including details of any plans that were put in place for Mr O'Brien / other consultants to raise their concerns to senior management (this relates to Mr O'Brien's statement that: '*In 2018, following discussion amongst our colleagues, it was agreed that we would set aside a whole day, Monday 24 September 2018, to meet with senior management to discuss this very issue, among others. We were requested to submit those issues which we wanted to have discussed (I have separately attached my submission). No clinical commitments were arranged for that day. The meeting was cancelled, with loss of all clinical activity that could have been scheduled. The meeting was rescheduled for Monday 03 December 2018, again with no clinical commitments scheduled. No senior management personnel could attend.'*

Please could you send me the information that is currently available by **17 August 2020**, in particular the medical records for the patients listed above? I am on leave from 31 July and return to the office on 17 August so if you are able to send any responses during this time, please could you also send these to Joanne Donnelly (Personal Information redacted by the USI), David Horkin (Personal Information redacted by the USI) and Syed Ahmed (Personal Information redacted by the USI)

Many thanks for your continued help Dr O'Kane

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

Email: Personal Information redacted by the USI
Website: www.gmc-uk.org
Telephone: Personal Information redacted by the USI

Working with doctors Working for patients

The General Medical Council helps to protect patients and improve medical education and practice in the UK by setting standards for students and doctors. We support them in achieving (and exceeding) those standards, and take action when they are not met.

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

Southern Health and Social Care Trust

Quality Care - for you, with you

17th August 2020 Ref: MOK/ec

Via email [redacted]

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

Dear Mr Brammall,

RE: GENERAL MEDICAL COUNCIL - MR AIDAN O'BRIEN GMC NO. 1394911

Further to your email dated 30th July 2020 requesting further information regarding concerns raised in relation to Mr Aidan O'Brien, Consultant Urologist employed by the Southern Health and Social Care Trust, please see below itemised responses and where required, attached items.

A copy of Mr O'Brien's job plan	Copies of the last two electronic job plans that are held in our job planning system for Mr O'Brien are attached in Appendix 1. Please note that they were not signed off by Mr O'Brien. These were previously sent to the GMC in response to this communication by Zoe Parks on 30th July 2020.
Any update that you may have about contacting the RCS for advice on the parameters of a possible lookback / patient recall exercise and information that	The Trust has hosted a discussion with the Royal College Surgeons Invited Review Service on the 28th July 2020 which explored the options for and extent of any potential lookback should this be required. A follow up call was conducted on 4th August with the

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Tel: [redacted] Email: [redacted]

may have arisen out of any review	Royal College of Surgeons Head of Invited Review manager where potential scale and scope of a lookback was discussed. The Trust will be discussing the potential for progressing with any lookback with the Department of Health over the next week.
An update about the new MHPS investigation that was being considered due to the additional concerns about Mr O'Brien that arose recently	The Trust has commenced preliminary enquiries in respect of the additional concerns which have now arisen under the MHPS Framework. Mr O'Brien's former clinical manager Mr Haynes, as Associate Medical Director, is the clinical manager co-ordinating preliminary enquiries under para 15 of Section I of MHPS. Mr O'Brien has been notified of this and a request has been made for his input to the preliminary enquiries process. A formal investigation has not been commenced at this point. Mr O'Brien is seeking advices in respect of his engagement in the MHPS preliminary enquires process and the Trust awaits his decision in this regard, via his solicitor.
Any updates concerning the SAI reviews for the following patients identified in the information originally sent to the GMC (if SAIs have been completed, please could you provide copies of these?): • Patient 14 (Personal Information redacted by the USI) • Patient 11 (Personal Information redacted by the USI) • Patient 13 (Personal Information redacted by the USI) • Patient 12 (Personal Information redacted by the USI)	The Serious Adverse Incident Reviews for the listed patients have been completed. Copies of the review which was provided in a consolidated single report can be found attached in Appendix 2.

Any updates concerning the SAI reviews for service user A and service user B as identified in the new concerns that were recently sent to the GMC	Both Service User A and B have been screened and meets the requirement for a Serious Adverse Incident review and are being progressed as per regional and Trust processes. Since our last update a third case, Service User C has also been identified as meeting the requirement for a Serious Adverse Incident review.
Any data that you may hold for comparison purposes regarding the triage process and Mr O'Brien's peers (for example, any audit data / data gathered in relation to other urology consultants) in relation to patients who may have been mis-triaged	The Trust does not have formal data on the triage comparison between Mr O'Brien and his peers. All incidents have been identified by exception; no other triaging related incidents have been identified with any other Urology Consultant.
The outcome (or a copy of) the independent review into the administrative procedures that is due to be concluded by September 2020 (when this becomes available)	The review of administrative procedures is underway and will be shared following completion in September 2020 at which point a copy will be shared with the GMC.
Any guidance or protocols that were put in place for the urology department in terms of triaging incoming referrals using the three tier system and how this was shared with the urology consultants including Mr O'Brien	The Trust do not use the three tier system for triaging but follow the Northern Ireland Cancer Network (NICaN) referral guidance, which is based on NICE guidelines. Appendix 3 show the prostate and bladder guidance for triage (which is usually updated every year) and which is shared and used by all urology consultants in Northern Ireland.

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The relevant medical records for service user A and service user B as identified in the more recent concerns.	Copies of Service Users A and B redacted notes are attached as Appendix 4.
The relevant medical records for the following patients as identified in the concerns originally sent to the GMC. • Patient 10 (Personal Information redacted by the USI) • Patient 14 Personal Information redacted by the USI) • Patient 11 (Personal Information redacted by the USI) • Patient 13 (Personal Information redacted by the USI) • Patien t 12 (Personal Information redacted by the USI)	Copies of the patient will not be available until 24th August 2020 and will be forwarded following this.
Please could you provide details of the circumstances of the cancellation of the meeting in September 2018 and the lack of senior management availability in December 2018 including details of any plans that were put in place for Mr O'Brien / other consultants to raise their concerns to senior management	The meeting that was scheduled to take place between Urology Consultants and management in September 2018 was cancelled following the unexpected sickness absence of the Head of Service for Surgery. The Consultant body agreed that in the absence of the head of service the meeting should not progress. The meeting scheduled for December 2018 did not progress as 3 of the 6 Consultant Urology staff were unable to attend.

I trust this provides the necessary detail required. Should you have any queries, please do not hesitate to contact me.

Yours sincerely

Personal information redacted by USI

Dr Maria O'Kane
Medical Director

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

Southern Health and Social Care Trust

Quality Care - for you, with you

9th November 2020 Ref: MOK/ec

Via email [redacted]

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

Dear Mr Brammall,

RE: GENERAL MEDICAL COUNCIL - MR AIDAN O'BRIEN GMC NO. 1394911

Further to your email dated 8th October 2020 requesting further information regarding concerns raised in relation to Mr Aidan O'Brien, Consultant Urologist previously employed by the Southern Health and Social Care Trust until his recent retirement, please see below itemised responses and where noted, attached items. Further to the below information and attached items a verbal update was provided to Joanne Donnelly Employer Liaison Advisor, General Medical Council on the 23rd October 2020.

A copy of correspondence was issued via the Trust's legal advisers Directorate of Legal Services to Mr O'Brien's solicitor on 25th October 2020 and is attached as Appendix A, this provides additional information regarding:

- Information regarding media interest in the case
- Details of additional concerns raised regarding Mr O'Brien's practice including concerns regarding the prescribing on the anti-androgen Bicalutamide
- The Chief Medical Officer decision to issue a Professional Alert as per guidance found in DHSSPS Circular HSS (TC8) 6/98

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The below table provides answers to the questions asked in your correspondence dated 8th October 2020

Any update that you may have the possible RCS lookback / patient recall exercise and information that may have arisen out of any review	The Trust is continuing to progress with a review of Mr O'Brien's activity since January 2019 to identify any additional issues with the quality of care delivered. The Trust is liaising with the Department of Health Northern Ireland, Health and Social Care Board and Public Health Agency to guide the review process. The Trust has also consulted with the Royal College of Surgeons who have provided guidance on developing the review criteria. To date as a result of this review further issues have been identified which have required screening as potential Serious Adverse Incidents, in total nine of these incidents have been deemed as meeting Serious Adverse Incident criteria and the patients/families affected have been informed accordingly. The Trust has also been made aware of the scale Mr O'Brien's significant private practice activity via discussions with GPs in the Southern Area. Mr O'Brien's private practice was conducted from his home not under the auspices of any private hospital or clinic; therefore all records of this activity will solely be in his possession. The Trust has no access to information on the scale of this private activity, however, the Trust has made the Department of Health Northern Ireland, Health and Social Care Board and Public Health Agency aware of this area of activity. Given Mr O'Brien's residence being located close to the border with the Republic of Ireland, there may be private practice issues involving patients from this

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	jurisdiction. In addition to this, GP colleagues have commented that on occasion they have referred patients to the Southern Health and Social Care Trust to later receive correspondence from Mr O'Brien regarding the same patient on documentation referring to the individual as a private patient. The Northern Ireland Minister for Health has issued a written statement to the Northern Ireland Assembly on 27th October 2020 regarding this issue; this can be found attached as Appendix B. The concerns have also received media coverage via the Irish News and BBC Northern Ireland websites. Mr O'Brien has not been named in any public releases however Urology being a smaller speciality and the news article referencing recent retirement means there is an increased risk of identification. The Department of Health Northern Ireland has established a Departmental Oversight Group to provide assurance surrounding all elements of each ongoing process.
An update about the new MHPS investigation that was being considered due to the additional concerns about Mr O'Brien that arose recently	The Trust sought advice from the Department of Health Northern Ireland regarding the new MHPS investigation. The Trust has been advised that as the formal MHPS process had not commenced when Mr O'Brien was still an employee; the Trust is no longer his designated body and I am no longer his responsible officer, that a formal MHPS investigation should not now be commenced after the termination of Mr O'Brien's employment through his retirement. A response received from Mr O'Brien's solicitor (Appendix C) also indicates that Mr O'Brien will not

	engage with any Trust MHPS process as he is no longer employed by the Trust. The Trust response to this correspondence is attached as Appendix D.
Any updates concerning the SAI reviews for service user A and service user B as identified in the new concerns that were recently sent to the GMC	The Trust has discussed the identified Serious Adverse Incidents with the Department of Health Northern Ireland, Health and Social Care Board and Public Health Agency. As a result the Trust has appointed an independent chairperson to conduct these Level 3 Serious Adverse Incident reviews with subject matter expert support provided by an independent Consultant Urologist nominated via the British Association of Urological Surgeons (BAUS). A wider review panel to support this has been appointed and work is preparing to commence. Further to this, the Trust has identified a further seven Serious Adverse Incidents relating to patients on Mr O'Brien's caseload. Case summaries for these patients are attached as Appendix E. During the initial stages of the Serious Adverse Incident reviews, immediate patient safety concerns have been raised by the chairperson in relation to the prescribing of Bicalutamide, an antiandrogen medication that is primarily used to treat prostate cancer, which should be prescribed at 150mg for a maximum of 8-10 weeks (and kept under review during that period) to patients prior to starting radiotherapy. The concern is with regard to patients that have been managed on Bicalutamide for extended periods, in excess of 8-10 weeks, without review during that period, and at 50mg, which is associated with making

	prostate cancer worse. It is also associated with a variety of harmful side-effects. The context is complex as Dr O'Brien advised the prescribing requirements, the GP issued the prescription in light of that advice, and the pharmacist dispensed as per the prescription. The Trust is currently identifying those patients who are prescribed this medication and providing review appointments as a matter of urgency. To date 26 patients have been identified as requiring review of which all have been offered review appointments. Of this number, 9 patients were reviewed face to face on week commencing 2 November, 2 patients couldn't attend on the day, 1 patient did not attend and 14 patients (or their main carer) declined face to face appointment and all 17 of these patients will be followed up by a telephone consultation over the next few weeks
The outcome (or a copy of) the independent review into the administrative procedures that was due to be concluded by September 2020 (when this becomes available)	The review into administrative procedures commenced in August 2020 and has been initially reported on. Further details on standard operating processes for administration of patient information has been requested to complete this work. This will be shared with the GMC on finalisation; this is expected 14th December 2020.

I trust this provides the necessary detail required. Should you have any queries, please do not hesitate to contact me.

Yours sincerely

Personal information redacted by USI

Dr Maria O'Kane
Medical Director

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

WRITTEN STATEMENT TO THE ASSEMBLY BY HEALTH MINISTER ROBIN SWANN – FRIDAY 27 NOVEMBER 2020 AT 5PM – COVID-19- UPDATE

The revelation that 100 covid-related deaths were registered in the week to Friday 20 November is a chilling illustration of the seriousness of the invisible threat of Covid-19 that Northern Ireland, like virtually every other county in the world, is facing.

From my last written update to Members I am able to report that the number of new coronavirus cases has continued to decline overall, however it should be noted there still remains concerns in regards to the number of cases in the over 60s.

Hospital admissions have continued to decline, albeit slowly, over the last week but remain at a relatively high level. Whilst today there remains 425 covid confirmed inpatients, thankfully the number of patients in critical care has stabilised.

That continued high number of inpatients however, combined with the fact that our HSC system is still endeavouring to deliver as much non-covid care as possible, is resulting in ongoing pressure across our hospitals in terms of capacity and bed occupancy.

Given the further restrictions that we have entered into today, we should expect that the numbers of new cases, the subsequent pressures on our health service will decline until shortly before Christmas when they may begin to rise again. The rate of increase will of course depend on how much Rt increases above 1 following the 11th December.

So whilst the situation remains serious, I would advise Members that the correct mood to adopt right now is one of cautious optimism. While nothing is guaranteed, the progress on a vaccine does offer us hope for 2021.

Yesterday I issued an encouraging public update on the roll-out of a Covid-19 vaccination programme from next month. Members should also know that I have appointed Patricia Donnelly – an experienced and adept HSC leader - head of my Department's Covid-19 Vaccine Programme. I will continue to keep Members informed on this important issue over the coming weeks.

Whilst there is much to be optimistic about this must not be the cause of any complacency, or any weakening of our resolve to keep the spread of the virus to a minimum.

Progress has been made in reducing new cases, with restrictions in place in recent weeks having a discernible impact. That progress must not just be maintained but accelerated.

The virus is still spreading in our community, is still making too many of our fellow citizens desperately ill, and tragically is still claiming lives.

For the sake of ourselves and our health workers we have to redouble our efforts to get through this winter. All our focus now should be on maximising the benefits of the lockdown that has just begun. That is why I sincerely hope we as a society make the most of these two weeks, that we follow the public health guidance and that we stay at home. Our actions today will determine what position our health and social care system will be in as we approach the crucial Christmas period.

There are conflicting views among Members and across society on how best to respond to this pandemic. We must find unity of purpose in making these next two weeks deliver in terms of pushing down infection rates. That is our duty.

We owe it to our frontline staff, to care home residents and to other vulnerable members of our community. We owe it to people who can be spared the devastating effects of the virus. We owe it to their families.

Let’s all of us across Northern Ireland carry each other through this winter, doing all we can to ensure as many people as possible get to enjoy Christmas and live to see a better New Year.

UROLOGY ASSURANCE GROUP

Friday 30 October 2020 at 11.30am, by Zoom

Agenda

1. Welcome and apologies
2. UAG Terms of Reference
3. SAIs – update (Southern Trust)
4. Patient Records Scoping Exercise – update (Southern Trust)
5. Assurance Oversight Arrangements (Jackie Johnston)
6. Communications / Management Plan
7. AOB
8. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP

Friday 6 November 2020 at 12.00, by Zoom

Agenda

1. Welcome and apologies
2. Minutes of previous meeting
3. UAG Terms of Reference
4. Assurance Oversight Arrangements (Jackie Johnston)
5. SAIs – update (Southern Trust)
6. Patient Records Scoping Exercise – update (Southern Trust)
7. Communications / Management Plan
8. AOB
9. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 30 October 2020 at 11.30, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Jackie Johnston, DoH (Chair)	Sharon Gallagher, HSCB
Michael McBride, DoH	Paul Cavanagh, HSCB
Lourda Geoghegan, DoH	Olive McLeod, PHA
Michael O'Neill, DoH	Brid Farrell, PHA
David Gordon, DoH	Shane Devlin, Southern Trust
Ryan Wilson, DoH	Maria O'Kane, Southern Trust
Lisa Wightman, DoH (Minute taker)	Melanie McClements, Southern Trust

Apologies: Richard Pengelly, DoH, Ann-Marie Bovill, DoH.

Welcome and apologies

1. The group was welcomed and apologies noted.

UAG Terms of Reference

2. The Terms of Reference were agreed subject to RQIA colleagues being removed from the membership, in the immediate term, and the name and role of the Southern Trust led urology working group being added.

   Action: Amend the TOR as agreed and circulate in advance of next meeting. **(Michael O'Neill)**

Assurance Oversight Arrangements (Jackie Johnston)

3. Jackie Johnston acknowledged the systematic approach to ongoing scoping work by the Southern Trust to assess the extent of the issues arising from the Early Alert notification to DoH in July 2020, including the provision of regular updates to the HSCB and the Department.

4. In terms of assurance arrangements, it was agreed that:
    a. the DoH-led Urology Assurance Group will provide external and independent oversight, as per the TOR, in order to reassure both patients and the public with regard to the current process and any future arrangements as may be required;
    b. the PHA & HSBC would continue to be involved in the Trust-led urology working group (with TOR to be established and formalised minutes introduced) which will now report to the UAG enabling the Department to withdraw from these meetings; and
    c. the UAG will continue to receive updates on the progress of the ongoing SAI investigations and scoping exercise, providing sign-off and Ministerial briefing at key steps as required.

5. It was noted that the consultant worked in a number of related disciplines (bladder removal etc) so there was not an obvious single external body to provide independent expert level of scrutiny for all elements of the review: this will remain under review and different bodies may need to be engaged depending on the issues arising. It was agreed that Maria O'Kane will liaise with the Royal College of Physicians (RCP) to seek input.

    Action: **Maria O'Kane** to liaise with Royal College of Physicians.

SAIs – update (Southern Trust)

6. A panel has been set up to investigate Serious Adverse Incidents (SAI's) identified through the current scoping exercise. Members include Dermott Hughes (Chair), Hugh Gilbert and other subject matter experts from across the

region. There are currently 9 SAI's and a further 6 awaiting screening, with more anticipated following completion of some scoping exercise strands.

7. DoH and PHA advised that the SAI process was not appropriate for investigating a potentially high number of patient cases, including around the likely duration, as the SAI process was not designed to meet the full requirements of a patient recall exercise of this nature. It was acknowledged that clear communication would be needed with patients/families who have been notified of the SAI process. It was agreed that CMO and DCMO would consider this issue further.

8. CMO raised the issue of patient support that had been a theme of recent Neurology Recall patient meetings, in which some participants felt that there was insufficient therapeutic support provided. It was agreed that the Southern Trust was consider this issue further.

Action: CMO/DCMO to consider suitability of SAI process.
Action: Southern Trust to consider issues around patient support.

Patient Records Scoping Exercise – update (Southern Trust)

9. An update was provided by Maria O'Kane & Melanie McClements based on the written report circulated previously to the group. From January 2019-July 2020 2,327 patients were treated by the consultant. Scoping work continues in the following areas:
    a. Elective Care;
    b. Management of Pathology and Cytology Results;
    c. Management of Radiology Results;
    d. Actions required as a result of Multidisciplinary Team Meetings;
    e. Oncology Review Backlog; and
    f. Patients on Bicalutamide.

10. The Trust opened public and GP helplines on 26 October and to date have received 134 calls from the public and 1 GP.

11. CMO asked whether the consultant had stopped his private practice. The Southern Trust advised that they contacted the individual's solicitor to advise that he should no longer be carrying out any appointments with private patients, however it was acknowledged there is no existing structure within which a consultant's private practice can be monitored or appraised by Trusts. It is therefore not possible to identify all patients who were seen privately, although it was acknowledge those who subsequently re-entered the public health system will be picked up by the current scoping exercise in the event of any concerns being identified. There may be the further possibility of some private patients from ROI as his private practice was believed to have been carried out at his residence which is close to the border.

12. Jackie Johnston sought information on the impact the additional scoping work was having on the ongoing provision of Urology services. Shane Devlin and Melanie McClements advised that there had been an impact and that a further assessment of this would follow, but that service was continuing to be provided based on clinical need. Melanie McClements further advised that there had already been contact with the Belfast Trust regarding the impact of the Neurology Recall and what additional resourcing may be required. Shane Devlin advised that the Southern Trust will consider what additional investment may be required to manage this work and emerging issues.

Action: Southern Trust to consider resourcing issues and develop an IPT for support to the clinical and non-clinical team**.**
Action: Southern Trust to provide further information on impact on ongoing service provision.

Communications / Management Plan

13. There was a discussion around the Minister's commitment to provide an oral statement to the Assembly in the coming weeks. It was agreed that this is likely to include updates concerning the ongoing scoping work, patient engagement and establishment of Departmental oversight arrangements, and that the Trust would provide up to date information for this as required. The Department's

Information Office will lead on the development of questions and answers for Assembly and media briefing with input from Trust Communications teams.

Action: DoH/SHSCT Press Offices to liaise on production of question and answer briefing.

Any other business

14. There was no further business.

Date of next meeting

15. The next meeting of the group will be on Friday 6 November 2020.

UROLOGY ASSURANCE GROUP

Friday 13 November 2020 at 11.00, by Zoom

Agenda

1. Welcome and apologies
2. Minutes of previous meeting
3. Assurance Oversight Arrangements - update (Jackie Johnston)
4. Patient Records Scoping Exercise – update (Southern Trust)
5. SAIs – update (Southern Trust)
6. Communications / Management Plan
7. AOB
8. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 6 November 2020 at 12.00, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH	Paul Cavanagh, HSCB
Jackie Johnston, DoH (Chair)	Sharon Gallagher, HSCB
Michael McBride, DoH	Brid Farrell, PHA
Lourda Geoghegan, DoH	Shane Devlin, Southern Trust
Michael O'Neill, DoH	Maria O'Kane, Southern Trust
David Gordon, DoH	Melanie McClements, Southern Trust
Anne-Marie Bovill, DoH	

Apologies: Olive McLeod & Ryan Wilson.

Welcome and minutes of previous apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting formed the majority of the agenda for this meeting and were discussed throughout.

UAG Terms of Reference

4. The UAG Terms of Reference were approve, with Melanie McClements, Southern Trust, added to the membership list.

   Action: Inclusion of Melanie McClements, Southern Trust, to the UAG membership list. **(Anne-Marie Bovill/Michael O'Neill)**

Assurance Oversight Arrangements (Jackie Johnston)

5. Jackie Johnston apprised the group of the preliminary discussions that took place with Brett Lockhart, Independent Neurology Inquiry (INI), and noted that Mr Lockhart would provide feedback from those discussion w/c 9 November 2020. It was noted that there the potential for considerable alignment between the ongoing work of the INI team and the issues arising for the UAG. It was agreed that the work of the INI should not be adversely impacted by any additional responsibilities relating to Urology.

6. Jackie Johnston further outlined the structures established to oversee the Urology Review going forward including the role of the Urology Assurance Group and the hitherto Trust-led Urology Working Group. It was agreed that this latter group would be chaired by the HSCB going forward.

   Action: HSCB to take lead on Urology Working Group. **(Paul Cavanagh)**

SAIs – update (Southern Trust)

7. The group received a verbal update on progress with the ongoing SAIs. There was also a discussion on the process for considering the current 9 SAIs, the further 6 awaiting screening and the potential for further SAIs following completion of some scoping exercise strands.

8. It was agreed that the panel established by the Trust to review the initial six SAIs should continue and that a separate clinical review panel would be established to conduct a wider review of the issues arising from this large group of SAIs which is unprecedented as a single group.

Action: **DoH** to confirm arrangements for establishing the clinical review panel prior to the Minister's Oral Statement in the Assembly.

Patient Records Scoping Exercise – update (Southern Trust)

9. A detailed update on the Patient Record Scoping Exercise was provided by Maria O'Kane and Melanie McClements including:
    - the Patient Facing Information Line - a total of 151 calls received (up to and including Thursday 5 November);
    - Independent Sector Clinics –191 oncology review patients transferred to the Independent Sector; and
    - the Bicalutamide Audit - 26 patients identified from the first look into the patients and 2 all-day clinics were held in Craigavon.

10. The issue of private patients was discussed including the challenges in accessing records and information. It was agreed that BSO Internal Audit should undertake a review, as far as possible, of those patients transferring into Trust provision. Further it was agreed that efforts should be made to secure records and patient lists from the consultant and his legal advisors.

11. A review of deceased patients was discussed and it was agreed that this strand may be required but should await in the first instance further information emerging from the ongoing scoping exercise.

12. It was noted that the consultant was attached to the Craigavon Urological Research & Education (CURE) organisation and it was agreed that efforts should be made to ensure that no ongoing healthcare provision or advice was taking place.

Action: **Maria O'Kane** to confirm support arrangements with Royal College of Surgeons prior to the Minister's Oral Statement in the Assembly.

Action: DoH to provide advice on engaging BSO Internal Audit to commence review**.**

Action: Southern Trust to establish if consultant has ceased activities relating to CURE. **(Maria O'Kane / Melanie McClements)**

Action: Southern Trust (DLS) to write to the consultant's legal representative w/c 9 November 2020 to ask that the Consultant provides a written assurance to the Trust that he will makes arrangements for his private patients to be reviewed by an independent urologist; or the Consultant provides details of his private practice and the Trust will make arrangements for the review of these patients and recharge the cost to him / his medical insurer. **(Maria O'Kane / Melanie McClements)**

Minister's Oral Statement – update (Jackie Johnston)

13. Jackie Johnston provided an update on preparations for the Minister's Oral Assembly Statement, due to take place on Tuesday 17th November 2020. It was noted that the Urology Consultant will be named (which will likely help with the identification and engagement of relevant private patients affected) and that this may also impact the number of calls made to the helpline.

14. It was also agreed that mention should be included in the statement of the potential for redress aligned to arrangements that may develop on the Neurology side.

Action: Southern Trust to review statement excerpts for factual accuracy, returning to Department by 11 November 2020. **(Melanie McClements / Maria O'Kane)**

Communications / Management Plan

15. David Gordon provided an update on the communications required to support the Minister's Oral Assembly Statement on 17th November 2020. There was a discussion around key messaging including the ongoing scoping work, patient engagement, patient support and the establishment of Departmental oversight arrangements.

16. The group noted the intention of the Southern Trust to release communications to the media relating to the Urology Review at the same time as the Minister's statement with both Press Offices would working closely together.

Any other business

17. Melanie McClements outlined the Southern Trust's current considerations of patient support including the helpline, counselling, third sector support, family liaison support and bereavement counselling. It was noted that the experience from Belfast Trust was to guard against underestimating the needs of patients affected by any recalls and reviews.

Date of next meeting

18. The next meeting of the group will be on Friday 13th November 2020.

UROLOGY ASSURANCE GROUP

Friday 20 November 2020 at ??, by Zoom

Agenda

1. Welcome and apologies
2. Minutes of previous meeting
3. Assurance Oversight Arrangements - update (Jackie Johnston)
4. Patient Records Scoping Exercise – update (Southern Trust)
5. SAIs – update (Southern Trust)
6. Independent Sector (Southern Trust)
7. Communications / Management Plan
8. AOB
9. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 13 November 2020 at 11.00, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Paul Cavanagh, HSCB
Jackie Johnston, DoH	Sharon Gallagher, HSCB
Lourda Geoghegan, DoH	Olive McLeod, PHA
Michael O'Neill, DoH	Shane Devlin, Southern Trust
Ryan Wilson, DoH	Maria O'Kane, Southern Trust
David Gordon, DoH	Melanie McClements, Southern Trust
Anne-Marie Bovill, DoH	

Apologies: Michael McBride, Brid Farrell.

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed. The group agreed that the Independent Sector will be a standard separate agenda item for future meetings.

Actions from previous meeting

3. The actions arising from the previous meeting formed the majority of the agenda for this meeting and were discussed throughout.

Assurance Oversight Arrangements (Jackie Johnston)

4. Jackie Johnston noted the finalised Urology Assurance Group Terms of Reference had been circulated to the group.

5. Jackie Johnston advised that the Independent Neurology Inquiry (INI) Review Panel were unlikely to have the required capacity to add the issues arising within Urology into their remit. They expressed concerns regarding the potential risk for delay in the completion of the INI.

6. It was agreed that further consideration, including a discussion with the Minister, is required regarding the establishment of an appropriate Urology Review Panel Jackie Johnston advised that the Ministerial Oral Statement would be deferred for a week (w/c 23/11/20).

Action: DoH to arrange a discussion with the Minister re the establishment of a Urology Review Panel. **(Richard Pengelly / Jackie Johnston)**

Patient Records Scoping Exercise – update (Southern Trust)

7. A summary of progress relating to the Patient Record Scoping Exercise, capturing details included in the update paper provided by the Southern Trust and circulated to UAG members prior to the meeting, was presented by Melanie McClements and Maria O'Kane.

8. It was noted that the Southern Trust continues to liaise with the General Medical Council (GMC) regarding professional issues and concerns. Maria O'Kane informed the group that probity issues (candour and openness) had been raised and that the GMC has provided confirmation that they plan to investigate the consultant's conduct in this regard.

9. The group noted the Southern Trust approach to the Royal College of Surgeons (RCS) Invited Review Service to request a review of Trust urology services. It

was highlighted that this engagement is at an initial stage and a meeting with a Clinical Lead from the RCS is due to take place shortly.

10. Melanie outlined the engagement by the Southern Trust, via the Royal college of Surgeons, with the British Association of Urological Surgeons (BAUS) who has provided two Subject Matter Expert Consultant Urologists to assist with the ongoing work. One Subject Matter Expert is providing independent expertise for the SAI process with the second engaged to assist with the review of electronic patient records.

11. The group also noted the Southern Trust is developing an Investment Proposal Template (IPT) to cover additional costs associated with current and projected future work relating to the Urology review. This work will include clinical, managerial and governance oversight costs and patient related support services including SAI Review costs, information/help lines, counselling, psychological support and family liaison.

12. Melanie confirmed 2 locum Urologists have also been recently appointed by the Trust which will increase capacity to progress clinical assessments and reviews.

13. Melanie provided a summary of the 236 oncology patients, deemed to be part of a backlog relating to Oncology Reviews. Progress was noted including confirmation that these patients will be reviewed by an Urologist in the Independent Sector, with 191 oncology review patients transferred and 23 management plans received back from Independent Sector for patients already seen.

Serious Adverse Incidents (SAI) Update (9)

14. The group noted that the SAI panel membership has been agreed and the Terms of Reference have been internally agreed and have been forwarded to the HSCB. The 9 SAI Reviews are due to be completed, accompanied with an overarching report, by end January 2021.

15. Melanie outlined the ongoing family engagement, including skilled psychological and counselling support, relating to the 9 SAIs and arrangements for meetings with the Chair of the SAI Panel and the families.

16. The group agreed the need to further consider the potential for redress arrangements which may develop from the Urology review.

17. Melanie confirmed to the group that the potential further 6 SAIs identified will be dependent on the agreement of the appropriate review process going forward.

Action: DoH to consider the potential for redress which may develop from the Urology Review. **(Jackie Johnston / Michael O'Neill)**

Bicalutamide Audit Update

18. Maria O'Kane provided the group with an update on the Bicalutamide Audit following the concerns regarding the consultant's prescribing which appears to be outside of established NICE guidance, regarding the diagnosis and management of prostate cancer. To date there have been 26 patients out of 300 identified (low dose) requiring an urgent appointment. Two all-day clinics were held in Craigavon Hospital clinical team. 26 patients were contacted and offered an appointment, 9 have attended so far.

19. It was noted that the next stage of this Audit is currently underway.

Independent Sector

20. The group noted the Southern Trust meeting with DLS regarding the consultant's private practice and the ongoing difficulty and potential challenges in accessing the records and information to identify all affected private patients.

21. The group noted that further work is required by the Southern Trust, along with their legal advisers, to provide an indication of the out-workings of possible

engagement with the consultant's legal representatives to determine the volume and impact on private patients.

22. Maria O'Kane highlighted a further potential complication of private patients living in RoI. Lourda Geoghegan confirmed that the consultant is not currently registered with the Irish Medical Council (IMC) but confirmation will be required to ascertain if the consultant was ever previously registered with the IMC. Richard Pengelly confirmed a meeting with his RoI counterpart is due to take place and he agreed to highlight this as a potential emerging issue.

23. Shane Devlin confirmed a letter has been issued requesting BSO Internal Audit to undertake a review, as far as possible, of those private patients transferring into Trust provision and progress updates will be provided to the group going forward.

24. Maria outlined the Royal College Surgeons advice on private practice review timescales (5 years). Lourda suggested that in consideration of future alignment structures relating to Southern Trust patients and private patients, that any lookback exercise for private patients should mirror the current lookback period (18 months) for Southern Trust patients. The group agreed that the required lookback period should be considered further by the Trust.

Action: Southern Trust to continue to engage with legal advisers to consider the out-workings of possible engagement with the consultant's legal representatives to support the determination of volume and impact on private patients. **(Maria O'Kane / Melanie McClements)**

Action: Southern Trust to provide confirmation on whether the consultant was ever previously registered with the IMC. **(Maria O'Kane / Melanie McClements)**

Action: Richard Pengelly to raise potential of emerging issue relating to private patients living in RoI with his RoI counterpart. **(Richard Pengelly)**

Action: Southern Trust to provide regular BSO Internal Audit progress updates to the UAG group going forward. **(Shane Devlin)**

Action: Southern Trust to consider the alignment of the look back period for trust and private patients. **(Maria O'Kane / Melanie McClements)**

Communication Plan

25. The communication plan continues to be drawn together liaising with HSCB, DOH and Trust Communications Teams and operational / professional staff. The group discussed previous, current and potential further media interest.

26. The group agreed it will be important to confirm the oversight arrangements and agreed Independent Urology Inquiry process within the Minister's Assembly Statement.

Any other business

27. Paul Cavanagh confirmed that the Terms of Reference for the Co-ordination Group will be available for discussion at the next UAG meeting.

Action: Co-ordination Group Terms of Reference paper to be circulated to members. **(Paul Cavanagh)**

28. Maria outlined the confirmations received regarding the consultant's connection with the Craigavon Urological Research & Education (CURE) organisation. This included confirmation that the consultant remains as a listed Director (since April 1997). It was agreed that links between the organisation and the Southern Trust should be reviewed.

29. The group agreed that the BSO Internal Audit process being initiated by the Southern Trust to review the independent sector patients provides an opportunity to extract and review information which may be available relating to CURE.

30. The group also agreed that director's disqualification issues with the Department for the Economy (DfE) and engagement with the Charity Commission for Northern Ireland maybe be required once further details are available, although the group acknowledged that legal advice would be necessary prior to any referrals to DfE or the Charity Commission for Northern Ireland.

Action: Southern Trust to establish further information including details of CURE charity events, Southern Trust staff attendance and/or donations provided and beneficiaries of CURE. **(Maria O'Kane / Melanie McClements)**

Action: Southern Trust to request BSO Internal Audit to review information available on CURE as an organisation, the consultant's involvement, Southern Trust staff connections and CURE beneficiaries. **(Shane Devlin)**

Date of next meeting

31. The next meeting of the group will be on Friday 20th November 2020.

UROLOGY ASSURANCE GROUP

Friday 4 December 2020 at 12:00, by Zoom

Agenda

1. Welcome and apologies
2. Minutes of previous meeting
3. Patient Records Scoping Exercise – update (Southern Trust)
4. SAIs – update (Southern Trust)
5. Independent Sector (Southern Trust)
6. Public Inquiry (Jackie & Michael)
7. Communications / Management Plan (David)
8. AOB
9. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 20 November 2020 at 13.00, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Paul Cavanagh, HSCB
Michael McBride, DoH	Olive McLeod, PHA
Lourda Geoghegan, DoH	Maria O'Kane, Southern Trust
Michael O'Neill, DoH	Ronan Carroll, Southern Trust
Ryan Wilson, DoH	Brid Farrell, PHA
David Gordon, DoH	

Apologies: Jackie Johnston, Sharon Gallagher, Shane Devlin, Melanie McClements, Anne-Marie Bovill.

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting formed the majority of the agenda for this meeting and were discussed throughout.

Patient Records Scoping Exercise – update (Southern Trust)

4. A summary of progress relating to the Patient Record Scoping Exercise, capturing details included in the update paper provided by the Southern Trust and circulated to UAG members prior to the meeting, was presented by Maria O'Kane.

5. The group noted that:
    a. 158 calls had been made to the patient information line;
    b. the next stage of the Bicalutamide Audit is underway with 203 WHSCT patient medication plans reviewed and that an update on findings would follow; and
    c. the Trust via the Royal college of Surgeons has engaged with the British Association of Urological Surgeons (BAUS) who has provided two Subject Matter Expert Consultant Urologists to assist with the ongoing work.

