NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Reference: FOI.ICB-2324/205

Subject: Never Events and Unexpected Deaths

*I can confirm that the ICB **does hold some of the information requested**; please see responses below:*

QUESTION	RESPONSE
Please send the thematic review into never events, as referenced in the ICB's board papers from its March public board meeting on page 3 of the BNSSG quality report (February report for month 9 and quarter 3): https://bnssg.icb.nhs.uk/wp-content/uploads/2023/02/07.1-Outcomes-Performance-and-Quality-Committee-ICB-Board-Mar-2023.pdf	Please find attached as requested.
Please send the briefing paper written in relation to an unspecified mental health provider, and please send the reports from two investigations into unexpected deaths. Reference to these documents can be found in the ICB's December 2022 public board papers on page 16 of the BNSSG Outcomes, Performance and Quality Committee: https://bnssg.icb.nhs.uk/wp-content/uploads/2022/10/07.1-Outcomes-Performance-and-Quality-Committee-ICB-Board-Dec-22.pdf	Please find attached briefing paper. Please note that personal information has been redacted under Section 40(2). The consideration of the public interest test is outlined below. The ICB has reviewed the request and identified the two reports requested. One report relates to a patient out of area. The lead provider has requested that BNSSG ICB does not disclose the information as the information contained within the report is not relevant to a BNSSG

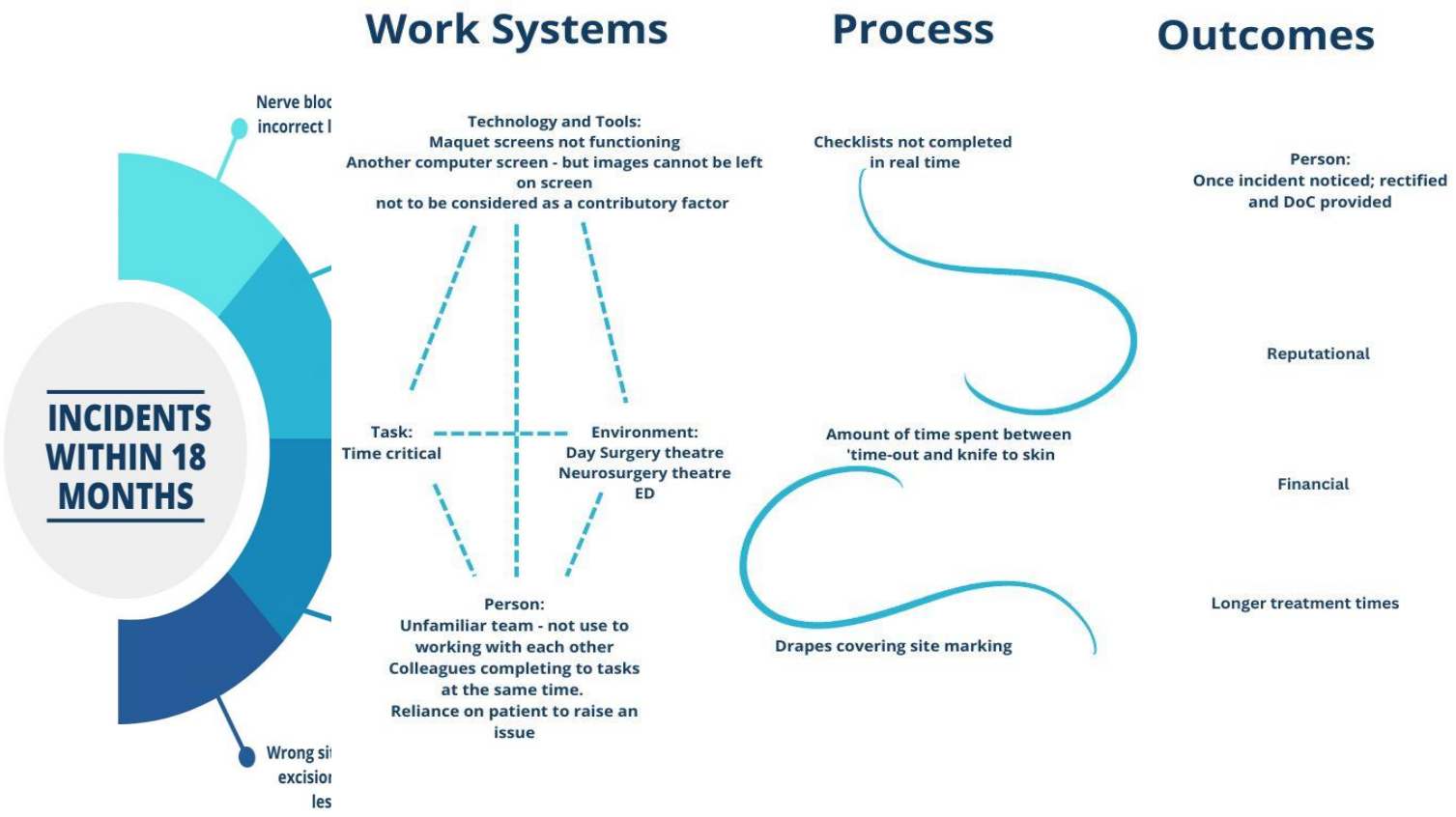
	patient and have suggested the requester contact them to respond to the request. The lead provider is Devon Partnership Trust and they have provided the following contact information: dpt.saferinformation@nhs.net The second report does relate to a BNSSG patient. Following review of the report, the ICB has concluded that the information if disclosed could make the patient identifiable and therefore have exempted the information under Section 40(2) of the FOI Act. The ICB notes that information relating to deceased individuals is not covered by data protection legislation. However, there is a duty of confidentiality which continues after death. The ICB has considered whether the report could be redacted or anonymised to support disclosure. The team have reviewed the report and concluded that the personal information is integral to the understanding of the report and therefore disclosure of any unredacted sections would not make sense. Therefore, the ICB has decided not to disclose the report. The ICB has considered the public interest test in relation to this request. **Disclosure of the information**

	The ICB has a duty of: • Transparency and accountability: It is important that the public can see and understand the work undertaken by the ICB • Upholding standards of integrity: It is important that the public can hold public authorities to account • Ensuring justice and fairness for all: The public needs to be assured that public authorities are reviewing significant events and applying learning for the future The ICB recognises that investigations into never events are of interest to the public. These are events which should never happen and therefore there is an interest in how these events have occurred and also interest in any learning which has been applied following the event. The public attend healthcare settings, often in difficult times, and there is an expectation that care is of the highest quality and the disclosure of these reports would provide assurance to the public that never events are being investigated and treated seriously. **<u>Maintaining the exemption</u>** The ICB has a duty of confidentiality for patients which extends to the deceased. Health information is considered special category data and therefore the ICB needs to take additional steps to ensure that information disclosed relating to health does not make patients

	identifiable. There is an expected high level of confidentiality regarding personal health records. As the personal data relates to the deceased, the ICB has to consider the impact of disclosure on the bereaved as well as the individual concerned. Never events are regularly discussed at Acute Trust public Board meetings as well as included within the ICB Board papers and the published Acute Trust Board papers contain the details of the never event and the result of any investigations, including any learning and process changes. NHS England also publishes a national list of never events data. All published data is anonymised.

The information provided in this response is accurate as of 30 October 2023 and has been approved for release by Rosi Shepherd, Chief Nursing Officer for NHS Bristol, North Somerset and South Gloucestershire ICB.

Never Event Themes



Never Events Thematic Review:

Thematic review of invasive procedure Never Event incidents occurring within North Bristol NHS Trust between 2015 to 2022

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Table of Contents

Never Events Review Introduction

Introduction

A thematic review of never event investigations conducted by the Trust over the past 2 years was commissioned due to the occurrence of four never event incidents within three months. Whilst the current never events are being investigated it was felt that looking to themes from previously reviewed never events may provide additional insight into the culture and inherent risk of these events occurring again.

The four never events that have occurred since November 2022 are all wrong side/site procedures:

- Incorrect labelling of fractured neck of femur x-rays (the left side was labelled as the right side). The patient had a nerve block in the Emergency Department on the incorrect side and went on to have a nerve block on the incorrect side in theatre ahead of a wrong side hemiarthroplasty (2 never events in one episode of care: wrong side nerve block and wrong side surgery)
- A patient attended Plastic Surgery minor operations clinic for removal of a lesion on his scalp. The patient had two lesions on his scalp; the wrong one was removed
- A patient went to Interventional Radiology for a left leg angioplasty. The right side common femoral artery was punctured, and a sheath was inserted

Investigation reports for the never events that have occurred since November 2022 will be presented for approval in February and March's Patient Safety Committee.

Key lines of enquiry

- Structured review of previous Never Events to identify any themes
- Review of actions from previous Never Events to establish if they have been completed, if they have been effective and if they had a wide enough scope
- Review of NBT's response to CAS alerts relating to Never Events
- Review of national reports and recommendations related to Never Events to understand if there are recommendations that NBT should be considering

Methodology (including inclusion and exclusion criteria)

The four latest commissioned never event investigations relate to performing invasive procedures on the incorrect side of the patient's body. Never events recorded within the last 2 years were screened for relevance to the new never events.

