



Centre for
Perioperative Care

National Safety Standards for Invasive Procedures 2 (NatSSIPs)

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Foreword

The original National Safety Standards for Invasive Procedures (NatSSIPs) were published in 2015. These new NatSSIPs 2 are published at a time when the healthcare system is under huge pressure. There are vacancies, overwork, burnout and unfamiliar teams working together. There are backlogs of patients needing treatment, some with increased problems due to deconditioning and treatment delays following the pandemic.

NatSSIPs 2 are intended to enable safe, reliable and efficient care to every patient having an invasive procedure. Central to NatSSIPs 2 are a focus on people, both staff and patients. It is definitely not just a tick-box checklist to help prevent rare “Never Events”. Our understanding of how to deliver safe care in a complex and pressurised system is evolving. These revised standards (NatSSIPs 2) are intended to share the learning and best practice to support multidisciplinary teams and organisations to deliver safer care.

NatSSIPs 2 have been written by a working group formed of patients and practising clinicians from across the four nations, across disciplines and professions. It is published by the Centre for Perioperative Care (www.cpoc.org.uk) – a partnership of all the major organisations involved in the patient perioperative journey. NatSSIPs 2 focuses on People, Processes and Performance. The NatSSIPs been strengthened through:

1. Bolstered Organisational Standard focus
2. Clearer regulatory, legal and national body expectations to ensure policy and inspection reflects the NatSSIPs aims and purpose
3. Introducing the concept of proportionality and emphasising professional application of the standards to practice

We hope that NatSSIPs 2 are more than a resource for healthcare professionals and will also be read and shared with patients, healthcare leaders, providers and all relevant bodies. They promote a reliable system that learns from excellence and requires organisations to act. NatSIPPs 2 are ambitious but aim to achieve the triple goals of improved patient safety, better team-working and enhanced efficiency.

Introduction

The original National Safety Standards for Invasive Procedures (NatSSIPs 1) in 2015¹ were a great step forward in providing an enhanced system and standards to provide safe care to patients undergoing invasive procedures. They followed the implementation of the WHO (World Health Organisation) Safe Surgery Checklist in 2009.² NatSSIPs 1, with associated Local Standards (LocSSIPs), provided the next steps in the evolution of checks, checklists and standards to enhance procedural safety and culture. NatSSIPs 1 promoted the concept of evidence-based implementation using quality improvement and human factors methodology to engage and create a learning system that standardised and harmonised safety across silos, specialties and beyond traditional boundaries, with education at its heart.

The new **National Safety Standards for Invasive Procedures (NatSSIPs 2)** represent the progression of the original NatSSIPs to demonstrate the collaboration across the four nations. The key aim to standardise, harmonise and educate (SHE) across organisations and procedural teams remains central to the NatSSIPs purpose. Critical changes include bolstered Organisational Standards and proportionate checks that recognise different levels of risk during major and minor invasive procedures, and the adaptations to processes that may be necessary in life-threatening situations. NatSSIPs 2 aim to reinforce safety themes by aligning them with other current landmark safety papers and reports^{3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20}

To support this, we recommend that NatSSIPs 2 is represented in syllabus documents, examinations and assessments of the relevant Royal Colleges, Association for Perioperative Practice (AfPP) and organisations within each of the UK nations that plan, commission and/or oversee education and training.^{21 22 23 24}

All of our organisations and teams face the challenge of creating a proactive safety culture and a learning safety system.²⁵ This should deliver meaningful improvement through understanding qualitative performance and a quest to learn from excellence. It should not be focussed on tick boxes or rare events. These NatSSIPs are an evolution based on safety science and national and local learning that has occurred. They aim to simplify, rationalise and bolster processes to further procedural safety. They acknowledge that there is a tension between standardisation of processes and adaptation to specific contexts or types of procedure. Perhaps most importantly, they set clear expectations for organisational support to deliver the Sequential Steps. Without adequately resourced organisational leadership and support, NatSSIPs are unlikely to deliver their full potential to improve quality and safety of care.

What did we learn from NatSSIPs 1?

According to the 2018 NatSSIPs implementation survey²⁶ conducted by NHS Improvement, the existence and implementation of the NatSSIPs and associated local standards (LocSSIPs) has been inconsistent and challenging. The survey found that the main barriers to embedding this important safety guidance were:

- a) time pressures and lack of protected staff time
- b) lack of opportunities for multidisciplinary training
- c) increasing focus on productivity and targets which can conflict with processes designed to ensure safety
- d) not seeing NatSSIPs as a priority
- e) lack of internal expertise as well as understanding of which areas / procedures qualify as an invasive procedure

It is noteworthy that these challenges and barriers are at organisational level, not at the detailed level of precisely what checks should be done when. These challenges were evident in Trusts/Healthcare Boards rated as outstanding as well as those rated as inadequate or requires improvement.