Independent Sector

6. The group noted that the consultant's private practice was discussed with DLS and a letter sent seeking data in relation to the number of patients treated since January 2019 and also seeking assurances in relation to how a review of his private patients would commence.

Communication Plan

7. There was a detailed discussion on the content and related timings of the Minister's intended Oral Statement on 24 November 2020.

8. The communication plan continues to be drawn together liaising with HSCB, DOH and Trust Communications Teams and operational / professional staff.

Action: Arrange briefing with Minister on Monday 23 November 2020 in advance of statement. **(Michael O'Neill)**

Any other business

9. Maria O'Kane advised that the consultant was registered with the Irish Medical Council until 1999, but not thereafter.

Date of next meeting

10. The next meeting of the group will be on Friday 4th December 2020.

UROLOGY ASSURANCE GROUP

Friday 18 December 2020 at 12:00, by Zoom

Agenda

1. Welcome and apologies
2. Minutes of previous meeting
3. Patient Records Scoping Exercise – update (Southern Trust)
4. SAIs and Structured Clinical Review– update (Southern Trust)
5. Independent Sector (Southern Trust)
6. Public Inquiry (Jackie & Michael)
7. Communications / Management Plan (David)
8. AOB
9. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 4 December 2020 at 12.00, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Jackie Johnston, DoH (Chair)	Paul Cavanagh, HSCB
Michael McBride, DoH	Olive McLeod, PHA
Lourda Geoghegan, DoH	Brid Farrell, PHA
Michael O'Neill, DoH	Shane Devlin, Southern Trust
Ryan Wilson, DoH	Melanie McClements, Southern Trust
Anne-Marie Bovill, DoH	Maria O'Kane, Southern Trust

Apologies: Richard Pengelly, Sharon Gallagher, David Gordon.

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting were confirmed as completed.

Patient Records Scoping Exercise – update (Southern Trust)

4. A summary of progress relating to the Patient Record Scoping Exercise, capturing details included in the update paper provided by the Southern Trust and circulated to UAG members prior to the meeting, was presented by Maria O'Kane and Melanie McClements.

5. The group noted that since the Minister's statement (until 3 December 2020) there have been 124 calls to the patient information line overall consisting of a range of individual issues requiring follow up, 1 email inquiry was received and no GP calls were received. 9 patients who had contacted the information line and a further 2 patients, who had come via Chief Executive's office, have been seen at clinics.

Bicalutamide Audit

6. The group noted the complexities involved in the next stage of the Bicalutamide Audit, which is underway, specifically relating to the review of patients' medication and the approaches which have been made to ensure independent diagnostic support is provided to this work.

SAIs

7. Jackie outlined that it is expected that the Public Inquiry will be established by February/March 2020 and the group agreed that it would be useful to draft Terms of Reference to support a SAI strand within the Public Inquiry in respect of the 9 SAIs currently under review.

8. The group discussed the need to agree an appropriate review process, prior to the establishment of the Public Inquiry, for the further 6 cases identified and the potential for further cases meeting the SAI threshold. It was agreed that a "Structured Clinical Review" process should be developed to ensure that patients are on the correct treatment pathway and that learning and areas for improvement can be captured, considered and implemented without delay.

9. The group highlighted the need for a communications plan with stakeholders, once the details of the Structured Clinical Review has been agreed, to ensure transparency and an understanding of the rationale and requirement for the SAI process and Structured Clinical Review process.

Action: Paul Cavanagh agreed to draft Terms of Reference for the SAI strand within the Public Inquiry for further consideration.

Action: Southern Trust (Melanie McClements and Maria O'Kane) agreed to draft Terms of Reference for a "Structured Clinical Review" process for further consideration.

Independent Sector

10. The group noted new information has been provided (3 cases to date), which is in the process of being verified, raising concerns that the consultant may be continuing private practice. The Trust confirmed that the GMC has been notified. The group agreed that this is potentially very concerning and the Department may be required to act urgently in the best interest of patients.

11. The group noted that BSO Internal Audit has commenced a review of Mr O'Brien's patients transferring into SHSCT as HSC patients and any Trust involvement with the Craigavon Urological Research & Education organisation. The group agreed the Terms of Reference, subject to amending the time period of audit from 1 January 2019 to 30 June 2020.

Action: Southern Trust (Maria O'Kane) agreed to provide an urgent assessment on potential private practice by 11 December 2020.

Action: Southern Trust (Shane Devlin) to circulate amended BSO Internal Audit Terms of Reference.

Public Inquiry

12. Jackie outlined the steps required under the Inquires Act 2005 to establish the Urology Public Inquiry. He outlined an indicative timeline for establishment by February/March 2020 including; the identification of a Chair and consideration of a QC led Inquiry; the development and agreement of the Terms of Reference with the Chair; and the identification of inquiry panel members.

13. The group discussed patient involvement in the agreement of the Public Inquiry terms of reference and potential patient group representatives to engage with. It was agreed to approach the trust Patient and Public Involvement (PPI) Group in the first instance.

14. The group agreed a letter to be issued to HSCB, PHA, Trusts, RQIA, NISCC and the Department to request the retention and security of all relevant information, documents and records to support the prompt access of information which may be required during the Public Inquiry investigation.

Action: Southern Trust (Shane Devlin) to approach the trust PPI Group to discuss potential patient representation to support the agreement of the terms of reference for the Urology Inquiry.

Action: DoH (Anne-Marie Bovill) to arrange to issue the retention letter to ensure retention and access to relevant information during the Public Inquiry process.

Communication Plan

15. The group acknowledged the impact of negative publicity associated with the review into urology services in the Southern Trust on staff morale within the trust. It was suggested that a staff engagement meeting with Richard Pengelly and Dr Michael McBride could be provided via a zoom meeting.

Action: Southern Trust (Shane Devlin) to consider and confirm if a staff engagement meeting would be beneficial.

16. The group noted that the Southern Trust website information has been updated regarding the information line and FAQ's has been revised.

Any other business

17. No other business was discussed.

Date of next meeting

18. The next meeting of the group will be on Friday 18th December 2020.

UROLOGY ASSURANCE GROUP

Friday 8 January 2021 at 11am, by Zoom

Agenda

1. Welcome and apologies
2. Minutes of previous meeting
3. Patient Records Scoping Exercise – update (Southern Trust)
4. SAIs and Structured Clinical Review– update (Southern Trust)
5. Independent Sector (Southern Trust)
6. Public Inquiry (Jackie & Michael)
7. Communications / Management Plan (David)
8. AOB
9. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 18 December 2020 at 12.00, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Paul Cavanagh, HSCB
Michael McBride, DoH	Sharon Gallagher, HSCB
Lourda Geoghegan, DoH	Olive McLeod, PHA
Michael O'Neill, DoH	Brid Farrell, PHA
Ryan Wilson, DoH	Shane Devlin, Southern Trust
Anne-Marie Bovill, DoH	Maria O'Kane, Southern Trust
	Ronan Carroll, Southern Trust
	Stephen Wallace, Southern Trust

Apologies: Jackie Johnston, Melanie McClements, David Gordon

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting were addressed during the course of the meeting.

Patient Records Scoping Exercise – update (Southern Trust)

4. A summary of progress relating to the Patient Record Scoping Exercise, capturing details included in the update paper provided by the Southern Trust

and circulated to UAG members prior to the meeting, was presented by Maria O'Kane.

5. The group noted that the Southern Trust continue to address calls to the patient information line including a range of individual issues requiring follow up. To date 144 calls, 8 emails and 3 GP calls and 1 inquiry via the trust complaints team have been received. 21 patients who have either contacted the information line/come via MLA/MP enquiry or from the GP query have been seen at clinic to date.

6. Maria outlined that Professor Sethia, Urology Subject Matter Expert, has agreed to look at all the patients that have contacted the Information Line. The group noted that as this will take some time an acknowledgement letter is being sent out to all the patients/relatives who have phoned in advising them that their case is being looked into and that they will be contacted as soon as the review is complete.

7. The group noted that 194 management plans have been received back from Independent Sector including 121 being referred by to the care of their GP, 32 being referred back to the Trust for further care/follow-up, 38 to be independently reviewed by Professor Sethia and 3 referrals to Oncologist for urgent reassessment of treatment.

8. The group noted the draft Terms of Reference (ToR) for the Invited Review Service by the RCS provided to the UAG group for information. Brid Farrell suggested it may be beneficial for the Trust to consider creating categories of relevant clinical conditions, within the sample of 100 cases to be reviewed, to support the structure of the review.

9. Maria informed the group that the Trust continues to work at ways to ensure all staff involved are and will be supported including fortnightly team meetings with the Clinical Teams and the Chief Executive, Medical Director and Director of Acute Services.

Action: Southern Trust (Maria O'Kane) to consider categorising the cases for review into relevant clinical conditions within the Invited Review Service by the RCS.

SAIs and Structured Clinical Review

10. Maria outlined that a mid-report of early identification of learning, relating to the 9 SAIs currently under review, was shared with HSCB on 17 December 2020 and full reports are anticipated by end January 2021.

11. Maria outlined to the group that the Trust has met with the Royal College of Physicians who were supportive of the use of Structured Judgement Review methodology to develop, support and ensure an appropriate structured clinical review process for any patient cases falling outside of the 9 SAIs already under review. The Trust is agreeing a core virtual training programme with the Royal College of Physicians team for a core group of reviewers.

Independent Sector

12. The group noted that on the 15th December 2020 the GMC interim orders panel suspended Mr O'Brien from the medical register for a period of 18 months and that the consideration of the potential need to re-issue the alert letters, following concerns that Mr O'Brien may be continuing private practice, is no longer required.

13. The Trust outlined their continued efforts to engage with Mr O'Brien's legal representatives in order to establish the number of private patients which were under his care.

14. The group noted concern that the information requested regarding Mr O'Brien's private practice has not been supplied to date which could restrict progress on measures which may be required to be taken in the patient's best interest. The Trust agreed to include updates to the group on this matter going forward.

Action: Southern Trust (Maria O'Kane) to include an update at future meetings on progress and engagement with Mr O'Brien's legal representatives in gaining information on patients within his private practice.

Public Inquiry

15. Michael O'Neill outlined that finance colleagues have been alerted to the fact that there will be additional financial pressures from 2021/22 and in future financial years associated with the establishment and completion of the Public Inquiry.

16. The group noted the chronology required to establish the Public Inquiry including the first step of appointing the Chair which will allow the Terms of Reference to be agreed supported by the appropriate stakeholder and patient/family engagement.

17. The Trust outlined that a small team will be required to support the work of the Public Inquiry and to address issues and consider and implement improvements as required. The Trust and HSCB are considering additional budget requirements to support this work from 2021/22 financial year.

Communication Plan

18. The group noted the management of communications raised through queries, correspondence and engagement continues to be directed and actioned through the appropriate processes and that the next key communication should be the announcement of the Public Inquiry Chair.

Any other business

19. No other business was discussed.

Date of next meeting

20. The next meeting of the group will be on Friday 8 January 2021.

UROLOGY ASSURANCE GROUP

Friday 22 January 2021 at 12.00pm, by Zoom

Agenda

1. Welcome and apologies
2. Minutes of previous meeting
3. Trust Update (Southern Trust)
    i. Patient Records Scoping Exercise
    ii. SAIs and Structured Clinical Review
    iii. Independent Sector
    iv. Private Practice
4. Public Inquiry (Jackie Johnston/Michael O'Neill)
5. Communications
6. AOB
7. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 8 January 2021 at 11.00, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Paul Cavanagh, HSCB
Jackie Johnston, DoH	Sharon Gallagher, HSCB
Lourda Geoghegan, DoH	Olive McLeod, PHA
Michael O'Neill, DoH	Shane Devlin, Southern Trust
Ryan Wilson, DoH	Melanie McClements, Southern Trust
Anne-Marie Bovill, DoH	Damien Gormley, Southern Trust

Apologies: Michael McBride, Brid Farrell, Maria O'Kane, David Gordon.

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting were addressed during the course of the meeting.

Patient Records Scoping Exercise – update (Southern Trust)

4. A summary of progress relating to the Patient Record Scoping Exercise, capturing details included in the update paper provided by the Southern Trust and circulated to UAG members prior to the meeting, was presented by Melanie McClements and Damien Gormley.

5. The group noted that the information line was stood down between 24th and 29th December 2020. Melanie highlighted that since the previous UAG update report (18 December 2020) a two further email inquiries have been received and no further messages/calls, inquiries via complaints team or GP calls have been received. No further patients have been seen at the clinic, further to the 21 patients already seen, due to staff availability and as outpatient activity is being stood down due to Covid pressures.

6. The group acknowledged the demands which the Covid pandemic currently presents across all Health and Social Care Trusts and that as a result there are no more planned outpatient appointments for patients who have contacted the information line until the end of January 2021 at the earliest. Melanie confirmed that acknowledgement letters have been issued to all the patients/relatives who have phoned the information line advising them that their case is being looked into and that they will be contacted as soon as the review is complete.

SAIs and Structured Clinical Review

7. The group noted that the plan to impart the full 9 SAI Reports and overarching SAI report remains on target to be provided to the Department by end January 2021.

8. The group noted the Trust has engaged with the Royal College of Physicians to discuss the use of Structured Judgement Review (SJR) methodology to support patient reviews and there has been agreement that it is an appropriate framework to use to conduct the described patient safety reviews in the absence of a full SAI process. The Trust is currently agreeing a core virtual training programme with the Royal College of Physicians team to establish a core group of reviewers.

Bicalutamide Audit

9. Melanie provided an overview of the support and quality assurance role which Professor Sethia, Urology Subject Matter Expertise, has agreed to provide to the Trust audit of patients prescribed the medication Bicalutamide.

10. Paul Cavanagh outlined that clarity on the structure and reporting arrangements of the Urology Subject Matter Expertise to support the Bicalutamide Audit had been discussed at the HSCB Urology Co-ordination Group meeting on 7 January 2020. The group agreed that this clarification would be required for consideration and agreement at the next UAG meeting.

Action: Paul Cavanagh agreed to establish clarity and to propose the appropriate structure and reporting arrangements of the Urology Subject Matter Expertise to support the Bicalutamide Audit for agreement at the next UAG meeting.

Independent Sector

11. The group noted that all 200 management plans have been received back from the Independent Sector with all patients having been seen by 22 December 2020 including; 124 being referred by to the care of their GP; 34 being referred back to the Trust for further care/follow-up; 39 to be independently reviewed by Professor Sethia and 3 referrals to Oncologist for urgent reassessment of treatment.

Invited Review Service

12. It was noted the Trust are currently considering views and comments provided on the draft Terms of Reference for the Invited Review Service by the RCS, which was previously tabled and discussed at the HSCB meeting on 17th December 2020 and the UAG meeting on 18th December 2020. It was agreed that the CMO and DCMO views would be sought to support the appropriate finalisation of the Terms of Reference.

Action: Southern Trust (Damien Gormley/Maria O'Kane) to seek CMO and DCMO comments on the draft Terms of Reference for the Invited Review Service.

Trust Staff Engagement

13. Melanie informed the Group that the Trust continues to work at ways to ensure all staff involved are and will be supported through the public inquiry process. Richard's offer to engage with Trust staff was acknowledged by the Trust and agreed to discuss this at the next fortnightly team meeting with the Clinical Teams and the Chief Executive, Medical Director and Director of Acute Services.

Action: Southern Trust (Shane Devlin) to discuss DoH Permanent Secretary and CMO staff engagement at next fortnightly team meeting and provide subsequent confirmation to the Department.

Independent Sector (Private Practice)

14. Melanie outlined that the Internal Audit into Mr O'Brien's private practice has commenced including a review of Mr O'Brien's patients transferring into SHSCT as HSC patients and consideration of Trust involvement with the Craigavon Urological Research & Education (CURE) organisation.

15. The Trust outlined their continued efforts to engage with Mr O'Brien's legal representatives in order to: establish the number of private patients which were under his care; ensure that private patients can have a review assessment carried out by an independent urology consultant; and confirmation of private patients prescribed Bicalutamide medication. The group noted that responses received to date have fallen short of the confirmations and information requested and that the Trust intends to issue a formal letter, following legal advice, to Mr O'Brien's legal representatives. Michael O'Neill agreed to provide comment on the proposed letter prior to issue.

16. It was agreed that an end point is required regarding engagement with Mr O'Brien's legal representatives to establish relevant details of Mr O'Brien's private practice.

Action: Southern Trust (Shane Devlin) to provide the draft letter to Mr O'Brien's legal representatives to Jackie Johnston & Michael O'Neill for comment prior to issue.

Public Inquiry

17. Jackie provided an update to the group regarding the establishment of the Public Inquiry including the intention to appoint the Chair which will allow the Terms of Reference to be agreed supported by the appropriate stakeholder and patient/family engagement.

18. The group noted that DSO have been engaged to assist with the identification of potential candidates for the Public Inquiry Chair as a first step and it is likely to be March/April 2021 before the Public Inquiry team is established.

19. The Trust asked the group to note that the letter received from Deputy Chief Medical Officer, requesting that all relevant information and material is retained and not subject to scheduled disposal in order to support the Public Inquiry, has been actioned within the relevant departments within the trust.

20. Richard Pengelly advised that it may be beneficial for the Trust to liaise with the Belfast Trust on lessons learned on ensuring effective lines of communication regarding the retention of documents and information experienced within the Independent Neurology Inquiry.

Action: Southern Trust (Shane Devlin) agreed to liaise with Belfast Trust to capture lessons learned on ensuring effective lines of communication relating to the retention of documents and information to support the Urology Public Inquiry.

Communication Plan

21. The group noted that the volume of communications raised through queries, correspondence and engagement has now reduced but there is an expectation

that public interest may potentially increase in the event of any future announcement/s relating to the Neurology Review.

22. It was agreed that it would be beneficial to inform the Trust of the timing of any future announcement/s relating to the Neurology Review, when known, to ensure arrangements can be put in place within the Trust to deal with any potential consequential increase in Urology Review queries received as a result.

Action: DoH (Michael O'Neill) to provide notification of future Neurology Review announcements, when confirmed, to the Trust to support arrangements which may be required to deal with any potential consequential increase in Urology Review queries received as a result.

Any other business

23. No other business was discussed.

Date of next meeting

24. The next meeting of the group will be on Friday 22 January 2021.

UROLOGY ASSURANCE GROUP

Friday 19 March 2021 at 1.00pm, by Zoom

Agenda

1. Welcome and apologies

2. Minutes of previous meeting

3. Trust Update (Southern Trust)

    i. Patient Records Scoping Exercise
    ii. SAIs and Structured Clinical Record Review
    iii. Implementation of SAI Recommendations
    iv. Private Practice

4. Public Inquiry (Jackie Johnston/Michael O'Neill)

5. Communications

6. AOB

7. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 5 March 2021 at 1.00pm, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Paul Cavanagh, HSCB
Jackie Johnston, DoH	Brid Farrell, PHA
Michael McBride, DoH	Shane Devlin, Southern Trust
Lourda Geoghegan, DoH	Melanie McClements, Southern Trust
Michael O'Neill, DoH	Maria O'Kane, Southern Trust
Ryan Wilson, DoH	Damien Gormley, Southern Trust
David Gordon, DoH	Stephen Wallace, Southern Trust
Anne-Marie Bovill, DoH	

Apologies: Sharon Gallagher and Olive McLeod.

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting were addressed during the course of the meeting.

Trust Update (Southern Trust)

4. The update report provided by the Southern Trust and circulated to UAG members prior to the meeting, including a summary of progress relating to the

Patient Record Scoping Exercise, SAIs, Structured Clinical Record Reviews and Private Sector, was presented by Melanie McClements.

Patient Record Scoping Exercise

5. The group noted that no further calls or inquiries have been received via the information line since the last update report on 19 February 2021.

6. Melanie confirmed that a core consultant urologist is commencing weekly telephone clinics and will chronologically review patients from Mr O'Brien's review backlog list from 6 March 2021.

SAIs and Structured Clinical Record Review

7. Melanie informed the group that the 9 SAI Reports and the overarching SAI report have been completed and outlined the intended timescales for communications and stakeholder engagement relating to the SAI reports. The group noted family engagement and support provided to date and that the Family Liaison Officer continues to be available to support the families.

8. The group agreed that the Trust should make arrangements to disclose the SAI report relevant to each respective family along with the overall recommendations included in the overarching SAI report at the earliest opportunity, and the Trust should write to Mr O'Brien's solicitors to confirm the position. The group noted that Mr O'Brien has not yet engaged with the SAI panel.

9. The group discussed the potential need to engage with the PSNI if there is a clear basis including specific concerns within the SAI reports. The Trust confirmed legal advice had been sought on this issue and would be considered further. The group agreed to keep the potential requirement to engage with the PSNI under review.

10. The group noted the need for the Public Inquiry Chair, when appointed, to consider the outcome of the SAI reports within the scope of the Inquiry Terms of Reference.

11. Shane Devlin confirmed that the recommendations and learning outcomes of the SAI Reports will be actioned by the Trust and the group agreed that the "implementation of SAI recommendations" will be a standard agenda item going forward with the HSCB Urology Co-ordination Group overseeing this work, in the first instance.

12. Melanie advised the group that a further eleven patients have been identified as potentially being a SAI. Ten cases have been screened on 17 February 2021 with five which appear to meet the criteria of a SAI. The group noted Professor Sethia has been asked for a urology opinion on these cases and that the Structured Clinical Record Review is the suggested mechanism to progress the cases.

13. The Trust has developed a draft proposal for the structured clinical record review which is currently with HSCB Urology Co-ordination Group for consideration.

Action: UAG members agreed to continue to review the potential need to engage with the PSNI on matters relating to the SAI Reports and the appropriate timing of any required engagement.

Action: The Trust (Shane Devlin) to implement the SAI recommendations which will be overseen by the HSCB Urology Co-ordination Group (Paul Cavanagh).

Action: DoH (Anne-Marie Bovill) to include the "Implementation of SAI Recommendations" as a standard UAG agenda item going forward.

Urology Subject Matter Expertise

14. Melanie informed the group that discussions with the British Association of Urological Surgeons (BAUS) and British Association of Urological Nurses (BAUN) are ongoing, to assist with the review of the patients in the backlog, to verify the outcome from the reviews that have currently been undertaken by the SHSCT urology team and to explore if there are any resources available to assist with the ongoing review of patients from the Inquiry.

Royal College of Surgeons Invited Review Service

15. The group noted that a stratified approach to sampling of cases from the calendar year 2015 has been agreed with the HSCB to complete the Royal College of Surgeons Invited Review Service.

Private Practice

16. The group discussed the correspondence via Mr O'Brien's solicitor on 5th February 2021 in response to the Trust letter issued 22nd January 2021 and the ongoing difficulty in identifying the private patients involved. The group noted the confirmation provided by Mr O'Brien's solicitors that 93 private patients were under his care between January 2019 and March 2020 and their advice that all patients have either been discharged to the ongoing care of their GP or have been transferred to NHS waiting lists or outpatient review.

17. The group agreed that there is sufficient grounds for concern relating to the validity of the confirmation received via Mr O'Brien's solicitor that no patients have attended Mr O'Brien privately since March 2020. It was agreed that legal advice should be sought to establish the appropriate action required to ensure a duty of care is provided to the private patients involved. The group also agreed that the Trust should request details of the 93 private patients involved, via Mr O'Brien's solicitors, with a definitive deadline for response.

18. Melanie confirmed that Internal Audit has identified one patient having been seen privately by Mr O'Brien, added to his NHS day case list with a procedure carried out within 2 weeks compared to patients with the same procedure having to wait for 91 weeks. The Trust agreed to consider the clinical priority of this case prior to consideration of any further action which may be required.

19. The group noted that engagement with GMC continues and the Trust intends to inform GMC that the overarching SAI Report can be made available on request due to its relevance to the ongoing GMC investigation.

Action: The Trust (Shane Devlin) agreed to seek legal advice on the legal action available to ensure a duty of care is provided to the private patients involved.

Action: The Trust (Shane Devlin) agreed to request the details of the 93 private patients confirmed, via Mr O'Brien's solicitors, including a firm deadline for response.

Action: The Trust (Melanie McClements) agreed to establish the clinical priority of the case identified by Internal Audit prior to consideration of any further action which may be required.

Public Inquiry

20. Jackie Johnston informed the group that the appointment of the Public Inquiry Chair would be announced on 8th March 2021, by written assembly statement, and an embargoed notification would be provided to all stakeholders prior to the announcement. The group was informed that it is intended that the Inquiry will commence by June/July 2021.

21. The group noted the first item of business with the Inquiry Chair would be the agreement of the Inquiry Terms of Reference and the appointment of other Panel Members. Chief Medical Officer (CMO) agreed to facilitate an entry point for the Chair's consideration of a panel member with the appropriate medical background at a national level.

Action: CMO to provide contacts to the Inquiry Chair to facilitate their consideration of a Panel Member with the appropriate medical background.

Communication Plan

22. David Gordon outlined the communication requirements to support the announcement of the Inquiry Chair on Monday 8 March 2021 and the sharing of the SAI Reports with families which may generate public, political and media queries and requests.

Any other business

23. No other business was discussed.

Date of next meeting

24. The next meeting of the group will be on Friday 19th March 2021.

UROLOGY ASSURANCE GROUP

Friday 16 April 2021 at 11.00am, by Zoom

Agenda

1. Welcome and apologies
2. Minutes of previous meeting
3. Action Points
4. Trust Update (Southern Trust)
    i. Patient Records Scoping Exercise
    ii. SAIs and Structured Clinical Record Review
    iii. Implementation of SAI Recommendations
    iv. Private Practice
5. Public Inquiry (Jackie Johnston/Michael O'Neill)
6. Communications
7. AOB
8. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 19 March 2021 at 1.00pm, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Paul Cavanagh, HSCB
Jackie Johnston, DoH	Brid Farrell, PHA
Michael McBride, DoH	Olive McLeod, PHA
Lourda Geoghegan, DoH	Shane Devlin, Southern Trust
Michael O'Neill, DoH	Melanie McClements, Southern Trust
Ryan Wilson, DoH	Maria O'Kane, Southern Trust
David Gordon, DoH	Stephen Wallace, Southern Trust
Anne-Marie Bovill, DoH	

Apologies: Sharon Gallagher.

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting were addressed during the course of the meeting.

Trust Update (Southern Trust)

4. The update report provided by the Southern Trust and circulated to UAG members prior to the meeting, including a summary of progress relating to the

Patient Record Scoping Exercise, SAIs, Structured Clinical Record Reviews and Private Sector, was presented by Melanie McClements and Maria O'Kane.

Patient Record Scoping Exercise

5. The group noted that no further calls or inquiries have been received via the information line since the last update report on 5 March 2021 and a core consultant urologist has commenced weekly telephone clinics, since 6 March, to chronologically review patients from Mr O'Brien's review backlog list, with 20 patients reviewed to date.

6. Maria confirmed the Subject Matter Expertise has commenced including the previous MDM patients that were under the care of Mr O'Brien from January 2019 - June 2020 and any concerns in respect of their care will be escalated as required.

SAIs and Structured Clinical Record Review

7. Melanie informed the group that the 9 SAI Reports and the overarching SAI report have been shared with the families, Mr O'Brien's solicitor, the Designated Reporting Officer, HSCB, the Urology Consultants, Urology Clinical Nurse Specialists and the Cancer and Clinical Services Management. The group noted that the families, the Urology Consultants, Urology Clinical Nurse Specialists and the Cancer and Clinical Services Management also received a copy of the letter from Mr O'Brien's Solicitor as per his request.

8. The group was informed that a meeting has been organised for Tuesday 23rd March with Chief Executive, Medical Director, Acute Director and the Urology Team to afford them the opportunity to share their thoughts on the SAI Reports.

9. The group noted that the families, the Clinical Team and Mr O'Brien's Solicitors have been given two weeks from the date of receipt to provide any comments on factual content that they may have on the draft reports. The Family Liaison Officer continues to be available to support the families and has advised all families that she will continue to be available for them once they have received and read through the reports.

10. Maria informed the group that the Royal College of Physicians (RCP) are conducting two train the trainer sessions for using Structured Clinical Record Review (SCRR) on 18th and 25th March. To support the SCRR process the Trust has identified an additional Consultant Urology subject matter expert via the Royal College of Surgeons to support reviews as required.

Implementation of SAI recommendations

11. The Trust confirmed they are in the process of establishing a working group to take forward an implementation plan for the recommendations and findings from the SAI Reports.

12. Maria outlined that the Trust has engaged with NICAN who are seeking guidance from Public Health England regarding a review of urology multi-disciplinary meetings.

Royal College of Surgeons Invited Review Service

13. The group noted, following the Trust meeting with the RCS on 11 March 2021, that the application of the Egress secure platform to support the transfer of data for the review has been agreed and work is underway to set up the relevant accounts.

Private Practice

14. The group discussed the ongoing difficulty in identifying the private patients involved in Mr O'Brien's private practice and the intention, following engagement with GMC, to request Mr O'Brien to issue correspondence to his private patients to support their self-referral to the NHS for review. It was noted that failure by Mr O'Brien to co-operate with this request may be considered unreasonable and may require further investigation by the GMC as a result.

15. The group agreed the need to be mindful of the potential for cross border issues arising from Mr O'Brien's private practice and the need for appropriate and timely

liaison with counterparts in RoI when details relating to the private practice patients are known.

16. Melanie confirmed that Internal Audit has identified a further two patients having been seen privately by Mr O'Brien and added to his NHS day case list with earlier access to healthcare services compared to NHS patients.

Action: The Southern Trust (Melanie / Stephen) to confirm legal reference with the GMC regarding the consultant cooperating with a Trust inquiry or review, and consider next steps to identify the private patients.

Public Inquiry

17. Jackie Johnston informed the group that engagement with the Public Inquiry Chair, Ms Christine Smith QC, has taken place to discuss the Terms of Reference, the appointment of further panel members and overall requirements associated with the establishment of the Public Inquiry by June/July 2021.

18. The group discussed the need for patient/family stakeholder engagement and noted the purpose of the engagement required is to seek their views but that the ToR for the inquiry would not be shared and will be agreed between the Chair and the Minister, as required under the Inquiries Act 2005. It was agreed that the Trust PPI Forum may offer an effective channel for engagement.

19. Jackie highlighted the need to gain clarification on DLS support to the Trust in light of the planned closure of HSCB and the implication of this restructuring on the legal support required by the Trust during the Public Inquiry process.

20. Shane Devlin discussed the requirements to service the Public Inquiry and agreed the need to prepare the Trust on the expectations of a full Public Inquiry in line with the Inquiry Rules 2006.

Action: DoH (Michael O'Neill) to liaise with the Southern Trust to make the appropriate arrangements for patient/family stakeholder engagement.

Action: DoH (Michael O'Neill) to seek clarification on the DLS support to the Southern Trust within the context of the planned HSCB closure.

Action: Southern Trust (Shane Devlin) agreed to prepare the Trust to support and service a full Public Inquiry in adherence to the Inquiry Rules 2006.

Communication Plan

21. David Gordon outlined the communications to support the sharing of the SAI Reports with families and the expectation of public, political and media queries and requests relating to the Public Inquiry process going forward.

Any other business

22. No other business was discussed.

Date of next meeting

23. The next meeting of the group will be on Friday 16th April 2021.

Annex 1

Action Log

Action	Date of Meeting	Owner	Date Actioned
Confirm legal reference with the GMC regarding the consultant cooperating with a Trust inquiry or review, and consider next steps to identify the private patients.	19/3/2021	The Southern Trust (Melanie / Stephen)	
Liaise with the Southern Trust to make the appropriate arrangements for patient/family stakeholder engagement.	19/3/2021	DoH (Michael O'Neill)	
Seek clarification on the DLS support to the Southern Trust within the context of the planned HSCB closure.	19/3/2021	DoH (Michael O'Neill)	
Prepare the Trust to support and service a full Public Inquiry in adherence to the Inquiry Rules 2006.	19/3/2021	Southern Trust (Shane Devlin)	

UROLOGY ASSURANCE GROUP

Friday 14 May 2021 at 3.00pm, by Zoom

Agenda

1. Welcome and apologies

2. Minutes & Action Points of previous meeting

3. Trust Update (Southern Trust)

    i. Patient Records Scoping Exercise
    ii. SAIs and Structured Clinical Record Review
    iii. Implementation of SAI Recommendations
    iv. Private Practice

4. Public Inquiry (Michael O'Neill)

5. Communications

6. AOB

7. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 16 April 2021 at 11.00pm, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Paul Cavanagh, HSCB
Lourda Geoghegan, DoH	Sharon Gallagher, HSCB
Michael O'Neill, DoH	Olive McLeod, PHA
Ryan Wilson, DoH	Shane Devlin, Southern Trust
Anne-Marie Bovill, DoH	Melanie McClements, Southern Trust
Paula Ferguson, DoH	Maria O'Kane, Southern Trust
	Stephen Wallace, Southern Trust

Apologies: Michael McBride, DoH, David Gordon, DoH and Brid Farrell, PHA.

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting were addressed during the course of the meeting.

Trust Update (Southern Trust)

4. The update report provided by the Southern Trust and circulated to UAG members prior to the meeting, including a summary of progress relating to the Patient Record Scoping Exercise, SAIs, Structured Clinical Record Reviews and Private Sector, was presented by Melanie McClements and Maria O'Kane.

Patient Record Scoping Exercise

5. Melanie confirmed one new email inquiry received since the last report on 19 March 2021. Up to 15 April 2021 - 155 calls/emails have been received. Weekly telephone clinics continue to review patients from Mr O'Brien's review backlog list.

6. Melanie advised the Subject Matter Expertise has finished reviewing virtually the previous MDM patients that were under the care of Mr O'Brien from January 2019 - June 2020. This exercise has identified 52 patients which have been shared with Mr Haynes for further review.

7. Melanie advised that Professor Sethia has highlighted concerns in respect to a patient he has reviewed who had a Transurethral resection of the prostate (TURP) with no apparent indication for this procedure. This has prompted the Trust to start a process of reviewing any patients of Mr O'Brien's who have been added to his waiting list for a TURP, to determine if they need this procedure.

8. Melanie confirmed that Professor Sethia has now commenced reviewing the Radiology Results (over 1,000) and this will follow the same process as the previous MDM patients.

9. Melanie confirmed that an additional Oncology MDT commenced on Thursday 8 April 2021, chaired by Professor Sethia. There were 15 cases listed for discussion with 2 deferred to the next MDT. From the 13 cases discussed there were 11 patients who were identified as having concerns regarding their treatment. It was noted that these cases are to be screened and follow the Structured Clinical Record Review process (SCRR). All 11 patients are being seen face to face at clinics by Mr Haynes over the next two weeks to discuss the recommendations from MDT and to advise them that their cases will be part of a review process.

10. The group noted there were a total of 2309 patients that have been identified as being under Mr O'Brien's care from January 2019- June 2020, with a number of these patients being identified as being in this cohort of patients with multi episodes and that work continues to refine this data.

11. The group agreed that a further look back will be considered following the completion of all 2,309 patients' reviews between the period January 2019 – June 2020.

12. Maria advised the group that the Trust was continuing to use the Patient Review form in order to capture patient cases identified as meeting the SAI threshold and cases below the SAI threshold where any concerns are identified. Maria advised that this approach has not been applied retrospectively and a lookback exercise will be required to ensure a consistent comprehensive review of all previous cases (prior to the Patient Review Form approach was introduced).

Action: The Southern Trust (Melanie McClements/ Maria O'Kane) to consider the Patient Review form going forward and retrospectively to ensure a comprehensive and consistent review.

SAIs and Structured Clinical Record Review

13. Melanie informed the group that following the sharing of the draft SAI Reports, as per previous UAG report (19 March), no comments have been received from Mr O'Brien's solicitor, one family has advised that they do not wish to engage with the SAI process, one patient has moved directly to initiating litigation proceedings and six of the families have provided comments with further meetings with the Trust taking place week commencing 12 April 2021. Melanie updated the group that one SAI patient, who had a delayed diagnosis, has recently deceased (29 March 2021) and the group noted the intention to allow the family time before making any further contact.

14. The group were advised there has been individual and collective responses from clinical teams which have been shared with the Chair of the SAI panel who met on 12th April to review and consider these responses.

15. Melanie also informed the group that the Board had a meeting on Thursday 8 April with DoH, Trust and PCC. It was agreed at this meeting that the families involved in the SAI process were well-supported and therefore PCC involvement was not required at this time. However the group noted the intention to arrange a workshop to have an informal discussion regarding how the PCC could meaningfully add value for families and relevant charity groups going forward.

Implementation of SAI recommendations

16. The Trust confirmed they are in the process of establishing a working group to take forward an implementation plan for the recommendations and findings from the SAI Reports.

Review of Urology Multi-disciplinary Meetings

17. The Trust advised they have engaged with NICAN who have offered details of PHE Peer review partners. The Trust is arranging a meeting with the PHE Peer Review team in the coming weeks. The Trust are progressing the suggestion by NICAN to, in the first instance, carry out an internal peer review audit while the external peer review is being agreed. In addition the Trust is making plans to conduct an enhanced assessment of MDM effectiveness using the National Cancer Action Team document titled *Characteristics of an Effective Multidisciplinary Team (MDT)* in order to further develop improvement plans.