Included:

Ref	Division	Speciality	Never Event Type	Brief Description
2021/86	NMSK	Neurosurgery	Wrong Implant	DBS Implantation, incorrect implantation of non-directional vercise electrode.
2021/8215	NMSK	Neurosurgery	Wrong Site Surgery	Burrholes for SDH evacuation drilled on wrong side of head.
2022/9120	ASCR	Vascular	Wrong Site Surgery	Foam sclerotherapy for varicose veins performed on wrong leg in outpatients' theatres.

2022/6851	ASCR	Neurosurgery	Retained Foreign Object	CVC guidewire left in during emergency craniotomy

Excluded:

2021/26020 – Wrong Route Medication. Excluded as neither theatre nor wrong site of procedure related.
2021/20012 - Wrong Level Surgery. Excluded as operation from 2014, Wrong level surgery excluded from never events revised list. As per the Never Events Policy and Framework 2018 section 7.7, this incident is not considered a Never Event. The policy states:

"Some definitions of Never Events have changed in this revision of the framework. Where incidents that used to meet the definition of a Never Event but no longer do so (for example, wrong level spinal surgery) are identified after publication of the new framework, they should not be reported as Never Events even if they occurred before publication. Previously reported Never Events, even if they no longer meet the definition of a Never Event, should not be retrospectively downgraded".

Review Process:

Each report was reviewed asking several structured questions related to three different themes:

- Patient details/outcome
- Procedure as standard
- Procedure as happened

Each report was also considered for indications as the organisational culture:

- Incident detection
- Organisational acceptance/practice

The four cases selected for review:

Wrong Implant – Deep Brain Stimulation (DBS) Implantation	The patient was admitted to NBT for a DBS implantation procedure to treat a long-term condition (central tremor). The WHO checklist was performed as expected, there was no LoCSIPP for using DBS implants in use at the time. Site marking was not applicable for this surgery as the procedure was bilateral. Non-directional (rather than directional) vercise electrodes were taken from the stock room and inserted during the surgery. Intraoperatively there were indicators that non-directional electrodes were being implanted, however, the operating surgeon was not aware that non-directional electrodes were available and the branding of the boxes for the two electrode types were near identical. The never event was discovered during the monthly stock check. The patient came to no harm as a result of the never event.
Wrong Site Surgery - Burrholes	The patient was admitted to NBT for an evacuation of a right sided sub-acute subdural haemorrhage via burrholes. The WHO checklist was completed as part of the procedure. Site marking is expected, and was performed, as part of the surgery. After time out the patient was prepped and draped as per standard procedure, which leads to the site marking being covered. Between time out and knife to skin there was an expected gap of around 20 minutes. During the 20 minutes, the patients head turned (unwitnessed). The surgeon proceeded to drill two burrholes, then paused before opening the dural membrane as they realised, they were on the wrong side. The patient was repositioned and the correct burrholes drilled.

Wrong Site Surgery – Varicose veins	Patient attended NBT for a right leg form sclerotherapy procedure to treat varicose veins, the right leg treatment was funded by the CCG as the varicose veins were impeding treatment of underlying ulcers. The procedure was completed in outpatient theatres. The WHO checklist process is different in outpatient theatres and relies on a reference poster (this was not on display at the time of the procedure). One person is required to do the WHO checklist and confirm laterality in the procedure. The incorrect leg was identified pre procedure (site marking was not in use for these procedures) and the foam sclerotherapy completed on the left leg. The incident was detected after the patient queried with the Trust as to which leg had had the procedure, the correct leg was then operated on.
Retained Foreign Object – CVC Guidewire	Patient was an emergency (lifesaving) admission and undergoing an emergency craniotomy. During the operation a central venous catheter (CVC) insertion was required (and transfer to interventional radiology) to try and stem blood loss. During the CVC insertion the guidewire was retained. CVC SOP checklist was completed retrospectively and indicated that the guidewire had been removed. The procedure was technically difficult and running concurrently with emergency neurosurgery. The individual preparing the drugs for the CVC was also assisting the line insertion and having to multitask. The patient was stabilised, the guidewire retention identified through a radiology image and removed. The patient subsequently died in hospital as a result of their condition.

Review Findings:

Outcome of review process:

Each report was reviewed against several questions relating to the three categories – patient details, procedure standard and procedure happened. Each report was also reviewed for themes relating to underlying local and organisational culture. The results of this are in the below table.

	21/86	21/8215	22/9120	22/6851	Comments	Theme
Patient Details and Outcome						
Age	68	80	77	40		n/a
Sex	F	M	M	F		n/a
Condition	Long term neurological condition.	Recently developed neurosurgical condition	Long term vascular condition	Emergency neurosurgical treatment	Although three of the surgeries were neurosurgical in nature, the conditions/procedures did not indicate a theme of neurosurgery speciality	Considered but not relevant
Contraindications	N	N	Y	N		n/a
Patient Outcome	No Harm	No Harm	No Harm	Pt Died	Patient died as a result of condition not as a result of the incident	n/a
Length of Care Episode	2 Days	5 Days	1 Day	48 Days		n/a
Readmitted to Theatre	N	N	Y	Y		n/a

Procedure as Should						
Date	23/12/2020	13/04/2021	20/02/2022	21/02/2022		n/a
What procedure	DBS Implantation	Evacuation of right sided SDH via burrholes	Right leg foam sclerotherapy	Craniotomy/CVC insertion		n/a
Elective?	Y	N	Y	N	21/8215 completed in emergency theatres	n/a
Consent?	Y	Y	Y	Consent 4		n/a
Site marking	n/a	Y	N	Y		n/a
WHO Checklist expected	Y	Y	Variant	Y		n/a
Was there a LOCSIP	N	N	N	Y		n/a
Procedure as Happened						
Was there unexpected pressure	N	N	N	Y		n/a
Was support called for	N	Y	N	Y		n/a
Anything unusual occur	Y	Y	Y	Y	All of the cases had an unusual event/situation that led up to the never event	Process responding to unusual occurrences
WHO Steps completed	Y	Y	Y	Y		n/a

WHO Point of error	TO	TO/KtS	?	SOP		n/a
Start on time	n/a	n/a	N	n/a		n/a
Timing of procedure	N	N	N	n/a		n/a
Equipment problems	Y	Y	N	n/a		n/a
Staffing issues	N	N	Y	n/a		n/a
Operational pressures	N	N	Y	Y		n/a
Medication involved	N	N	N	Y		n/a
Other learning points	Y	Y	Y	Y	Each of the four cases had learning points outside of the main review questions. These learning points were independent of each of the cases. Each case highlighted a specific unique risk.	n/a
Culture						
Detection	Stock Check – No Opportunity post procedure to detect	In Procedure	Patient reported	Detected on X-Ray. Multiple opportunities to detect post-procedure.		n/a
Practice outside of guidance	Y	Y	Y	Y	All cases had an element of a workarounds outside of official guidance	Workarounds outside of national guidance
Organisational acceptance?	Y	Y	Y	Y	All cases had an element of organisational structures enabling workarounds from official guidance	Workarounds outside of national guidance

Review Considerations

"Underneath every simple, obvious story about 'human error', there is a deeper, more complex story about the organization." Sydney Dekker

The review of the description of the incidents and what led up to the never event occurring found no underlying themes that could be attributed to an individual area, speciality, type of procedure etc. What was evident through the review was that there does not appear to be a standard invasive procedure process (SIPP) that specialities and divisions have to follow in order to perform invasive procedures. All the incidents were as a result of a specific set of circumstances that tested the underlying processes put in place at the local level. This finding indicates that quality improvement plans may be best targeted at an organisational level and how the organisation learns from events as a whole.

How does the Trust respond to a never event?

The first consideration is whether the recommendations and actions described within the reports have been successfully embedded. The second consideration is whether the recommendations and actions were determined for the speciality involved in the never event, that there might be a wider risk to the organisation and other specialities that undertake similar procedures/operations.