¹ Key papers and reports include: the Ockenden review,³ the Paterson Inquiry,⁴ The Morecombe Bay Inquiry,⁵ Joshua's Story,⁶ The Cumberlege Report,⁷ The NHSE National Safety Syllabus⁸ and Strategy,⁹ NHS Wales Quality and Safety Framework,¹⁰ NHS Scotland Patient Safety Programme,¹¹ the Northern Ireland Quality Strategy,¹² Healthcare Safety Investigation Branch (HSIB) national investigations,¹³ reports from safety bodies (Confidential Reporting System in Surgery (CORESS)),¹⁴ Safe Anaesthesia Liaison Group (SALG),¹⁵ Learn from patient safety events (LFPSE) service,¹⁶ the former National Reporting and Learning System (NRLS),¹⁷ the former National Patient Safety Agency (NPSA),¹⁸ and Coroners' Preventing Future Deaths (PFD) reports.¹⁹

National Safety Standards for Invasive Procedures (NatSSIPs) 2

These standards pose many challenges for those in senior leadership roles both within and outside organisations, as well as for those delivering invasive procedures for our patients. The Organisational Standards and performance monitoring are aimed to address some of these barriers and support teams to be enabled and empowered to deliver safer care.

Clinical teams have fed back that at times there is a **perception** of, too many, and non-relevant checks focussed on preventing rare events, rather than driving improvements in quality, safety and efficiency of care for all. A focus on measurement of Never Event numbers as a leading measure of safety is meaningless and risks diverting resource and attention from other areas of unsafe, unreliable or inefficient care.^{27 28}

The standards include clear concepts of proportionality, areas needing particular caution and priorities for implementation. These are coupled with expectations for inspections and reviews, and the role of Colleges and education/training bodies to embed the NatSSIPs within their curricula. A short version, communication plan and resource pack will also be available.

NatSSIPs 2 are very much an evolution from NatSSIPs 1;

To renew the need for human factors knowledge and to recognise the complexity of invasive procedure work and how 'work is done'.²⁹ Healthcare requires a 'systems thinking'³⁰ approach throughout the organisation to manage risk and improve quality.³¹

- To build team-work. Invasive procedures require the whole team to work together effectively. We recognise that 'teams' change or may be newly formed on the day of a procedure, and therefore require clear processes.
- To foster '[Respect](#)'³² and tackle poor [behaviours](#)³³ - building upon other work, in emergency/trauma protocols, in the aviation and other safety-critical industries,
- To define checks to confirm a safe pathway and to discuss patient-specific details. Appropriate and proportionate checks can save misunderstandings, reduce risk, provide clarity and set expectations.³⁴
- To reinforce the aim to Standardise, Harmonise and Educate invasive processes across traditional specialty boundaries. The 30-plus invasive specialties should follow the same standards wherever possible.
- To represent the patient voice as central and a key participant in safety checks. The opportunities for patient involvement and engagement are defined within this document, not as a passive recipient of care, but in partnership to make the procedure safe.
- To provide checks which are proportionate to risk. There are risks that are inherent to any procedure such as incorrect identification of a patient or wrong procedure. These are addressed in basic checks which should occur for any invasive procedure. We have recognised and defined the difference between major and minor procedures and subsequent required checks. We have defined a 'proportionate count' rather than a full count, for relevant procedures, focussing on the main risks, such as retained guidewires, demonstrating our commitment to proportionate concepts and the real world.
- To reinforce the WHO² Five steps to safer surgery of Team Brief, Sign In, Time Out, Sign Out and Handover/Debrief and include the addition of three more steps to make the Sequential Standards (Steps): Consent and Procedural verification (Step 1); Safe use of implants (Step 5); and Reconciliation of items (to prevent retained foreign objects) (Step 7)). 'The NatSSIPs Eight' should be in place for every relevant patient.
- A notable change in the Sequential Standards is a move away from an arbitrary categorisation of risk of (greater than 500ml) blood loss to a context sensitive discussion and confirmation of patient blood management plans³⁵ at [Sign In](#) and [Time Out](#).
- To bolster [Organisational Standards](#) recognising the interplay between culture and patient safety and that organisations need to create conditions to enable safer care.