18. The group discussed and agreed further consideration is required on a number of wider Trust issues concerning MDMs including: assurance that all Trusts MDMs process' are effective; quality of MDMs; and required skills set for Clinical Director positions and required training to support this role.

Action: HSCB (Paul Cavanagh / Sharon Gallagher) to consider the MDM issues raised at a system level and on a Trust wide basis.

Staff Engagement

19. Melanie advised that regular Team meetings are continuing with the Clinical Teams and the Chief Executive, Medical Director and Director of Acute Services. Shane advised that early learning has been shared with Trust staff who are feeling vulnerable, both personally and professionally, as a result of the Urology Review and forthcoming Public Inquiry.

20. Shane advised that the offer for staff engagement by Richard Pengelly and Dr Michael McBride was appreciated and may be timely in the coming weeks.

Action: Southern Trust (Shane Devlin) agreed to establish a suitable date for Trust staff engagement meeting with Mr Pengelly and Dr McBride.

Private Practice

21. Melanie confirmed that the Trust has issued correspondence to Mr O'Brien requesting that he forwards a Trust letter addressed to his private patients between the period January 2019 – August 2020 and that non-compliance with this reasonable request may result in a further potential GMC referral. The Trust has requested Mr O'Brien to confirm that this has been actioned by the 20th April 2021.

Public Inquiry

22. Michael O'Neill provided an update on the ongoing progress relating to the recruitment of inquiry team staff and accommodation requirements to support the establishment of the Urology Public Inquiry.

23. Michael informed the group that Jackie Johnston and the Public Inquiry Chair, Ms Christine Smith QC, are finalising the draft Terms of Reference and it is hoped that the Terms of Reference will be approved by the Minister by the end of May 2021.

24. The group discussed the Trust having sight of the draft Terms of Reference for comment. Michael agreed to liaise with the Chair on this matter.

25. Michael confirmed that patient/family stakeholder engagement has been arranged for 21st and 22nd April to support the finalisation of the draft Terms of Reference. Families have been advised they may submit written comments should they not wish to meet. The Trust welcomed this approach due to the patient/families feeling overwhelmed at this time.

26. Michael confirmed that clarification had been received regarding DLS support to the Trust, as result of HSCB closure and restructuring. The group noted that there will be no change to the DLS support required by the Trust.

Action: DoH (Michael O'Neill) to liaise with the Inquiry Chair, Christine Smith, to discuss sharing the draft Terms of Reference with the Trust for comment.

Communications

27. Shane highlighted that a number of MLAs were strongly campaigning in support for Mr O'Brien.

Any other business

28. The group noted that the first neurology clinical negligence hearing had commenced in April 2021 and agreed that Urology was at too early a stage to require medical negligence as a urology review work strand in the short term.

Date of next meeting

29. The next meeting of the group will be on Friday 14th May 2021.

Annex 1

Action Log

Action	Date of Meeting	Owner	Actioned
To consider the Patient Review form going forward and retrospectively to ensure a comprehensive and consistent review.	16/4/2021	The Southern Trust (Melanie / Maria)	
To consider the MDM issues raised at a system level and on a Trust wide basis.	16/4/21	HSCB (Paul Cavanagh / Sharon Gallagher)	
To establish a suitable date for Trust staff engagement meeting with Mr Pengelly and Dr McBride.	16/4/2021	The Southern Trust (Shane Devlin)	
Liaise with Christine Smith, to discuss sharing the draft Terms of Reference with the Trust for comment.	16/4/2021	DoH (Michael O'Neill)	
Confirm legal reference with the GMC regarding the consultant cooperating with a Trust inquiry or	19/3/2021	The Southern Trust (Melanie / Stephen)	Completed – letter issued confirming non-compliance

review, and consider next steps to identify the private patients.			may lead to further GMC referral
Liaise with the Southern Trust to make the appropriate arrangements for patient/family stakeholder engagement.	19/3/2021	DoH (Michael O'Neill)	Completed – arranged for 21/22 April
Seek clarification on the DLS support to the Southern Trust within the context of the planned HSCB closure.	19/3/2021	DoH (Michael O'Neill)	Completed – confirmed with UAG 16/4/21
Prepare the Trust to support and service a full Public Inquiry in adherence to the Inquiry Rules 2006.	19/3/2021	Southern Trust (Shane Devlin)	Ongoing

UROLOGY ASSURANCE GROUP

Friday 18 June 2021 at 2.30pm, by Zoom

Agenda

1. Welcome and apologies

2. Minutes & Action Points of previous meeting

3. Trust Update (Southern Trust)

    i. Patient Records Scoping Exercise
    ii. SAIs and Structured Clinical Record Review
    iii. Implementation of SAI Recommendations
    iv. Private Practice

4. Public Inquiry (Michael O'Neill)

5. Communications

6. AOB

7. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 14 May 2021 at 3.00pm, by Zoom

Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Paul Cavanagh, HSCB
Michael McBride, DoH	Olive McLeod, PHA
Lourda Geoghegan, DoH	Shane Devlin, Southern Trust
Jim Wilkinson, DoH	Melanie McClements, Southern Trust
David Gordon, DoH	Heather Trouton, Southern Trust
Michael O'Neill, DoH	Maria O'Kane, Southern Trust
Ryan Wilson, DoH	Stephen Wallace, Southern Trust
Anne-Marie Bovill, DoH	
Paula Ferguson, DoH	

Apologies: Sharon Gallagher, HSCB and Brid Farrell, PHA.

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting were addressed during the course of the meeting.

Trust Update (Southern Trust)

4. The update report provided by the Southern Trust and circulated to UAG members prior to the meeting, including a summary of progress relating to the

Patient Record Scoping Exercise, SAIs, Structured Clinical Record Reviews and Private Sector, was presented by Melanie McClements and Maria O'Kane.

Patient Record Scoping Exercise

5. Melanie McClements confirmed no new inquiries have been received since the last report on 16 April 2021. Weekly telephone clinics continue to review patients from Mr O'Brien's review backlog list.

6. Melanie advised that 52 identified MDM patients require a second opinion review to be carried out by Mr Haynes.

7. Melanie confirmed that Professor Sethia has completed a further 89 Radiology reviews since the last report. 750 have now been reviewed to date, a further 786 reviews are still to be completed.

8. Melanie confirmed that two extra Oncology MDTs were held, chaired by Professor Sethia, with 28 cases discussed. Melanie advised from the 28 cases discussed there were 25 patients who were identified as having concerns regarding their treatment. All 25 patients will be seen face to face through clinics, by Mr Haynes.

9. The group noted that 425 Review Backlog patient records are still to be reviewed and highlighted that resource and capacity to address this backlog is a concern. Melanie confirmed the three other Trusts (Belfast, SET and Western Trust) have been approached to establish they can assist with this work. One Trust has responded to date, unable to offer assistance. Melanie confirmed a Service Specification is being prepared by the Trust, for the provision of Urology outpatient reviews from Independent Sector providers, to help address the resource and capacity issue.

10. Stephen Wallace advised that the lookback and guidance policy documentation regarding "Conducting of Lookbacks in HSC services" will be issued imminently. Melanie advised that the Trust will discuss any implications for the urology review with the HSCB.

11. Maria introduced Heather Trouton to the group, as the new Lead Director for the Urology Public Inquiry. Melaine advised that the Trust has identified a number of areas that require additional staff to support the Public Inquiry and are now in the process of preparing for the required recruitment.

SAIs and Structured Clinical Record Review

12. Melanie informed the group that all of the SAI reports have been shared with DoH and HSCB. 8 out of 9 SAI Reports have been finalised. The family of the recently bereaved patient have requested more time to consider the report and the Trust have agreed to extend their time for feedback.

13. The group were advised the Trust is currently making arrangements to formally apologise to the 9 families and a letter of apology is currently being drafted to send to the families.

14. The group noted that a workshop will be held on 20th May to have an informal discussion regarding how the PCC could meaningfully add value for families and relevant charity groups going forward.

15. Melanie informed the group there has also been a further 14 patients identified through the review clinics as receiving sub-optimal care which will require consideration through the SCRR process.

16. A total of 39 cases are being considered under the SCRR process which represents a conversion of approximately 20%. The group noted that the 20/25% conversion rates warranted a further lookback in respect of the Neurology recall.

Implementation of SAI recommendations

17. The Trust confirmed they have developed a Project Initiation Document (PID) to support the operationalisation and fulfilment of the SAI recommendations. The work includes developing 4 workstreams to manage the 134 learning points and recommendations provided. The group noted that

a Quality Improvement Group to oversee and coordinate this work is also being established to take this work forward.

18. The group noted it is expected that recommendations will be made as a result of the internal audit report and SAI reports which may have implications for other consultants and other Trusts. The group discussed a number of reports (NI Audit Office, Patterson Inquiry Report and RQIA Review of Governance Arrangements in Independent Hospitals and Hospices in NI Report) which should be reviewed in conjunction with SAI recommendations to ensure an appropriate and a comprehensive response.

Action: DoH (Michael O'Neill/Anne-Marie Bovill) to liaise with the Southern Trust (Shane Devlin) to consider other relevant reports (NI Audit Office, Patterson Inquiry Report and RQIA Report) in conjunction with the SAI recommendations.

Review of Urology Multi-disciplinary Meetings

19. Melanie informed the group that the Trust is meeting with the PHE Peer Review team and following the advice received, is progressing an internal peer review audit.

20. The group noted that an audit has commenced to conduct an enhanced assessment of MDM effectiveness using the National Cancer Action Team document titled *Characteristics of an Effective Multidisciplinary Team (MDT)* in order to further develop improvement plans. This audit will include all Trust MDM's.

Private Practice

21. Melanie confirmed the Trust continues to seek DLS advice and to liaise with the GMC as required. The group noted that Mr O'Brien's Solicitor confirmed that the letter from the Southern Trust to Mr O'Brien's private patients has been issued to patients under his care for the period between January 2019 and June 2020.

22. Melanie advised the letter included contact details for the patient information line however no additional calls have been made to the helpline and no further GP requests have been received.

23. The group discussed the difficulties in gaining direct access to Mr O'Brien's private patients due to his private practice operating outside of RQIA regulations. The group agreed that GDPR exemptions may be applicable in these circumstances due to the level of concern for patients and that these matters are a public interest issue. The group agreed GDPR exemptions should be explored further on this basis.

Action: Southern Trust (Shane Devlin) to explore if GDPR exemptions can be applied in order to gain direct access to Mr O'Brien's private patients.

24. The group also agreed there is merit in considering a media statement to reach private patients and GPs, possibly alongside the timing of apologies to SAI families.

Action: DoH (David Gordon) agreed to liaise with Southern Trust (Shane Devlin) to consider the letters of apology being issued to SAI families and the potential for further wider media communications with private patients and GPs.

Public Inquiry

25. Michael O'Neill informed the group that SAI patient/family engagement meetings took place in April to support the finalisation of the draft Inquiry Terms of Reference (ToR). The group also noted that a letter received from Mr O'Brien's solicitor regarding the Inquiry ToR was being considered.

26. The group agreed that Michael should engage with Shane Devlin to discuss the overarching themes within the draft ToR to allow the Trust to make staff preparations to serve the Public Inquiry when established.

Action: DoH (Michael O'Neill) to engage with the Southern Trust (Shane Devlin) to provide an outline of the overarching themes within the draft Inquiry ToR.

27. Michael provided an update on the ongoing progress relating to the recruitment of inquiry team staff and accommodation to support the establishment of the Urology Public Inquiry. The group noted the intention remains for the Public Inquiry to commence in September 2021.

Communications

28. David Gordon confirmed no requests or media interest had been received since the previous meeting.

29. The group noted the action agreed to liaise with the Trust regarding the SAI letters of apology and wider media which may be required relating to Mr O'Brien's private practice.

Any other business

30. No other business.

Date of next meeting

31. Friday 18 June at 2.30pm via zoom.

Annex 1

Action Log

Action	Date of Meeting	Owner	Actioned
To consider other relevant reports (NI Audit Office, Patterson Inquiry Report and RQIA Report) in conjunction with the SAI recommendations.	14/5/2021	DoH (Michael O'Neill/Anne-Marie Bovill) and Southern Trust (Shane Devlin)	
To explore if GDPR exemptions can be applied in order to gain direct access to Mr O'Brien's private patients.	14/5/2021	Southern Trust (Shane Devlin)	
To consider the letters of apology being issued to SAI families and the potential for further wider media communications with private patients and GPs.	14/5/2021	DoH (David Gordon) and Southern Trust (Shane Devlin)	
To provide an outline of the overarching themes within the draft Inquiry ToR.	14/5/2021	DoH (Michael O'Neill) and Southern Trust (Shane Devlin)	

To consider the Patient Review form going forward and retrospectively to ensure a comprehensive and consistent review.	16/4/2021	Southern Trust (Melanie / Maria)	Ongoing
To consider the MDM issues raised at a system level and on a Trust wide basis.	16/4/2021	HSCB (Paul Cavanagh / Sharon Gallagher)	Ongoing
To establish a suitable date for Trust staff engagement meeting with Mr Pengelly and Dr McBride.	16/4/2021	Southern Trust (Shane Devlin)	Ongoing
Prepare the Trust to support and service a full Public Inquiry in adherence to the Inquiry Rules 2006.	19/3/2021	Southern Trust (Shane Devlin)	Ongoing

UROLOGY ASSURANCE GROUP

Monday 6 September 2021 at 11am, by Zoom

Agenda

1. Welcome and apologies
2. Minutes & Action Points of previous meeting
3. Trust Update (arising issues)
4. Preparations for extending the recall
5. Cohort 1 Outcomes Report
6. Public Inquiry
7. Communications
8. AOB
9. Date of next meeting – TBC

UROLOGY ASSURANCE GROUP (UAG)

Friday 18 June 2021 at 2.30pm, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Paul Cavanagh, HSCB
Lourda Geoghegan, DoH	Damian Gormley, Southern Trust
Michael O'Neill, DoH	Shane Devlin, Southern Trust
Ryan Wilson, DoH	Melanie McClements, Southern Trust
Sharon Gallagher, DoH	Heather Trouton, Southern Trust
Paula Ferguson, DoH	Martina Corrigan, Southern Trust

Apologies: Jim Wilkinson, DoH, David Gordon, DoH, Michael McBride, DoH, Anne-Marie Bovill, DoH, Olive McLeod, PHA, Brid Farrell, PHA, Maria O'Kane, Southern Trust, Stephen Wallace, Southern Trust.

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting were addressed during the course of the meeting.

Trust Update (Southern Trust)

4. The update report provided by the Southern Trust and circulated to UAG members prior to the meeting, including a summary of progress relating to the

Patient Record Scoping Exercise, SAIs, Structured Clinical Record Reviews and Private Sector, was presented by Heather Trouton.

Patient Record Scoping Exercise

5. Heather Trouton confirmed one new inquiry received via email since last report on 14 May 2021. Weekly telephone clinics continue to review patients from Mr O'Brien's review backlog list.

6. Heather updated the group that the British Association of Urological Surgeons (BAUS) has identified another Subject Matter Expert Consultant Urologist who is willing to help with the review of patients. This Consultant has now been set up with remote access and is commencing the review of some patients.

7. Heather shared concerns with the group on the huge waiting list numbers. The Trust met with the Board to discuss and it was suggested by the Trust that any patients not from the Southern Trust that are on our waiting lists, could be repatriated back to their own areas (Belfast and Western Trusts – 307 requiring in-patient/day case surgery and 679 outpatients, as yet unseen). Paul confirmed the Southern Trust should speak with the Trusts concerned in the first instance. It was agreed this would be a formal request from this group.

Action: Southern Trust to approach Belfast and Western Trusts to accept the repatriation of Urology patients as a formal request from the Urology Assurance Group.

8. Heather informed the group that a Service Specification is being prepared by the Trust for the provision of Urology outpatient reviews from Independent Sector providers (1000 cases, initially all from Mr O'Brien's lists) to support the Urology Team in seeing the patients identified as needing reviewed.

9. The group discussed the impending introduction of regional policy and guidance regarding Conducting of Lookbacks in HSC services. Lourda assured

the group that the guidance had been widely shared in draft form and would not expect large gaps within this urology review.

SAIs and Structured Clinical Record Review

10. Heather informed the group that letters of apology for each of the patients / families have been prepared for issue which will include timelines when the Trust will contact the families regarding updates on implementation of recommendations.

11. Heather informed the group that the DoH, Board, Trust and PCC met on 20 May 2021 to discuss how the PCC can meaningful contribute going forward. PCC are considering this with regard to the other patients and families identified/affected through and by the Inquiry.

12. Heather updated the group that the GMC have advised that they have decided the 9 SAI cases will now formally be considered as part of the ongoing investigation into Mr O'Brien's practice.

    The group noted that the scheduled GMC interim suspension panel met on 2nd June to discuss Mr O'Brien's case and agreed his interim suspension from the Medical Register should continue for a further 6 months, in the first instance.

13. Heather advised that a further patient had been identified and was being considered under SCRR, this brings the current total to 40 patients. The Trust has contacted the British Association of Urology Surgeons to seek additional Subject Matter Expertise (SME) to help conduct these reviews.

Implementation of SAI recommendations

14. Heather advised that the Trust has discussed the recommendations from each of the 9 SAI reports and the overarching report with the chair of the reviews Dr Dermot Hughes. Dr Hughes has confirmed that the 11 recommendations contained in the overarching report will meet the requirements specified in each

of the individual reports. Dr Hughes has agreed to write an addendum to the Trust to confirm this.

15. Heather informed the group the Trust had set up a task and finish group to take forward the 11 recommendations.

Review of Urology Multi-disciplinary Meetings

16. Heather advised the Trust is in the final stages of finishing a qualitative audit of urology service MDM functions. This audit has also been carried out in Breast and Gynae and will be expanded to include all Trust Cancer MDM's. The group noted that the resulting gap analysis and findings will be available in late June 2021.

Private Practice

17. Heather advised that Mr O'Brien's solicitor has confirmed to DLS that by 4th June 2021, 200 Trust letters have been issued to Mr O'Brien's private patients and this process is continuing. Mr O'Brien's solicitor has stated his intention is to contact all those patients whom he still has contact details for. The Trust, via DLS, has asked for progress on this to be provided urgently. The Trust has asked for letters to be issued to private patients from all time periods, not solely limited to January 2019 – June 2020. The group noted that some feedback has been received and the Trust is assured the letters are issuing.

18. Heather confirmed that the Trust has reviewed the GDPR legislation and has noted a potential clause that may allow, on a lawful basis, to access private patient records. Michael O'Neill confirmed this was ongoing and the potential exemption came under "public safety".

    The group discussed exploring the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 that may refer to the potential scope of RQIA's authority to regulate medical private practice that occurs outside of an established hospital or independent clinic. It was confirmed this is not an option as Mr O'Brien was practising from his home.

The Trust agreed they would only continue to explore the GDPR legislation with DoH.

Action: Southern Trust (Heather Trouton) to explore if GDPR exemptions can be applied in order to gain direct access to Mr O'Brien's private patients.

Public Inquiry

19. Michael O'Neill informed the group that a meeting with Shane Devlin to discuss the overarching themes within the draft ToR took place. Shane expressed concerns that clinical practice would not be included within the ToR. The group discussed the role of the Inquiry and the following points noted:
    - Focus will be on governance, including clinical governance, however each case would not be clinically reviewed again;
    - A urology clinical specialist will be on the inquiry team;
    - Will identify systematic issues;
    - GMC have the responsibility for the clinical aspect, this will inform the future of Urology practice, the Public Inquiry findings will inform all practices;

Action: DoH (Michael O'Neill) to share concerns with Inquiry Chair

20. The group discussed looking forward to the Outcomes Report. Paul advised this could not be drafted until the Cohort 1 of patients had finalised, therefore March 2022. It was agreed that learnings from the Neurology Outcome Reports should be identified and considered going forward.

Action: DoH (Michael O'Neill) and Paul Cavanagh (HSCB) to consider Outcomes Report learnings.

Action: Outcomes Report to become standing agenda item.

21. Michael informed the group the submission on the ToR would be submitted to the Minister next week for consideration.

22. Michael advised the group that the accommodation for the inquiry business case was in final stages. The group noted an indicative start date for the inquiry to start in September 2021.

Communications

23. The group noted the Irish News published an article on Monday 7 June 2021 after they had received an anonymous copy of the report into the 2016 SAI's. There was a subsequent follow-up article on Tuesday 8 June 2021. After the Trust was alerted to the possible publication of this article they contacted all 9 families from the current SAI's and the previous six patients/families affected by the 2016 SAI's. The group recognise and appreciate the relationship the Trust has with the families.

Any other business

24. The group discussed the potential of a further lookback. The following was noted:
    - The Trust is starting to identify trends within the current review, this may inform if a further look back is required;
    - The Trust has sent a sample of patient charts dating back to 2015 to the British Association of Urological Surgeons, with a range of clinical pathways. This will also inform if a further lookback is required;
    - The Trust is investigating the total number of patients under the care of Mr O'Brien dating back to 2010;
    - Patient safety was foremost important to ensure patients were on the correct pathway, hence the current date of January 2019.

25. The group agreed to amend the format of the meeting. The Trust update paper is very helpful and should remain, however this will not be required as a full update within the meeting. Any issues arising should be updated under

Trust Update. It was agreed two new items would be added to the agenda: Preparations for extending the recall and Outcomes Report Cohort 1. As the Public Inquiry nears commencement, it will also be appropriate to move items to AOB and allow the Trust to leave prior to these discussions.

Action: DoH to amend UAG agenda to reflect changes agreed.

Date of next meeting

26. The next meeting will take place at the end of August. It was agreed information lines will remain open; the Trust update will be circulated to the group in July and any other issues arising can be circulated if required.

Annex 1

Action Log

Action	Date of Meeting	Owner	Actioned
To consider other relevant reports (NI Audit Office, Patterson Inquiry Report and RQIA Report) in conjunction with the SAI recommendations.	14/5/2021	DoH (Michael O'Neill/Anne-Marie Bovill) and Southern Trust (Shane Devlin)	
To explore if GDPR exemptions can be applied in order to gain direct access to Mr O'Brien's private patients.	14/5/2021	Southern Trust (Shane Devlin)	
To consider the letters of apology being issued to SAI families and the potential for further wider media communications with private patients and GPs.	14/5/2021	DoH (David Gordon) and Southern Trust (Shane Devlin)	
To provide an outline of the overarching themes within the draft Inquiry ToR.	14/5/2021	DoH (Michael O'Neill) and Southern Trust (Shane Devlin)	

To consider the Patient Review form going forward and retrospectively to ensure a comprehensive and consistent review.	16/4/2021	Southern Trust (Melanie / Maria)	Ongoing
To consider the MDM issues raised at a system level and on a Trust wide basis.	16/4/2021	HSCB (Paul Cavanagh / Sharon Gallagher)	Ongoing
To establish a suitable date for Trust staff engagement meeting with Mr Pengelly and Dr McBride.	16/4/2021	Southern Trust (Shane Devlin)	Ongoing
Prepare the Trust to support and service a full Public Inquiry in adherence to the Inquiry Rules 2006.	19/3/2021	Southern Trust (Shane Devlin)	Ongoing

UROLOGY ASSURANCE GROUP (UAG)

Friday 22 January 2021 at 12.00, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Paul Cavanagh, HSCB
Jackie Johnston, DoH	Sharon Gallagher, HSCB
Michael McBride, DoH	Olive McLeod, PHA
Lourda Geoghegan, DoH	Shane Devlin, Southern Trust
Michael O'Neill, DoH	Melanie McClements, Southern Trust
Anne-Marie Bovill, DoH	Maria O'Kane, Southern Trust

Apologies: Ryan Wilson, Brid Farrell, David Gordon.

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting were addressed during the course of the meeting.

Trust Update (Southern Trust)

4. The update report provided by the Southern Trust and circulated to UAG members prior to the meeting, including a summary of progress relating to the Patient Record Scoping Exercise, SAIs, Structured Clinical Reviews, Independent Sector and Private Sector, was presented by Melanie McClements and Maria O'Kane.

Patient Record Scoping Exercise

5. The group noted that no further calls or inquiries have been received via the information line which may be a positive indication of reduced concerns from patients, families and GPs.

SAIs and Structured Clinical Review

6. Melanie informed the group that the plan to impart the full 9 SAI Reports and overarching SAI report remains on target to be provided to the Department by end January 2021. The learning that has been identified to date has been shared with HSCB, Trust's Urology Oversight Group and Clinical Teams.

7. The group noted the family engagement and psychological support services available to patients and families and the support arrangements planned when the individual SAI reports are shared with them. The group noted that all families have been offered the support services and two families have been signposted to the support services to date. The Chair of the SAI's has also planned meetings with the Trust Urology Oversight Group and the Clinical Teams to discuss the final reports.

8. Maria updated the group on the meeting which took place on 21 January 2021 with the Royal College of Physicians (RCP) to finalise discussions for the use of Structured Judgement Review (SJR) methodology to support patient reviews outside of the current SAIs. The Trust has now agreed a core virtual training programme with the Royal College of Physicians team for a core group of reviewers.

9. Maria confirmed that UAG approval will be sought on the finalised proposals using the SJR methodology for patient reviews outside of the current 9 SAIs.

10. The group agreed that the title of this patient review process along with a communication plan to ensure stakeholder clarification on its process and purpose including the difference to the SAI process and purpose would be required.

11. The group noted that the SAI and patient review processes would be matters for consideration by the Public Inquiry Chair when appointed.

Action: Southern Trust (Maria O'Kane), in collaboration with the RCP, agreed to bring forward a finalised proposal using the SJR methodology for patient reviews outside of the SAI process, including the proposed title of the patient review process and a communication plan for stakeholders to the UAG for ratification.

Royal College of Surgeons Invited Review Service

12. The group was informed that a meeting will take place on 28th January 2021 with the Chief Medical Officer, Deputy Chief Medical Officer, Trust Chief Executive and Medical Director to discuss and agree the draft Terms of Reference for the Invited Review Service by the RCS and once approved the Trust will commence this invited review with the RCS.

13. Maria outlined broad timescales for the completion of this work including agreement of the Terms of Reference with the RCS and approximately 10-12 weeks to complete the review.

Trust Staff Engagement

14. Melanie confirmed regular team meetings are continuing with the Clinical Teams and the Chief Executive, Medical Director and Director of Acute Services. The offer from Richard Pengelly to engage with Trust staff and provide support to the Team was made and the Trust confirmed that this should be facilitated once there was more information on the Inquiry (e.g. Chair appointed/TOR agreed).

Independent Sector (Private Practice)

15. Melanie outlined that Internal Audit are continuing to review Mr O'Brien's private patients transferring into SHSCT as HSC patients and consideration of Trust involvement with the Craigavon Urological Research & Education (CURE) organisation.

16. The group noted that the Trust have corresponded to Mr O'Brien via his Solicitor in respect his Private Patient work and have ask for a response by 5th February 2021 and also continue to engage with the GMC as appropriate.

17. Richard confirmed his discussions with his RoI counterpart regarding the potential of RoI patients within Mr O'Brien's private practice and the group agreed that further confirmation regarding RoI patients within Mr O'Brien's private practice will be required when Mr O'Brien's private patient records have been accessed and verified.

Action: The Department will be required to provide confirmation to RoI colleagues regarding the identification of any RoI patients within Mr O'Brien's private practice, when the relevant private practice patient information is made available.

Public Inquiry

18. The group noted that engagement with DSO continues to identify a Public Inquiry Chair and accommodation requirements for the Public Inquiry are currently being considered.

19. Shane Devlin highlighted the concerns of Trust staff as a result of the certainty of when and how the Public Inquiry will be taken forward and that engagement would be required with them when a clear pathway is known.

20. Maria confirmed that the Trust has liaised with the Belfast Trust on lessons learned on ensuring effective lines of communication regarding the retention of documents to support the Public Inquiry from previous experiences within the Independent Neurology Inquiry.

Communication Plan

21. The Trust informed the group of the online support campaign for Mr O'Brien and approaches and inquiries including Assembly Questions received specifically relating to grievances Mr O'Brien may have raised with the Trust and the Public Inquiry. The Department confirmed that similar queries have been received.

22. The group noted that the Health Committee has requested, via written correspondence, the evidence to support the need for a Public Inquiry. It was agreed that a copy of Hansard including the Minister's Oral Assembly Statement, which includes the rationale and requirement for a Public Inquiry, would be circulated to UAG members for information.

Action: DoH (Anne- Marie Bovill) to circulate a copy of Hansard relating to the Minister's Oral Assembly Statement on 24 November 2020 to UAG members.

Any other business

23. No other business was discussed.

Date of next meeting

24. The next meeting of the group will be on Friday 5th February 2021.

UROLOGY ASSURANCE GROUP (UAG)

Monday 6 September 2021 at 11.00am, by Zoom

Draft Minutes

FOI Implications: May not be disclosed Section 22 Information intended for future publication, Section 33 audit functions, Section 35 formulation of Government policy refers.

Richard Pengelly, DoH (Chair)	Shane Devlin, Southern Trust
Jim Wilkinson, DoH	Stephen Wallace, Southern Trust
Robbie Davis, DoH	Maria O'Kane, Southern Trust
Anne-Marie Bovill, DoH	Heather Trouton, Southern Trust
Sharon Gallagher, DoH	Martina Corrigan, Southern Trust
Paula Ferguson, DoH	Aidan Dawson, PHA
Paul Cavanagh, HSCB	Caroline Cullen, HSCB

Apologies: Michael McBride, DoH, Lourda Geoghegan, DoH, David Gordon, DoH, Ryan Wilson, DoH, Brid Farrell, PHA, Melanie McClements, Southern Trust

Welcome and apologies

1. The group was welcomed and apologies noted.

Minutes of previous meeting

2. The draft minutes of the previous meeting were agreed.

Actions from previous meeting

3. The actions arising from the previous meeting were addressed during the course of the meeting.

Trust Update (Southern Trust)

4. The update report provided by the Southern Trust and circulated to UAG members prior to the meeting, including a summary of progress relating to the Patient Record Scoping Exercise, SAIs, Structured Clinical Record Reviews and

Private Sector was noted by the group. The following matters were discussed by the group.

SAI Patient Involvement

5. Heather explained that two families had expressed an interest in being part of the SAI recommendations improvement work and the first meeting took place 1 September 2021. he intention of the SAI meetings will be to share actions planned with the family representatives, seek their feedback and be assured that they are involved in and content with progress made.. Heather stated this was a positive meeting and the families involved are working closely with the Trust.

Clinical Review

6. Heather informed the group that securing the additional consultants resource required to support the Urology Team to complete the clinical review of patients to be difficult. The group noted that consultant support from a local independent sector provider is not available and engagement is underway to consider support options with a Limited Liability Partnership Group (LLP) from Manchester.

Private Practice

7. The group noted the Southern Trust engagement with RQIA to explore GDPR exemptions and possible RQIA remit to assist in accessing Mr O'Brien's private patient records. Stephen Wallace advised the group that DLS had presentational concerns regarding the proposed letter to Mr O'Brien relating to the private patients. The group agreed that the Trust will continue to explore the role which RQIA may be able carry out and confirm with DLS that the request is a Trust request, not a DoH request.

Action: Southern Trust (Shane Devlin / Stephen Wallace) to continue to engage with RQIA regarding possible assistance in gaining accessing Mr O'Brien's Private patients.

Action: Southern Trust agreed to liaise further with DLS, to provide clarity on presentational concerns and to ensure that the letter to Mr O'Brien issues in early course.

Staff Engagement

8. Heather Trouton confirmed that staff engagement is continuing within the Trust and it is felt, given the Urology Services Inquiry has now been established, that Trust staff would benefit from a meeting with Richard Pengelly, as previously offered. It was agreed a meeting would be arranged for October 2021.

Action: DoH to arrange a meeting with Trust Staff in October 2021.

Preparations for extending the Urology Review

9. The group noted there has been some debate with using the term "recall" and whether "lookback review" is more appropriate. The group noted that a meeting will take place between the Trust, HSCB and DoH to discuss and agree the appropriate terminology moving forward.

10. Heather Trouton informed the group that the Trust are continuing to work through patient records between the period January 2019 and June 2020, with the Royal College of Surgeons lookback, involving 100 patient records, covering a 5 year period . The group noted that if going back to 2009, there are approximately 10,300 patients involved and Heather advised work is continuing to determine if the review should be extended beyond January 2019.

Action: DoH to meet with HSCB and the Trust to agree urology recall/lookback review terminology and revise future UAG agenda items accordingly.

Cohort 1 Outcomes Report

11. Paul Cavanagh confirmed the structure of the Outcomes Report will be dependent on the outcome of the meeting to determine the appropriate urology terminology.

12. The group noted the differences required for the urology review and outcomes report compared to the Neurology Recall Outcome Reports, including the urology surgical related questions. The group agreed that the urology review cohort sizing/population, specific questions and likely timing of an outcomes report should be considered further and that a paper presenting the options for the outcomes report should be prepared for UAG consideration at the next meeting.

Action: HSCB (Paul Cavanagh) to prepare a paper to present Urology Outcomes Report options for UAG consideration at the next meeting.

Public Inquiry

13. The group noted the Written Statement from Minister on 31 August 2021 regarding the USI Terms of Reference and the appointment of panel members. Maria O'Kane advised that staff were anxious about the Public Inquiry following the USI announcement.

14. Jim Wilkinson suggested a communique from the USI Chair, Christine Smith, using layman's terms of reference may be of use and a comfort to staff. It was agreed to explore if USI are intending to issue communications directly to Trust staff, and if not, the Department could consider issuing a note to Trust staff.

Action: DoH (Jim Wilkinson and Robbie Davis) to liaise with Christine Smith to discuss issuing a communique to SHSCT staff on the USI Terms of Reference.

Communications

15. The group noted some news articles had been published following the Ministers statement on 31 August 2021.

Any other business

16. No other business

Date of next meeting

17. The next UAG meeting will be confirmed in due course.

Annex 1

Action Log

Action	Date of Meeting	Owner	Actioned
To continue to engage with RQIA regarding possible assistance in gaining accessing Mr O'Brien's Private patients.	6/9/2021	Southern Trust (Shane Devlin / Stephen Wallace)	
To liaise further with DLS, to provide clarity on presentational concerns and to ensure that the letter to Mr O'Brien issues in early course.	6/9/2021	Southern Trust	
To meet with HSCB and the Trust to agree urology recall/lookback review terminology and revise future UAG agenda items accordingly.	6/9/2021	DoH (Robbie Davis)	
To prepare a paper to present Urology Outcomes Report options for UAG consideration at the next meeting.	6/9/2021	Paul Cavanagh	

To liaise with Christine Smith to discuss issuing a communique to SHSCT staff on the USI Terms of Reference.	6/9/2021	DoH (Jim Wilkinson and Robbie Davis)	
To approach Belfast and Western Trusts to accept the repatriation of Urology patients as a formal request from the Urology Assurance Group.	18/6/2021	Southern Trust	Completed
To consider Outcomes Report learnings.	18/6/2021	DoH (Michael O'Neill) and Paul Cavanagh (HSCB)	Ongoing
Outcomes Report to become standing agenda item.	18/6/2021	DoH	Completed
To amend UAG agenda to reflect changes agreed.	18/6/2021	DoH	Completed
To consider other relevant reports (NI Audit Office, Patterson Inquiry Report and RQIA Report) in conjunction with the SAI recommendations.	14/5/2021	DoH (Michael O'Neill/Anne-Marie Bovill) and Southern Trust (Shane Devlin)	Ongoing

To explore if GDPR exemptions can be applied in order to gain direct access to Mr O'Brien's private patients.	14/5/2021	Southern Trust (Shane Devlin)	Ongoing
To consider the letters of apology being issued to SAI families and the potential for further wider media communications with private patients and GPs.	14/5/2021	DoH (David Gordon) and Southern Trust (Shane Devlin)	Ongoing
To provide an outline of the overarching themes within the draft Inquiry ToR.	14/5/2021	DoH (Michael O'Neill) and Southern Trust (Shane Devlin)	Completed
To consider the Patient Review form going forward and retrospectively to ensure a comprehensive and consistent review.	16/4/2021	Southern Trust (Melanie / Maria)	Ongoing
To consider the MDM issues raised at a system level and on a Trust wide basis.	16/4/2021	HSCB (Paul Cavanagh / Sharon Gallagher)	Ongoing
To establish a suitable date for Trust staff engagement meeting with Mr Pengelly and Dr McBride.	16/4/2021	Southern Trust (Shane Devlin)	Ongoing

Prepare the Trust to support and service a full Public Inquiry in adherence to the Inquiry Rules 2006.	19/3/2021	Southern Trust (Shane Devlin)	Ongoing

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this *just culture guide*, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - **Q1. deliberate harm test**

1a. Was there any intention to cause harm?

Yes → **Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. **END HERE**

No go to next question - **Q2. health test**

2a. Are there indications of substance abuse?

Yes → **Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. **END HERE**

2b. Are there indications of physical ill health?

2c. Are there indications of mental ill health?