Ref	Recommendation	Action	Target of Action	Could this be audited	Potential risk outside of speciality?
21/86	Speciality theatres should develop a LocSSIP for intra-operative checking of implants	Write LocSSIP detailing when and how implants will be checked	Speciality	Yes	Yes
		Issue safety alert to raise awareness whilst LocSSIP is being developed	Speciality	n/a	n/a
	Feedback on the design of implant packaging should be given to the manufacturers	Share investigation with Medical Devices Safety Officer (MDSO) who can provide feedback to manufacturers.	Implant Suppliers	No	No
		Assess whether non-directional leads have had on impact on outcome of treatment	Speciality	No	No
		Remove non-directional leads from theatre stock room	Speciality	Yes	Yes
21/8215	Time-out or a 'stop before you block' type pause must occur immediately before knife to skin, and the exact surgical site must be	Surgeons and anaesthetists to agree whether time out should be moved closer to knife to skin, or whether an additional pause is needed	Specialities	Yes	Yes
		Surgical site marking policy must be updated to say that exact site	Policy author	Yes	n/a

	marked at this point. Imaging must be available on screen at this point.	of cranial surgery should be marked during time out or surgical pause.			
		Investigate a fix for the Maquet screens. If a fix is not possible the risk register entry must be reviewed.	Division	Yes	Yes
22/6851	The Vascular Access Service Lead should review the Vascular Access Device Policy & Central Venous Access policy for adults to: Standardise practice so that the operator will complete the checklist retrospectively Confirm the CVC checklist to be used and include in the prepared central line kits Review and consolidate the policies into one policy		Policy author	Yes	n/a
	Anaesthetics governance lead should explore trialling CVC packs with a wire release system which requires the guidewire to gain access to the CVC dressing and sutures as a human factors solution to prevent guidewire retention		Speciality	Yes	Yes
22/9120	It is recommended the vascular speciality governance lead should implement operation/procedure site and side marking in Gate 24 for the Vascular speciality to ensure standardised safe practice to reduce the chance of a wrong site surgery		Speciality	Yes	Yes
	It is recommended the Gate 24 clinical coordinator engages with staff in Gate 24 Theatres to revisit the key principles and correct use of the WHO checklist to ensure critical safety measures are performed effectively to reduce the risk of surgical errors.		Speciality	Yes	Yes

The recommendations from the four reports target, in the main, the specialities that were involved in the incidents. This, in the short term, enables assurance that these specific circumstances are unlikely to occur again for the respective specialities. It does, however, raise the question whether there is a responsibility for the Trust to expand the scope to ensure that other specialities and divisions are considered for their risk in terms of these individual learning points and/or how the Trust shares and communicates learning across Specialities/Divisions/organisation.

Implementation of Actions Following Safety Recommendations

Within the recommendations and actions from the four never events, there are three that if implemented should have resulted in observable changes Trust-wide.

Recommendation 1 - 21/8215 - Investigate a fix for the Maquet screens.

One of the actions identified through the Burrhole never event was to "Investigate a fix for the Maquet screens. If a fix is not possible the risk register entry must be reviewed." There should be two screens available for use in theatre, allowing one screen to be used for theatre administration such as completing the WHO checklist, and the other to display patient imaging at all times. Without two working screens imaging has to be taken down from screen to complete theatre admin, meaning the surgeon will need to leave the sterile field to log back into the computer in order to view imaging.

A report from a consultant surgeon is that theatre screens are not reliably working, requiring staff to log in and out to switch between imaging and Bluespier. Large non-maquet screens have been installed in most theatres, but not all of these are able to access non-NBT imaging. This is currently on ASCR risk register as a patient safety risk (risk ID 243) scored at 2.

Recommendation 2 - 21/8215 - Surgical site marking policy must be updated to say that exact site of cranial surgery should be marked during time out or surgical pause.

The guidance relating to surgical site marking is contained within the "Marking the correct patient for the correct operation" policy (CG-1). There is no visible audit trail available via the policy website to understand the status of previous versions of this policy, it is unclear when it was first approved or what changes have been made since first ratification. The cover sheet of the policy would suggest that it wasn't reviewed or updated between 2006 and 2021.

The "Marking the correct patient for the correct operation" policy, section 6.4 to 6.11 (see below table) describes how sites should be marked. Point 6.7 directly references the patient safety investigation (reference 11) on, this indicates that the policy was updated following the recommendation. However, the wording within the policy in relation to site marking is out of date e.g., for point 6.10 there is no clinical risk department within NBT, and specialities work within Divisions not Directorates. This indicates that although there was an amendment made to the policy this was to a small section and no further significant review has been completed.

Section	Wording
6.4	Marking of the operation site and side It is the responsibility of the clinician performing the procedure to ensure that the operation site and side is marked with an indelible marker in accordance with national standards (See Appendix 1).
6.5	It is accepted that on certain parts of the face and head, less direct marking or use of a washable marker is reasonable. In these circumstances particular care and attention is required when referring to the patient's records and when draping the patient and the patient and ward staff should be advised (verbally and in writing) to avoid disturbing the mark.
6.6	The process of marking should involve the patient and/or significant others wherever possible
6.7	In cranial surgical procedures, a surgical "Time-Out" or "Pause" must be adhered to immediately prior to skin incisions are performed, similar to the anaesthetic "Stop Before You Block" pause to confirm and mark the exact site and correct side of surgery about to be performed. Imaging must be available to review. (Reference 11)
6.8	When marking of the operation site may not be appropriate Emergency surgery should not be delayed due to lack of pre-operative marking
6.9	Some operation sites may not be appropriate for marking e.g. teeth, mucous membranes, bilateral simultaneous organ surgery such as bilateral tonsillectomy or squint surgery. Additionally, marking may be inappropriate where the laterality of surgery needs to be confirmed by exploration in theatres etc

6.10	Directorates should identify procedures that routinely cannot be marked, along with additional safety measures necessary, for circulation with this policy is other areas (a copy of which will be kept in the Clinical Risk Department)
6.11	Information as appropriate (see patient leaflet "Correct site surgery-making your surgery safer" – Appendix 2). This can either be photocopied or a copy can be obtained from (alerts and advice – correct site surgery – patient briefing) and their refusal documented in the health record. The Peri-Operative Record of Care should still be completed, and all checks undertaken, but documented that marking was refused.

22/6851 - The Vascular Access Service Lead should review the Vascular Access Device Policy & Central Venous Access policy for adults.

The Vascular Access Device Policy was due for review in September 2022, having last been ratified at the Clinical Effectiveness Committee in September 2019. A risk assessment was carried out in August 2022 as part of clinical policy review programme and a 6-month extension to the review date was granted by the Clinical Policy and Documentation Group. One of the recommendations following the investigation approved in July 2022 into a retained guidewire was to review and update this policy and the Central Venous Access Device Policy and consolidate the two policies into one. The Central Venous Access Device Policy is no longer available on the intranet; the Quality Governance Team are unable to find an audit trail of when this happened and believe it may have been prior to the transfer of policies onto LINK, rather than as a result of the two policies being amalgamated.

The recommendation from the actions is:

- The review recommends as an immediate action for specialities and divisions to provide a list of areas and procedures in which they perform invasive procedures (or plan to in future) outside of the theatre environment.
- Escalate risk of never events occurring due to faulty IT systems to get immediate action to repair or replace.
- The review recommends the "Marking the correct patient for the correct operation" policy is re-written in its entirety to ensure it is up to date with the current hospital environment and that it is compliant with National Guidance.

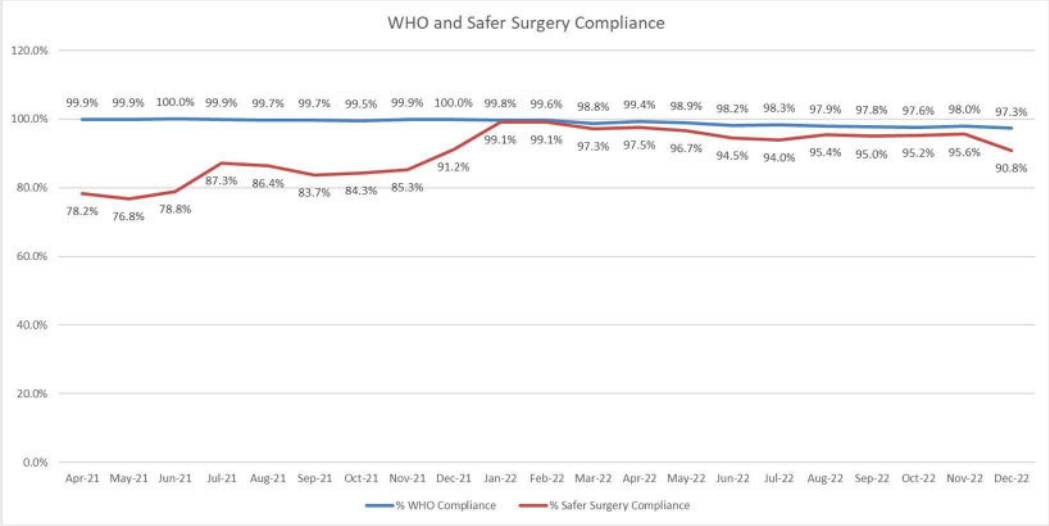
WHO Checklist Compliance

The surgical safety checklist is a simple tool designed to improve communication and teamwork by bringing together the surgeons, anaesthesia providers and nurses involved in care to confirm that critical safety measures are performed before, during and after an operation. This checklist was launched by the World Health Organisation (WHO) in June 2008 and was mandated for use in the NHS in January 2009.

The main governance measure of good practice for invasive procedures is adherence to the WHO checklist. This is recorded via Bluespier (previously Galaxy) and pulled through into the Trust's business intelligence software Qlik.

- WHO compliance is recorded as cases with all 3 WHO elements achieved (sign in, time out and sign out)

- Safer Surgery Compliance is recorded as cases with all 5 safer surgery elements achieved (pre-list brief, sign in, time out, sign out, session debrief).