Yes → **Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. **END HERE**

if **No to all** go to next question - **Q3. foresight test**

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

If **No** to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. **END HERE**

if **Yes to all** go to next question - **Q4. substitution test**

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

If **Yes** to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. **END HERE**

if **No to all** go to next question - **Q5. mitigating circumstances**

5a. Were there any significant mitigating circumstances?

Yes → **Recommendation:** Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. **END HERE**

if **No**

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. **END HERE**

improvement.nhs.uk

Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

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Effective clinical governance for the medical profession:

A handbook for organisations employing, contracting or overseeing the practice of doctors

Contents

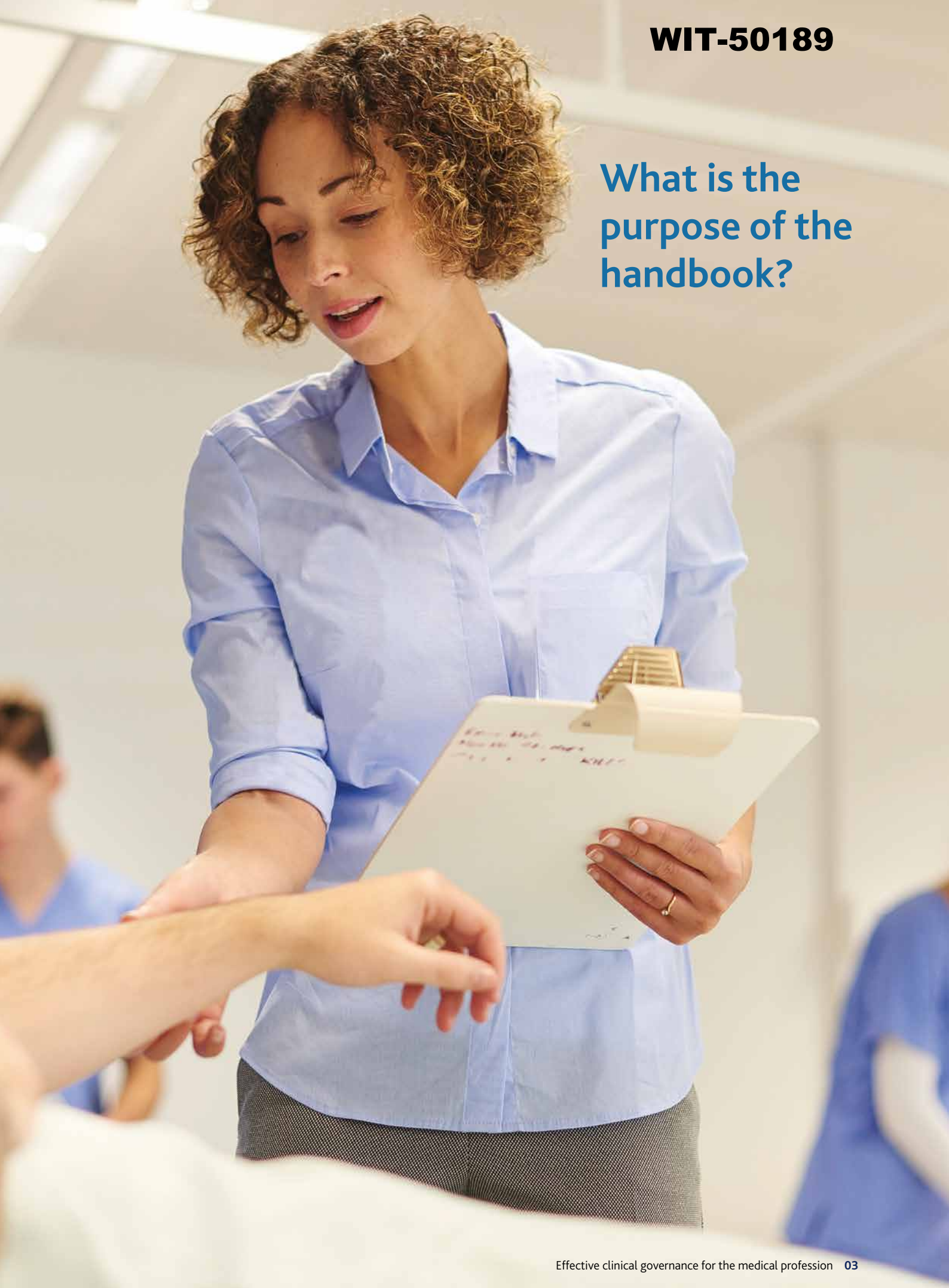
Who is the handbook for?

This handbook is aimed at organisations which employ, contract or oversee the practice of doctors in the UK. In the majority of cases these organisations will also be designated bodies (DBs). It is also relevant for healthcare providers in the crown dependencies and suitable persons.*

In particular, the handbook is designed for those individuals or groups of individuals who play an important leadership role in delivering and assuring the quality of clinical governance processes for doctors. In most cases this will be the board or governing body of an organisation but it may also include owners of private organisations and, in some circumstances, individual doctors. Those involved in managing and delivery clinical governance will also find the handbook a useful resource.

For ease of reference the handbook will use the terms 'organisation' and 'board' when referring to individuals or groups of individuals responsible for leading in the delivery and assurance of clinical governance processes in an organisation. In addition when we refer to patients we do so in the broadest sense. This includes, for example, service users, customers and clients.

* https://www.gmc-uk.org/registration-and-licensing/managing-your-registration/revalidation/becoming-and-acting-as-a-suitable-person



What is the purpose of the handbook?

It aims to provide boards with a description of the core principles underpinning effective clinical governance for doctors focussing particularly on responsibilities outlined in the Responsible Officer (RO) regulations.* In doing so it acts as a resource to support organisations in evaluating the effectiveness of their local arrangements including:

- Leadership, delivery and quality of clinical governance for doctors
- Medical revalidation
- Identifying and responding to concerns about doctors
- Pre-employment checks for doctors†

Responsibilities for and delivery of various aspects of clinical governance for doctors are different across the UK, sectors and type of organisation. They are also dependent on whether an organisation acts at a national or local level. For this reason the handbook may require a certain level of interpretation by organisations to ensure they maximise its benefits. It should also be used in conjunction with other relevant clinical governance guidance.

There is no specific requirement to report against the Handbook but organisations may find it useful to record, alongside other relevant standards and guidance, how it has been used in practice, when preparing for future inspection and internal audit work. It may also be used as an aid to annual board reporting.

More information about the signatories can be found on their websites:

Care Quality Commission
Crown Commercial Service
General Medical Council
Healthcare Improvement Scotland
Healthcare Inspectorate Wales
National Guardian
NHS England
NHS Improvement
Regulation Quality Improvement Authority

* https://www.gmc-uk.org/registration-and-licensing/managing-your-registration/revalidation/making-a-recommendation-about-a-doctors-revalidation

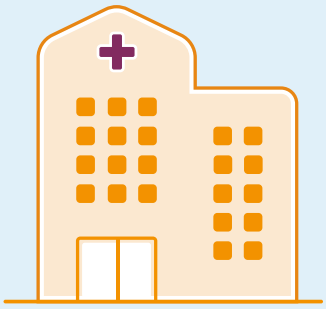
† The RO Regulations only impose obligations in respect of pre-employment checks on responsible officers in England; Reg. 16(2) Medical Profession (Responsible Officers) Regulations 2010.

Effective clinical governance for the medical profession

> Clinical governance is the system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which clinical excellence can flourish.
>
> Effective clinical governance contributes to the safety and quality of patient care. Good clinical governance must support the early identification of risks and concerns that lead to individual, team and wider organisational learning.

Roles and responsibilities in clinical governance

Responsibility for ensuring the quality and safety of healthcare services sits first and foremost with organisations and the individual professionals working within them. Regulatory and quality improvement bodies also play an important role in promoting this.



Organisations

- Put in place clinical governance systems which promote and protect the interests of patients.
- Create an environment which supports doctors in meeting their professional obligations.

Doctors

- Practise in accordance with the principles and values set out in Good Medical Practice and participate in revalidation.
- Participate in the systems and processes put in place by organisations to protect and improve patient care.

Regulators and quality improvement agencies

Improve the quality of care by:

- Monitoring, and where relevant, enforcing compliance with standards and regulations.
- Sharing information and intelligence in relation to patient-safety.
- Promoting a culture of continuous improvement and learning
- Acting decisively to protect the public when risks to patient-care or well-being emerge.

Clinical governance for doctors

Developing, operating and quality assuring clinical governance for doctors is a key responsibility for organisations and boards. It includes making sure there are clear lines of accountability throughout organisations and visible leadership from boards. Encouraging and actively supporting the professional development of doctors is also an important feature.

There are a number of processes and activities which can support clinical governance for doctors. This Handbook focuses particularly on those outlined in the RO regulations:

- Medical revalidation
- Identifying and responding to concerns
- Pre-employment checks.*

Medical revalidation is a fundamental part of clinical governance for doctors. It provides patients and the public with assurance that doctors in the UK are part of a governed system which checks their fitness to practise on a regular basis and supports their continuous improvement and development. It also supports the identification and management of concerns at an early stage.

Specific roles and responsibilities for those involved in the management and delivery of medical revalidation, including responsible officers, can be found on the GMC's website.

* The RO Regulations only impose obligations in respect of pre-employment checks on responsible officers in England; Reg. 16(2) Medical Profession (Responsible Officers) Regulations 2010.

Principles

The following four principles underpin effective clinical governance for the medical profession. Embedding them will help organisations develop systems and processes in a way which supports the delivery of high quality patient care.

1

Organisations create an environment which delivers effective clinical governance for doctors.

Clinical excellence and the well-being of doctors are at the centre of the organisation's approach to deliver high-quality patient care.

2

Clinical governance processes for doctors are managed and monitored with a view to continuous improvement.

Well-structured and governed systems with learning and continuous improvement at their heart promote confidence in patients and doctors.

3

Safeguards are in place to ensure clinical governance arrangements for doctors are fair and free from bias and discrimination.

It is important patients, doctors, and other healthcare professionals have confidence that clinical governance arrangements for doctors are fair. Transparency of processes, including sharing of information and how decisions are made, play a key role in this.

4

Organisations deliver clinical governance processes required to support medical revalidation and the evaluation of doctors' fitness to practise.

Organisations have a responsibility to ensure their clinical governance arrangements support the medical workforce to practise safely and meet their professional obligations. But also to identify and respond to concerns about doctors as they emerge.

Effective clinical governance for the medical profession checklist

The checklist below provides further detail on the principles and how to apply them in practice (outcomes and associated descriptions). It also contains a series of questions (prompts) which organisations and boards can use to help them evaluate whether their clinical governance arrangements for doctors are effective. The checklist should be considered as a tool to support the development of good practice rather than defining a set of additional requirements for organisations to meet.

A checklist self-assessment template along with other supporting materials can be found on the GMC's website.

Effective clinical governance for medical profession checklist

Effective clinical governance for medical profession checklist

Principle 1 – Organisations create an environment which delivers effective clinical governance for doctors

Outcome	Description	Prompts
1a **Your organisation's board has the knowledge, skills, competences and access to relevant information to enable it to exercise its responsibilities effectively with respect to clinical governance for doctors.**	Your organisation's board receives training and development opportunities necessary to effectively discharge their responsibilities around clinical governance for doctors, and to understand their accountability for the quality of care provided by doctors. Your organisation's board has access to summary information and data from clinical governance processes for doctors (including complaints, incident reporting, medical appraisal, management of concerns about doctors and clinical indicators) and the ability to interpret and scrutinise the information appropriately. Clinical/medical leaders including responsible officers are given access to your organisation's board and provide input on matters relating to clinical governance for doctors. A suitably qualified and trained non-executive director has a specific role in providing support and challenge to the board on clinical governance systems for doctors including revalidation and management of concerns.	How does your organisation ensure the board (including non-executive directors) has the right training and development opportunities to support the effective oversight of clinical governance arrangements for doctors? How does your organisation identify the clinical governance information about doctors it needs to undertake its role effectively? How does your organisation ensure the board is kept up dated on changes to clinical governance processes for doctors and the impact of those changes? How does your organisation's board engage with clinical/medical leaders?

Outcome	Description	Prompts
1b **Your organisation's board provides leadership on promoting the importance of clinical governance for doctors.**	Your organisation actively promotes the benefits of effective clinical governance processes for doctors (including those that support access to supporting information for appraisal and medical revalidation). This includes the positive contribution those processes make to the professional development of individuals and ultimately safe and effective patient care. Your organisation works with local patient groups to publicise and promote awareness of the revalidation processes it has in place to make sure doctors are up to date and fit to practise, including an understanding of how concerns about doctors are dealt with. Your organisation ensures all doctors working within the organisation including locum doctors, doctors in training and clinical academics, for example, have access to clinical governance information about their practice.	How does your organisation demonstrate its commitment to the delivery of effective governance processes for doctors? How does your organisation ensure doctors (including locum doctors, doctors in training and clinical academics, for example) have access to information about their practice and are encouraged to use it as part of their professional development? How does your organisation work with local patient groups to promote awareness of revalidation processes and how they are applied locally?

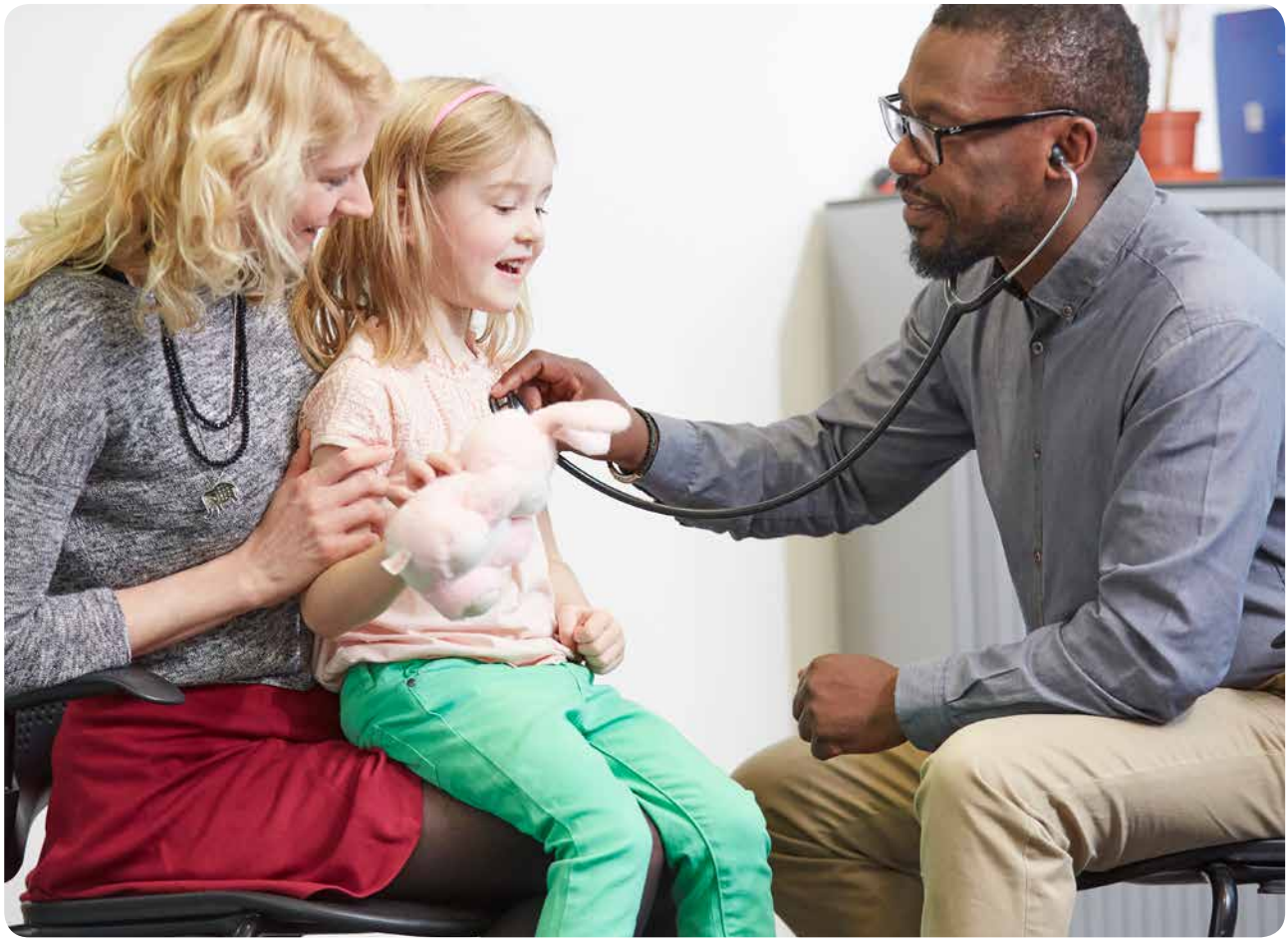
Outcome	Description	Prompts
1c **Your organisation's board actively encourages a culture of honesty, learning and improvement.**	Your organisation makes sure systems are in place to give early warning of any failure, or potential failure, in the clinical performance of individuals or teams. These may include systems for conducting audits and considering patient feedback and making sure any concerns about the performance of an individual or team are investigated and, if appropriate, addressed quickly and effectively. Your organisation ensures there are readily available and accessible policies and processes in place which encourage doctors to speak up and which ensure doctors are not at risk of detrimental treatment as a result of doing so. This includes ensuring your organisation can demonstrate how decisions made about the issues raised by doctors speaking up are fair. Doctors have a professional duty of candour. Your organisation puts in place processes to support them in reporting adverse incidents, and near misses, and in being open and honest with patients if something goes wrong with their care. Your organisation puts systems in place to monitor, review, and improve patient care by: • Collecting and sharing information on patient experience and outcome • Training staff in patient safety and supporting them to report adverse incidents And makes sure systems or processes are in place so that: • lessons are learnt from analysing adverse incidents and near misses • lessons are shared with the healthcare team • concrete action follows on from learning • practice is changed where needed.	How does your organisation make sure it responds quickly when things go wrong? How does your organisation evaluate whether its policies for speaking up are effective? For example, do they result in creating unintended barriers to those who wish to speak up? Does your organisation offer sufficient assurance to those raising concerns that they will not suffer as a result of speaking up and that there is a zero tolerance approach to victimising staff who speak up? What steps does your organisation have in place to support doctors who have spoken up? How does your organisation make sure that decisions made about doctors who speak up are fair and transparent, and this can be demonstrated if necessary? How does your organisation make sure challenges made about clinical governance processes are recorded, acted on, and the outcomes fed back to those who raised concerns? How does your organisation identify opportunities for learning and improvement from matters raised by workers speaking up? How does your organisation support and encourage staff in being open and honest with patients when things go wrong?

Outcome	Description	Prompts
	Doctors are supported in giving honest and open feedback on their colleagues, and there are systems and processes in place to make sure that any workplace issues raised are addressed fairly.	How does your organisation support doctors to provide honest and open feedback about their colleagues?
1d **Your organisation's board monitors risks associated with clinical governance systems for doctors.**	Your organisation's board plays a proactive role in identifying, monitoring and manging risks to clinical governance systems for doctors. Your organisation makes use of available information to inform their clinical governance arrangements for doctors, such as the GMC's organisational dashboard for revalidation and fitness to practise.	How does your organisation ensure it has a clear view of risks associated with clinical governance systems for doctors? How does your organisation assure itself that the risks are being reviewed and managed appropriately? How could the reporting systems for your organisation's board on risks associated with clinical governance systems for doctors be improved?

2 Principle 2 – Clinical governance processes for doctors are managed and monitored with a view to continuous improvement

Outcome	Description	Prompts
2a **Your organisation's board ensures internal and external quality assurance is undertaken to ensure the robustness of clinical governance processes for doctors.**	Your organisation seeks internal and external assurance that clinical governance systems for doctors are operating effectively. Your organisation ensures recommendations from quality assurance exercises are taken forward and reviewed on a regular basis. Your organisation encourages lay involvement in their quality assurance processes, to provide independent scrutiny and challenge, and to increase public confidence that local governance is robust. Local medical education providers meet the requirements within the GMC's Promoting Excellence guidance. This includes making sure: • That education and training for doctors is a valued part of the organisational culture • Doctors are actively supported to participate in education and training. • That the environment and culture with your organisation meets learners' and educators' needs, is safe, open, and provides a good standard of care and experience for patients.	What quality assurance activity does your organisation undertake to assess the robustness of its clinical governance processes for doctors? How does your organisation assure itself clinical governance processes generate accurate, timely and reliable data to support continuous monitoring? In what ways does your organisation use lay representation to support and improve clinical governance for doctors? How does your organisation measure whether quality improvement activities undertaken have improved patient care?

Outcome	Description	Prompts
2b **Your organisation's board ensures learning is used to continually improve clinical governance processes for doctors.**	Your organisation demonstrates a commitment to making clinical governance processes for doctors more robust, by overseeing their continuous improvement. Your organisation encourages learning drawn from your own organisation's systems and experience, as well as from good practice in other organisations and feedback from patients and patient groups.	How is the continuous improvement of clinical governance for doctors planned, delivered and reviewed within your organisation? What examples can you provide of incorporating learning from good practice in other organisations and patients and patient groups into your organisation's clinical governance systems for doctors?



3 Principle 3 – Safeguards are in place to make sure clinical governance processes for doctors are fair and free from discrimination and bias

Outcome	Description	Prompts
3a **Your organisation's board provides leadership on equality, diversity and inclusivity (EDI) by overseeing and scrutinising development and implementation of EDI strategies.**	Your organisation's board members act as role models and ambassadors for EDI issues. Your organisation ensures clinical governance policies for doctors are fair and free from bias and discrimination by ensuring they: • Remove or minimise disadvantages experienced by doctors who share protected characteristics. For example by making reasonable adjustments to processes underpinning clinical governance for disabled doctors. • Identify barriers different groups of doctors and patients may face in engaging with the systems supporting clinical governance, and put steps in place to remove these barriers. Your organisation encourages consultation with and involves people who share personal characteristics in developing clinical governance processes for doctors whenever it is appropriate and relevant to do so. Your organisation ensures emerging EDI challenges and risks associated with clinical governance for doctors' policies and practices are actively monitored and regularly reviewed.	How does your organisation make sure its policies and practices which support clinical governance for doctors are fair, non-discriminatory, and comply with legal requirements? How does your organisation ensure barriers to accessing the systems supporting clinical governance for doctors are identified and addressed? How does your organisation engage with EDI issues, and what benefits does this bring?

Outcome	Description	Prompts
3b **Your organisation's board ensures decision-making processes are fair and free from bias and discrimination.**	Your organisation puts in place principles and criteria to ensure decisions made in support of clinical governance for doctors are fair, impartial and evidenced based, and these principles and criteria are applied consistently. Decisions are internally monitored and audited to ensure the quality, fairness and consistency of decisions, and to review the procedures put in place to support decision making. Mechanisms exist for doctors to appeal, or request a review of, decisions made in relation to them.	What are your organisation's principles of fair decision making, and how do these ensure your decisions are free from bias and discrimination? What changes has your organisation made to its procedures in relation to supporting fair decision making based on learning from the monitoring and audit of decisions? What training does your organisation provide to its staff to ensure decisions are fair, free from bias, and meet the requirements of equality legislation? How does your organisation make sure that doctors are aware of processes to appeal or review a decision? And what safeguards are put in place to ensure these appeals and reviews are handled consistently and fairly?

4 Principle 4 – Organisations deliver processes required to support medical revalidation and the evaluation of doctors' fitness to practise

Outcome	Description	Prompts
4a **Your organisation's board appoints a responsible officer (RO).**	If your organisation is a designated body it must: • Appoint or nominate a responsible officer and appoint a replacement as soon as manageable when necessary (for example where your RO leaves, is under investigation, or absent from work due to ill-health) • provide its RO with sufficient funding and resources, to enable them to effectively carry out their statutory responsibilities. Your organisation ensures its RO is appropriately trained to undertake their responsibilities, and is given support to regularly participate in local RO network activities that provide shared learning opportunities and support consistency of approach.	How does your organisation ensure its RO is able to deliver all aspects of their statutory functions as defined in the RO regulations? How do you make sure your organisation's RO has sufficient resources to undertake their statutory role? How does your organisation ensure its RO has the quality of information they need to carry out their statutory duties (including to inform revalidation recommendations to the GMC)? How has learning from your RO's participation in local RO network activities improved local processes and provided assurance on the consistency of their approach?

Outcome	Description	Prompts
4b **Your organisation's board ensures medical appraisal is delivered in line with GMC and other national and local requirements.**	Your organisation ensures all doctors requiring an annual appraisal receive one and it covers the whole of a doctor's practice including any work undertaken outside of your organisation during the appraisal period. Your organisation ensures doctors are clear which appraisal requirements are prescribed by the GMC for the purpose of revalidation: • Guidance on supporting information for appraisal and revalidation • GMP framework for appraisal and revalidation Your organisation ensures doctors are supported to collect the required supporting information by being given access to relevant data and systems* and sufficient time to participate in annual appraisal effectively. This includes locum doctors, doctors in training and clinical academics, for example. Your organisation ensures doctors taking breaks in practice due to maternity/paternity or sick leave, for example, are supported through appraisal and revalidation. Your organisation's appraisal system is subject to quality assurance, including monitoring of appraiser's performance.	How does your organisation monitor whether all doctors requiring annual appraisal have been appraised? How does your organisation identify barriers to participation in appraisals and the steps taken to remove those barriers? What policies and processes does your organisation have in place to manage doctors who are not engaging in appraisal and other clinical governance processes? How does your organisation make sure information relating to a doctor's practice from other organisations informs their whole practice appraisal? How do you assess whether doctors have adequate resources to support their appraisal (such as sufficient time and access to the information needed) including educational and development activities? How does your organisation quality assure its appraisal process to identify opportunities for reducing the burden on doctors in terms of preparing for appraisal and collecting supporting information? How does your organisation manage and monitor the performance of appraisers and the resources needed to support them?

* For example, quality data, performance data, audits, compliments, complaints and significant events.

† ARCP in the case of doctors in training.

	Your organisation ensures doctors have the opportunity to feedback on the quality of the appraisal process and discussion. Your organisation ensures outputs from the appraisal system are integrated into wider clinical governance systems.	Does your organisation's guidance for appraisers include how to appropriately escalate patient safety concerns (including concerns about colleagues) that may form part of the appraisal discussion? How does your organisation ensure there are no unintended barriers for doctors participating in learning and education activities?
4c **Your organisation's board ensures revalidation recommendations are made in line with GMC requirements.**	Your organisation ensures revalidation recommendations for doctors are made in accordance with the GMC's protocol for making recommendations. Doctors are told promptly about the revalidation recommendation made to the GMC about them. The reasons for recommendations are discussed before they are submitted, particularly where the recommendation is to defer or for non-engagement'. Your organisation ensures revalidation continues to deliver benefits by considering how best to track its impact over time.	How does your organisation monitor revalidation recommendations to ensure they are made in accordance with the appropriate guidance? Does your organisation compare recommendation rates, for example, deferral rates with similar organisations to identify whether there are any differences and if there are differences explore why? Does your organisation monitor the number of late recommendations? How has your organisation improved the revalidation recommendation process? For example, how does it learn from revalidation decisions to defer and for non-engagement'? What steps does your organisation take to make sure revalidation recommendations are fair, transparent, based on all the relevant evidence, and have been discussed with the doctors concerned in a timely manner?

Outcome	Description	Prompts
4d **Your organisation's board ensures processes for responding to and managing concerns including monitoring the on-going fitness to practise of doctors are in place.**	Your organisation has systems in place to monitor the conduct and performance of doctors including locum doctors, doctors in training and clinical academics, for example. Your organisation ensures performance information about doctors (including clinical indicators relating to outcomes for patients) is regularly reviewed and issues identified (such as variations in individual performance, and between clinical teams). It also ensures steps are taken to address any issues identified. Your organisation proactively responds to concerns locally, with referrals to the GMC made by the RO where and when appropriate. Speciality or other central or local advice is taken where appropriate from, for example: • Medical Royal Colleges and Faculties • GMC's Employer Liaison Service (ELS) • NHS Resolution. Your organisation's investigations into concerns about doctors take into account, where appropriate, the GMC's principles of a good investigation. These key principles help to ensure investigations into concerns about doctors are objective and effective. They are intended to supplement and complement existing requirements and guidance in place at a national level. Your organisation ensures doctors' compliance with any GMC or local conditions imposed on them or undertakings agreed with GMC is monitored.	What processes does your organisation have in place to address issues identified relating to the conduct and performance of doctors, including, locums, doctors in training and clinical academics for example? How does your organisation make sure information derived from complaints, significant events and performance data held by the organisation, is regularly reviewed and feeds into the monitoring of the conduct and performance of doctors? How does your organisation ensure advice from external sources is considered early when responding to emerging concerns? What areas for learning and improvement has your organisation identified from the triangulation of outputs from different clinical governance processes? Questions relating to the GMC's principles of a good investigation.

Outcome	Description	Prompts
4e **Your organisation's board ensures there are processes in place to handle and share information relating to clinical governance systems for doctors appropriately.**	Your organisation makes sure records are accurately and securely maintained in line with all relevant data protection legislation and the Caldicott principles. This includes: • records relating to pre-employment checks, medical revalidation, and appraisal, and systems supporting these processes. • local investigations and management of concerns. Timely sharing of information is an essential component of robust clinical governance. Any organisation using the services of a doctor must inform that doctor's responsible officer of any concerns that could impact on patient safety or public confidence as soon as they arise. This should be done in line with the GMC's information sharing principles.	How do you make sure that records are accurately and securely maintained in line with relevant data protection legislation and guidance? How does your organisation make sure it is complying with information sharing principles? How does your organisation monitor the effectiveness of its information sharing processes (for example, sharing information with other organisations in which your doctors work)?

Outcome	Description	Prompts
4f **Your organisation's board ensures the necessary checks are in place for doctors before they start work.**	Your organisation ensures the following arrangements are in place across the medical workforce (whether they are employed, contracted, in training, working with practising privileges, hired or volunteering): • Making sure doctors working in your organisation have the appropriate registration, and a licence to practise, for their type of post or practice. • Verifying identity and language checks have taken place, and undertaking these checks if it can't be verified. • Ensure appropriate references are obtained and checked • Granting and monitoring of practising privileges is undertaken where necessary. Your organisation should not rely on registration and licence checks undertaken for previous employment or by another organisation, as a doctor's registration and licence status can change. It's important doctors working in your organisation have appropriate insurance or indemnity. Your organisation ensures there are induction arrangements (particularly those to support doctors new to the UK - the GMC holds regular Welcome to UK Practice events, for example) in place for all doctors including locum doctors and doctors in training.	How do you make sure that pre-employment, and other pre-contract checks undertaken for your medical workforce (including locums) are comprehensive, accurate, and in keeping with statutory and other requirements? How do you make sure that arrangements to grant and monitor practising privileges where relevant are robust? What induction arrangements does your organisation have in place and how does it monitor their effectiveness? How do you know doctors working in your organisation have the appropriate insurance or indemnity?

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www.crowncommercial.gov.uk/

General Medical Council
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www.gmc-uk.org/contact-us

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www.healthcareimprovementscotland.org/about_us/contact_healthcare_improvement.aspx

Healthcare Inspectorate Wales
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Regulation Quality Improvement Authority
9th Floor Riverside Tower
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Southern Trust IEAP approach summarised

i. In the Southern Health & Social Care Trust Outpatient Pathway Review undertaken in January 2019 when HSCB highlighted apparent issues in relation to the chronological management of outpatients at the Trust Performance Management Meetings it appeared that some patient appointments were not being made in chronological order with some routine patients being seen within three weeks while others were waiting over nine weeks. The HSCB decided to undertake a short pathway review to assess the systems in process as currently in place with the booking of outpatient services regionally to ensure they support the consistent application of the Integrated Elective Access Protocol (IEAP).

ii. As part of the methodology the performance against chronological management especially levelled within each trust was analysed and those specialties with a higher percentage of routine new patients being seen out of chronological order were selected for review. In addition specialties where there was a particular concern regarding patients currently waiting over nine weeks were also selected for review. One of these included Urology. The review process was described and in this there was a description of how registration was made in relation to patients. On page 5 of this report under triage it stated that in the NHSCT red flag referrals and appointments were managed by a dedicated team. They are not administered by the RBC and are therefore not part of this review. Where red flags are downgraded they will be forwarded to the RBC which stands for Referral and Booking Centre.

iii. It states (d) for Urology a new process of triaging and booking was introduced in December 2014 and referrals are now hand delivered to the Thorndale Unit in the main OPD (Outpatients Department) several times a day for triage and referrals which have already been triaged, collected and updated on PAS (Patient Administration System). For the majority of Urology referrals, daily triage is now achieved but there is a longstanding issue with turn around time for one Consultant and referrals not returned from triage continues to be a key issue for booking staff.

iv. Under point (f) in this report it also states that when referrals are returned from triage the PAS registration is updated and patients added to the outpatient waiting list. On examination of patient level information for those patients who attended within 0-3 weeks there were incidences of priority type not reflecting the urgency with which patients attended. For example a patient was referred as urgent and booked into an urgent outpatient slot but the priority type on PAS was routine. The red flag trackers some secretaries and RBC staff have contributed to this and would indicate that further training is required with regard to updating PAS registration following triage within clinical priority is not changed.

v. Under clinic template (2a) it states that a small number of dedicated protected review slots have been allocated for patients following MDT's although trackers will ask RBC if they can book into other slots where they need to.

vi. (b) For urology since December 2014 all clinic slots are designated red flag. Unallocated slots are notified to the RBC who books the patients from the PTL selecting urgent patients first then proceeding to routines. Urgent patients are mostly seen within four to six weeks but the waiting time for new routine patients is currently at forty weeks. Available slots released from red flags for PTL patients can range from 2-6 slots depending on the day.

vii. (d) RBC manages Urology templates for clinics at Craigavon, South Tyrone and also in SWAH as there was high demand for clinics in Enniskillen to facilitate patients from the West of the Trust. Patients may have their new appointment at Craigavon or South Tyrone but can be reviewed at SWAH. It goes on to state that in relation to chronological management in the period April to October 2014 the number of new routine patients who were appointed in less than six weeks varied and was 4% for Urology. In some specialties, e.g. Urology the RBC will be contacted by referrers with information about a change of clinical priority and a second referral usually sent in. Staff will administer this on the system maintaining the patient's original date but amending the clinical priority and appointment type. This can mean that some urgent patients will appear to have waited longer than routine and at booking process (b) it states the process for booking new routine and review patients was in line with regional guidance. In the new Urology model all patients are now telephone booked.

viii. Following on from the recommendations in Maintaining High Professional Standards in autumn 2018 review of admin processes was carried out and reported on 22nd November 2021. The review looked at areas identified by the MHPS investigation (1) non-triage of G.P. and other Consultant referrals; (2) non-dictation on patients who had attended outpatient clinics; (3) hospital notes being stored off Trust premises namely the Consultant's home; (4) the Consultant has scheduled his private patients sooner than outside of clinical priority. In the report it highlights and describes the issues of concern identified the gap that led to the concerns raised, advises on the policies and processes now in place, describes the ongoing risks and flaws and explains the escalation process.

ix. In point 1 of the report it states that pre-2014 due to the delayed triage of referrals the decision was taken to add to the outpatient waiting list a referral as a clinical priority that the GP had assigned. The escalation process is now described. Under undictated clinics it identifies that a limitation with the G2 system in use is that it simply records speech and generates a letter, however G2 is unable to correlate the letter against the outpatient attendance. In relation to hospital notes when patient hospital records were required but same not in the tracked location at a time previously health records did complete IR1 forms but were advised to stop by the director at the time.

Rationale and Metrics for Triage

i. In his compound report dated May 2020 using the Organisations Unique Case Identifier: 69120 in relation to the Root Cause Analysis report and Serious Adverse Incident involving five service users namely JL, SB, PF, AM, TF, Dr. Johnston describes the rationale for triage of GP referrals in 5.1. In this he states "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 they will respond also promptly to confirm or exclude the diagnosis of cancer.

ii. 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".

iii. Cancer specialists working in networks have formulated lists of symptoms 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 designs, they can provide an efficient referral system.

iv. NICE have been instrumental in ensuring uniformity and validity of these cancer recognition referral lists of symptoms and signs. They have also formulated guidance regarding how safety nets should be set up to ensure patients are not missed. Local programmes using the type of guidance have been established under the auspices of NICaN and the HSCB, set up these triage pathways and safety nets.

v. The process of Urology triage in Southern Trust is based up the NI Referral Guidance for Suspected Cancer of 2012 as described above, i.e. it is based on 2005 NICE CG 27 Guidelines. In the Southern Trust Triage of referrals is performed by the Consultant Urologist of the week.

vi. The Southern Trust Urological Cancer Multidisciplinary Team (MDT) was led at the time in 2012 by Mr. O'Brien who was also a joint chair of NICaN.

vii. Over a period of decades within the Southern Health & Social Care Trust there were occasions when triage was not performed. Acute Services had a particular problem with this issue. Preliminary discussions by the review team of the SAI revealed that triaging within Acute Services was a "very haphazard process going back for approximately twenty five years. There were many Consultants who would not triage but Mr. O'Brien was the most persistent and there were multiple attempts to tackle this issue".

viii. NICaN urology cancer clinical guideline highlights the urology care pathways. Mr. O'Brien was present at the workshop discussing those on 02/10/2008 and clearly indicates, that for the prostate pathway the G.P. referral would be triaged by the Urology Consultant.

ix. Triage of G.P. referrals Northern Ireland is standard practice and is based on The N.I. Referral Guidance for Suspected Cancer from NICE Clinical Guideline CG 27 (2005) – Referral Guidelines for Suspected Cancer published in June 2005. Within this there was a section on Urological cancer. It was introduced to G.P.s 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 G.P., prioritisation".

x. This is still the only set of referral criteria for suspected urological cancer available online on the NICaN website.

xi. The 2005 CG27 Guidance was replaced by NICE Clinical 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 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 G.P.s for implementation. Trusts are expected to review guidance against a baseline assessment and provide HSCB with an assurance that the guidance has been implemented. This assurance process does not however apply to primary care and G.P.s.

xii. 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 Mr. Aidan O'Brien.

xiii. The review team's evaluation of the advantages of NICE NG12 over the CG27 Guidelines reveals fewer cases would be ratified for Urology as a result of

- A reduction in numbers of non-visible haematuria patients; and
- Increase in age criteria of 45 years and over.

xiv. However roll out of NG12 by the HSCB does not appear to have happened. The review team for the SAI understand that the reason NG12 had not been implemented was because of ongoing discussions between the HSCB and G.P.s.

Southern Health and Social Care Trust

Quality Care - for you, with you

Review of the Senior Management Structures – June 2022

1.0 Introduction

The purpose of this paper is to outline final plans for changes to the senior management structure for the Southern HSC Trust.

2.0 Need for Change

Although the pandemic presented a considerable number of challenges, it also opened up new ways of thinking and working. These included:

- Leaders at all levels in the organisation stepping forward and leading on major pieces of work.
- Decision making timelines in many occasions were shortened considerably with bureaucracy replaced with technology enabled meetings.
- New fast decision making structures were created. These included SMT Bronze comprising of SMT, IPC, Microbiology, Primary Care and Emergency Planning and the Operational Bronze with a range of senior managers and clinicians from across the Trust. At the height of the pandemic these groups met on a daily basis to review, make and implement decisions.
- Directorate worked closer together with a single focus on delivering Covid-19 safe services.

In addition, the Trust has also faced an uncertain period as three Directors retired during 2021 – Director of Mental Health & Disability (March 2021), Executive Director of Finance, Procurement & Estates (June 2021), and Executive Director of Social Work / Director of Children & Young People (September 2021). Both the Director of Mental Health & Disability and Executive Director of Finance, Procurement & Estates have however now been filled on a permanent basis.

In 2021, the previous Chief Executive, Shane Devlin led discussions with a range of teams across all Directorates in relation to involving staff in shaping the new organisational structures. Pending the outcome of these

restructuring discussions, the existing vacancy of Director of Older People and Primary Care (OPPC) continued to be filled on an interim basis and the Executive Director of Social Work / Director of Children & Young Peoples' Services has been filled on an interim basis until new structures were finalised.

Following the appointment of the Executive Medical Director to Chief Executive in May 2022, the resignation of the Director of Performance & Reform in February 2022, and the pending retirement of the Director of Acute Services in August 2022, these three additional vacancies provide an ideal opportunity to conclude the discussions in relation to organisational restructuring. Dr O'Kane has a clear focus on stabilising the organisation, driving improvement and embedding our collective leadership approach.

Existing vacancies at Assistant Director level in both Acute Services and Older People & Primary Care Services have been filled on an interim basis until we finalise the key changes, after which they will be recruited permanently.

3.0 Approach to the review of structures:

The approach led by the then Chief Executive, Shane Devlin, in 2021 was to define the key parameters for change, in the context of delivering safe, effective care. In addition, he undertook a review of structures in other NHS organisations to gain an understanding of other models. The Senior Management Team then carried out a number of workshops with representatives from across Directorate teams and trade union side to begin to draft a proposed structure in the context of the agreed principles, learning from Covid19 and listening to views.

4.0 Structure design principles:

The following set of design principles was defined to guide the structures conversations and test any new model:

1. Patient / User focused – whatever is designed should ultimately ensure that the organisation is focused on care delivery;
2. Safety and Governance – the new structure must allow for an improvement in safety through good governance;

3. Succession Planning - a successful element of the new structure must be that it provides an attractive stepping-stone for progression for senior leaders;
4. External environment – any new structures must be designed around the changing external situation e.g. integrated care systems;
5. Attractive – any new structure should be seen as attractive to potential candidates;
6. Scale, Scope and Balance – it is important that new directorates / divisions are created in a balanced way with comparable management portfolios;
7. Drive upstream / prevention – new structures must ensure a focus on improved population health;
8. Corporate and Collaborative – the new structure must drive a collaborative approach, which ensures a single corporate focus across all Directorates;
9. Strategic agenda – the new structure will reflect the strategic priorities and culture we want to develop;
10. Meets statutory requirements;
11. Is affordable.

5.0 Final plan for this phase of restructuring

1. Restructuring of Directorate of Acute Services and Directorate of Older People & Primary care to create 3 separate Directorates:

- Medicine & Unscheduled Care Directorate
- Surgery & Elective, Integrated Maternity & Women's Health, Cancer & Clinical Services Directorate.
- Adult Community Services Directorate.

Timescale: June 2022 subject to DOH approval.

The portfolio of services within each Directorate is as follows:

MEDICINE & UNSCHEDULED CARE	SURGERY & ELECTIVE, INTEGRATED MATERNITY & WOMEN'S HEALTH, CANCER & CLINICAL SERVICES	ADULT COMMUNITY SERVICES
OVERALL BUDGET - £137M WORKFORCE – c2,100	**OVERALL BUDGET - £147M WORKFORCE – c2,200**	**OVERALL BUDGET - £134M WORKFORCE – c2,800**
• Emergency Departments • Urgent Care Centre • GP Out of Hours services • Acute Medical Wards & Outpatients • Non-Acute Hospitals • Hospital Social Work • Acute Medical Unit • Ambulatory • Patient Flow Teams • Pharmacy & Medicines Management • Allied Health Professionals	• Critical Care • Theatres & Recovery (Elective & Emergency) • Surgical Wards & Outpatients • Ambulatory services • Cancer Services • Clinical Services including Laboratories, Radiology & Audiology • Integrated Maternity & Women's Health – wards / outpatient / ambulatory services	• Acute Care at Home Service • Community AHP services, including Reablement Service • Intermediate Care Service • Community Equipment • Specialist Primary Care Services • Statutory Residential Homes • Day Care Services for Older People • Day Hospitals, Rapid Access Clinics & Older People's Assessment Unit • PWB Health Improvement, Community Development, User Involvement, Access & Information • Domiciliary Care Service and Care Bureau • Independent Sector Monitoring / Oversight • Care Home Support Team • Integrated Care Teams

The current scope of Acute Services Directorate is twice that of any other Operational Directorate in the Trust. This is therefore an extreme challenge for one post holder to manage given the range of service reform that is planned across many of the services. A restructuring has been under consideration for quite some time and the imminent retirement of the

current Director provides the ideal opportunity to progress this structural change.

Strategically for the organisation, safety and governance are key areas of focus for the Trust, and therefore the sub division of the Acute Services Directorate is key to achieving improvements in safety alongside robust governance arrangements.

The Trust's new Corporate Plan, has three key areas of focus.

- Stabilise, rebuild and grow
- Improve access to planned services for our patients
- Supporting unplanned, urgent and emergency services

Unscheduled demand is increasing and this affects a range of services. Two new directorates will ensure equal priority is given to both unplanned patient care whilst aiming to protect elective services, including priority patients who require surgery and outpatient services.

The inclusion of non-acute hospitals within the Medicine & Unscheduled Care Directorate aims to facilitate the patient pathway from access of services to discharge. This pathway will be supported by Allied Health Professionals and Pharmacy Teams working in the spirit of collaborative patient care. The relationship with colleagues in Primary Care, GPs, Urgent Care Centres and Emergency Departments will be facilitated by alignment within one management structure with a collaborative approach for patients.

The rationale for amalgamating:

- Surgery and elective care,
- Anaesthetics, theatres and intensive care,
- Cancer and clinical services, and
- Integrated maternity and women's health

is because of their patient cohorts requiring access to both emergency and elective services across ICU, theatres and clinical services, in addition to input from the range of specialists in each of their areas.

The Directorate of Older People & Primary Care has been reshaped as described in the new structures above. The title, Adult Community Services Directorate has been chosen to reflect the age range of the

population served in the Directorate, which is all adults and not just older people.

Community Planning, which is currently supported within the Community Development function, will be reviewed when permanent Director of Performance & Reform and permanent Director of Adult Community Services are in post.

Interim plan – cover for Acute Services

Given the pending retirement of the existing Director of Acute Services in Summer 2022, it is planned to issue an expression of interest for 2 interim posts in mid June:

1. Interim Director of Surgery & Elective, Integrated Maternity & Women's Health, Cancer & Clinical Services, and
2. Interim Director of Medicine & Unscheduled Care Services

to ensure maximum time working alongside the current Director to be supported and induced into the roles.

This will ensure robust handover, and enable time to work through the structures under each Director role to prepare for consultation on final directorate structures with staff and trade unions.

2. Transfer of Functional Support Services to Directorate of Nursing, Midwifery & AHPs.

Timescale to be agreed: proposed - 1st September 2022

The full structure currently associated with Functional Support Services Division within Acute Services will transfer under the Executive Director of Nursing, Midwifery & AHPs. It is intended that the following Support Services will be permanently located within this Directorate as a Corporate Directorate:

Catering Services Domestic Services Portering Switchboard Sterile Services Laundry / Linen Services Chaplains

Once Support Services has transferred, after an initial embedding period Transport Services will then transfer permanently from Mental Health and Disability Services and align with the Support Services portfolio given the corporate nature of Transport. This is likely to be before the end of 2022/23 financial year. This will ensure all support services are managed collectively, reflecting more visibly in our organisational structure the existing Trust wide nature of these services. This will also facilitate effective succession planning.

Currently the Functional Support Services portfolio also has a number (not all) of the Acute Services administrative functions aligned. The following arrangements will apply:

- Secretarial functions and ward clerks will be aligned alongside the services within Medicine & Unscheduled Care Services Directorate and Surgery & Elective Care, Integrated Maternity & Women's Health, Cancer & Clinical Services Directorate;
- Health Records and Referral & Booking Centre will transfer on an interim basis to Executive Director of Nursing, Midwifery & AHPs; and
- A review of administrative services is to be undertaken of administrative services and structures within the Trust.

Whilst it not envisaged Health Records & Referral & Booking Centre will be permanently located with the Executive Director of Nursing, Midwifery & AHPs they will transfer there under their existing management structure until the review is completed. This review is timely given the move to Encompass in the next number of years.

3. Mainstreaming of Covid-19 Vaccination Programme under Public Health Nurse Consultant and transfer to Promoting Wellbeing Division in the Adult Community Services Division.

Currently Lead Director for Covid-19 vaccination is the Director of Human Resources & Organisational Development. This programme has largely been a public facing programme and therefore it is considered best fit to align the programme under the Public Health Nurse Consultant and transfer this role and service to Promoting Wellbeing Division within Adult Community Services. **Transfer of this service will begin immediately.**

4. **Quality Improvement function will transfer from Directorate of Performance & Reform to Medical Directorate.**

Timescale: Following appointment of permanent Medical Director. (Recruitment process is due to conclude during June 2022, and commencement date will be subject to notice period)

The Executive Medical Director has responsibility for clinical & social care governance across the organisation. To ensure that any learning is incorporated into professional practice and systems, the Trust's Quality Improvement function would align more effectively with the learning for improvement remit of the Executive Medical Director role and to provide greater opportunities to embed the safety, quality and experience agenda across the Trust. A newly appointed Medical Director will want to consider where in their Medical Directorate structure the Quality Improvement function will be placed for greatest impact, and therefore the timescale for transfer will be agreed with the Quality Improvement Team after the Medical Director has taken up post.

7.0 Potential future restructuring phase (post September 2022)

Whilst there may be a need identified for further ongoing restructuring across and within directorates on a smaller scale beyond phase 1, one key remaining Director role which requires some further consideration is:

Director of Children and Young People / Executive Director of Social Work / Social Care role

At present, the Executive Director of Social work (and Social care) retains a combined function with the Director of Children & Young People's Services. This post is currently filled on an interim basis. Whilst there is agreement that the overall remit and responsibilities of the Children and Young People's (CYP) Directorate will remain unchanged following the review of structures, further consideration is currently being required regarding the role, function and remit of the Executive Director of Social Work. This is considered necessary in the context of the expanding social care workforce in recent years, including professional responsibilities in respect of the Domiciliary Care workforce and similar posts across the operational Directorates. The Executive Director of Social Work professional responsibilities are continuing to expand within the context of

Delegated Statutory Functions pertaining to the Mental Capacity Act, the pending Adult Safeguarding Bill, increasing remit within Children and Young People's Services and associated professional governance responsibilities.

There is ongoing regional consideration of Executive Director of Social Work roles, which will require examination to explore consistency of function regarding interfaces, professional and legal responsibilities. Furthermore, cognisance needs to be afforded to the current Department of Health sponsored Review of Children's Social Work Services and associated implications.

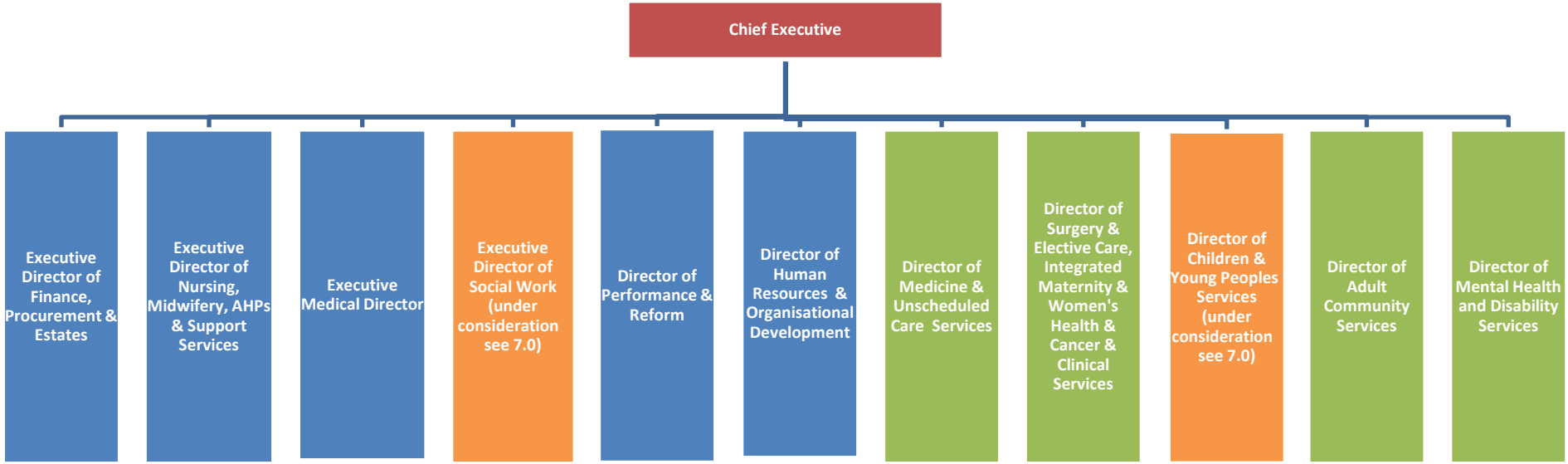
8.0 Management of Change

It is important to provide clear reassurance that it is not anticipated there will be a detriment to any member of staff whose role may be affected by future changes to structures under Director level. The Trust's Management of Change Framework will apply to all new structures designed across the affected Directorates, with ongoing Trade Union consultation. How the Corporate Directorates support the work of the Operational Directorates given the structural changes outlined above will also require careful consideration and potential investment.

Appendix one outlines the new Senior Management Team structure, with Director of Children & Young People's Services / Executive Director of Social Work still requiring further consideration.

Appendix one

PROPOSED SENIOR MANAGEMENT TEAM STRUCTURE



Southern Health and Social Care Trust

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Southern Health and Social Care Trust

INTRODUCTION

Our People Framework is for everyone who works in the Trust. Whatever your role, each of us is key to delivering safe, exceptional care and support to our patients and service users...

If we want to provide the best care for our patients and service users, we need to provide the best care for our people.

Our People Framework sets out what we can all expect - from our formal leaders and from each other. It has been influenced by national, regional and local priorities and by listening to you through our staff surveys, big coffee conversations and COVID-19 lessons learned listening events. It is informed by what you have told us - what is important to you, what works well and how we can get better.

Our ambition, put simply, is **to create a great place to work**, a workplace where we are engaged, feel valued and work well together.

COVID-19 has presented one of the most unexpected and difficult challenges imaginable. The pandemic has affected us all in different ways both professionally and personally.

It has reminded us of the need to look after each other and ourselves. Your response has been incredible. Your compassion, professionalism and dedication demonstrated how important you are in delivering health and social care to our local community.

We have been operating in extreme conditions, far outside our usual practice, and we could not be prouder of how you have managed the challenges and the changing work environment. We recognise if we want to provide the best care for our patients and service users, we need to provide the best care for our people. We are absolutely committed to becoming an employer of choice by creating a great place to work.

Southern Health and Social Care Trust

ABOUT OUR FRAMEWORK

Our People Framework is about enabling us all to thrive and be our best to support the delivery of safe, high quality, compassionate care and support. It outlines what we will focus on to achieve the desired cultural change, supporting the transformation of our workplace to enable the transformation of our care. It is an enabling strategy that responds specifically to the strategic ambitions relating to our culture and valuing our people.

Positivity, compassion, respect, dignity, engagement and high-quality care are key to creating the culture we need.

This framework outlines our three people priorities – **WELLBEING, BELONGING AND GROWING**, including what we will focus on over the next three years in order to continue to care for, engage, retain and recruit colleagues.

It focuses on how we must all continue to look after each other and foster a culture of inclusion and belonging, as well as actions to grow our workforce, train our people, and work together differently to deliver care to our patients and service users. It recognises the need to deal decisively, consistently and quickly with behaviours inconsistent with our values and, just as importantly, it highlights that your health and wellbeing needs to be at the heart of all we do.

Our People Framework will enable us to deliver our vision of care, achieve our objectives and be ready for future changes and challenges. It will serve as a living, breathing commitment to value and support our people and will provide a route map towards a thriving organisation, where we all work together.

'..cultures of engagement, positivity, caring, compassion and respect for all – staff, patients and the public - provide the ideal environment within which to care for the health of the nation. **When we care for staff, they can fulfil their calling of providing outstanding professional care** for patients.'

PROF MIKE WEST

OUR PEOPLE FRAMEWORK 2022-2025

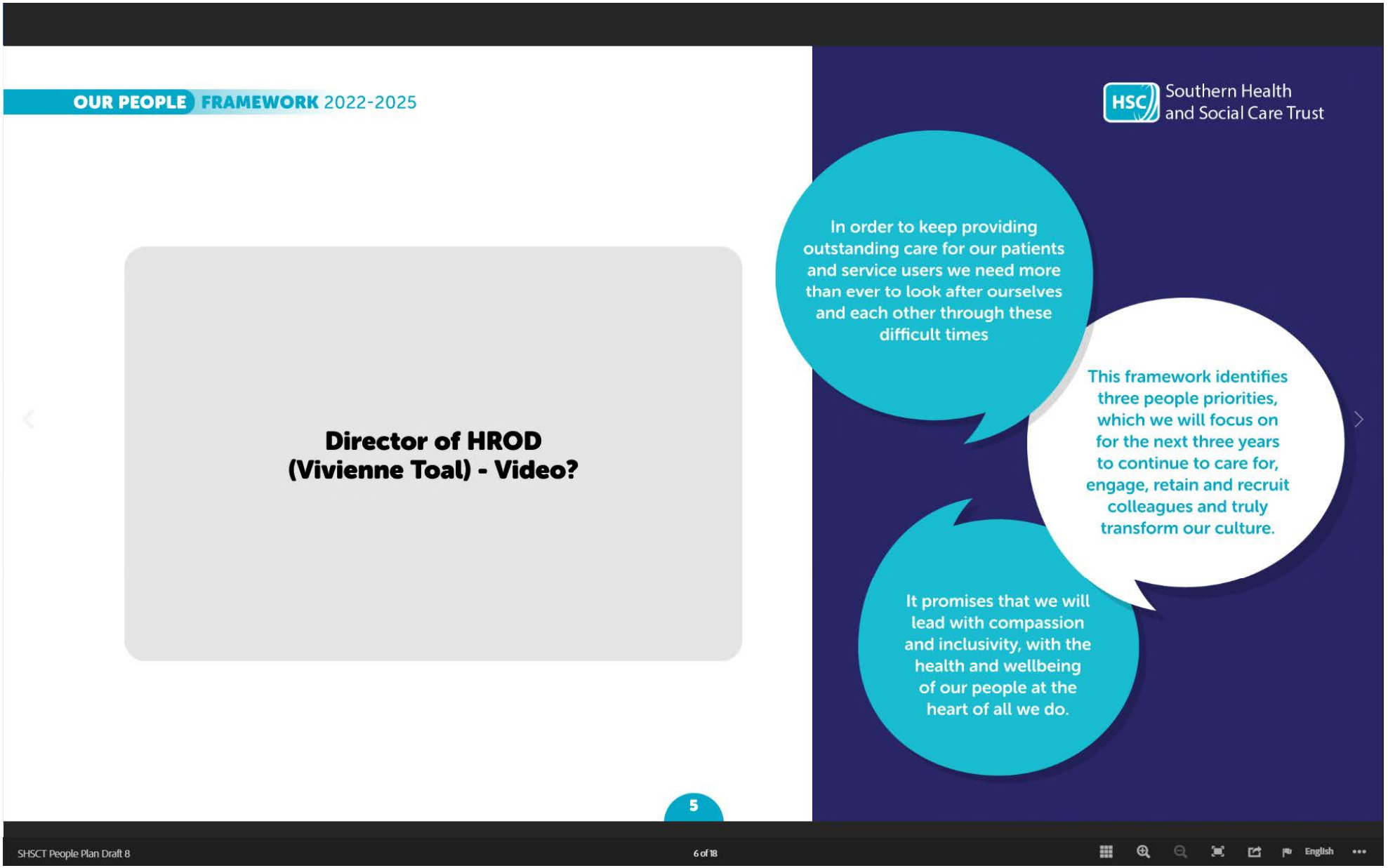
TRUST APPROACH

Southern Health and Social Care Trust

Our Corporate Plan sets out our key priorities for our staff and the population we are here to serve.

This is supported by 'Our People' – our key enabling framework for transforming the workplace through our staff.

Our approach to delivering our Corporate Plan is also enabled by a number of strategies which provide a focus on improvement in key areas such as safety, patient and service user experience, estates, finance, digital.



Our HSC Values

Developed by our people, our HSC values support how we deliver our purpose and our vision. Our HSC values of **compassion**, **openness and honesty**, **working together** and **excellence** and associated behaviours guide us all and define the way we work.

Our values are at the heart of our people priorities and guide our thinking and actions to help create a positive workplace culture.

Southern Health and Social Care Trust

Our People Promise

This is a commitment we all make to each other.

We must commit to **ensuring our values are at the core of everything we do and to behave in line with our values** in order to create a workplace where we enjoy coming to work, feel cared for, respected, and can give of our best in order to provide outstanding service and care.

We will work together to improve the experience of everyone working in our Trust.

OUR PEOPLE FRAMEWORK 2022-2025

Southern Health and Social Care Trust

WORKING TOGETHER

What does this mean?
We work together for the best outcome for people we care for and support. We work across Health and Social Care and with other external organisations and agencies, recognising that leadership is the responsibility of all.

What does this look like In practice? Behaviours
- I work with others and value everyone's contribution
- I treat people with respect and dignity
- I work as part of a team looking for opportunities to support and help people in both my own and other teams
- I actively engage people on Issues that affect them
- I look for feedback and examples of good practice, aiming to improve where possible

EXCELLENCE

What does this mean?
We commit to being the best we can be In our work, aiming to Improve and develop services to achieve positive changes. We deliver safe, high-quality, compassionate care and support.

What does this look like In practice? Behaviours
- I put the people I care for and support at the centre of all I do to make a difference
- I take responsibility for my decisions and actions
- I commit to best practice and sharing learning, while continually learning and developing
- I try to improve by asking 'could we do this better?'

COMPASSION

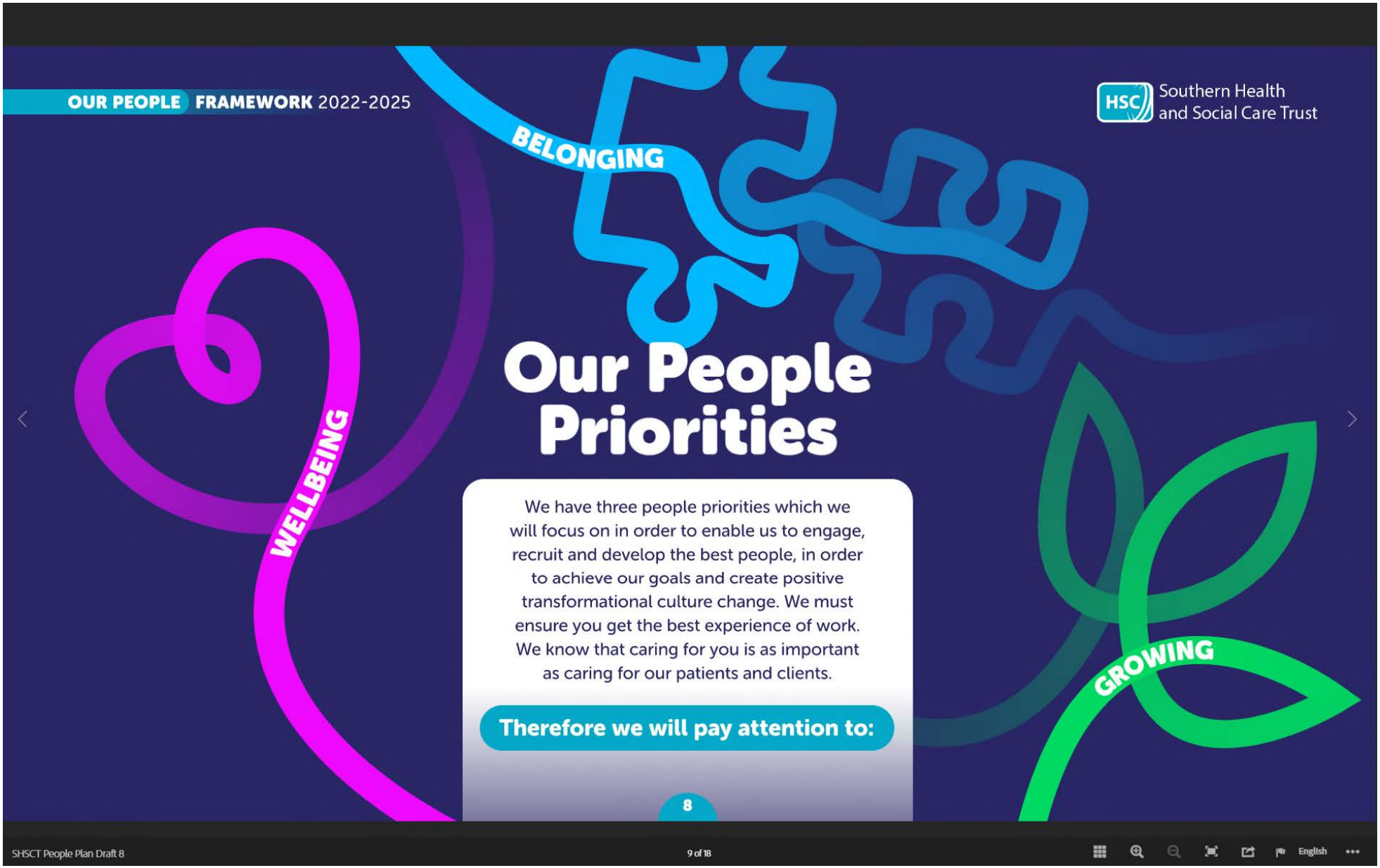
What does this mean?
We are sensitive, caring, respectful and understanding towards those we care for and support and our colleagues. We listen carefully to others to better understand and take action to help them and ourselves.

What does this look like In practice? Behaviours
- I am sensitive to the different needs and feelings of others and treat people with kindness
- I learn from others by listening carefully to them
- I look after my own health and well-being so that I can care for and support others

OPENNESS & HONESTY

What does this mean?
We are open and honest with each other and act with Integrity and candour.

What does this look like In practice? Behaviours
- I am open and honest In order to develop trusting relationships
- I ask someone for help when needed
- I speak up If I have concerns
- I challenge Inappropriate or unacceptable behaviour and practice



Southern Health and Social Care Trust

Look after the wellbeing of our people

This means:

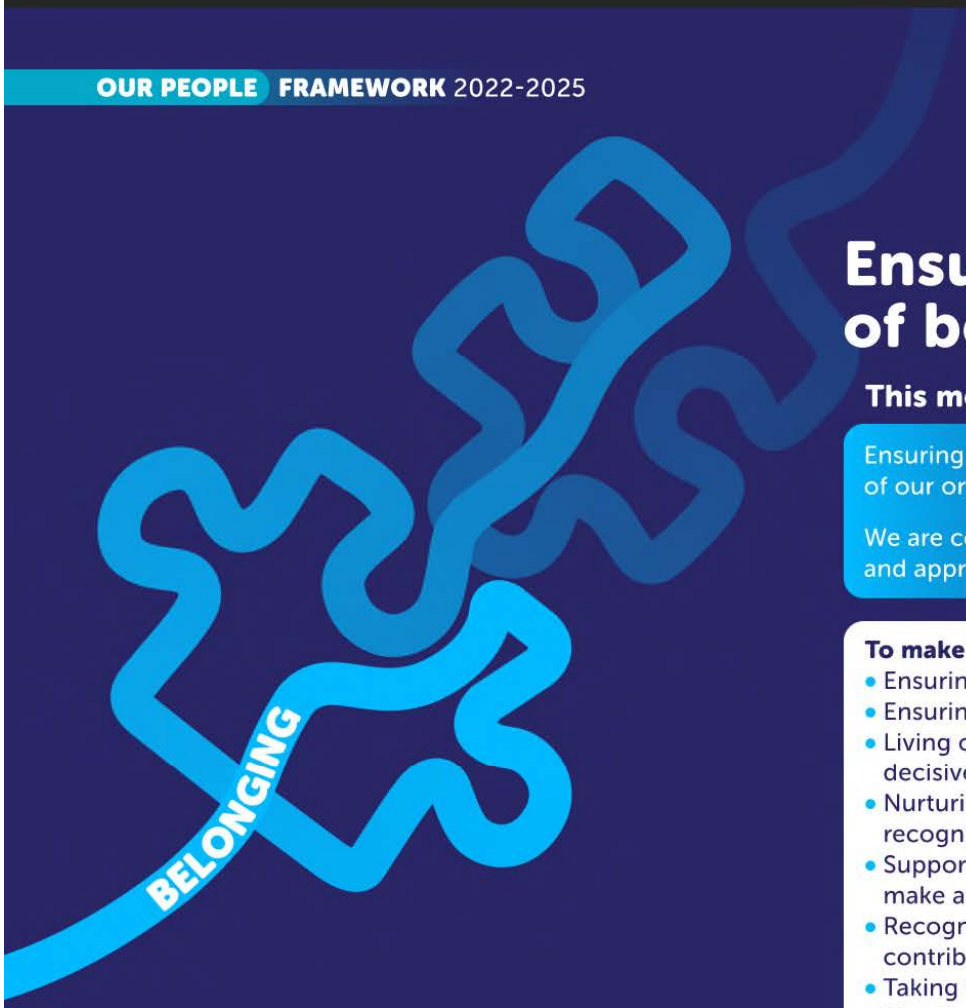
Investing in creating a safe and healthy working environment for us all and promoting a culture of wellbeing, recognising the changing nature of work.

Through our behaviours we show we care about colleagues and ourselves, listening to needs and concerns so that together we can take action to create a safe and supportive environment that becomes the best place to work for us all.

To make this happen we will focus on:

- Supporting our people to seek help and develop their skills in compassionate self-care and other personal coping mechanisms
- Supporting and developing the capacity and capability of our managers to ensure their approach has a positive impact on the experience and wellbeing of their staff and themselves
- Promoting and nurturing a culture of compassionate leadership and teamwork as a way of ensuring our people feel cared for and supported
- Taking all necessary measures and efforts required to keep our people safe and well
- Continuing to promote, protect, and improve the health and wellbeing of our people
- Ensuring a relentless focus on the safety, quality and experience of our staff, patients, and service users

Southern Health and Social Care Trust



Ensure people feel a sense of belonging in our Trust

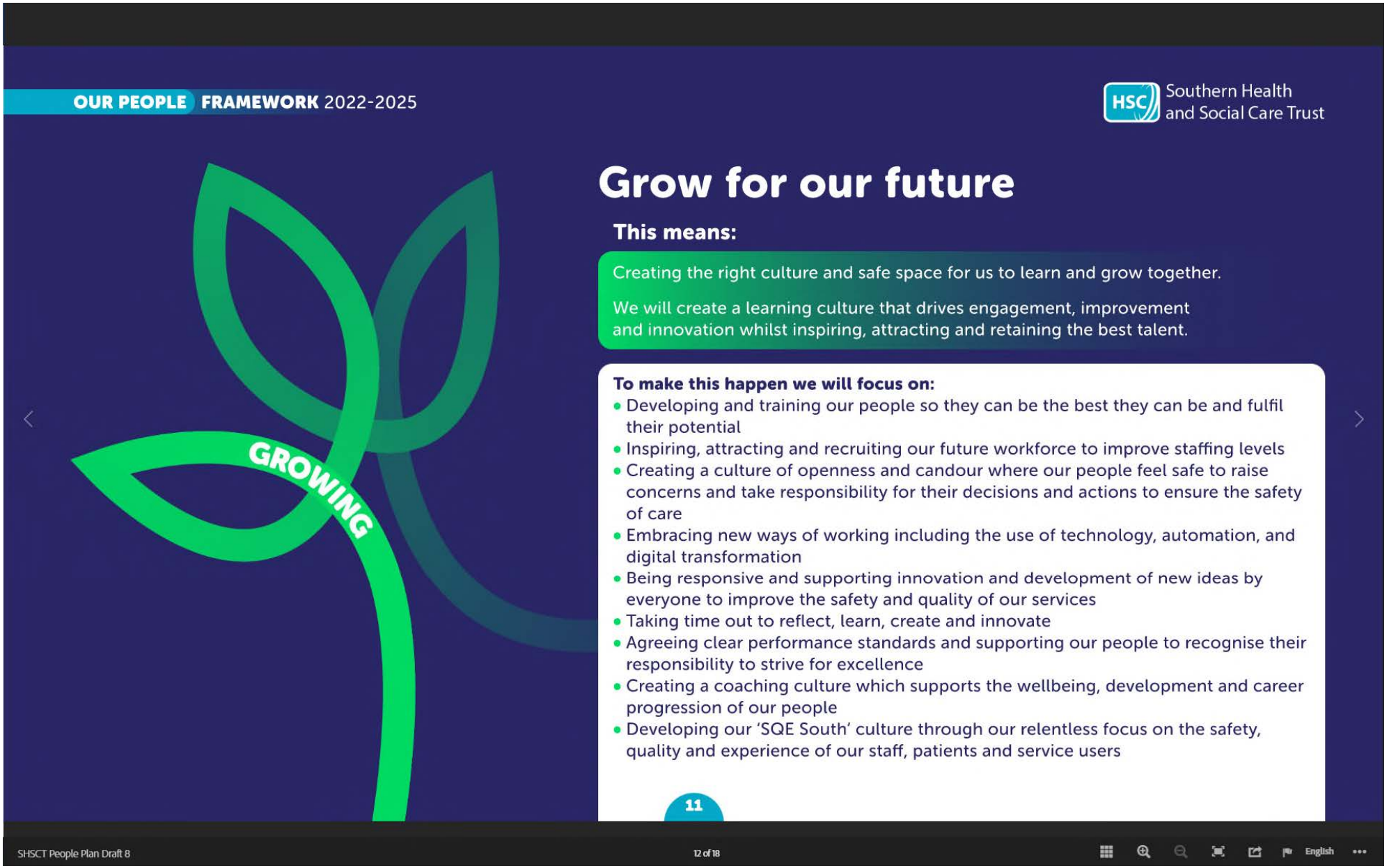
This means:

Ensuring we all feel a sense of belonging by being connected to the core purpose of our organisation, each of us feeling valued, cared for, respected and supported.