The Trust targets for WHO compliance is 100% and safer surgery over 95%. There is evidence of a significant improvement trajectory in the safer surgery metrics in 2021 and early 2022 which is now showing a steady decrease. The WHO checklist compliance has also seen a similar trend with close to 100% compliance up to the early stages of 2022 and a slight but consistent decrease in the latter part of 2022. Closer examination of the data for October 2022 shows that of the 213 cases that were not safer surgery compliant, 148 were emergency cases that were failing because there was no evidence in Bluespier that a list debriefs took place. In order to count as a "yes" for debrief the patient must be marked as last on the list on the time out, this then brings up the option to confirm whether a debrief took place. The patients in October 2022 that are reported in Qlik as failing for having no debrief were all marked as not being last on the list, therefore there was no opportunity to say whether a debrief did or did not take place, skewing the data available in Qlik.

All the never events described within the review had evidence that the WHO checklist had been completed. The review also notes that where compliance targets have not been met this has primarily been in relation to the holding of debriefs and not site marking/checking. Although a decrease in compliance to safer surgery and WHO is seen, it is not considered contributory.

- The review recommends considering the use and scrutiny of the WHO and safer surgery compliance data, the quality of the data supplied.

Healthcare Safety Investigation Branch (HSIB) thematic analysis

In January 2021 HSIB published a national learning report titled Never Events: analysis of HSIB's national investigations. It reviewed 10 never event investigations and noted the following common themes that have been mapped to NBT's never events.

HSIB Common Theme	21/86	21/8215	22/9120	22/6851
People used mental shortcuts in complex situations which were not always reliable				
Not all staff had adequate training to undertake the clinical task key to the Never Event	1		1	
Variation in team composition and unclear roles and responsibilities impaired team performance			1	
Interruptions were common, resulting in unintentional or missed actions during tasks				1
Variability in task performance resulted from organisational influences and individual beliefs				1
The design of technology, including its usability, created risk and contributed to its misuse				
Similar tools and technology with different designs and similar labelling introduced risks of mis-selection	1			
Physical workplaces that have been designed without consideration of the people working within them created risks				
Local responses to national policy, guidance and alerts varied, were sometimes limited and created risks	1	1	1	1
Barriers to the Never Events explored by HSIB were ineffective in preventing the Never Events				

As expected, following the individual reviews, all the never events mapped to different themes within the HSIB analysis. In addition, all four never events all mapped to one of the common themes of the HSIB report (a common theme was defined as being present in more than two thirds of the investigation reports that were reviewed): "local responses to national policy, guidance and alerts varied, were sometimes limited and created risks"

Reference	Why linked to HSIB local response?
21/86	No LoCSIPP for intra-operative implant checking
21/8215	Surgical site marking policy did not include need to ensure site marking was still visible after patient was draped
22/9120	No procedure/site marking undertaken as standard practice
22/6851	Two SOPs available – one LocSIPP one not.

HSIB made 3 safety recommendations, all of which were aimed at national bodies:

Safety recommendation R/2021/111: It is recommended that NHS England and NHS Improvement revises the Never Events list to remove events, such as those presented in this national learning report, that do not have strong systemic safety barriers.

Safety recommendation R/2021/112: It is recommended that NHS England and NHS Improvement develops and commissions programmes of work to find strong and systemic safety barriers for specific incidents where barriers are felt to be possible but are not currently available.

Safety recommendation R/2021/113: It is recommended that the Centre for Perioperative Care reviews and revised the National Safety Standard for Invasive Procedures (NatSSIPs) policy to increase standardisation of safety critical steps that are common across all procedures.

They made one safety observation: It would be beneficial if significant safety events, such as those presented in this national learning report, continue to be reported and investigated by NHS organisations without apportioning blame or liability, using a recognised systems-based approach such as the Systems Engineering Initiative for Patient Safety (SEIPS) as used in this report.

National Standards for Invasive Procedures

Never event reporting and investigating is nationally mandated, there is additional scrutiny and recommendations provided to the Trust. National patient safety alerts are often developed as a result of patient safety incidents and may, overtime, seek to develop a set of control measures to eradicate those incidents occurring. Many present Never Event categories were preceded by one or more related patient safety alerts.

In September 2015, a patient safety alert was issued that required all NHS Trusts to review and fully implement the NatSIPPs (National safety standards for invasive procedures). All the four incidents reviewed, and the three new never event investigations involve invasive procedures that should be covered by the NatSIPPs.

NatSIPPs (National Safety Standards for Invasive Procedures)

As the four never events all mapped to the local response HSIB theme of “local responses to national policy, guidance and alerts”, these were mapped to the NatSIPP requirements to see whether the implementation of the NatSIPP could have impacted on the risk of these never events occurring.

Ref	Why linked to HSIB local response?	Reference within NATSIPPs	Comment
21/86	No LoCSIPP for intra-operative implant checking	4.10 Prothesis verification I. LocSSIPs should define how specific prosthesis requirements are communicated by surgical and other clinical teams to operating theatre and procedural teams.	A LocSIPP describing how prosthetics are checked would reduce the likelihood of this Never Event happening.
21/8215	“Marking the correct patient for the correct operation” policy (CG-1 did not include need to ensure exact site marked during time out	4.6 Procedural verification of site marking. 8. The mark must be placed such that it will remain visible in the operative field after preparation of the patient and application of drapes.	A LocSIPP stating that the site marking must be visible after draping would reduce the likelihood of this Never Event happening.
22/9120	No procedure/site marking in SOP.	4.6 Procedural verification of site marking.	A LocSIPP setting out correct marking would

		3. Surgical site marking is mandatory for all procedures for which it is possible.	reduce the likelihood of this Never Event happening.
22/6851	Two SOPs available – one LOCSIPP one not.	4.1 Governance and Audit 2. The organisation must identify sufficient time and human resources to support full implementation and audit of all LocSSIPs. This will include regular multidisciplinary meetings of the workforce.	Full implementation of LocSSIPs should ensure that no duplicate policies or process documents are available.

The NATSIPP guidance provides a governance framework (see table below) that should be implemented to ensure that the Trust monitors and responds appropriately and reduce the risk of never events occurring.

All the never events reviewed saw a deviation from the NatSIPP guidance.

"This standard will ensure that Local Safety Standards for Invasive Procedures (LocSSIPs) become part of a cycle of continuous quality improvement. It details the minimum expectations of local governance in terms of audit, local reporting and learning, and contribution to national surveillance and quality improvement."

NATSIPP governance framework			
No.	Description	NBT Requirement	Oversight committee?
1	The organisation must ensure that LocSSIPs are compliant with all National Safety Standards for Invasive Procedures (NatSSIPs).	NBT needs to have a process that identifies what procedures require a LoCSIPP and that these LoCSIPPs have a robust approval process and are regularly monitored.	Policy Review Group/CEAC
2	The organisation must identify sufficient time and human resources to support full implementation and audit of all LocSSIPs. This will include regular multidisciplinary meetings of the workforce	NBT must identify a committee and resource to manage the governance of LocSIPPs	Policy Review Group/CEAC
3	The organisation's clinical governance processes must include the requirement for regular audit of compliance with all LocSSIPs. This should include: • Compliance of LocSSIPs with NatSSIPs. • Compliance of local practice with LocSSIPs. • Evidence of action plans incorporating timescales for addressing noncompliance. • Evidence of regular review of LocSSIPs and their adjustment as required	An appropriate oversight committee must maintain a list of and oversee an audit schedule of LoCSIPPs	Policy Review Group/CEAC
4	Governance processes should support proactive improvement of safety systems as well as reactive responses to reported incidents	Never event reporting should be included and supported as part of the patient safety incident response plan (PSIRP)	Patient Safety Committee
5	All patient safety incidents and near misses should be documented and reported to the	Never event reporting should be included and supported as part of the	Patient Safety Committee

	organisation's incident reporting system. These should be analysed, investigated as appropriate, and learning should be fed back to staff for continuous improvement. This should be in accordance with organisational policy, ensuring compliance with the Serious Incident Framework and Never Event Framework.	patient safety incident response plan (PSIRP)	
6	The organisation must promote transparency and openness when near misses or patient safety incidents occur, in line with the statutory Duty of Candour.	Never event reporting should be included and supported as part of the patient safety incident response plan (PSIRP)	Patient Safety Committee
7	The organisation should ensure that outcomes of its governance activities in relation to LocSSIPs, such as audit of compliance, are disseminated to staff and commissioners.	Never event reporting should be included and supported as part of the patient safety incident response plan (PSIRP). Evidence of audit activity should be regularly feedback to clinical staff as appropriate.	Policy Review Group/CEAC/Patient Safety Committee
8	Each procedure team should have an identified team member responsible for collating relevant briefing and debriefing documentation, e.g. reviewing action logs and sharing information with local governance and management systems on a regular basis.	Specialities should have a process and designated role for collating WHO checklist compliance.	Divisional Management Teams/Patient Safety Committee
9	There must be arrangements that promote the escalation of issues identified that may have implications for the safety of services in other parts of the organisation. Organisations must comply with local and national processes that promote the sharing of information about safety issues with other organisations that provide NHS-funded care	Never event reporting should be included and supported as part of the patient safety incident response plan (PSIRP). The divisions and oversight committee must ensure that local findings are communicated across the Trust.	Divisional Management Teams/Patient Safety Committee
10	The organisations that created NatSSIPs will disseminate learning from the development, implementation and audit of LocSSIPs to organisations providing NHS-funded care. Organisations should develop ways of learning from this process and should work with NatSSIPs and other groups to share best practice and learning in relation to LocSSIPs and NatSSIPs.	NBT needs to ensure that learning from NatSSIPs and other organisations is incorporated into local governance processes	Policy Review Group/CEAC
11	When safety processes for invasive procedures are being introduced or changed, the organisation must assess the impact on compliance with these standards.	Oversight committee should ensure that new processes for invasive procedures are appropriately reviewed and are compliant with the NatSIPP standards	Policy Review Group/CEAC

The findings from the never event thematic review indicates that the Trust is not able to evidence implementation of the NatSIPP Patient Safety Alert from September 2015. There does not appear to be a robust governance arrangement to support policy and process behind invasive procedures.

In addition to the 5 investigations reviewed, there have been an additional 7 never events where the NatSIPPs may have been relevant. These seven investigations were reviewed in relation to whether their findings and recommendations linked to the implementation of NatSIPPs.

Ref	Description	Pre/Post	NatSIPP Relevant
18/25909	Retained foreign object – guidewire following right internal jugular central line placement	Post PSA Closure	Yes (LocSSIP was part of recommendations)
17/27681	Wrong site ureteric stent	Post PSA Closure	Yes (additional or emergency procedures require formal sign-in)
17/16753	Wrong size femoral head component implanted.	Post PSA Closure	Yes (NatSSIPs talk about compatibility of prosthesis)
16/33616	NG Tube misplaced and x-ray taken to confirm position was misinterpreted	Post PSA Closure	No
16/20889	Wrong site nerve block	During PSA	Yes (Surgical site mark covered)
16/17143	Wrong prosthesis used, left sided femoral and tibial base plate used for right sided operation	During PSA	Yes (SOP for checking process for surgical implants)
16/13361	Wrong site nerve block	During PSA	Yes (Surgical site mark covered)

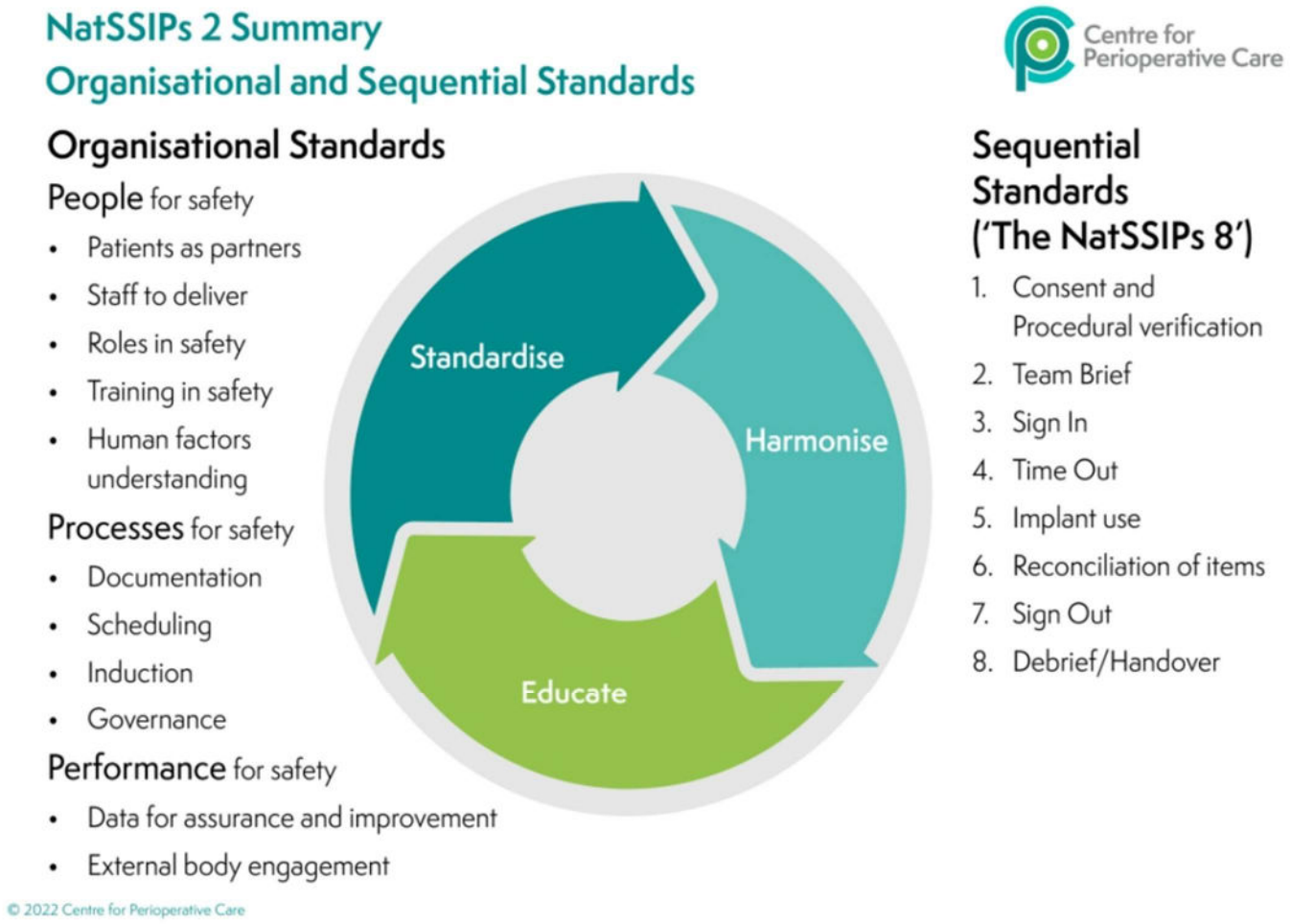
The review of the seven additional investigations indicates that six of the seven had links to the NatSIPPs requirements.

On 23rd January 2023 the Centre for Perioperative Care published NatSSIPs 2 which is a revision of the original NatSIPPs published in 2015. NatSIPPs 2 consists of two inter-related sets of standards; the organisational standards (expectations of what Trusts and external bodies should do to support teams to deliver safe invasive care) and sequential standards (procedural steps that should be taken where appropriate by individuals and teams, for every patient undergoing an invasive procedure).

The new guidance has several key principles to guide organisations in implementing NatSIPPs which the review supports and recommends is used as the guiding principles for any subsequent quality improvement programmes defined because of the review.

These include, but are not limited to:

- The need for a learning safety system supported by insight, involvement, and improvement.
- A structure of People, Processes and Performance within the organisational standards
- The requirement for adequately resourced organisational leadership and support for safety.



- The review recommends the creation of a working group to implement LocSIPPs and NatSIPPs 2, provide a gap analysis as to the governance arrangements for policies and processes relating to invasive procedures and circulate any related recommendations and findings to specialities who complete invasive procedures.

Themes of Actions from previous reports

The action plans and recommendations from the four invasive never event reviews alongside the seven additional invasive never events were reviewed for common themes in relation to how the organisation as a whole has learned from events of this kind.

From the 11 reports considered there were 44 specific actions. These broadly were related to one of four themes: documentation (8), process review (16), Staff learning (15) and equipment (3). There were also 5 actions that involved external organisations: GMC (1), MHRA (2) and Reps (2).

	Speciality			Trustwide	
Documentation of Process	Speciality Checklist	Speciality SOP	Speciality Led LocSIPP	Trustwide LocSIPP	Policy Updated
	1	2	2	2	1

For the documentation of process theme the majority of the documentation changes were at a speciality level (5 of 8), in that the decisions and range of the document change were described only on the speciality level. 1 of the actions specified a change in a Trustwide policy and two referred to the creation of Trustwide LocSIPPs.

Actual process	Compliance to existing process		Consider process change	
	Description of what should happen	Audit practice	Policy to be reviewed	Speciality to agree process
	7	2	4	3

An action was considered relating the actual process where the action describes considering a change or putting a process to review. There were also 7 actions that described what the process should have been rather than suggesting a change or action to prevent deviation from the process in future.

Staff Learning	Safety alert	Poster	Email staff group	Discussed speciality	Training compliance	Training content
	3	2	4	2	3	1

Equipment	Speciality check stock	Fix equipment	Trial equipment
	1	1	1

The actions relating to staff learning were generally short-term alerts, emails, or discussions. There were also three actions that related to equipment usage.

In the main if an action was to have a Trustwide consideration it was related to documentation, updating, or creating a Trustwide document stipulating the process to be followed. Decisions relating to process and compliance to process were focused on the speciality/team level.

With the launch of the Patient Safety Incident Response Plan (PSIRP) in June 2021 the process of developing safety recommendations and actions has been reviewed and significantly improved. Patient safety investigations follow a systems-based investigation model which enables actions to be targeted to the system rather than at the individual team and speciality level.