We are compassionate and inclusive, investing in our relationships with colleagues and appreciating the value of good team working.

To make this happen we will focus on:

- Ensuring everyone understands our vision and the future direction of our Trust
- Ensuring an inclusive and diverse workforce
- Living our values and demonstrating associated behaviours including dealing decisively and quickly with incivility and behaviours not in line with our values
- Nurturing a culture of collective leadership where everyone in the organisation recognises their role as a leader
- Supporting development of teams where everyone can get involved, contribute and make a difference
- Recognising and appreciating our people for the work that they do and the contribution they make
- Taking time for sharing, laughter and chat
- Creating networks and communities that develop strong trusting relationships



OUR PEOPLE FRAMEWORK 2022-2025

Southern Health and Social Care Trust

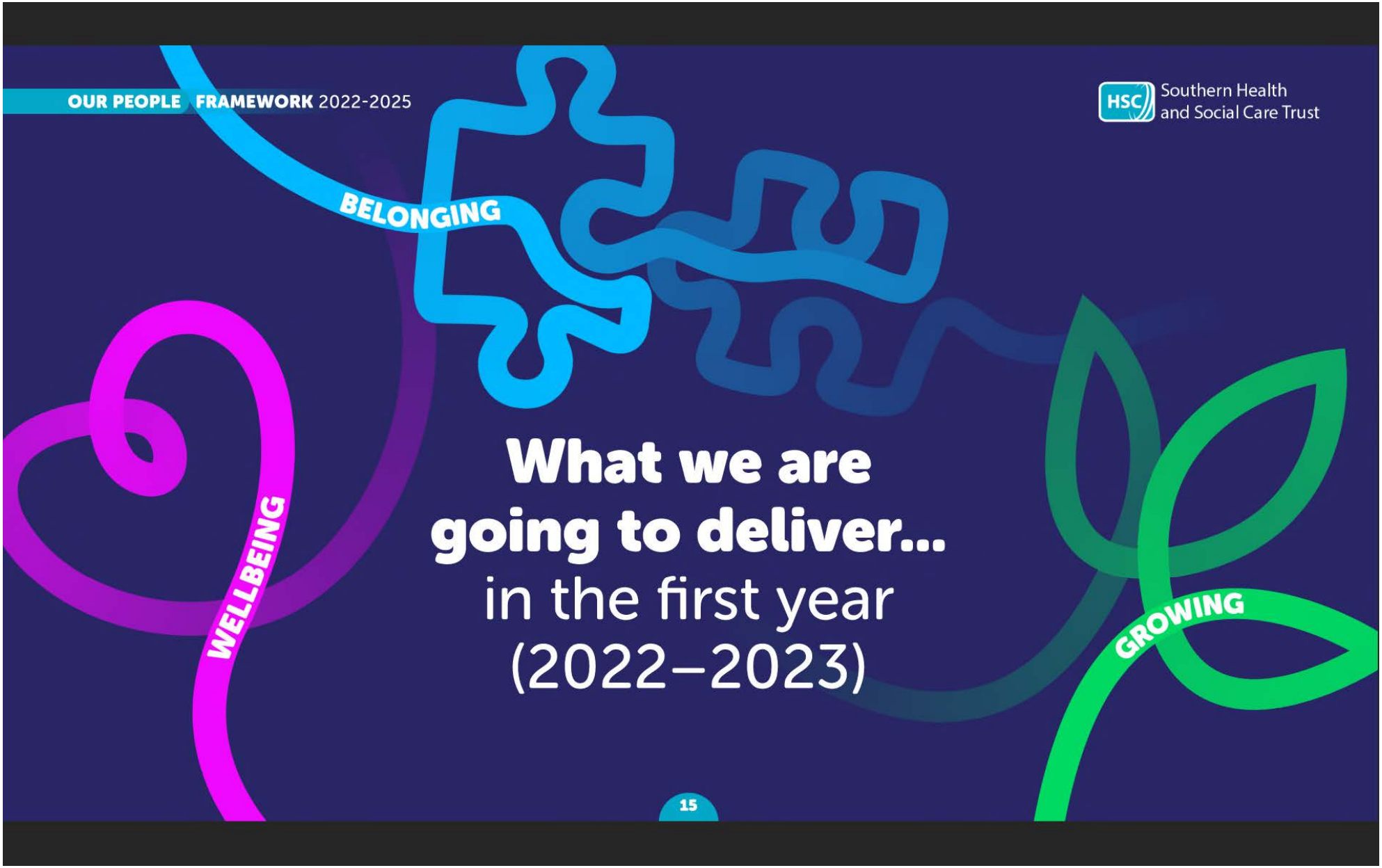
GOVERNANCE AND ACCOUNTABILITY

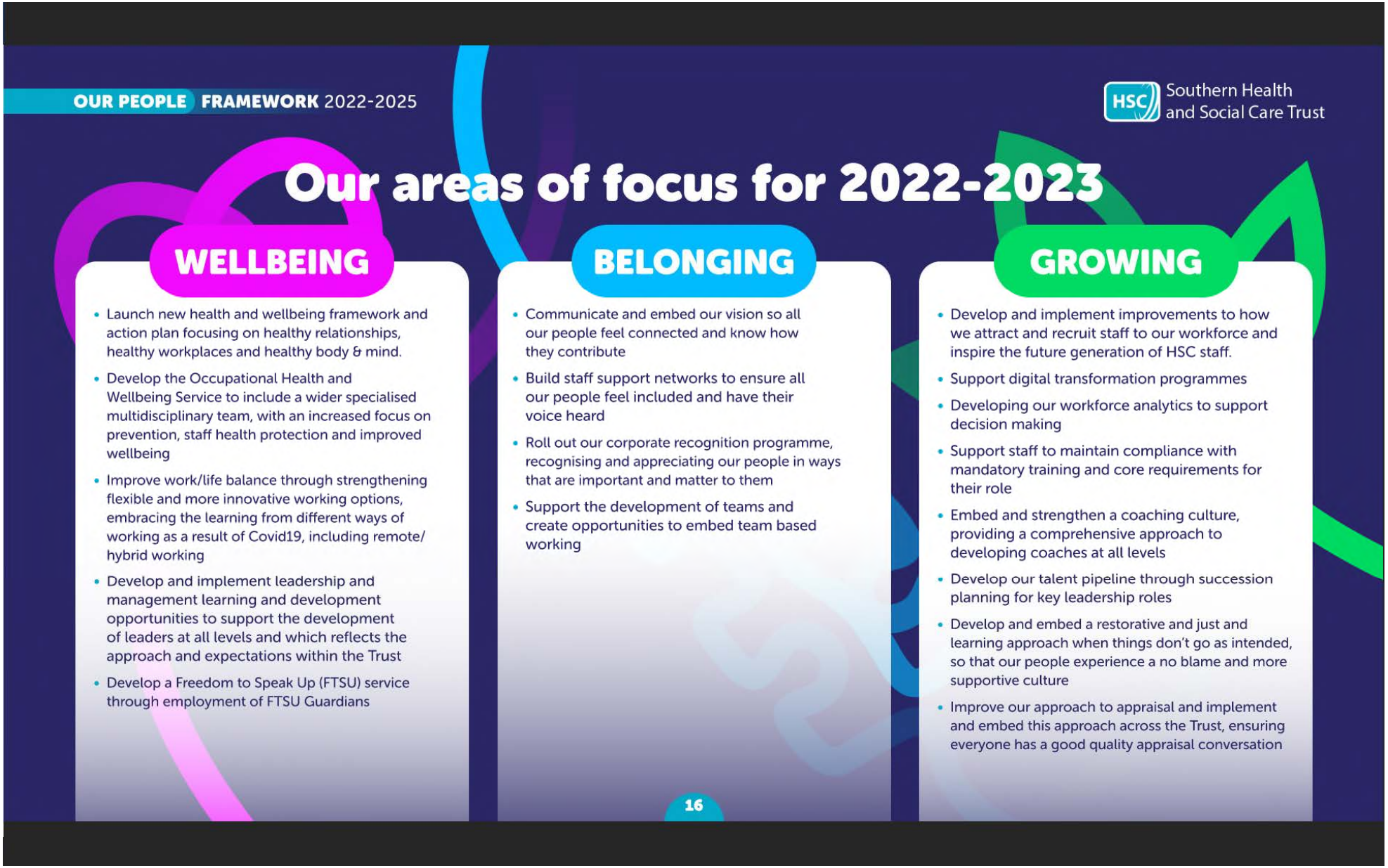
This framework affects each of us and therefore **we all have a part to play** in bringing about the change we want to see in transforming the culture in our Trust.

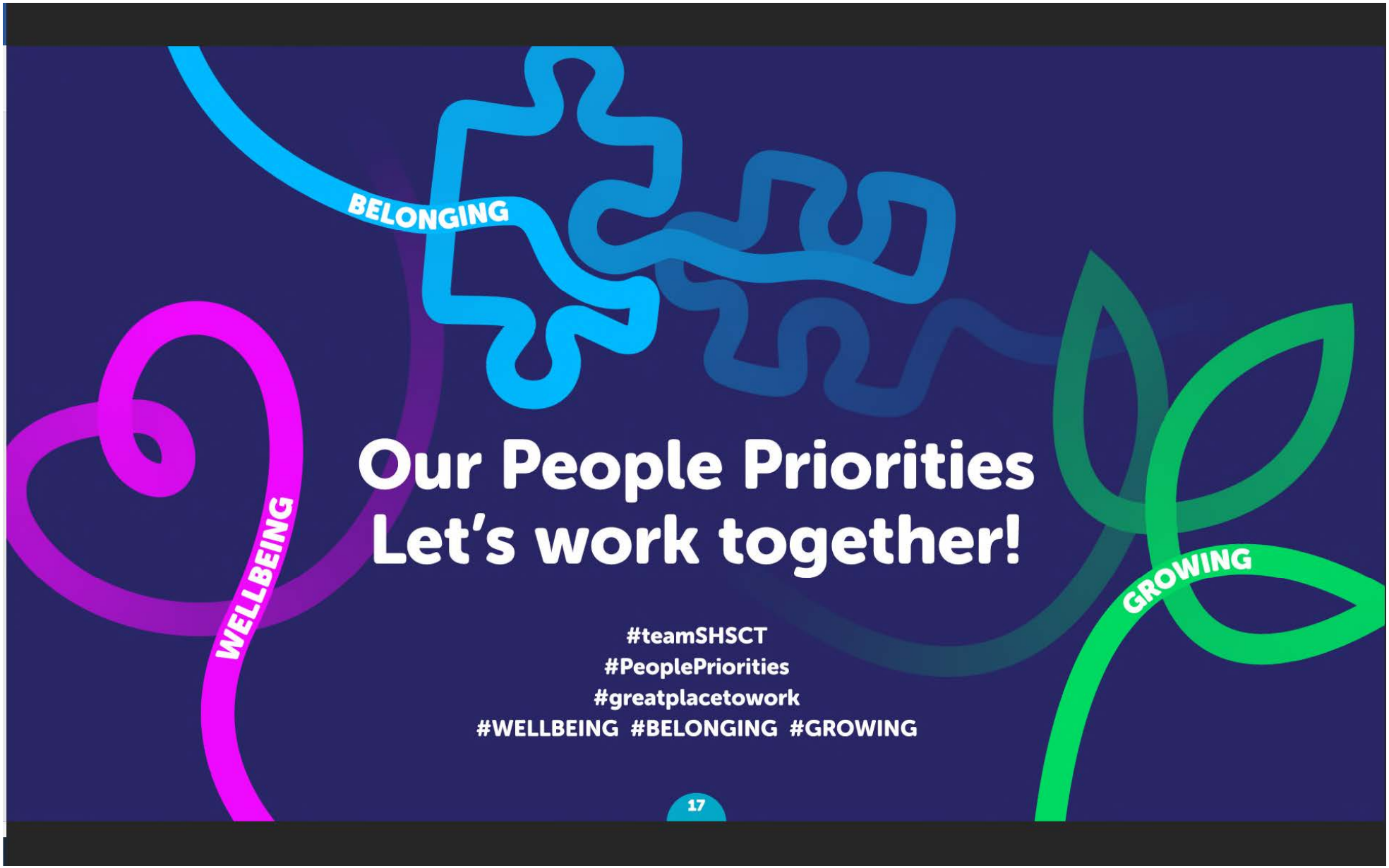
As well as having a corporate response to our people priorities we recognise the way they will be translated at service and team level will be different for each Directorate. It is important our people priorities are brought to life at individual, team, Directorate and Trust level.

The framework sets out our people priorities for the next three years, with an initial year one plan. Delivery and oversight of the operational plan will take place through the People and Culture steering group who will report SMT and subsequently to Trust Board. Year 1 will provide a baseline against which to measure progress and success.

We will annually refresh our action plan and measures to ensure they remain fit for purpose and produce a bi-annual report on progress and outcomes in relation to our people priorities. The Director of HR and Organisational Development will be responsible for reporting on progress.







The Regulation and Quality Improvement Authority

RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland

June 2022

The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is the independent body responsible for regulating and inspecting 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. RQIA reports are submitted to the Department of Health (DoH) and are available on the RQIA website at www.rqia.org.uk.

Acknowledgements

RQIA wishes to thank all those who facilitated this review by participating in discussions, meetings, surveys and by providing relevant information.

Membership of the Expert Review Team

Maria Dineen	Managing Director of Consequence UK, Consultant to the National Patient Safety Agency 2001-2003, approved investigator - NHS England's serious incident framework and author of Six Steps to Root Cause Analysis.
Dr David Evans	Former Medical Director and Interim Chief Executive Northumbria Healthcare National Health Service Foundation Trust, England.
Dr Lourda Geoghegan	Former Director of Improvement and Medical Director, Regulation and Quality Improvement Authority (role in review ceased March 2020)
Emer Hopkins	Director of Hospital Services, Independent Healthcare, Audit and Reviews, RQIA (role in review commenced March 2020)
Mr Hall Graham	Professional Advisor, Regulation and Quality Improvement Authority.
Mrs Vivien Jess	Lay Representative and Independent Expert Advisor to the review
Mr Brian O'Hagan	Lay Representative and Independent Expert Advisor to the review
Dr Richard Wright	Former Medical Director of Southern Health and Social Care Trust and Professional Medical Advisor, Regulation and Quality Improvement Authority.

Table of Contents

Glossary of Terms

Belfast Trust	Belfast Health and Social Care Trust
CAMHS	Children and Adolescent Mental Health Services
CQC	Care Quality Commission
DoH	Department of Health
DRO	Designated Review Officer
HSC	Health and Social Care
HSCB	Health and Social Care Board
IHRD	Inquiry into Hyponatraemia-related Deaths
Multidisciplinary	Involving professionals from different disciplines who have different professional skills, expertise and experience.
NIAS	Northern Ireland Ambulance Service
Northern Trust	Northern Health and Social Care Trust
PCC	Patient Client Council
PHA	Public Health Agency
PPI	Personal and Public Involvement
RCA	Root Cause Analysis
RQIA	Regulation and Quality Improvement Authority
SAI	Serious Adverse Incident
South Eastern Trust	South Eastern Health and Social Care Trust
Southern Trust	Southern Health and Social Care Trust
SPPG	Strategic Performance and Planning Group (formerly Health and Social Care Board)
Western Trust	Western Health and Social Care Trust

Foreword

This Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland resulted from the independent Public Inquiry led by Justice O'Hara which investigated the deaths of five children in hospitals in Northern Ireland. After hearing evidence from a wide range of individuals and organisations, it concluded that deaths had been avoidable and that the culture of the health service at the time, arrangements in place to ensure the quality of services and behaviour of individuals had contributed to those unnecessary deaths.

A key finding of the Public Inquiry was that the internal investigations into the deaths and their surrounding circumstances were inadequate. They had failed to identify the underlying causes. It also found that, as guidance on fluid management on children became available, it was not disseminated and actioned effectively across the Health and Social Care (HSC) system.

The reality is that similar situations, where events leading to harm have been inadequately investigated and examples of recognised good practice have not been followed, have been, and are likely to be repeated in current practice.

Such inadequacies bring distress and suffering to the individuals affected and their loved ones; and the staff whose efforts to provide good and safe care are undermined.

Serious Adverse Incident (SAI) reviews are a fundamental part of how the whole system should learn from harm, and make improvements to Health and Social Care services in Northern Ireland.

This Review, commissioned by the Department of Health (DoH), in its response to the recommendations of the Inquiry, and undertaken by the RQIA, has assessed the effectiveness of the current SAI process.

It has been one of our most significant Reviews, which has benefited from engagement with a wide range of individuals, organisations and groups across the Health and Social Care system.

We would especially like to thank all families who contributed to the Review, as their experience of the reality from a patient and family perspective has been a key feature in shaping the Review's findings.

The Expert Review Team found that neither the SAI review process nor its implementation is sufficiently robust to consistently enable an understanding of what factors, both systems and people, have led to a patient or service user coming to harm.

HSC leaders and managers must work to make sure that if something goes wrong, all staff are confident to speak up, through a competent and independent review process, knowing that doing so will help them keep their patients and service users safe and improve the quality of care they are able to deliver.

Patients and service users, and their loved ones and advocates, must be able to take part freely and fully in the process, so they find out what happened and can help make sure it won't happen again.

On behalf of RQIA, we hope that the recommendations in this Review, which have been produced with the assistance of a wide range of patients, service users, families, clinicians and managers from across HSC, will be accepted, implemented fully, and drive improvement in safety and quality throughout the system.

Christine Collins MBE
Chair

Briege Donaghy
Chief Executive

Executive Summary

Background and Context

Serious Adverse Incident (SAI) reviews are a fundamental component of how we learn from harm and subsequently make improvements to the systems for the delivery of safe patient care. Regional guidance for the reporting and follow-up of SAIs in Northern Ireland has been in place since 2004. However, over the last decade, the SAI process and its implementation has come under scrutiny both regionally and nationally. Concerns have been raised around the current procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAIs) in Northern Ireland (November 2016)[1] (here-after the SAI procedure). It has also been highlighted that there is a clear need for improvement in terms of how patients, their families and staff are engaged in reviews and how subsequent learning is derived and implemented. These issues are not unique to Northern Ireland or indeed the United Kingdom. Ensuring the effective implementation of SAI reviews and subsequent learning is a considerable undertaking. Not only does the procedure itself need to be robust, but its effective application necessitates an open and supportive learning culture with SAI reviewers who are trained in the necessary skill set to undertake effective SAI reviews.

In April 2018, the Regulation and Quality Improvement Authority (RQIA) was commissioned by the Department of Health (DoH) to examine the application and effectiveness of the SAI procedure. Terms of Reference for this review were approved by the Department of Health in October 2019 and fieldwork on this review concluded in January 2021. The time taken to complete and publish this review has been significantly impacted by the system response to Covid-19 Pandemic.

Terms of Reference

The terms of reference for this review, as agreed with the DoH, were as follows:

1) To review the systems/ processes in place for reporting and follow-up of Serious Adverse Incidents (SAIs) across the six Health and Social Care (HSC) Trusts, the HSCB and Public Health Agency in Northern Ireland, between 30 November 2016 and 31 March 2018.

2) To engage with families affected by SAIs reported between 30 November 2016 and 31 March 2018, to determine their level of involvement in the Serious Adverse Incident process.

3) To assess the process for the classification of the severity of SAIs and to determine whether incidents are appropriately classified through this process.

4) To assess the level of independence of the SAI reviews progressed and assess whether a multi-disciplinary systems-wide approach to reviews has been undertaken.

5) To assess the development and effectiveness of action plans and recommendations arising from SAIs reviews.

6) To assess whether appropriate learning has been identified from the SAIs and disseminated regionally, and whether the learning can deliver measurable and sustainable improvements in the quality and safety of care.

7) To determine current understanding of the role of respective organisations, including the Coroner, in the process for SAI reviews, and how this understanding compares to the published roles and responsibilities as outlined in the procedure for the Reporting and Follow up of Serious Adverse Incidents.

8) To assess the level of professional support provided to (i) staff who were delivering care at the time of the SAIs, as well as (ii) staff conducting the review of the SAIs.

9) To provide a report of the findings to the Department of Health, making recommendations for improvement as relevant to the overall response to SAIs, their assessment and review, and the learning arising through these processes.

Methodology

The Expert Review Team developed a methodology specific to this review incorporating extensive engagement with a range of key individuals and organisations and patients their relatives and representative groups. Focus Groups and individual interviews were undertaken. The engagement was supported by the development of a number of semi-structured questionnaires. An important aspect of this review was the undertaking of a rigorous assessment of 66 serious adverse incident reports from all HSC Trusts in Northern Ireland.

Findings

The Expert Review Team determined that the current SAI procedure and its implementation in Northern Ireland **does not** support:

- Fulfilment of the statutory duty of Personal Public Involvement as set out in the Health and Social Care (Reform) Act (Northern Ireland) 2009.
- Reasonable application of the principles of effective SAI review practice.
- Confidence in the independence of chairs of SAI reviews at Level 2, or Level 3. Particularly in the case of Level 3 reviews, where the appointed chair is a former employee of an HSC Trust.
- Accountability of Health and Social Care organisations for:
    - decisions made regarding the level of review conducted
    - involvement and engagement with a patient and/or relatives
    - the quality of the review conducted and the acceptance of its findings and approval processes
    - evidencing that HSC Trust services have improved and are safer because of the reviews conducted
    - ensuring that issues requiring regional action to improve safety are appropriately identified and then escalated to the right people in the right organisations

- The formulation of evidence-based recommendations.
- The design of action plans that will enhance the safety and quality of healthcare provision across the region both in the short and longer term.
- The production of SAI review reports that are well-formulated, evidence-based and readable.

The Expert Review Team identified a number of reasons for this:

- The implementation of the SAI procedure focuses too heavily on process and non-attainable timescales instead of focusing on consistently conducting these reviews to a high standard.
- There was an absence of clear regional guidance on how to execute Personal Public Involvement duties and in relation to patient rights as part of an SAI review.
- There was no regional patient safety training strategy and curriculum.
- There were not clearly defined competencies required of lead investigating officers and SAI review panel chairs.
- There were not sufficient numbers of trained independent advocates for families and patients.
- There was a lack of effective training in how to execute an effective and meaningful SAI review.
- Furthermore, even where training had been delivered, the appointed chair or review leads, they did not always have sufficient authority to independently devise a review plan that fully delivers the required quality of review.
- There were also a large number of reviews identified as requiring an in-depth review but which did not require this, which was creating an unsustainable work pressure within the system.

The conclusion of the Expert Review Team is that current practice for reviewing and learning from SAIs in Northern Ireland is not achieving the intended purpose of the SAI procedure. Improving this situation will require both the SAI procedure and the system in which it operates to be re-designed.

Summary of Recommendations

The following recommendations are made to support the delivery of a new regional policy/procedure for reporting, investigating and learning from adverse events.

Number	Recommendation	Priority
1	The Department of Health should work collaboratively with patient and carer representatives, senior representatives of Trusts, the Strategic Performance and Planning Group, Public Health Agency and Regulation and Quality Improvement Authority to co-design a new regional procedure based on the concept of critical success factors. Central to this must be a focus on the involvement of patients and families in the review process.	**2**

2	Health and Social Care organisations should be required to evidence they are achieving these critical success factors to the Department of Health.	**3**
3	The Department of Health should implement an evidence-based approach for determining which adverse events require a structured, in-depth review. This should clearly outline that the level of SAI review is determined by significance of the incident and the level of potential deficit in care.	**3**
4	The Department of Health should ensure the new Regional procedure and its system of implementation is underpinned by 'just culture' principles and a clear evidence-based framework that delivers measurable and sustainable improvements.	**3**
5	The Department of Health should develop and implement a regional training curriculum and certification process for those participating in and leading SAI reviews.	**3**

Key Benefits

The Expert Review Team concluded that, should these recommendations be fully implemented and embraced by the Health and Social Care system in Northern Ireland, they would deliver the following key benefits:

- A clear regional framework which provides for learning from unexpected harm.
- Greater flexibility in the SAI review process, which is aligned to international best practice and allows a better opportunity for learning and safety improvement.
- A single, new report template and regional style guide that supports consistency across the region but is flexible enough to allow reviewers to add and remove sections as required.
- A lower number of in-depth Root Cause Analysis (RCA) reviews, where early case assessment shows that this level of review is not required or proportionate.
- Increased capacity within HSC to deliver structured, in-depth reviews, where early assessment indicates this is necessary.
- An appropriate amount of time to conduct a review well and involve patients and families in a way that is meaningful.
- A review process that does not cause further harm to patients, their families or staff.
- A culture of safety, openness and compassion.

1.0 Background and Context

1.1 Introduction

Health and Social Care services are used extensively across Northern Ireland daily, and most patients and their families are satisfied with their care. However, it is inevitable that some will not have a satisfactory experience while others may even experience harm. When harm occurs, there is a moral, ethical and professional duty on those involved in the delivery of care to review what happened.

When such an incident is identified, the process of reviewing an event in an effort to learn is known as an Adverse Incident (AI) review, and some will warrant a Serious Adverse Incident (SAI) review. The SAI review aims to:

- Determine if any element of the care delivery or treatment plan contributed to the harm and any underlying systemic reasons for this.
- Ensure that the necessary improvements are made to the standard of care delivered and to the underlying systems and processes that support patient safety.
- Facilitate the recovery of the patient and their family from the harming experience, so that reconciliation can occur, including continuing trust in the Health and Social Care services.

Fundamental to achieving these aims is a clear, regionally agreed approach to identifying, reporting, reviewing and learning from incidents of harm, including serious near-miss events or apparent near-miss events. Furthermore, this approach must be clearly articulated within policies and procedures.

Throughout this report, the term 'patient and family' is used to represent those that would fall under the category of patient, service user, carer, family, or family member. The Expert Review Team recognises that users of mental health and learning disability services are normally referred to as service users rather than patients.

1.2 Context

Regional guidance for the reporting and follow-up of SAIs has been in place in Northern Ireland since 2004. Over the last decade, the SAI process has come under scrutiny both regionally and nationally. Following the Public Inquiry into Mid-Staffordshire NHS Foundation Trust in 2014[2] the Chief Medical Officer in Northern Ireland wrote to HSC Trusts to remind them of their statutory duty in relation to the review and reporting of SAIs. This correspondence outlined a need for candour alongside meaningful engagement with patients and their families when incidents of harm have occurred.

The Donaldson Report in 2014[3] highlighted concerns around the reporting of adverse incidents, ineffective processes for review, lack of expertise amongst reviewers (particularly in relation to human factors) and a failure for learning to translate into improvements in systems and patient safety. Donaldson also outlined

a need for a 'just culture' for healthcare staff participating in SAI reviews, in addition to a need for candour and openness with patients and families.

In 2018, Justice O'Hara published his long-awaited inquiry report; Hyponatraemia-related Deaths (IHRD) in Northern Ireland[4]. It called for a statutory duty of candour and made a number of recommendations in relation to reporting, investigating and sharing of learning from SAIs, including a need to increase the involvement of families in these processes. This served to further highlight a need for a review of the regional procedure for SAI reviews in Northern Ireland.

In April 2018, the RQIA was commissioned by the Department of Health (DoH) to examine the effectiveness of the current procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAIs) (November 2016) and its implementation within Health and Social Care services and make recommendations for improvement. A final Terms of Reference for this work was agreed with the DoH in October 2019 and fieldwork on this review concluded in January 2021.

The review was conducted in phases, with interim reports submitted to DoH upon completion of each phase. This document is the culmination of this work and is an overall assessment of the effectiveness of the SAI procedure and its implementation across Health and Social Care in Northern Ireland

1.3 Overview of Regional SAI Procedure

The system for reporting adverse incidents was first introduced in Northern Ireland in 2004 by the former Department of Health, Social Services and Public Safety (DHSSPS), now known as the DoH. Reporting arrangements were transferred to the Health and Social Care Board (HSCB), now the Strategic Planning Performance Group (SPPG) within the DoH, in partnership with the Public Health Agency (PHA), in 2010. Updates to this procedure were implemented in 2010, 2013 and 2016.

The current version of the regional SAI procedure which was last updated in 2016, advises that SAI reviews should be conducted at a level appropriate and proportionate to the complexity of the incident under review.

Incidents which meet the following criteria may be classified as an SAI.

- 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 Children and Adolescent Mental Health Services (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.

Three levels of review are described in the regional procedure. The expectation in respect of each level is summarised below:

Level 1 Review: Significant Event Audit (SEA)

For Level 1 reviews, membership of the SEA review team should include all relevant professionals, yet be appropriate and proportionate to the type of incident and professional groups involved.

The review panel undertakes an SEA of the incident to assess what happened; why it happened; what went wrong and what went well; what has changed or what needs to change; and identify any local or regional learning.

Level 2 Review: Root Cause Analysis (RCA)

For Level 2 reviews, the level of review undertaken will determine the degree of leadership, overview and strategic review required. A core review panel should be comprised of a minimum of three people of appropriate seniority and objectivity. Review panels should be multidisciplinary and have no conflict of interest with the incident concerned. The review should have a chairperson who is independent of the service area involved, while possessing relevant experience of the service area in general and of chairing reviews.

The chairperson should also not have been directly involved in the care or treatment of the individual or be responsible for the service area under review.

The review panel undertakes a RCA to a high level of detail, using appropriate analytical tools to assess what happened; why it happened; what went wrong and what went well; what has changed or what needs to change; and identify any local and regional learning.

Level 3 Review: Independent Review

For Level 3 reviews, the same principles as Level 2 reviews apply; however, team membership must be agreed upon between the reporting organisation and the HSCB/ PHA (PHA) Designated Review Officer (DRO) prior to the review commencing.

The 2016 procedure states that: "The review panel undertakes an in-depth review of the incident, to a high level of detail, using appropriate analytical tools to assess: what happened; why it happened; what went wrong and what went well; what has changed or what needs to change; and identify any local and regional learning."

In 2016, the Regional SAI procedure was updated to guide SAI review panels in relation to providing patients and families with an opportunity to contribute to the SAI review.

The guidance outlined that:

- The level of involvement depended on the nature of the SAI and the patient and family's willingness to be involved.
- Teams involved in the review of SAIs should ensure sensitivity to the needs of the patient and family/carer involved.
- Teams should agree on appropriate communication arrangements with the patient and family/carer involved.

To support the involvement process, an SAI leaflet[5] was designed by the HSCB and PHA for organisations to give to patients and families prior to their initial discussion regarding the SAI which had occurred.

1.4 Patient and Family Involvement and Engagement

Health and Social Care services across Northern Ireland have a legal duty to involve service users and their carers. Personal and Public Involvement (PPI) is a legislative requirement for Health and Social Care organisations as set out in the Health and Social Services (Reform) Northern Ireland Act 2009[6].

The Act states that service users and carers must be involved in and consulted on:

- The planning of the provision of care.
- The development and consideration of proposals for changes in the way that care is provided.

- Decisions to be made by the body that has the responsibility for the provision of that care.
- The efficacy of that care.

PPI is the active and meaningful involvement of service users and carers in the planning, commissioning, delivery and evaluation of Health and Social Care (HSC) services, in ways that are relevant to them. It is the process of empowering and enabling those who use services and their carers to make their voices heard, ensuring that their knowledge, expertise and views are listened to.

Given this statutory duty, service user and family involvement were considered a pivotal aspect of this review. Throughout the review, the effectiveness and extent of patient and family engagement have been examined from the perspective of patients and families, frontline staff and managers.

2.0 Terms of Reference

The terms of reference for this review, as agreed with the Department of Health, were as follows:

1) To review the systems/ processes in place for reporting and follow-up of Serious Adverse Incidents (SAIs) across the six HSC Trusts, the HSCB and Public Health Agency in Northern Ireland, between 30 November 2016 and 31 March 2018.

2) To engage with families affected by SAIs reported between 30 November 2016 and 31 March 2018, to determine their level of involvement in the Serious Adverse Incident process.

3) To assess the process for the classification of the severity of SAIs and to determine whether incidents are appropriately classified through this process.

4) To assess the level of independence of the SAI reviews progressed and assess whether a multi-disciplinary systems-wide approach to reviews has been undertaken.

5) To assess the development and effectiveness of action plans and recommendations arising from SAIs reviews.

6) To assess whether appropriate learning has been identified from the SAIs and disseminated regionally, and whether the learning can deliver measurable and sustainable improvements in the quality and safety of care.

7) To determine current understanding of the role of respective organisations, including the Coroner, in the process for SAI reviews, and how this understanding compares to the published roles and responsibilities as outlined in the procedure for the Reporting and Follow up of Serious Adverse Incidents.

8) To assess the level of professional support provided to (i) staff who were delivering care at the time of the SAIs, as well as (ii) staff conducting the review of the SAIs.

9) To provide a report of the findings to the Department of Health, making recommendations for improvement as relevant to the overall response to SAIs, their assessment and review, and the learning arising through these processes.

3.0 Review Methodology

The review used a range of methodologies to ensure each term of reference was addressed. Each methodology aimed to optimise the quality of information sought by the expert panel to ensure a robust evidence-base for their recommendations.

The methods included:

1) The assessment of SAI review reports, by the Expert Review Team. The criteria for assessment as agreed with the Department of Health.

2) The design of a structured assessment questionnaire which was applied by the Expert Review Team to all SAI review reports submitted by the participating HSC Trusts.

3) Questionnaires issued to a range of Trust staff, from senior management to frontline practitioners, and SAI panel chairs, seeking their views of their involvement in the SAI review process.

4) Engagement of patients and families who had experienced healthcare-induced harm and the offer of face-to-face conversations to learn about their experiences and hear their views as to how these experiences could have been improved.

5) Focus groups involving staff involved in an SAI, as well as staff involved in the SAI review process.

6) Meetings with individuals and groups of staff in HSC organisations involved in SAI reviews.

7) Engagement with other relevant organisations.

It was intended that the effectiveness of implementation of SAI recommendations would be examined in specific detail by the Expert Review Team to explore further the arrangements within services to deliver on sustained and measurable improvements to patient safety. However due to the COVID-19 pandemic, this aspect of the methodology was unable to be performed in full, but was explored though other aspects of the methodology.
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3.1 The Identification and Selection of SAIs

For the aspect of this review SAIs selected had been conducted between 30 November 2016 and 31 March 2018 and fell within the following categories:

- Deaths of women and babies related to pregnancy and childbirth: maternal deaths, stillbirths and neonatal deaths. Serious illness of women and babies where this has been related to pregnancy and childbirth.
- Sepsis
- Choking on Food
- Never Events[1]
- Cases where private hospitals or private nursing homes feature in the care pathway.
- People with a learning disability who have died from a treatable physical condition.
- People with a learning disability in residential care.
- Primary Care
- Any other categories RQIA considered appropriate for inclusion the review.

The information relating to these SAIs was obtained from the HSCB. After validation, 54 SAIs were identified for inclusion. A total of 12 additional SAIs were subsequently selected, comprised of Level 2 and Level 3 reviews, resulting in a total of 66 SAIs being selected for expert review (Appendix A).

3.2 The Structured Assessment of SAI Reports

A structured assessment tool was developed and applied to each SAI report reviewed. The assessment captured the perspectives of members of the Expert Review Team who were:

- Experienced investigators.
- Clinicians.
- Lay and family representatives.

Two distinct types of structured assessment tools were developed, one for use by the lay members of the Expert Review Team and one for the technical assessment of the SAI reports by other Expert Review Team members. This approach ensured consistent and objective assessment of each SAI report.

Due to the differences in templates used and levels of review required, for Level 1 and Level 2 SAI reviews set out in the regional procedure, the core assessment tool, which applies to Level 2 SAIs, was modified to meet the requirements of a Level 1 SAI report.

[1] Never Events are serious, wholly preventable safety incidents that should not occur if the available preventative measures are implemented. They include things like wrong site surgery or foreign objects left in a person's body after an operation. The full scope of Never Events is detailed in the Care Quality Commission report, Learning from Never Events (July 2018).

To ensure a robust approach, members of the Expert Review Team with either a clinical qualification or extensive prior experience in the conduct of SAI review were grouped in pairs. This resulted in each pair reviewing a total of 33 SAI reports.

The lay members of the Expert Review Team reviewed all 66 SAI reports individually before comparing their assessments and discussing any differences of opinion. This resulted in three subgroups with two members of the Expert Review Team in each, assessing the SAI review reports.

Table 1 below shows the breakdown of trusts and reports allocated to each technical team.

Table 1: Breakdown of trusts and reports allocated to each technical team

Team	Organisation	Number of SAI reports for review
Team 1	Northern Trust	10
	South Eastern Trust	13
	Western Trust	10
Team 2	Belfast Trust	11
	Southern Trust	14
	NIAS	4
	Integrated Care Team, HSCB	4
TOTAL		**66**

Source: RQIA Structure Assessment Exercise

3.2.1 Quality Assurance of the Structured Assessments

The structured assessment tool developed by the Expert Review Team considered the extent to which the SAI report described:

- The incident under review and why it was being reviewed.
- The level of independence of the review panel members and the competencies and skills they had to conduct the review.
- The degree of patient and family engagement with the review process.
- The nature of the recommendations made and their relevance to improving patient safety.
- The robustness of the action plans constructed to deliver the recommendations and whether they would deliver a measurable and sustained improvement in quality and safety.