Organisational Culture

"Safety improvements come from organizations monitoring and understanding the gap between procedures and practice" Sydney Dekker

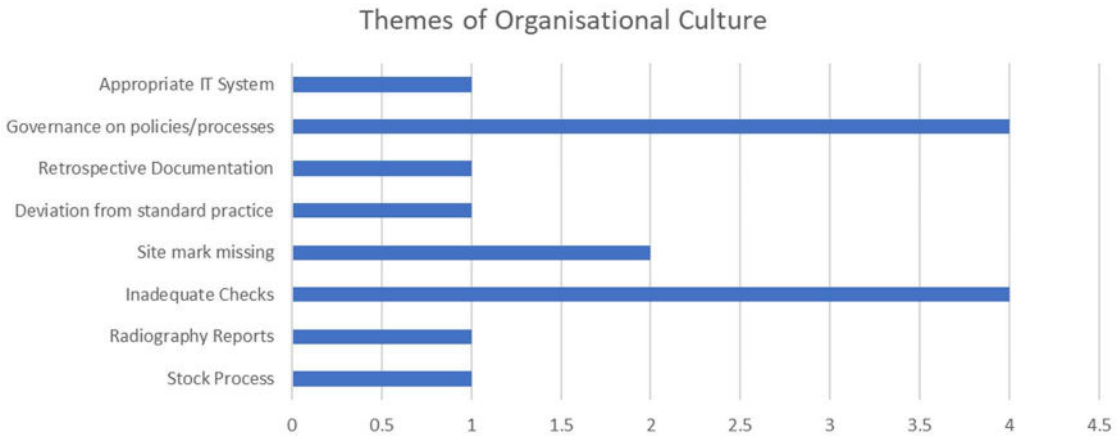
"the existence of procedures does not ensure their use. Without psychological safety, micro-assessments of interpersonal risk tend to crowd out proper responses." Amy Edmondson

In a human factors model of review its important to consider the specific aspects of each case as above, but also the organisational characteristics that influence work behaviour in a way which can affect patient safety. Is the job that is being required to be performed achievable by the individual that is being asked to do it. Does the culture of the organisation and its leadership support or influence group behaviour?

A key point to consider is what message is provided corporately through the rigour of systems of internal control – for example - governance mechanisms, scrutiny of information and assurance and the implementation of actions. This review recognises that governance mechanisms within a large and complex organisation require significant time and resource that this review has not explored. However, it is important to recognise the impact of this "corporate voice". How systems and processes are implemented, adopted, and used on a daily basis is an important

communication stream that should be listened to. For this review, a key consideration is the response to the NatSIPPs alerts, for which there is limited evidence of implementation. However, other considerations that show in Never Events include policies/procedures, work as imagine versus work as done and other parts of the infrastructure that support safety and improvement (for example, IT, equipment, and staffing).

Each of the investigations was reviewed for human factors elements and themes that provide us with insights into the relationships to organisational culture.



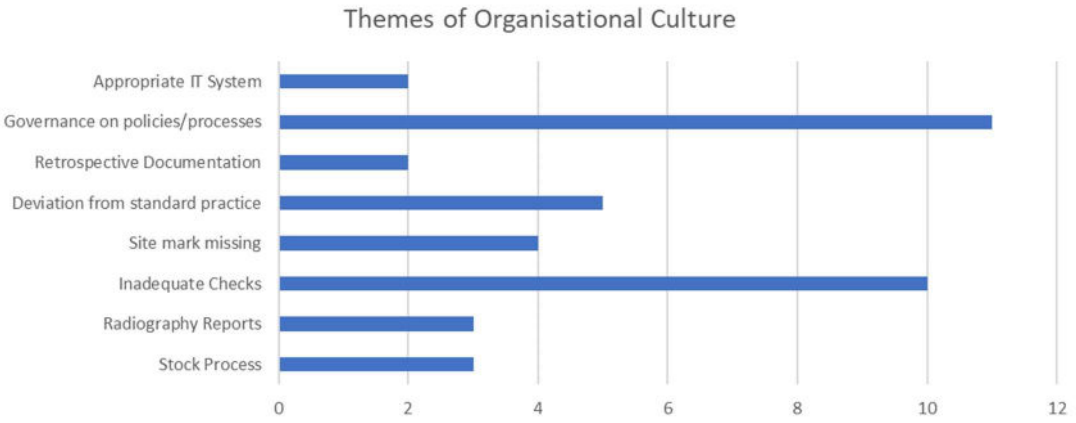
The thematic analysis indicates that there is allowance within the formal structure and processes to use workarounds and perform procedures without the appropriate checks. There was also an additional theme of governance of policy and processes and how these may deviate from national guidance.

The additional seven reviews were also considered for the cultural themes highlighted in the deep dive review. All of the seven had links to themes found in the original review.

Ref	Description	Pre/Post	Culture Relevant
18/25909	Retained foreign object – guidewire following right internal jugular central line placement	Post PSA Closure	Yes (Governance on policies/process, inadequate checks, retrospective documentation)
17/27681	Wrong site ureteric stent	Post PSA Closure	Yes (Radiography reports, Deviation from standard procedure, Governance on policies/process, inadequate checks)
17/16753	Wrong size femoral head component implanted.	Post PSA Closure	Yes (Stock process, Deviation from standard practice, Governance on policies/process, inadequate checks)
16/33616	NG Tube misplaced and x-ray taken to confirm position was misinterpreted	Post PSA Closure	Yes (Radiography reports)
16/20889	Wrong site nerve block	During PSA	Yes (deviation from standard practice, Governance on

			policies/process, site marking, inadequate checks, equipment)
16/17143	Wrong prosthesis used, left sided femoral and tibial base plate used for right sided operation	During PSA	Yes (Stock process, Governance on policies/process, inadequate checks)
16/13361	Wrong site nerve block	During PSA	Yes (deviation from standard practice, Governance on policies/process, site marking, inadequate checks)

Updated to include the additional never event reviews the themes the top two themes remain the same



The review indicates that most if not all the reported never events that have occurred since the release of NatSIPPs and the Patient Safety Alert in 2015 could have been prevented or had the risk of occurrence reduced significantly had the NatSIPPs been implemented fully within the Trust.

An absence of evidence of the governance of LocSIPPs and policies/procedures relating to invasive procedures may enable permission for workarounds and deviation from national guidance at a local level.

- The review recommends the creation of a working group to implement LocSIPPs, provide a gap analysis as to the governance arrangements for policies and processes relating to invasive procedures and circulate any related recommendations and findings to specialities who complete invasive procedures.
- The review recommends that the local culture of theatres and services/teams performing invasive procedures is reviewed whilst the wider Trust-wide governance structure is implemented.

Elective programme recovery and the impact of Covid

The Trust has changed significantly between 2016 and today and is subject to unprecedented operational pressures brought on by Covid-19. There are two incongruent themes of additional pressure that the Trust is managing, the pressure on bed capacity for emergency and non-elective admissions (compounded with the difficulty of providing safe care within the community) and the increasing wait times for elective procedures.

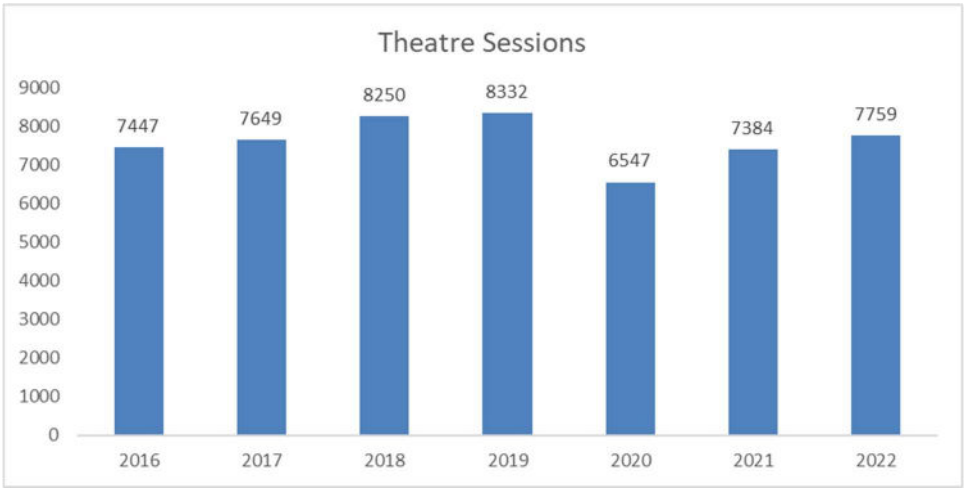
All elective theatre procedures and operations were paused during the first wave of Covid-19. There is a national and Trust strategic objective to reduce waiting lists and increase elective capacity. This is difficult to satisfy when there is reduced bed capacity and reduced staffing levels.