3.2.2 Technical Assessment

To ensure reliable and accurate assessments of the SAI reports, two quality assurance exercises were undertaken.

Firstly, for each of the three technical teams referenced above, an intra-team reliability exercise was undertaken. This required the assessors to submit a sample of four assessments to each other for a repeat assessment to ascertain the similarity or differences in assessment outcome. This process demonstrated a high level of consistency between the assessments. Where there were significant differences in the assessments, these were presented and discussed at a round table conversation between the technical assessors to reach consensus. A lay member of the Expert Review Team was included in this process.

The second quality assurance exercise was undertaken upon completion of the assessment of all SAI reports.

This involved a sample of four completed assessments being selected from each technical assessment team and reassessed by the other team. Following this, the technical assessment teams met to compare findings. There were few discrepancies between the teams which confirmed a high level of consistency. Any discrepancies were discussed, and a consensus position was reached.

3.2.3 Lay Assessment

The lay members of the Expert Review Team assessed all 66 SAI reports adopting the perspective of a family member who might receive these reports. To achieve a comparable process of quality assurance, each lay member assessed all 66 reports and subsequently met with their lay counterpart to discuss each report, including any differences in perspective.

As with the technical assessments, there were few discrepancies between the assessments conducted by the two lay members of the Expert Review Team, and any differences were resolved by discussion thereby reaching a consensus view.

3.2.4 Analysis of the SAI Report Assessments

Themes were extracted from SAI report assessments and collated to inform key findings. These findings informed engagement with the HSC organisations during subsequent phases of this review. During the review, emerging findings and key messages were shared with the Department of Health via interim reports.

3.3 How each Trust responds to Significant Unexpected Harm Events

Questionnaires were developed for and issued to each HSC Trust, the HSCB and the PHA. These were designed to gather information from each organisation about their respective approaches to SAI review and the related structures and processes in place, including the extent of patient and family involvement.

A thematic analysis of the responses received was subsequently undertaken.

3.4 Patient and Family Engagement

Initially, it was intended that the Expert Review Team would make direct contact with those patients and/or families affected by the 66 SAIs which were included in the structured review undertaken in the first phase of this review. Recognising the potential for further psychological impact, the Expert Review Team agreed the following patients and/or family members would not be contacted:

- Where there had been an expressed wish by the patient and family not to be contacted further or where there were issues of confidentiality.
- Families of cases who were subject to a coroner's investigation.
- Patients/families of cases which were subject to legal proceedings.
- Patients/families of those involved in significantly distressing SAIs (including suicide of a family member).

This resulted in 38 out of the 66 patients/families being contacted to seek their involvement in the review process. Of the invitations sent to each patient and family, only six responses were received. Following this, two decided not to be involved. This resulted in four out of 38 individuals contacted agreeing to become involved. Individuals subsequently met with RQIA staff members. This number was considered too few for the purposes of this review. As such a decision was made to supplement the engagement and further seek experiences via several additional routes, including approaching the Department of Health and the Patient Client Council (PCC) to supplement the experiences of those four initially contacted. Both organisations had previously engaged with patients/families who have had an experience of the SAI process following an incident of unexpected harm.

The PCC agreed to meet with the Expert Review Panel to share the views of patients/families with whom they had engaged. Communication with the Department of Health also resulted in three additional families agreeing to participate and share their experiences.

3.4.1 Additional information considered on engagement with patients and families

Experiences of patients and families involved in SAI reviews were also ascertained through engagement with other groups and work streams:

- In November 2019, the Inquiry into Hyponatraemia-related Deaths Implementation Programme (Work stream 5, Serious Adverse Incidents), held a workshop in conjunction with the PCC to engage with families on their experience of the region's SAI review process. The findings from the workshop were shared with RQIA and considered by the Expert Review Team.

- In October 2019, the PCC shared its Serious Adverse Incident Complaints A Thematic Review of Client Support Service Cases 2014-2018 report. It outlined the experiences of families who had been through the region's SAI review process and the findings were considered by the Expert Review Team.

- In December 2020, the Expert Review Team met with staff from Cause NI[2] who shared the experiences of families they had supported through the SAI review process and provided insight into how to achieve quality family engagement in the process.

These findings were articulated in the Expert Review Team's interim report on Patient and Family Engagement. .

3.5 Staff Engagement

As part of this review, the Expert Review Team engaged with those staff involved in the care of the 66 patients who were the subject of the SAI review reports involved in the structured assessment undertaken in the earlier phase of the review. Several methods of staff engagement were utilised:

- Focus group meetings using a café style approach.
- A private post box method.
- An online survey.
- One-to-one telephone interviews.

3.5.1. Focus Groups

Focus groups were held between 5 November and 21 November 2019. To accommodate the range of staff involved in the SAI process, each focus group had a different emphasis:

- Staff involved in the care of the patient who was harmed.
- Staff involved in the SAI review process.
- Staff involved in a named SAI review.

The focus groups focused on three primary areas:

- The experience of staff who had been involved in the SAI process.
- Their experience of engaging and involving patients/families in the SAI process.
- The views of staff in relation to how the SAI process could be improved.

Table 2 below shows the number of staff who attended each of the focus groups.

[2] Cause NI is an organisation which supports people with a mental health problem and their family members.

Table 2: Staff Engagement Focus Groups by Participation and Organisation
Source: Information recorded by RQIA during the focus groups

	Focus Group 1	Focus Group 2	Focus Group 3	
Organisation	Staff involved in an incident	Staff involved in reviewing an incident	Team involved in reviewing an incident	Total number of staff by organisation
Belfast Trust	5	12	4	21
Northern Trust	19	16	2	37
South Eastern Trust	14	15	4	33
Southern Trust	12	10	3	25
Western Trust	5	19	4	28
NIAS	2	8	n/a	10
Integrated Care	n/a	8	n/a	8
Total number of staff by focus group	**57**	**88**	**17**	**162**

3.5.2 Confidential Post-Box Feedback

At each staff focus group, a confidential post-box was provided to enable staff to share their experiences of the SAI process should they not be comfortable with speaking out in front of a group.

3.5.3 Online Survey

The third method to support staff engagement was via an online survey. All staff working within HSC Trusts were offered an opportunity to respond, provided they had experienced the SAI review process.

Overall, 201 staff completed the survey. However, 114 of those had not been involved in an SAI process, either as a member of a care team involved in an incident or as a member of the SAI review panel. Their responses were therefore not included in these analyses.

Of 87 respondents who had an experience of the SAI review process, 40 staff members had been involved in care and treatment related to an incident and 47 staff members had been part of the panel reviewing an incident.

3.5.4 Telephone Interview

All staff who attended the focus group meetings were also offered the opportunity to speak confidentially with a member of the Expert Review Team by telephone interview. Four staff members were subsequently interviewed.

3.6 Meetings with HSC Organisations

The Expert Review Team met with Senior Managers in each of the HSC Trusts. The meetings focused on the management and oversight of the SAI review process within the organisations and included a discussion on potential improvements to the SAI review process.

The Expert Review Team also met with the HSCB and PHA to discuss their regional responsibilities, their roles in oversight of the SAI review process and the role of the Designated Review Officer. This meeting also included a discussion on potential improvements to the SAI review process.

3.7 Engagement with other Organisations

The Expert Review Team met with representatives of the RQIA's Mental Health inspection team and the Coroners Service in NI, both of which were identified as having had frequent engagement with the SAI process. The purpose of this discussion was to gain an insight into their experience of the SAI process and what improvements they considered could be made.

A broad range of organisations are involved and impacted by the regional SAI review process. Engagement with these organisations focussed on those that had most frequently experienced the process. Other organisations, such as other regulatory bodies, trade unions, and the Police Service for Northern Ireland were provided with information about the review and asked if they would like to make a written submission regarding their views and opinions in relation to the current SAI process and their suggestions for change to the SAI process.

Of the organisations contacted, the following eight responded. These were; the Royal College of Nursing, the Eastern Local Medical Committee, the Pharmacy Forum, the Coroner's Service, the Northern Ireland Public Sector Alliance, the Northern Ireland Medical and Dental Training Agency, the Information Commissioners Office and the Health and Safety Executive Northern Ireland.

The full list of organisations contacted is outlined in Appendix B.

4.0 Findings

4.1 Overall findings of the Expert Review Panel

After full consideration of all the evidence gathered from each of the contributors to this review, the Expert Review Team was confident in their determination that the current regional policy for SAI review in Northern Ireland must change. It was clear that the current procedure and its implementation does not support:

- Fulfilment of the statutory duty of PPI as set out in the Health and Social Care (Reform) Act (Northern Ireland) 2009.
- Reasonable application of the principles of effective review practice.
- Confidence in the independence of Chairs of SAI reviews at Level 2, or Level 3 - particularly so for Level 3 reviews where the appointed chair is a former employee of an HSC Trust.
- Health and Social Care organisations embracing their accountability for:
    - decisions made regarding the level of review conducted
    - how they involve and engage with a patient and family
    - the quality of review conducted, acceptance of its findings and approval processes
    - demonstrating how HSC Trust services have improved and are safer because of the reviews conducted
    - ensuring that issues requiring regional attention to improve safety are escalated to the right people/organisations.
- The formulation of evidence-based recommendations.
- The design of action plans that will enhance the safety and quality of healthcare provision across the region both in the short and longer-term.
- Review reports that are well-formulated, evidence-based and readable.

The Expert Review Team identified a number of reasons for this:

- The implementation of the regional procedure focuses too heavily on process and non-attainable timescales instead of focusing on consistently delivering the practice of conducting high quality SAI reviews.
- There was an absence of clear regional guidance on PPI duties in relation to patient rights within the serious adverse incident process.
- There was no defined regional patient safety training strategy and curriculum.
- There were not defined competencies required of lead investigating officers and serious adverse incident panel chairs.
- There were insufficient numbers of trained independent advocates to support family involvement in the process.
- There was a regional lack of effective training in how to conduct a meaningful review. Furthermore, even where training had been delivered, the appointed chair or investigative leads did not have sufficient authority to independently devise a review plan that fully delivers the required quality of a review.

The evidence underpinning these findings was derived across a broad range of engagements and is detailed further in the following sections under three key themes.

1) Patient and family engagement.
2) Staff engagement.
3) The effectiveness of the procedure and approach for delivery of SAI reviews.

4.2 Patient and Family Engagement

A hallmark of success in any approach to the review and learning from incidents of unexpected and avoidable harm is the manner in which a health provider organisation engages with the patient and their family through the review process. The families who provided information to the Expert Review Team, the PCC and the lay members of the Expert Review Panel (who themselves have lived experience of healthcare induced harm) provided consistent reflections on how this aspect of SAI Reviews is delivered in Northern Ireland.

The Expert Review Team identified several of themes after listening to the views and experiences of patients and families:

- There was inconsistency in the practice of HSC Trusts in when and how they informed families about:
    - the incident
    - the decision to conduct an incident review process
    - the rights of patients and families to be engaged at all stages of the review, including shaping the terms of reference or lines of enquiry
    - sharing of the interim findings of the review process to allow commenting and feedback from the patient and family to be incorporated.

- There was inconsistency in the quality and frequency of communications with the patient and their family. This includes written correspondence as well as verbal communications. A common concern was the level of empathy, respect in the nature and tone of communications and levels of planning with the patient and their family about what mode of communication was best and with what frequency.
- Families reported there was not sufficient transparency about the process.
- There was a deficit in the availability of independent support or advocacy for patients and families.
- There were concerns about the timeliness and amount of information provided about the plan for the review process and its intended conclusion date.
- They described HSC organisations across the region were unable to apologise for the harm that had occurred. In their words, it was not enough to say, “sorry, we are at fault”. Rather, the apology should say: “Sorry this has happened to you. We will look after you and help you understand what happened”.

- They experienced an unwillingness to seek the testimony of the patient and family members as an integral component of the review process, thus diminishing the status of the patients and their families.
- Many stated that the interim findings of the review process were not shared with the patient or their family members so that they could contribute constructive comments and ensure their voice is appropriately represented and heard.
- There was not a sufficient level of openness and candour about what had happened and why. They described the shrouding of the SAI review findings in technical language which was not accessible and perceived it to be defensiveness.
- There were some who were concerned about potential 'cover-ups' and a lack of transparency in the process, as well as in the report subsequently written.
- Several described Chairs of the SAI review whose communication skills and ability to work constructively with a family were poor.
- Several were not confident in the independence of Chairs of the SAI review.

Of particular note was the view expressed by Cause NI, a charity that specialises in offering practical and emotional support to families whose loved ones have experienced harm as a result of serious mental illness or suicide. They considered that the current requirement within the SAI procedure, for the investigation of all deaths that have occurred as a result of mental illness (where the individual who dies was known to Mental Health Services in the preceding 12 months), was not the best approach. It was suggested SAI reviews would be most appropriate in those cases where it was suspected there were care deficits preceding the death.

The Expert Review Team reflected, that overall, the expressed views of patients of families in Northern Ireland regarding their experiences of involvement, were similar to findings of independent reviews and inquiries elsewhere in the UK, such as the Care Quality Commission (CQC) review, '*Learning, Candour and Accountability 2016*[7], the *Mid Staffordshire NHS Foundation Trust Inquiry* and *The Report of the Morecambe Bay Investigation.* It was therefore disappointing that in Northern Ireland, more progress had not been made in implementing best practice in how HSC organisations work with families after unexpected harm.

The Expert Review Team was impressed with the attitude of staff who expressed a willingness to have greater engagement and involvement with the patient and their family in the process. Most staff appreciated that patients and families are an important component of a successful approach to learning from harm. They reported feeling constrained by an overly bureaucratic process, which they perceived placed completion of arbitrary timescales and narrow performance targets above the requirement for meaningful involvement.

The most significant barriers to achieving meaningful involvement of patients and their families were described as:

- Uncertainty about what staff could and could not say to a family and what constitutes an acceptable level of disclosure.
- How to achieve realistic expectations with a patient and their family about what the SAI process can and cannot deliver.

- The time allowed for the delivery of the SAI process, and the time available to an SAI review panel chair, who would have additional managerial or frontline clinical duties and which is not conducive to meaningful patient and family engagement.
- The availability of dedicated support for patients and their families through the SAI process. Without support, it is difficult for Chairs of SAI reviews to also attend properly to the needs of the patient and family.
- Absence of constructive guidance on how to capture family involvement and engagement within the SAI review report, exacerbated by lack of space within the review report template to record the level of family involvement.
- Staff were concerned about legal issues and reported anxiety about how to describe the findings that then might result in a claim for damages. A small number of staff described instances where legal services have requested modifications to a report which diluted the findings of the SAI review panel.

The Expert Review Team is clear that concerns regarding future claims for damages must not interfere with conduct of an SAI review or with the integrity of the resulting report. It is wholly unacceptable that report authors could be asked by a manager or by legal services to dilute their findings. Furthermore, such action should have serious implications for health professionals who have breached their professional duty of candour.

However, there are good reasons for a legal services team to review an internal SAI review report document:

- To sense check the use of language.
- To test the strength of the evidence base underpinning the report's findings and conclusions.
- To determine a report's readability.

Feedback made to a report author in the context of the above must be considered and acted upon.

Across the HSC, it was not the cultural norm to share interim findings of an SAI review with a patient and their family. Enabling the patient and family to have a voice in the report, to comment on the report content, and to influence the content and tone of the final report appears not to be a primary consideration. Ineffective and insufficient patient and family engagement can cause further harm. Families report having experienced some of the following adverse effects:

- Increase in stress.
- Delay in starting the grieving process.
- Post-traumatic stress disorder.
- Loss of income.
- Feelings of anger.
- Loss of life enjoyment.

The Expert Review Team considered that, for many families, it is possible to avoid causing further harm if HSC organisations engage in a compassionate process. The

founders of the Harmed Patients Alliance[8], a campaign group founded to raise awareness of harmed patients and families, effectively communicate the kind of compassion families need following healthcare harm.

"In the aftermath of our loss, we needed healthcare to fully acknowledge and thoroughly understand our experience of what had happened to our children and the impact it had on us. We needed answers to all of the questions that we had, that were important to us, and we needed those regardless of whether anyone else felt our question relevant or important. We needed staff to be supported to give us honest accounts of their actions and their reflections. We needed a collaborative approach to reach a truthful and evidence-based explanation of events. We needed help and support to understand what all the processes were that were happening and how to engage with them. We needed the system to learn and to see meaningful change, but we also needed the system to help us heal, recover, and restore our trust. Meaningful engagement coming from a place of care could have provided that."

Harmed Patients Alliance

4.2.1 Working with patients and their families in a way that delivers a restorative process and maintains candour

The Expert Review Team determined that the Department of Health with associated stakeholders must describe the region's statement of intent regarding how patients and families are involved in the SAI review process and the core objectives in relation to patient and family involvement for which each HSC provider must evidence achievement.

Examples of objectives relating to patient and family involvement are:

- Families and patients are supported as active partners in the review process as much as they wish to be engaged, including the involvement of an appointed advocate.
- Patients/families experience a compassionate and empathetic approach, which is demonstrated by the nature and frequency of contact throughout the review process.
- The voice of the patient and family is heard, their testimony captured, and they have the same status as any professional contributing information to the review process.
- The patient and family has a named source of support, outside of the review panel. The role of this individual is clearly defined, including the basis authority to act as advocates in the best interests of the family.

- Questions asked by the patient and family are responded to fully, with honesty, integrity and candour.
- The patient and family are encouraged to contribute to the terms of reference for incidents identified as requiring in-depth review.
- Patients/families are taken through the interim findings of the review and are provided with enough time to read, comment on, and influence the content of the final report.

In the event of new information becoming available after the conclusion of an SAI review, or if there is a change in conclusion or material findings from such review, then this information must be shared with the patient/families as soon as possible.

How individual HSC organisations undertake to deliver the objectives should be for them to determine. However, what is required from all HSC organisations is clear evidence that they have achieved the objectives. In particular, they should provide evidence that patients and families are given the same opportunity for involvement in an SAI review as the staff and others involved in an incident. This evidence should be validated by patients and families who have experienced unexpected healthcare harm of the nature that warrants an SAI review. The Expert Review Team considered that a co-production model for development and further improvement of the SAI procedure, involving frontline staff and patients and their families, should be adopted going forward.

4.3 Staff Engagement (staff engaged in the care and management of the patient who experienced harm)

Every SAI review must involve the collection and analysis of a sufficient amount of information from multiple sources. This requires the active engagement of staff involved in the care and treatment of the harmed patient and the engagement of a wider sphere of individuals who have experience in the field and understand the system at work.

The purpose of the SAI review process is to:

- Find out what happened.
- Understand how and why it happened.
- Implement any appropriate early remedial actions to address any identified deficits in care.
- Identify areas for improvement in order to support the delivery of safe patient care.
- Implement appropriate improvements based on the findings of the SAI review.

In circumstances where patients have been harmed, it is understandable that frontline staff may feel vulnerable and experience emotional pain, as well as feelings of anger, shame, fear, sorrow or regret.

To enable HSC staff to fully inform the review process, they must feel safe to do so. They must also have confidence in both the competence the appointed review panel and feel secure that the information they provide will be used fairly.

What staff employed within Health and Social Care trusts across the region had to say

Comments about the SAI procedure and its implementation:

In the online survey completed by HSC staff:

- 89% (179) said they agreed, or strongly agreed, that SAI reviews were an essential activity for a learning organisation.

- 74% of respondents (149) said SAI reviews generated improvement for safety within their organisations.

- 64% (129) said they agreed or strongly agreed that they were aware of more than one improvement resulting from an SAI review.

- 61% (123) said outcomes from SAI reviews were regularly discussed at team or service meetings.

While the survey results cannot definitively conclude whether or not SAI reviews enabled the collection of quality information upon which to formulate evidence-based findings, face-to-face meetings conducted with staff in HSC organisations did, however, provide a useful insight into the experiences of staff involved in SAI reviews.

The information gathered at staff focus groups, for example, highlighted that the principle of a 'just culture' was not embedded across the region.

Staff consistently reported:

- Insufficient openness about the process and the standards of conduct expected of the SAI review panel members.
- Insufficient communication about the progress of an SAI review and why it was being conducted. The key lines of enquiry, progress, findings, and recommendations were frequently unknown by staff who had been involved in the care and treatment of the patient to which the SAI review related.
- The experience of the review felt like it was designed to apportion blame.
- Terms of reference for SAI reviews did not suggest they were grounded in a constructive or learning process.
- There was variable engagement in the process, with some staff unaware the SAI review was even being conducted, only to find out at a later point in time. Some staff described an over-emphasis on the collection of written submissions and a lack of detailed exploratory conversations being conducted by SAI review panels.
- Some staff described insufficient notice of, or information about, SAI panel meetings or interviews staff were asked to attend.
- Some staff did not have an opportunity to read the interim findings before these were finalised in the SAI report.

- Some staff said they were not able to respond to any criticisms made in the SAI report before it was signed off as completed.

Regarding the constitution of the SAI review panel, and how those panels operated, the following concerns were described by frontline staff who participated in this review:

- Concerns about the appropriateness of members of the panel in terms of technical and subject matter competency and insight.
- Concern about the lack of factual accuracy checking by review panels, both in terms of the sequence of events leading to the incident under review, but also regarding the accuracy of notes of face-to-face meeting. Staff said that this meant they were unable to correct the SAI review panel's misinterpretation of words spoken at interviews, or during panel meetings.
- Some staff described too narrow a field of focus by SAI review panels, with little consideration of the system within which frontline staff work. For example, workload, workplace design, task design, skill mix, staffing issues, team dynamics, and cultural factors, leadership and factors which may contribute to an incident.

Although negative experiences were reported, some staff reported a more positive experience and had been involved fully throughout the SAI review. These staff reported that they felt they had been involved throughout the SAI review, in terms of being kept up to date with progress of the SAI review and were able to contribute to the learning from the SAI review.

During discussions with the Expert Review Team, frontline staff reflected on the support mechanisms available to them in coming to terms with the SAI event and its subsequent review. Although we received many comments about a lack of support, a small number of staff did share positive experiences of being supported by both managers and colleagues. These staff highlighted that the people who had provided the support, had themselves been previously part of a SAI review. The overwhelming message from all focus groups across all Trusts was that staff had experiences of inadequate support as they went through the SAI process.
Frontline staff acknowledged that it was not the role of the chair of the SAI panel or the Trust staff member who oversees the review to provide appropriate support for staff as their role was to deliver an effective, unbiased review process. However, they did consider that better quality support ought to be forthcoming from:

- Their own line managers.
- Independent providers of psychological support.
- Their employer via staff supports and counselling services.

In several focus groups, the Expert Review Panel members were struck by the level of emotion expressed by staff who had participated in an SAI reviews. It was evident that these staff had not been through a supportive, reflective process of learning.

4.3.1 Achieving a way of working with staff that delivers a supportive, learning-orientated process within a 'Just Culture'.

The Expert Review Team determined that the Department of Health, working with appropriate stakeholders, must set out, in its strategic direction, its expectations for how staff in HSC organisations and those they report to are engaged and when participating in an SAI review. As with family engagement, the principles for effective staff engagement must be developed and defined before an effective process can be designed.

An example of a statement of success could be:

'*Staff are treated well, their voice is heard, and they actively contribute to the SAI review process.'*

The core objectives for HSC organisations which will ensure this is delivered could be:

1) Staff experience a compassionate and empathetic approach.
2) The voice of the staff involved in an incident is heard, including their experience of the incident, and the context in which it occurred.
3) Staff are well informed throughout the review process.
4) Staff are treated fairly and equitably, in line with the principle of a 'just culture', including having the opportunity to read any criticisms made about them and to respond.
5) Staff involved in the incident (and other key staff) are given the opportunity to read the interim findings of the SAI review panel and to provide feedback in relation to factual accuracy, tone, and style.
6) Staff involved in the incident and service in which the incident occurred are actively engaged in designing the action plan to deliver measurable and sustained improvement.

Again, individual HSC organisations should determine for themselves how to deliver these objectives but should be able to evidence achievement of the objectives. This evidence should be validated by staff that have experienced the SAI process. Perspectives of staff who have delivered the SAI process should also be gathered and evaluated. The Expert Review Team again advises that a cooperative approach be adopted for involving frontline staff, patients and their families in designing of these improvements.

4.4 Staff Engagement (staff with experience undertaking SAI reviews)

A robust SAI review requires staff delivering the process to have the right technical knowledge, along with a range of non-technical skills and attributes. At the time of this review there was no competency framework in place to ensure the required competencies to deliver the review process. It cannot be assumed individuals have these skills simply because of their professional background or seniority. Implementing an effective approach for SAI reviews will require upskilling of staff before it can be practised and evaluated.

For the implementation of the review procedure to be effective and for optimal learning to be achieved, a structured and feasible policy framework needs to be embedded alongside cultural change.

The consistent messages provided to the Expert Review Panel from staff engaged in the delivery of the SAI procedure and its implementation were:

- It was challenging to undertake the SAI reviews alongside their pre-existing professional duties. There was no protected time for this, nor any account taken of their day-to-day workloads or frontline patient care duties.
- There was insufficient supervision and mentorship by experienced reviewers who hold the necessary technical and non-technical skills and attributes.
- There was a lack of training in conducting SAI reviews and related methodologies.
- There were challenges in engaging with staff involved in the care giving, such as established off duty rotas, the need to provide a 6–8-week lead time to medical staff before meeting with them, challenges in locating agency and locum staff, and the delay between the incident occurring and the SAI review being commissioned.
- Communication with all relevant parties was described as a persistent challenge.
- The classification of an SAI, and how it was determined that an incident met Level 1 or Level 2 criteria, was difficult for staff to understand. There was not always full understanding that the current procedure directs reviews should be conducted at a level appropriate and proportionate to the complexity of the incident and significance of event under review rather, that the impact or outcome for the patient. Most staff considered that the criteria for classification were not clear.
- The current approach of imposed regional terms of reference does not support an effective review practice. Staff understood effective reviews require the right technical questions to be asked about the patient's care and treatment; this is not supported by the current process. When asked why the terms of reference were not changed to something more relevant, staff reported that they did not believe they had the authority to do so.
- The regional report template did not support the formulation of an evidence-based, well-structured or readable report. Participants reported that the design of the regional template made it difficult to reflect the level of an engagement that an SAI review panel may have achieved with the family. Overall, the template was considered to be not fit for purpose.
- Recommendations were a particular source of concern for participating staff, with many reporting their perspective that recommendations often did not get implemented due to a lack of resources. Staff also displayed some frustration members of review panels felt obliged to make recommendations even if they suspected that nothing would happen as a result.

In addition to the above, staff with experience in conducting SAI reviews provided insights into the review methodology of Root Cause Analysis (RCA) and the extent to which learning is implemented. The information provided by staff indicated that there is confusion about what constitutes an RCA method. The fact that many staff believed completion of the regional report template constituted a valid review and an

RCA is concerning. Staff did not demonstrate an informed understanding of what constituted a review and were not aware of the broad range of tools and approaches they could employ to deliver this. The tools that participating staff were aware of were simple chronology, the 'five-whys' technique, and the 'fishbone' diagram.

The Expert Review Team was left with an impression that HSC Trusts across Northern Ireland are using the language of RCA without an embedded understanding of what this means, or where RCA fits into a structured and auditable review. The regional guidance does not address this, nor does it provide practical advice on how to conduct a review to an acceptable standard.

The Expert Review Team could not be confident that across the HSC Trusts, consistent systems based learning was happening, and that changes were embedded or that there was a robust system in place for sharing learning beyond the investigating organisation. The issuing of regional learning letters by the HSCB was referred to, but most frontline staff were not aware of this and only two of those interviewed had ever seen a learning letter.

Staff with experience as an SAI reviewer understood why staff asked to provide information to the review panel may suspect the existence of a 'blame culture'. They considered that most of the staff they interviewed often appeared anxious about the process and were sometimes defensive when questioned. Some staff who had undertaken several SAI reviews considered that the level of anxiety among staff being interviewed had increased over time.

The Expert Review Team considers from their assessment of the 66 review reports that the language used in SAI review reports might also contribute to a sense of blame. For example, root causes of incidents were described as 'human error', which may unfairly suggest that an individual member of staff is responsible. This is further compounded by the lack of deconstruction of events from a systems perspective, meaning that the true root causes and contributory factors which underlie errors in care and treatment are not identified, placing an unreasonable weight of responsibility on frontline staff.

Staff acting as SAI reviewers on behalf of their employer also considered the way the media in Northern Ireland reported on incidents that had reached the public domain. Subsequent media interest and commentary fuelled their feeling of a blame-driven approach and culture, alongside concerns about medico-legal consequences.

As with staff involved in care delivery, those who had an experience of conducting SAI reviews also believed that there was a lack of constructive support. Staff asked to chair SAI review panels were particularly concerned. They considered that there was no account taken of the true time required to deliver the role well, or how the time required conflicted with their other professional responsibilities. Some staff reported having to write SAI reports in their own time and late into the night, which then impacted their wellbeing and concentration levels at work the next day.

The Expert Review Team considers this situation to be wholly unacceptable. If the objective is to learn and improve safety, the system cannot overload staff already working at full capacity. Failing to provide protected time to lead the SAI review

process infers that it lacks importance. In the rail, marine, and airline industries, where an incident merits careful analysis, only trained individuals with time to undertake the work are appointed to the task.

The lack of administrative assistance for review chairs was also cited by staff as evidence of lack of support. There is considerable administration associated with the conduct of an SAI review. The Expert Review Team considers that it is not appropriate for a frontline clinician, who has been asked to lead an SAI review process, to also be responsible for administering it.

4.4.1 How to ensure chairs and members of SAI review panels are equipped to deliver the job adequately and with enough time

The Expert Review Team considers that the first step in achieving a sustainable situation across the region is to review how decisions are made regarding the level of SAI review required. This should be informed by:

- The frequency by which the incident type occurs.
- Whether there is a safety review already ongoing to explore and address any safety issues.
- Whether the conduct of the review is likely to deliver more learning than has already been achieved by previous reviews.
- Whether there is a safety improvement plan already underway.

It is widely recognised that many individual reviews involving the same incident type often do not lead to tangible safety improvements. Therefore, the practice of defining the need for an SAI review on the basis of adverse patient outcomes should be discouraged and is not in line with the current guidance contained within the SAI procedure which states,

"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".

An approach that allows a sensible period of time for the early assessment of 'what happened', and consideration of early information gathered about the care and incident, might enable a more structured and evidence-based approach to deciding which cases require an in-depth systems analysis. Treating the review as a process, where reviewers and chairs can determine an evidenced-based stop point, might be more successful than a static approach which assumes that all incidents can be treated the same. One of the expert review panel members has supported several NHS Trust mental health teams to implement such an approach. As a result, mental health teams reported a reduction in the number of in-depth reviews, greater engagement from staff and a formalised process whereby the review is led by the team lead; now recognised to be an important aspect of the process.

A more flexible approach is required to enable families to understand the process and what it can deliver. For example, it can deliver learning and provide answers to questions but it cannot provide justice.

In terms of the time allocated to conduct an SAI review, it will always be necessary to stipulate timescales, but it is important that they are realistic. They must allow at least to six-months for complex cases, and it would be reasonable to require a structured project management approach that can be monitored and quality assured.

The second step is to define the core competencies required of:

- People acting as review leads and/or chairs of review panel.
- The subject advisors supporting the process.

Furthermore, a regional training curriculum and certification process must be agreed. All training providers across the region should meet the minimum content requirement in order to enable competency achievement. For such an approach to work well, all HSC Trusts and independent providers responsible for delivering training should be required to demonstrate their competency and knowledge in order to be approved as training providers. Requiring all training providers to apply to be on a regional register or preferred provider list would support the achievement of this.

Finally, to support the implementation of a training curriculum it was considered that a mentorship and coaching approach could also be adopted. A person independent of the HSC Trust in which the incident occurred could provide external support to the lead reviewer/chair. This has the added advantage of providing an independent quality assurance check of the process and its outcomes.

4.5 SAI Reports: The extent they demonstrated a reasonable standard of review and positive contribution to patient safety in Northern Ireland

As previously outlined in the methodology in section 3.0, the Expert Review Team reviewed 66 SAI reports as part of this review.

In undertaken the review of reports, it was evident to the Expert Review Team that having two separate report templates for Level 1 and Level 2 reviews is not working. The design of the templates also does not support staff to write up their findings in a way that delivers confidence in the standard of the review or in the appropriateness of the level of review undertaken. Furthermore, the templates are designed in a way that limits important information being included, such as the questions that have been asked by patients and family members.

Upon assessing the report of a significant adverse incident review, the expectation is that it demonstrates that an effective method has been used to underpin the review. Indicators of an effective methodology are:

- The methods, tools and techniques used by the SAI review panel are clearly stated and appropriate to the incident under examination.
- The evidence upon which findings and conclusions are based have been clearly triangulated.
- An appropriate range of subject advisers have been engaged in the review process

- The SAI review report outlines the key elements of the processes and procedures relevant to the expected standards of care and treatment.
- There is a clear account of:
    - what happened
    - where policy, process or procedural expectations were met
    - where there was a deviation from procedural expectations.
- Where deviation from procedural expectations is identified, there is an explanation of:
    - whether the deviations were reasonable and justified based on the presentation of the patient, their clinical needs at the time, and the unfolding situation
    - whether the deviations were not reasonable and therefore not justifiable.
- In the instance of a non-justifiable deviation from the expected standard of care, there should be an indication of whether this contributed to or caused the harm to the patient, and whether the deviation represents a breach in standards to such an extent as to pose an ongoing threat to the safety of another patient should it reoccur.
    - In all such instances, a report should outline a human factor and systems-based explanation of how and why the deviation(s) occurred.
- Recommendations should address the most significant factors identified which contributed to or directly caused the incident.

In addition to the above, all significant adverse incident reports should deliver the following:

- Clarity about the questions posed by the family. The answers to these questions should be included in the findings section of the report.
- A good standard of writing with correct use of grammar, punctuation, and syntax. There should be no abbreviations, unless already in common usage in Northern Ireland.
- A readable report written in non-technical language.

4.5.1 Expert Review Team Findings following review of 66 significant adverse incident reports, comprising Level 1 and Level 2 reviews

The Expert Review Team found that all HSC Trusts utilised the relevant regional templates for the Level 1 or Level 2 review reports. Therefore, the Expert Review Team's findings are as much a reflection of the design of the templates as the quality of the reports assessed.

Style and structure of the reports

The Expert Review Team considered the presentation of the review reports and there was consensus that both report templates would benefit from a basic front page that simply states the name of the reviewing organisation, the title of the report and the publication date. It was proposed that any demographic information required for regional collection purposes could be accommodated within an appendix.

In both the Level 1 and level 2 report templates, space is provided to record 'what happened'. Mostly, this was comprehensively completed. However, in many reports, the sequence of events was recorded in too much detail and at the expense of the detailed analysis expected in the findings section of both reports, accepting that the Level 1 report is intended to be more succinct than the Level 2 report.

In the Level 1 report, there is no 'findings' section but instead, a section titled 'why it happened'. This title is erroneous. It implies that 'why' is determinable and automatically infers that the incident was preventable. It does not promote a balanced, constructive, analytical process.

In the Level 2 reports, there was a 'findings' section, but this was not structured. There were no uniform subheadings to guide a report author about what they should be recording. For example:

- Evidence that shows that expected standards of care were delivered as intended.
- Evidence of deviations from the expected standards of care.

Some reports made statements of policy and procedural compliance but did not say what these were and did not present an evidence base for the reported levels of compliance.

Some review reports stated their findings in relation to human factors, such as team elements, education and training. However, in the majority of instances the Expert Review could not link these findings to a systematic analysis of these areas of concerns in keeping with the approach of the National patient Safety Agency.[9] This indicates that the review panel, the author of the SAI review report and those signing off the reports did not fully understand how to effectively implement a human factors approach.

Some reports reviewed by the Expert Review Team did outline deviations in the care and management of the patient but did not make clear the significance or seriousness of these in relation to the patient outcome. As stated above, rarely was this accompanied by any structured or evidence-based explanation regarding how and why these deviations occurred. As a result, there was a lack of outcome-focused recommendations within the reports reviewed.

In stating the above, the Expert Review Team is not inferring that staff who undertook the reviews or wrote the reports were failing to deliver what was required of them, rather, the lack of structure and quality of the reports is a consequence of:

- A lack of investment in those tasked with leading the reviews in terms of their knowledge, skill base and time required to do the job adequately.
- A report structure that is not fit for purpose (Level 1 and Level 2 templates).
- A lack of effective quality assurance of reports at senior management levels across HSC Trusts.
- A lack of empowerment in HSC Trusts to adopt a more comprehensive approach and a better style of report, based on the principles outlined in regional policy and guidance.
- A lack of an effective quality assurance process within each HSC organisation and at a regional level. There appears to be no reliable process through which reports are peer reviewed to ensure delivery of an acceptable standard of review, including outcome-focused recommendations. Nor are they quality assured with a view to ensuring that there is a standard of report writing suitable for sharing with patients and their families.