These two competing pressures are impacting on staff well-being and how able staff are to adapt to the changing care environment, burn out and turnover are higher than ever before. The RCN and ambulance strikes are indicative of a national picture of the pressures the health service and its staff are facing. The risks associated with operational pressures and ongoing strikes are recognised on NBT's risk register, with multiple risk entries:

- Risk 1310 There is a risk that delays in handing over patients arriving at NBT ED via ambulance may create immediate and ongoing risks for the patients in the ambulance. Score 16
- Risk 1497 There are risks to patient safety, experience, workforce, and regulation as a result of the implementation of urgent mitigating actions to address delays in ambulance offloads to ED as described in risk 1310. Score 20
- Risk 1455 There is a risk of low staff morale and a negative impact on their mental health wellbeing due to ongoing operational pressures and high levels of nursing staff vacancies. Score 20
- Risk 1596 There is a risk that patient safety may be compromised due to planned RCN Nurse's strike action in December 2022. This may also cause anxiety and stress to staff and a poor patient experience. Score 20
- Risk 1609 There are multiple risks to the Emergency Department posed by the planned Ambulance Strikes. The risk impact types are safety, experience, workforce, service delivery and regulation. Score 25

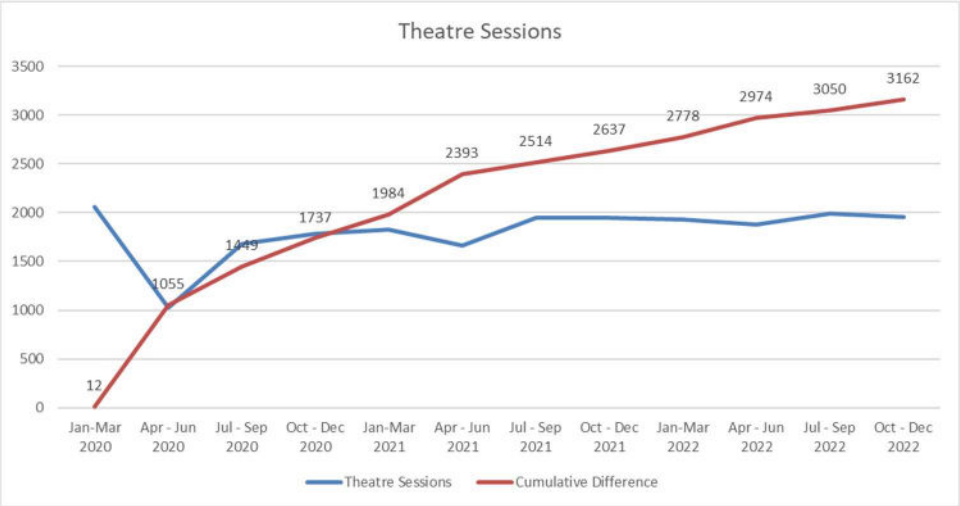
How impactful was Covid?

The graph below shows the elective theatre sessions performed from 2016 to 2022. There is an obvious dip in 2020 and an increase to average levels.



Although the capacity appears to be returning to what would be considered average (for the 7 years the average is 7624 a year), what isn't considered is the increased theatre sessions leading up to the Covid pandemic (suggestive of an increase in service demand). What is the cumulative effect of the missed theatre sessions during this time period?

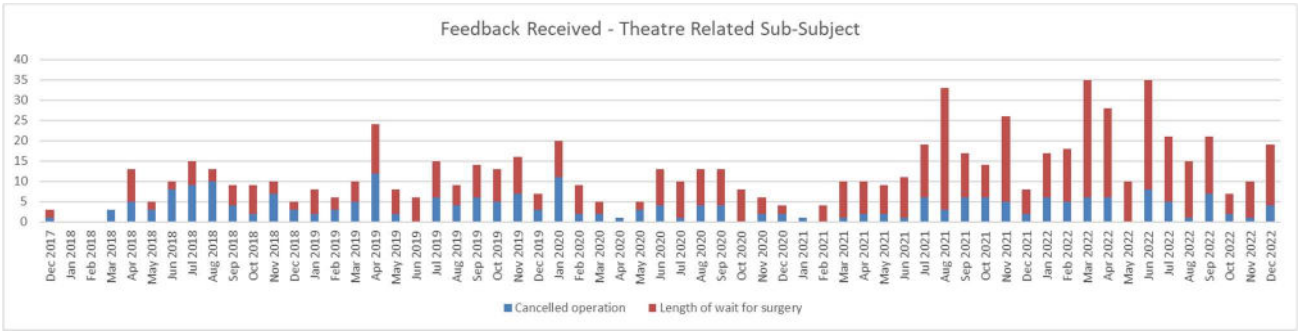
For 2019 the average theatre sessions for each quarter was 2071. For the second quarter of 2020 the total of theatre sessions that took place was 1028, this is a difference of 1055 theatre sessions. Mapping the cumulative effect of the missed theatre sessions as compared with the average 2019 quarter, the differential is more evident.



Although the difference is slowly reducing, there is still an increase in the cumulative difference between the average sessions in 2019 to now.

Patient Experience

The Patient Experience team code all feedback received to the Trust on Datix using subjects and sub-subjects. There are two specific sub-subjects that relate to operations – cancelled operation and length of wait for surgery.



The graphs indicate that there has been an increase in feedback received that relate to waiting times for surgery. This information will be the tip of the iceberg in relation to the experiences of patients, as most will likely be in contact with coordinators and outpatients' services in the first instance before formally feeding back to the Trust. These results will likely be replicated in specialities which will add additional pressure to an already pressed service.

Move from theatres to outpatient procedures

One theme noted within the more recent never events is the occurrence of the incident being outside of the regular theatre environment. In the example of wrong leg foam sclerotherapy previously this procedure would have been

completed within the Brunel theatres following the opening of the Brunel building and move from Frenchay. It is now a nurse led procedure within day-case outpatients. The move to day case outpatient procedures will likely support the reduction in the backlog and improve the waiting times for patients, however, it may also inadvertently increase the risk of never events. This review did not explore governance processes that support and inform decision making when moving a procedure from a theatre environment to a non-theatre environment. However, it is likely that a theatre environment has more established and embedded safety control mechanisms. Governance processes in moving such procedures should consider the impact on quality, for example, the gaps between safety processes and consideration of the minimum requirements for the new procedure location. The review recommends that an urgent review of the governance processes used in making such decisions is carried out and that the findings of this review report into the Patient Safety Committee.

- The review recommends as an immediate action for specialities and divisions to provide a list of areas and procedures in which they perform invasive procedures (or plan to in future) outside of the theatre environment.
- The review recommends that a Quality Impact Assessment (QIA) is completed for procedures usually conducted in a theatre environment that are now, or in future, carried out in a non-theatre environment. The QIA should consider the change in control mechanisms and the impact on the likelihood of a Never Event occurring in a less controlled environment.

Ongoing never event investigations

At the time of writing this review, three new never event PSIIs are still in progress so additional learning and recommendations are likely to be determined through the investigation process. However, preliminary considerations suggest that they also link to the themes discussed within the review.

Investigation 1: Wrong site surgery and wrong site block

The patient was admitted to NBT with a fractured neck of femur. During admission to ED there was an incorrect labelling of admission X-rays (wrong side) (21/10/22) and a subsequent nerve block performed on incorrect limb. A Left hemiarthroplasty was then performed on 22/10/22 when it should have been right hemiarthroplasty. As part of the patient's peri-operative preparation for surgery, a wrong site nerve block was performed prior to the left hemiarthroplasty.

The final report and safety recommendations are due for sign off in February 2023 Patient Safety Committee, with the action plan signed off in the following month's committee meeting.

Investigation 2: Wrong site surgery

Patient attended clinic after being referred by GP for lesion on forearm. During consultation a lesion was found on the frontal scalp. On day of treatment a second lesion on the head was removed. The correct lesion was removed during a separate procedure. Normal practice is to take photos if there is a concern of risk of wrong site surgery,

which did not take place in this instance as it was believed that there was a low risk of this occurring due to the description on the TCI.

The final report and safety recommendations are due for sign off in March 2023 Patient Safety Committee, with the action plan signed off in the following month's committee meeting.

Investigation 3: Wrong site surgery

Patient attended for left leg angioplasty. During procedure the right common femoral artery was punctured, and sheath inserted. During the procedure it was noted that the wrong side had been punctured. The incorrect sided sheath was removed, and manual compression was given. Once able, with patient consent, a left leg angioplasty was successfully performed.

The final report and safety recommendations are due for sign off in March 2023 Patient Safety Committee, with the action plan signed off in the following month's committee meeting.