Expert Review Team findings in relation to specific indicators of a robust SAI review

These are the findings from the Expert Review Team's structured assessment of the 66 review reports.

Indicator 1: The methods, tools and techniques used by the review panel are clearly stated and appropriate to the incident under examination

The following list describes what was found to be commonly recorded in terms of the methodology and approach to reviewing SAIs:

- The patient's notes were reviewed.
- A tabular timeline established.
- Relevant staff were interviewed.
- Family was invited to participate in the review.

The above elements are not sufficient to be considered a methodology, nor do they provide clarity regarding the approach taken by the relevant review panel. As previously articulated in this report, the primary reason for this is a lack of understanding about what constitutes a fair and reasonable review, with a regional approach that is too limiting and not embracing a tool-kit method.

Indicator 2: The evidence upon which findings and conclusions are based has a clear triangulated evidence-base

None of the reports reviewed satisfied the Expert Review Team that there was a triangulated, and thus validated, evidence-base for what was written in the findings section of the reports. This represents an unacceptable situation. A credible review aims to establish what happened, how it happened and why it happened.

An SAI Review Panel Chair understands the importance of triangulating and validating information and understands the dangers of not delivering this standard of practice. The SAI reports reviewed demonstrated a region-wide lack of adherence to

defendable review practice. This is mostly due to a lack of training, an unclear competency framework and insufficient professional supervision.

Indicator 3: An appropriate range of subject advisers have been engaged in the process

Regarding the independence and appropriateness of subject advisers, in 93% of reports this was either unclear or absent. Regarding relevant experience of subject advisers, this was unclear in 45% of the reports reviewed. The lack of clarity was in part influenced by the design of the regional report template which did not require precision in the recording of this information.

Indicator 4: The key elements of processes and procedures relevant to the effective care and management of the patient's condition are recorded

This was missing from almost all reports reviewed. It is not a current requirement of the regional report template, and its absence underlines the lack of appreciation about what is necessary for a structured and credible review.

Each report should give a clear account of:

1) What happened.
2) Where policy/process/procedural expectations were delivered as expected.
3) Where there was deviation from policy/process/procedural expectations and an explanation for such deviations.

Although there was a clear account of what happened, few reports provided an analysis that enabled the reader to know where expectations were delivered, where they were not, and where the design of the process for care delivery and management was incomplete.

This is a significant shortcoming in the SAI protocol which does not require systems based analysis as part of its approach to conducting SAI reviews or within its regional report template.

Reports of reviews must determine:

- What was expected.
- Where the evidence supports that the standard of care was delivered as expected.
- Where the evidence shows deviation from what was expected.
- Where the evidence shows there was a pre-existing deficiency in the design of care and treatment requirements and associated systems and processes.

Where deviation from policy, process or procedural expectations is identified, there is an explanation of any or all of the following:

- Whether the deviations were reasonable and justifiable based on the presentation of the patient, their clinical needs at the time and the unfolding situation.

- Whether the deviations were not reasonable and therefore not justifiable.

Where deviations in care standards and the care and treatment delivered were identified, there was little evidence regarding the reasonableness of such deviations. It is accepted across all domains of clinical practice that sometimes it is necessary to do things differently than what is outlined in policy and procedure. Clinical professionals are trained to apply their clinical skills and to have a clear reason why a different approach in any given situation is right for the patient under their care. It is possible to make a correct decision at the time care is delivered to alter the normal plan and for this to be later contemplated as a contributor to an incident that occurred later. The rights and wrongs of these decisions must be carefully contemplated, alongside the application of principles such as the substitution test (that is, what would a similarly qualified group of professionals, providing care under the same/similar set of circumstances, reasonably have done). There was no evidence from the reports reviewed that these core principles have been applied.

The situation is uncomplicated if the review panel and the care team agree that an unjustifiable deviation occurred. The problem arises when there is a difference of opinion between the care team and the SAI review panel. In all such instances, the SAI review panel must apply the substitution test.

There was no indication in any of the reports reviewed as to whether the care teams had agreed or disagreed with the findings and conclusions of the SAI review panel.

Many report authors and SAI review panels tried to draw conclusions regarding contributory factors and causal factors. However, there was a lack of robustness in the evidence-base on which such important conclusions were being made. In some cases, where a finding of causality had been made, it was clear from the content of the report and the Expert Review Team's clinical knowledge that the conclusion of causality would not stand up to independent scrutiny. It is the lack of a robust evidence base for such conclusions that contributes to the widely-held view, supported by some members of staff during focus groups, that a culture of blame pervades reviews.

Regarding the human factors and systems-based analysis, report authors and the review panels clearly tried to undertake this analysis and present its outputs in the review report. However, based on most of the reports assessed by the Expert Review Team, there is a lack of understanding about how this needs to be approached, and how the findings need to be structured and presented. The design of the regional report template will have further compounded this.

Indicator 5: Recommendations to address the most significant influencing factors to the identified contributory and causal factors

The quantitative assessment of the 66 SAI reports reviewed by the Expert Review Team revealed:

- There was a lack of clarity about whether the report made recommendations. This was found in 14 (21%) of the SAI reports.

- Recommendations were only made in 26 (39%) of the SAI reports, but what they were trying to achieve was unclear.
- In terms of whether there was a correlation between the incident, the report content, and the recommendations, in 30 (45%) of the SAI reports this was clear, in 32 (48%) it was unclear, and in 4 (6%) it was difficult to make a judgement about this.
- In terms of the appropriateness of recommendations, in 22 (33%) of the SAI reports the recommendations seemed reasonable, but in 40 (61%) they did not. In 4 reports (6%) it was difficult to make a judgement about this.
- Regarding any correlation between recommendations and the subsequent action plan, this was clear in 29 (44%) of SAI reports while in 36 (55%) it was not. In 1 report (2%) it was difficult to make a judgement about this.

In no report was there evidence that a structured approach was taken to the formulation of recommendations. The regional guidance on SAIs does not describe any requirements for this and neither do the regional report templates.

An example of a structured approach to recommendations is:

- Clear identification of the intended recipient of the recommendation.
- A clear statement of what is required.
- A clear statement about what the recommendation should deliver.
- A clear statement of what risk the recommendation is meant to contain.
- A clear statement of the scope of the recommendation (local, regional).

Indicator 6: Regarding the non-technical aspects of SAI reports

SAI review reports should adhere to the following non-technical requirements:

- Clarity about the questions posed by the family and the answers to these questions.
- A good standard of writing, with the correct use of grammar, punctuation, and syntax, with no abbreviations, unless already in common usage within the population of Northern Ireland.
- A readable report, written in non-technical language.

Each of the reports was assessed in relation to these factors. Regarding the level of family engagement and understanding, it is the Expert Review Team's perspective that most SAI review reports did not deliver any evidence, or at least convincing evidence, of compliance with candour.

The standard of writing was variable as was the use and non-use of technical language.

Regarding the degree of satisfaction a patient and family might have with the report presented, the lay members of the Expert Review Team considered that they would be satisfied with 16 (24)% of SAI reports reviewed. They considered that they would not be satisfied with (23) 35% of the SAI reports and were unable to determine an opinion of their satisfaction with the remaining 27 (41%).

Regarding the inclusion of evidence that patient and/or family questions had been asked and responded to during the SAI review process, there was evidence in 15 (23%) of SAI reports reviewed that this had happened. In 44 (66%) of SAI reports, there was no such evidence, while in 7 (11%) of SAI reports it was unclear.

Regarding readability and comprehension of SAI review reports, the lay members of the Expert Review Panel considered most reports 89 of 132[3], (67%) as easy to read in terms of structure and flow, but this dropped to 26 of 66 (39%) in terms of ease of comprehension of report contents.

Wider Consideration from Structured Assessment of 66 SAIs

On consideration of the implications of the overall findings of the structured assessment of the 66 SAI review reports, the Expert Review Team considered the necessary steps to ensure SAI reviews and their reports are of good quality, readable, respond to family questions and provide evidence an acceptable standard of review.

They agreed on a number of general issues that need to be addressed regarding the procedure and its implementation, if the overall standard and credibility of the SAI report, which sets out the findings, conclusions and recommendations of the significant adverse incident review process, are to improve. These include:

- A regional framework that makes clear what the approach to learning from unexpected and unintended harm is intended to deliver; that is, what are its measurable markers of success.
- A regional approach to SAI reviews that delivers recognised international good practice in the science of review.
- A reasonable amount of time to conduct an effective review and include the patient and family in the process in an empathetic, meaningful, and respectful way.
- A single, new report template and regional style guide that enables a consistent approach to SAI reviews across the region but is flexible enough to allow SAI review report writers to remove and add sections to the template.

There is no single activity that will achieve the above. The Expert Review Team wish to make clear that re-writing the regional standards will not achieve the standard of practice that harmed patients and their families are rightfully demanding of this specialist field across the HSC. This is a standard of practice that is comparable to other industries where the activity of reviewing and learning from unexpected harming incidents deliver the core components necessary for an evidence-based review, undertaken by investigators who are skilled for the job, so the right lessons are learned and the right safety improvements are implemented.

[3] The denominator in this indicator is 132 as there was not consensus. 132 reviews were undertaken 2 of each 66 reports. One by each lay reviewer.

It is the Expert Review Team's assertion that there must be a comprehensive recalibration of the approach to the requirement for, and delivery of, SAI reviews across Northern Ireland.
A new approach must achieve:

- Greater flexibility in an approach that focuses on the opportunity for learning and safety improvement.
- A lower number of in-depth reviews. Where early assessment indicates that this depth of review is necessary, there should then be capability and capacity in the system to do this well.
- A process by which individuals and/or organisations who want the opportunity to deliver 'Investigating Well' training to HSC staff, are asked to undertake an assessment process so that it can be determined that they have the right knowledge and skills to deliver such training. This would preferably then lead to a regional register of preferred providers from which individual HSC Trusts can source training.
- A register of individuals and organisations who are authorised and have been assessed as competent to lead the review of unexpected harm events that meet the threshold for an in-depth fully independent review - for example, mental health homicide, removal of a body part in error, in-patient suicide.

Northern Ireland is in the envious position of having only six HSC Trusts. This provides an opportunity to reset the compass in a way that is not possible in regions with larger populations. Achieving this reset and designing a fit-for-purpose approach to reviewing and learning from SAIs will require unified and cooperative work across all involved organisations. Furthermore, it will require frontline senior clinicians to be prepared to provide straightforward, peer-to-peer assessment, reflection and feedback to colleagues in neighbouring Trusts about the care and treatment provided to patients when the outcome constitutes unexpected and unintended healthcare harm. This is a core element of professionalism and clinicians of all disciplines need to meet this challenge head-on. It should not be the case that trusted independent clinical opinion has always to be sought from outside of Northern Ireland.

5.0 Conclusion

The work undertaken for this review has, alongside other related projects, determined that the SAI procedure and its implementation across Northern Ireland is not working as intended.

It frequently fails to:

- Answer patient and family questions.
- Determine where safety breaches have occurred.
- Achieve a systemic understanding of those safety breaches.
- Design recommendations and action plans to reduce the opportunity for the same or similar safety breaches in future.

Patients and their families are not fully enabled to engage with the process as partners and their questions are not always sought. They do not always receive open, honest and straightforward answers to their questions. The witness testimonies of patients and families are not routinely collected and, when they are, they are not treated as they should be; that is, as evidence in the same way staff testimonies are treated. The current situation is not tenable and must change.

Frontline staff, who come to work to help and support patients to achieve the best quality of health they can, consider the current process to be blame-orientated and not learning-orientated. It does not embrace the basic principles of a credible review process, a reasonable expectation of fair treatment, or the right to know of any criticism that is to be made and its relevant evidence-base. Staff are most frequently engaged as passive recipients to the process, which is not a good platform for learning and positive change.

The SAI review reports largely do not evidence a defendable approach to the review and identification of learning arising from unexpected patient harm. There are several contributory factors, including:

- Staff asked to lead the reviews are mostly asked to do this on top of pre-existing work commitments, including frontline patient care duties.
- The level of training provided to staff that are tasked with leading SAI reviews is insufficient and is not informed by regionally agreed competencies or a core patient safety training strategy or curriculum.
- The regional timescales allowed for undertaking a complex review, including meaningful engagement with a patient and their family, are unrealistic and lead to a bureaucratic process.
- The regional report templates are not designed to support the delivery of a quality, evidence-based report.

It is worth noting that since this review was commissioned, a number of Public Inquiries, patient recall and lookback exercises have been initiated in Northern Ireland. The Expert Review Team considers that such lengthy inquiries and large-scale pieces of work could be avoided by a robust system for deriving and implementing learning from SAIs. Ineffective systems and processes for review

and identification of learning emerging from SAIs, not only damage public confidence and trust in the SAI process, but also adversely impact on the trust of patients, their families and the public in the healthcare system as a whole.

There is now an important opportunity to achieve better for patients, for staff and for Health and Social Care services across the region. It is patently evident that continuing as we have been is not an option. The Expert Review Team has made five recommendations that, if implemented, should transform the current approach to learning from and preventing recurrence of harm within Health and Social Care in Northern Ireland. The RQIA look forward to working in partnership with DoH, PHA, HSC Trusts, patients, families and carers to deliver on a new and improved regional system for optimising the learning from adverse incidents which occur in Health and Social Care services and ensuring every opportunity is seized to improve the safety of Health and Social Care services.

6.0 Recommendations

The following recommendations are intended to deliver a new regional policy for reporting, investigating and learning from adverse events.

Recommendation 1:

The Department of Health should work collaboratively with patient and carer representatives, senior representatives of Trusts, the Strategic Performance and Planning Group, Public Health Agency and Regulation and Quality Improvement Authority to co-design a new regional procedure based on the concept of critical success factors. Central to this must be a focus on the involvement of patients and families in the review process.

Recommendation 2:

Health and Social Care organisations should be required to evidence they are achieving these critical success factors to the Department of Health.

Critical success factors

Appendix D provides an example of the critical success factors the Department of Health may wish to use to commence the work of redesigning the region's approach to learning from SAIs.

An example of a critical success factor and its core objectives:

- Families and patients are supported as active partners in the review process as much as they wish to be involved, including the involvement of an appointed advocate.
- Patients/families experience a compassionate and empathetic approach, which includes the method and frequency of contact throughout the review process.
- The voice of the patient and family is heard, their testimony is captured and they have the same status as any professional contributing information to the review process.
- The patient and family have a named source of support outside of the review panel. The role of this individual is clearly defined, including their authority to act in the best interest of the family.
- Questions asked by the patient and family are responded to fully, with honesty and integrity.
- The patient and family are encouraged to contribute to and influence the terms of reference for incidents identified as requiring in-depth.
- Patients/families are taken through the interim findings of the review and they are provided with enough time to enable them to read, comment on and influence the content of the final report.

How individual HSC organisations deliver these objectives is for them to determine. However, what must be required from all HSC organisations is evidence of achievement and an equal opportunity to be involved. This must be validated by patients and families who have experienced unexpected healthcare harm of a nature that warrants a dedicated review.

The Expert Review Team recommends that a co-production model, involving frontline staff, patients and their families, be adopted regionally to shape any way forward.

Implementing this recommendation will achieve:

Meaningful involvement of patients and families as partners in the SAI review process. This should incorporate a restorative process delivered within a culture of learning and improvement. The incident of harm and its resulting impact is one which the patient and their family must manage and live with. Therefore, it is essential that the patient and their family are at the centre of the review process if their trust in the Health and Social Care service concerned is to be retained.

This recommendation should address the risk of:

Further loss of public confidence in the systems of learning from healthcare harm and, importantly, risk of unnecessary harm to patients/families.

Recommendation 3:

The Department of Health should implement an evidence-based approach for determining which adverse events require a structured, in-depth review. This should clearly outline that the level of SAI review is determined by significance of the incident and the level of potential deficit in care.

What is required:

RQIA has found throughout its inspection and review work, widespread practice, where adverse outcome for the patient often drives the requirement for a Level 2 or Level 3 review. This practice must change. Not all unexpected harm, irreversible harm, and unexpected deaths are attributed to mistakes in the care or treatment provided.

Clear guidance is necessary which includes the implementation of a system of early, structured case assessment, taking place within one to two weeks of the incident occurring. This will deliver a greater degree of clarity regarding the degree of variance from expected care and treatment standards, and, on this basis, a proportionate decision can be made regarding the subsequent level of review required.

The Expert Review Team suggests:

- In all cases where there is concern that an identified variance may have contributed to the outcome for the patient, an in-depth examination of those variances is required.
- Where a serious breach in the expected standards of safe care is identified, an in-depth examination is warranted – even if the variance itself is not considered to have contributed to the patient's outcome.
- Where the incident represents issues known to have been previously examined individually, that consideration is given to conducting a structured, in-depth, whole system review rather than repeating another individual incident review which, by its nature, is unlikely to include systems-based learning and improvement.

In all the above suggestions, it is expected that there will be involvement and engagement with the harmed patient and their family.

Other considerations that should be incorporated into a decision-making process:

- It should be considered whether a further Level 2 or Level 3 review will achieve more learning than has already been achieved by a previous review.
- It should be considered whether a safety improvement plan, regarding issues relevant to this SAI, is already underway. If yes, then the value of an individual incident review should be determined. Consideration must be given to incorporating this case into the pre-existing safety improvement project.

Implementing this recommendation will achieve an approach that:

- Is proportionate.
- Makes appropriate use of public funds.
- Allows review panels to focus in-depth reviews on those cases where there is the greatest opportunity for learning and improvement.
- Enables the relevant clinical teams and service managers to retain ownership of incidents that do not reach the threshold for a level 2 or 3 review. This ensures recognition of the skill, competence and integrity of staff that are entrusted with the delivery of safe patient care.

In summation, this recommendation should address the risk of perpetuating a situation where the volume of level 2 reviews required exceeds the capacity and capability to deliver to a credible standard. The resulting proportionality will also support measurable improvements in safety and quality. This will also serve to address the risk of prolonging the dissatisfaction with the process that has been expressed by patients, their families, and frontline staff.

Recommendation 4:

The Department of Health should ensure the new Regional procedure and its system of implementation is underpinned by 'just culture' principles and a clear evidence-based framework that delivers measurable and sustainable improvements.

Recommendation 5:

The Department of Health should develop and implement a regional training curriculum and certification process for those participating in and leading SAI reviews.

What is required:

There are several issues that must be addressed if the overall standard of how serious incidents are reviewed and learnt from is to improve. These include:

- A regional framework that makes clear the key factors for success[4], against which each Trust/DoH (SPPG) is performance managed.
- A regional approach that delivers international good practice in the science of review. The development of a standard operating procedure that focuses on the practice of investigating rather than performance targets would support this.
- A process that embraces a just and fair culture where staff are supported through a constructive learning process and not scapegoated should deficiencies in systems or processes be found.
- A quality assurance system that makes explicit the accountability of senior managers within each Trust/DoH (SPPG) organisation, alongside a mechanism for holding them to account for SAIs signed-off as acceptable.
- A regional training curriculum, competency framework, certification or accreditation process and mentorship programme.
- Investigators of SAIs must demonstrate that they have the competencies to do so and have completed a programme of training in line with regional curriculum requirements.
- Educators/trainers and mentors must demonstrate that they have the right knowledge and competencies. Furthermore, they must complete an assessment process in order to be included on a region-wide approved provider register. Only providers on this register can provide review training to Trusts/DoH (SPPG).
- A fair and reasonable amount of time to conduct a credible review must be provided. This must include time to engage and involve the family/patient in an empathetic, meaningful and respectful way.
- A single new report template and regional style guide must be designed. This must facilitate a consistent approach to report formulation and presentation, with enough flexibility to allow a report writer to adapt it to meet the needs of the review conducted.

[4] That is the critical success factors and the core objectives for each success factor are agreed, and adopted by all Trusts and HSCB.

A new approach must achieve:

- Greater flexibility in approach, that focuses on the opportunity for learning and safety improvement.
- A lower number of in-depth RCA reviews. However, where early assessment indicates that this depth of review is necessary, there must then be the capability and capacity in the system to do this well.

Implementing this recommendation will achieve:

An approach to learning from harm that HSC staff and the public can have confidence in, in terms of:

- Learning lessons.
- Measurable safety improvement.
- Transparency.
- Alignment with the core principles and hallmarks of a robust review process.
- Restoration and reconciliation.

This recommendation should address the risk of:

A system of learning that is overwhelmed by too many reviews, few of which lead to measurable improvements in safety or learning of any significance. This will enable the HSC Trusts to develop a flexible and innovative approach to learning from harm; one which engages the patient and their family in the process and mitigates the risk of perpetual mistrust.

There is no single activity that will achieve the above recommendations. There must be a comprehensive recalibration of the approach to the requirement for, and delivery of, SAI reviews across the region.

Appendix A: SAIs by Category and by HSC Organisation

	SAI Level	Belfast Trust	Northern Trust	South Eastern Trust	Southern Trust	Western Trust	NIAS	Primary Care	Total
Maternity related	Level 1	2	5	3	0	4	0	0	14
	Level 2	0	0	1	1	0	0	0	2
Sepsis	Level 1	1	0	2	0	0	0	0	3
	Level 2	0	0	0	1	0	0	0	1
Choking	Level 1	0	0	1	0	0	0	0	1
	Level 2		1	0	0	0	0	0	1
Never Event	Level 1	1	0	3	0	1	0	0	5
Reference to Private Hospital/Nursing Home	Level 1	1	1	0	0	1	1	0	4
Person with a learning disability who died from a treatable condition	Level 1	0	0	0	0	0	0	0	0
Primary Care	Level 1	0	0	0	0	0	0	4	4
Reference to a person with a learning disability in Residential Care	Level 2	0	0	0	1	0	0	0	1
Other Level 1 SAIs	Level 1	0	0	1	0	0	3	0	4
Other Level 2 SAIs	Level 2	5	3	2	11	4	0	0	25
Other Level 3 SAIs	Level 3	1	0	0	0	0	0	0	1
Total SAIs reports to be assessed		**11**	**10**	**13**	**14**	**10**	**4**	**4**	**66**

Source: Information provided by HSCB and HSC Trusts. Categories suggested by DoH

Appendix B: Other Organisations that were offered the Opportunity to Input Into this Review

Organisation
Medicines & Healthcare products Regulatory Agency (MHRA)
Northern Ireland Adverse Incident Centre (NIAIC)
Health and Safety Executive Northern Ireland (HSENI)
Police Service for Northern Ireland (PSNI)
Safeguarding Board for Northern Ireland (SBNI)
Northern Ireland Adult Safeguarding Partnership (NIASP)
Information Commissioner Office (ICO)
British Medical Association (BMA)
General Medical Council (GMC)
General Dental Council (GDC)
Northern Ireland Medical and Dental Training Agency (NIMDTA)
Pharmaceutical Society Northern Ireland (PSNI)
Northern Ireland Social Care Council (NISCC)
Royal College of Nursing (RCN)
Nursing and Midwifery Council (NMC)
Health Care Professional Council (HCPC)
Northern Local Medical Committee (NLMC)
Eastern Local Medical Committee (ELMC)
Southern Local Medical Committee (SLMC)
Western Local Medical Committee (WLMC)
UNISON
Unite the Union
Northern Ireland Public Sector Alliance (NIPSA)

Appendix C: Improvements Suggested by Staff

During the engagement process, staff were asked to share any suggestions they felt would improve the SAI review process or patient and family engagement. Staff suggestions were used to formulate the following suggested improvements.

Suggested improvements to the SAI process

Classification of incidents

- The identification of incidents requiring an in-depth review must be driven by a structured assessment, which identifies:
    - a significant learning opportunity
    - the presence of significant care lapses, or care concerns
    - the depth and range of family questions

  Eliminating the determination for an in-depth review based on incident type and/or patient outcome alone can minimise the number of reviews with little impact on improving safety.
- Incidents involving suicide should not automatically be classified within the SAI process.

Timescales for Conducting SAI reviews

- Overwhelmingly, HSC staff consider that the timescales for conducting SAI reviews need to allow greater flexibility and take account of the complexity and the needs of the patient and family.
- A structured timescale approach that outlines the importance of capturing factual accounts and situational context within the first 48 hours post-incident, and early capture of information from families followed by a realistic period to allow an initial assessment of the information before determining what subsequent review is required, along with its depth and approach.

Terms of Reference

- The terms of reference for SAI reviews should be specific to the incident and referred to as key lines of enquiry to reflect a more learning-based approach.
- Terms of reference must include patient and family questions, where the patient and family have questions.
- The practice of pre-determined terms of reference that are used for all SAIs should desist as it provides no meaningful structure for the review process.

Staff Involvement

- Staff said that to achieve a ‘just culture’ and optimal learning they needed to be more involved in the process, specifically:
    - Their team leaders need to be involved in decisions over what to review, at what depth, and why

- Involved staff need an early invitation to capture a full account of what had happened and the situational context of the day, shift, or relevant period
- There needs to be a shift away from only reviewing documents to engaging involved staff in conversation about what had happened
- More group learning approaches could be utilised, such as after-action review
- Providing feedback on a high quality draft of the review report, that their comments are listened to and taken account of by the review panel
- In formulating recommendations
- In contributing to the design of action plans
- In participating in a post review learning event.

Communication with Staff

- Staff involved in an incident should receive notification that an SAI has been requested and be provided with a copy of the agreed terms of reference or key lines of enquiry, as well as information about who is conducting the review.
- Staff involved in an SAI ought to expect their team leader to receive update reports regarding the progress of the review so that the whole team is informed about this.
- Several staff thought a website or shared area should be established to keep those staff involved in an incident up to date on the progress of the SAI review while maintaining confidentiality.

SAI Review

- Currently, the SAI process is perceived as a negative review that does not support a 'just culture'. It must be mandated that the aspects of care that met or exceeded care standards, as well as those aspects that could have been improved, are reported on. This includes interventions that may have mitigated the impact of the incident.

SAI Review Panel

- Where it is identified that there were, or may have been significant care lapses, staff considered a dedicated SAI review panel from outside the Trust was required. This includes the lead reviewer and the subject advisors/field experts. Staff considered that such a team needed to be appointed by an external agency such as the HSCB/PHA.
- There should be a set of competencies, skills and knowledge required of the chair of an SAI review panel/lead reviewer, and the subject advisors/field experts asked to work with this individual.

Independence

Staff recognised that achieving complete independence was not feasible. However, they considered that:

- The lead reviewer/chair should not come from the service involved in the incident.
- Mentorship should be available for lead reviewers/chairs to support them in maintaining objectivity and impartiality.
- Ideally, a non-clinician with the right investigatory skills and competencies should chair the SAI review panels.
- A lay person or trained family advocate should be included in the SAI review panels. This would support meeting family needs and writing a report that is understandable by a non-technician.
- Optimal use of interventions such as web-conferencing and remote web-based interviews could be utilised to support involvement of independent technicians without the excessive cost often associated with this.

Staff Support

- Staff involved in an incident must be given protected time to prepare and attend interviews or meetings during the SAI review.
- Staff involved in an incident must be given the opportunity for pastoral/psychological support to deal with traumatic incidents.
- A rapid team debrief post incident must become normal practice.
- All SAI teams must include an administrator to support its smooth delivery and to ensure that the time of frontline, professionally qualified staff is used appropriately.
- Corporate teams responsible for patient safety must have the necessary competencies required to provide support and mentorship to SAI leads/chairs.
- Staff asked to lead SAIs must have received a minimum of two days training, plus mentorship and coaching support so that they can lead the process competently.
- Staff required to conduct the initial reviews of incidents before a decision is made to progress to SAIs need to know how to conduct a structured review, and what information is required to do this competently.

Advocacy

- Northern Ireland needs to engage with patient advocacy organisations to develop a system where lay people can become accredited advocates for families following patient safety incidents.
- Publicly funded independent advocacy should be available for patients/families that require this and where there are concerns about the adequacy of care and/or treatment offered.

Recommendations

- Staff need protected time to participate/lead in Quality Improvement Action plans emerging from SAI reviews.
- Multidisciplinary staff should be brought together to help develop outcome-focused recommendations. This should not be the sole domain of the SAI review panel.

- Recommendations from SAI reviews should be benchmarked against core criteria, and the teams and services involved in the incident must be invited to comment on the appropriateness of the recommendations made.
- When contemplating whether a recommendation is or is not accepted and how it is treated, due consideration must be given to pre-existing safety and quality improvement projects already underway or planned.
- Recommendations from SAI reviews need to be outcome-focused and drive action plans that deliver measurable and sustainable improvements in the quality and safety of care.

Learning

- There must be more formal processes for disseminating learning from SAI reviews. The Oxford Model developed in the 1990's and successfully utilised by Mersey Care NHS Trust is an example of this.
- Each Trust must be required to demonstrate not only what it has learnt but how it has improved. This will drive disseminated learning.
- RQIA and other regional bodies must show how the learning within individual Trusts is captured and used for learning across Northern Ireland.

SAI Review Reports

- Feedback from all key staff involved should be considered in the finalisation of an SAI review report. This assures factual accuracy and greater engagement by frontline professionals.
- A meeting with all staff associated with the incident, and who provided information to the SAI review panel, should be conducted to enable findings, conclusions and recommendations to be discussed and agreed.
- The SAI review report template should be revised to include a section that allows greater articulation of patient and family engagement.

Action Plans

- How action plans are developed must be in line with good practice, rather than copying and pasting recommendations into an action plan template. This does not deliver sustainable or measurable change.

General

- The practice of retrospective recordkeeping in the 72 hours post incident needs to be enabled. Where this is not possible for whatever reason, accounts of involvement must be collected.
- SAI reviews should focus less on assigning blame and scapegoating, and instead embrace the principles of a ‘just culture’ and justifiable accountability.
- The SAI process should be reviewed to examine how best to review future incidents in a more proportionate way.

Suggested improvements for patient and family engagement

Information for Patients/Families

- Patients/families should be better informed of the SAI review process. For example, there could be better quality information leaflets available, or a video or podcast explaining the process on the DoH or RQIA's website.
- The SAI process must be explained to patients/families before the process commences so they can have realistic expectations.

Communication with Patients/Families

- There must be clear standards of how a patient and family should be communicated with during the SAI process, with patients/families asked for formal feedback at the end of the process via a questionnaire or online survey tool. This should also accommodate requests for anonymity.
- The terms of reference/key lines of enquiry must be shared with patients/families prior to an SAI review commencing, and these must include the patient and family questions alongside technical clinical/process-based questions.

Patient and Family Engagement

- Trusts must demonstrate their commitment to the SAI process and to the patients/families affected by SAIs by ensuring senior management are actively involved in communications with families. This is particularly important at the start and end of the process.
- Staff must receive training from experienced advocates and families who have experienced the SAI review process so they know how to achieve and maintain positive engagement with a family.

Appendix D: Examples of Critical Success Factors

The factors listed below are examples of critical success factors (CSF), previously developed by an HSC organisation in the UK and provided to this review by Maria Dineen, member of the Expert Review Team. This list is not intended to serve as a definitive list; rather, its purpose is to provide an initial starting point for a wider conversation about what the critical success factors could look like in Northern Ireland.

Critical Success Factor 1:

We consistently value and engage meaningfully with patients and their families through the entire review (including complaints) process.

The core objectives for this CSF are proposed as:

- Patients/families experience a compassionate and empathetic approach.
- The voice of the patient and family is heard.
- The patient and family are well informed throughout the process.
- Questions asked are responded to with honesty and integrity.
- Patients/families are provided with the opportunity to contribute to and /or influence the terms of reference for incidents identified as requiring in-depth review.
- Patients/families are taken through the draft review report, and provided enough time to enable them to read, comment on and influence the content of the final report.

Critical Success Factor 2:

We consistently value and engage meaningfully with staff throughout the entire review (including complaints) process

The core objectives for this CSF are proposed as:

- Staff experiences a compassionate and empathetic approach.
- The voice of the staff involved in an incident is heard. This includes their experience of 'the day', and the 'context' in which the incident occurred.
- Staff involved are well informed throughout the review process.
- Staff are treated fairly and equitably, in line with NHS Improvements Just Culture Guidance.
- Staff involved in the incident, and other key staff informants to the review, are facilitated in reading the draft report and providing feedback on it relating to factual accuracy, tone and style.
- Staff involved in the incident and service(s) in which the incident occurred are actively engaged in designing the action plan to deliver measurable and meaningful improvement.

Critical Success Factor 3:

We will consistently show that measurable improvements in standards, safety and quality occurs, is sustained, and known about by staff.

The core objectives for this CSF are proposed as:

- There is a corporate action planning/lessons learnt group that acts as a repository for those issues identified in one division, but which have wider implications for other services / divisions within the Trust. A central approach will ensure these issues are assessed and addressed corporately.
- Within each division the safety governance group, lessons learnt and recommendations arising from reviews are a standing agenda item.
- Recommendations are targeted towards i) the local team ii) the local service/division and iii) corporate wide. Further they are mostly addressing systems improvement and not individual practice.
- There is an action planning method/approach that facilitates engagement of staff involved in service delivery and sets out clearly the range of activities required to deliver the intent of the recommendation.
- All action plans include how success is to be measured and at what frequency to assure sustainability.
- Recommendations are formulated to make clear their intent (i.e. what needs to be achieved if they are accepted and implemented).
- Staff are aware of the improvements implemented in their service and division as a consequence of reviews conducted, and more widely across the organisation.

Critical Success Factor 4:

Incidents will be reviewed proportionately i.e.: right level, right depth, and right breadth of review according to the volume and magnitude of errors (if any).

The core objectives for this CSF are proposed as:

- The Trust has an achievable and defined method/process through which harming incidents that meet the threshold for Duty of Candour (i.e. moderate harm and above) are assessed to determine the depth of review required and with what degree of independence.
- The Trust has a clear categorisation system for incidents that meet the threshold for Duty of Candour (and above) so that there is clarity between those that occurred despite good care, and those that were caused by mistakes in care delivery. (E.g. Category A means care and treatment was appropriate, and category D means there were several lapses in care and treatment that may have contributed to the outcome).
- The Trust assigns the review of cases where there may have been a contribution to the harm because of mistake to a case reviewer who has the right competencies to lead and deliver a more complex review.

- Terms of reference for reviews are bespoke and make clear the relevant technical questions that must be asked and answered, alongside any family questions that have been posed.
- The Trust has a review framework, and approach, that allows a range of methods and tools to be employed to meet the discrete requirements of each review.
- The Trust has in place a process to enable early preservation of information including memory capture, so that the assessment of incidents and any subsequent review is well informed and can be explored to the right depth and breadth.

Critical Success Factor 5:

Reviews are conducted using appropriate methods and tools, and in line with good project management principles, assuring delivery within an agreed and realistic timescale.

The core objectives for this CSF are proposed as:

- The Trust will have enough staff trained to undertake the case screening element of the review journey within 10 working days of incident occurrence.
- The Trust will have enough staff trained to a higher level of knowledge and competency to delivery those reviews that are categorised C or D (i.e. care/ management a bit 'hit or miss' or serious lapses are identified).
- The Trust will commit to a stepped review process including clear boundaries for the review arising from carefully formulated terms of reference that make clear the necessary technical questions as well as including family questions.
- Staff asked to act in a case screening or lead reviewer/case reviewer capacity will have the necessary adjustments made to their pre-existing diary commitments so that they have a fair amount of dedicated time to deliver the review project.
- Specialist advisors will be allocated to the appointed case reviewer in a timely manner so that avoidable delays do not occur.
- The Trust will ensure for all category C and D reviews that there is reasonable administrative support provided to the case investigator so that working practices are as efficient as possible. (Category C and D - i.e. care/ management a bit 'hit or miss' or serious lapses are identified).

Critical Success Factor 6:

Review reports are consistently produced and meet the following standards:

- Well written.
- Understandable by a non-technician.
- Reasoned (i.e. evidence and not opinion orientated).
- Clear findings, conclusions and recommendations.
- Answer all family questions where it is possible to do so.
- Accessible.
- Validated.

The core objectives for this CSF are proposed as:

- The Trust has a practical approach to proof reading reports that includes insights from:
    - a technical advisor
    - a lay person
    - someone who has good grammar, and spelling
    - someone who is good at formatting documents, using 'smart report' technology.

- The Trust has a well-designed report template that includes:
    - acknowledgements
    - contents list
    - an executive summary
    - introduction (case over view and context of care, as well as outcome and reasons for the review)
    - a family section
    - a findings section (what was delivered to a reasonable standard, what could have been improved, any significant or serious lapses in care standards.)
    - what has changed / improved since the incident
    - what additional lessons learnt arose from this review
    - conclusions
    - recommendations
    - appendices

- Both the patient / family and the staff involved are provided with the opportunity to read and comment on the report when in good draft format. Their comments are listened to and incorporated into the final report document as far as it is possible to do so. Where it is not, they are advised of this and why not.
- Review reports are written empathetically and compassionately.
- Review reports are written in plain language so they understandable by all readers.
- Staff required to write review reports have a mentor who can support the development of their writing and presentation skills.

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