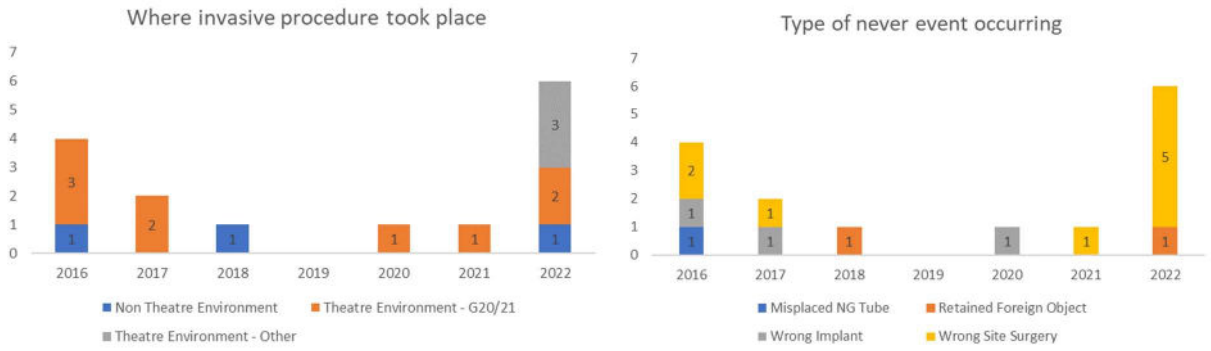
Immediate Actions

The three never event investigations resulted in the following immediate actions being undertaken:

- Commissioned Never Events Thematic review to review underway and due to report to the February 2023 Patient Safety Committee.
- Circulated internal safety alert with immediate actions to take.
- All consultants contacted by the Chief Medical Officer to highlight the issue and risk.
- All doctors contacted by Chief Medical Officer and Deputy Medical Director to clarify all site marking procedures.
- Supporting policies being urgently reviewed and updated to ensure clarity
- Understanding risk and exposure: To understand each Division's exposure to a wrong site surgery never event occurring, we have requested that each Division risk assesses.
- Never Events and related risks presented to the Quality Committee January 11th, 2023, which will report to Trust Board in January 2023. Quality Committee is very supportive of actions being taken and future planned actions.
- Liaison with UHBW re. joint working, learning and improvement. Agreement that both organisations will jointly work to share learning and improvement.

Whilst the investigations are ongoing there are some relevant underlying themes within the events, all are relating to procedures completed on the wrong site. All of the investigations have a never event occurring outside of the Brunel theatres (1 wrong side nerve block in the emergency department, 1 wrong site surgery in outpatients'

theatres and 1 wrong site surgery in interventional radiology). It is, therefore, worth considering if there is anything more unique regarding the latest three never events that could highlight additional emergent risks.



Looking at the occurrences of never events since the NatSIPPs was published and today the two emergent risk themes are evident in the most recent never events. Wrong site surgery is the Trust's most common invasive procedure never event type but here has been an increase in these in the last year. It is also showing that these never events involving invasive procedures are occurring outside of Brunel theatres situated on Gate 20 and 21. These two emergent themes support the findings of the review, in that by not fully implementing the NatSIPPs there is a higher risk of checking errors occurring generally. This is then potentially increased for invasive procedures being completed outside of the traditional theatre environment as without a robust governance structure they may not be risk assessed for chance of never events against the national guidelines.

- The review acknowledges that the three ongoing patient safety investigations are still in progress. The review recommends that any subsequent recommendations and actions developed through the three investigations be considered within the wider response to Never Events and implementation of LocSIPPs and NatSIPPs within the Trust.

Recommendations

Recommendations from the report

The review has highlighted several recommendations based on its findings. Overall, the report recommends immediate action to implement the National Safety Standards for Invasive Procedures with the additional requirement for specialities performing invasive procedures to risk assess their risk of never events occurring. This will provide the governance safety net and set the expectation for what is required in order to expand services to meet the elective programme recovery targets.

The implementation of NatSIPPs was estimated by the National team as requiring 12 months (the patient safety alert from 2015 provided a 12-month timeframe for completion).

Shorter Term Recommendations:

- The review recommends as an immediate action for specialities and divisions to provide a list of areas and procedures in which they perform invasive procedures (or plan to in future) outside of the theatre environment.
- The review recommends asking the divisions and specialities to risk assess their risk of invasive procedure never events.
- Escalate risk of never events occurring due to faulty IT systems to get immediate action to repair or replace.
- The review recommends the "Marking the correct patient for the correct operation" policy is re-written in its entirety to ensure it is up to date with the current hospital environment and that it is compliant with National Guidance.
- The review recommends that a Quality Impact Assessment (QIA) is completed for procedures usually conducted in a theatre environment that are now, or in future, carried out in a non-theatre environment. The QIA should consider the change in control mechanisms and the impact on the likelihood of a Never Event occurring in a less controlled environment.
- The review acknowledges that the three ongoing patient safety investigations are still in progress. The review recommends that any subsequent recommendations and actions developed through the three investigations be considered within the wider response to Never Events and implementation of LocSIPPs and NatSIPPs within the Trust.

Longer Term Recommendations:

- Review the use and reliability of the WHO and Safer Surgery Compliance Data, what it's purpose and escalation process is. Consider whether there are additional metrics that could provide a more rounded indication of underlying safety culture.
- Create a working group to implement LocSIPPs and NatSIPPs. The group should look to provide a gap analysis as to the governance arrangements for policies and processes relating to invasive procedures and circulate any related recommendations and findings to specialities who complete invasive procedures.
- The review further recommends that the working group investigate the local culture of theatres and performing of invasive procedures whilst the wider Trust-wide governance structure is implemented.
- The review recommends using a variety of engagement and learning methods to embed improvements and changes within the organisation for example: learning forums, symposiums, simulation training, and Swartz rounds.
- The review supports a collaborative and inclusive approach to quality improvement within the Trust and further recommends engaging with training bodies and external partners to develop and embed SSIPs at all levels as core principles of safe working.

Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Cygnet Kewstoke - Quality Improvement Group Update

Author: [redacted] **Deputy Director of Nursing**
23 June 2023

1. Introduction

The most recent meeting of the Kewstoke Quality Improvement group meeting took place on 5 June 2023. This was the latest in a series of meetings following the unexpected deaths of some patients in Cygnet Kewstoke last year. The structure of a Quality Improvement Group is laid down by the National Quality Board, NHSE, and is a way of providing not only enhanced surveillance but also a structure for providing system support for providers who may need it from time to time.

2. Updates on change of use for [redacted]

The environmental works and total refurbishment are now complete, and the ward has been reopened as a 16-bed male acute ward known as [redacted] The ward is fully staffed and there is a programme of practical skills-based training currently being undertaken.

3. Updates on Cygnet's internal SI investigations

Both internal investigations are nearing conclusion and are going through Cygnet's internal governance and being shared with system partners including [redacted] ICB and the [redacted] collaborative (where the original TOR were agreed) where appropriate for the respective investigations. In terms of the second investigation the ICB is arranging a meeting with [redacted] and Cygnet to determine where there is alignment and differences in findings in order to help with the feedback to the family.

4. [redacted] collaborative investigations (Parts 1 and 2)

4.1 [redacted] Report (Part 1)

This was commissioned as an independent investigation and report, using a PSIRF approach to learning focussing on the cultures and practice on [redacted] Ward where patient [redacted] died. As has been conveyed at earlier QIG meetings and SQGs, while no immediate risks to patient safety were found, the environment was not felt to be suitable for forensic psychiatry and so a phased approach was used to relocating patients. Many of the historical issues outlined in the report such as the leadership and management, staffing and culture was recognised by the QIG at making good progress in being addressed. It was also acknowledged that the local leadership team at Kewstoke had worked hard and effectively with the [redacted] [redacted] to ensure the patients had safe pathways in their transition to new settings.

4.2 Focussed investigation into the death of [redacted] (Part 2)

This is now complete, and as referred to in section 3, both internal and external investigations are to be looked at together for when feeding back to the family. Cygnet support the overall recommendations but have challenged the accuracy of parts of the report, hence the need to ensure recommendations are fully aligned from both internal and external reports.

Note there is a separate complaints process being followed by AWP who are liaising with the family over elements of [redacted] care pathway before they were transferred to Kewstoke. Cygnet have challenged in writing the accuracy of some of the findings however they do support the overall recommendations, and these are being incorporated within the overall action plan.

5. Overall improvement action plan

Good progress is being made on the overall improvement action plan which includes the actions from the ICB and [redacted] Collaborative visits; some actions remain amber which Cygnet do not want to change to green (despite good progress) until the changes have been embedded. Good progress has been made on all safeguarding actions (which has been triangulated by LA and ICB colleagues). Liaison with system partners continues, including attending the operational governance meetings at [redacted] and [redacted] to build relationships. A project is currently underway to review all serious incidents over the last 3 years, for themes and trends, and to determine whether the practices and protocols that have been put in place as a result are either embedded or still appropriate. The new hospital matron is settling in well and providing much leadership with these changes.

A new pharmacy provider has been secured, who can meet the stipulations of the specification that was developed because of the hospital visits last year (which includes ward-based medicines management) and will be commencing in September.

6. Conclusion

It was recommended unanimously at the QIG that Kewstoke should be stepped down from enhanced surveillance within [redacted] and the [redacted] Collaborative. The QIG feels assured that all recommendations are in the overall action plan and being embedded at sufficient pace. The need to share learning across other Cygnet sites was acknowledged by Cygnet and is to be actioned. This approach was supported by NHSE and CQC at the meeting. The ICB will be meeting with the provider regularly to offer support with the ongoing improvement work and transition to a new pharmacy provider.