NatSSIPs 2 in summary; Organisational and Sequential Standards

Organisational Standards

People for safety

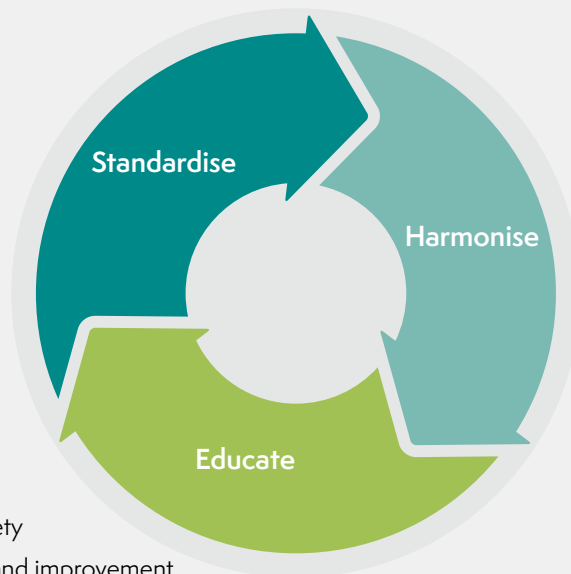
- Patients as partners
- Staff to deliver
- Roles in safety
- Training in safety
- Human factors understanding

Processes for safety

- Documentation
- Scheduling
- Induction
- Governance

Performance for safety

- Data for assurance and improvement
- External body engagement



Sequential Standards ('The NatSSIPs 8')

1. Consent and Procedural verification
2. Team Brief
3. Sign In
4. Time Out
5. Implant use
6. Reconciliation of items
7. Sign Out
8. Debrief/Handover

Terminology

1. **Must and should.** In accordance with standard terminology of regulators, Royal Colleges and specialty associations:
 - i. **'Must'** is used for an overriding duty or principle. The term 'must' is used for standards that are integral to modern invasive procedure practice and are markers of basic safety. A lack of embedded practice related to 'musts' should be seen as a red flag and should prompt processes to improve. Simply not wishing to follow a 'must' standard, either at individual or organisational level, is unlikely to be viewed as an acceptable justification by patients, inspectors, accreditation bodies or those investigating practice. The term **'not recommended'** is an explicit 'do not' in the same vein as 'must'.
 - ii. **'Should'** is used when we are providing an explanation of how you / the team / the organisation will meet the overriding duty. 'Should' is also used where the duty or principle will not apply in all situations or circumstances, or where there are factors outside your / the team's / the organisation's control that affect whether or how the guidance can be followed. There will be entirely legitimate occasions when a 'should' statement cannot, and / or should not, be followed to the letter. These may be due to individual patient circumstances, or because there is some common aspect of a process that makes application of that statement a less safe option. Individual clinicians and organisations should be able to justify these decisions with risk assessment.
 - iii. The terms **'could'** and **'may consider'** are suggestions from the NatSSIPs working party of actions that have theoretical or anecdotal evidence of usefulness but may not be appropriate in all situations or may have insufficient evidence / consensus to mandate their global adoption.
2. **Patient.** Where the term patient has been used this should generally be interpreted to include a child's parents / guardians, consultees, legally appointed proxies etc. where relevant.
3. The terms **basic, advanced and priority** within the standards are an indication of what is seen as core safety practice that must be provided for every invasive procedure, with advanced aspects demonstrating processes that are informed by learning based on risk.

4. **What is an invasive procedure?** An invasive procedure is a procedure that is performed where a hole or incision is made in a patient or via a patient orifice and usually where a documented consent is required. Invasive procedures can occur in many healthcare specialties including surgery, radiology, medicine, maternity, emergency care, and in theatres, wards and outpatient care. It is not possible to be completely prescriptive about what is and is not an invasive procedure. Organisations – including external bodies - are expected to consider the spirit and intent of these standards where there may be differing interpretations, rather than expending time and energy deciding whether or not a procedure falls inside the formal remit of NatSSIPs.
5. **Operator** refers to the individual undertaking the invasive procedure, which may be a doctor, nurse or AHP from almost any specialty.
6. **Major and Minor procedures;** Within invasive procedure settings there are a wide range of procedures and specialties. To have standards proportionate to the setting and context, the term major and minor procedures can ensure the standards are appropriate to risk and procedural area (more detail is provided in the Sequential Standards).
7. **Organisational Standards and Sequential Standards (Steps);** The NatSSIPs include Organisational Standards that an organisation must follow to provide the conditions to support teams in delivering safe patient care. Sequential Standards (steps) are those safety steps (known as 'The NatSSIPs Eight') that are carried out by the team in the patient pathway and are based on proportionate risk assessment and organisational learning to reduce harm.
8. **Local standards for invasive procedures;** (LocSSIPs) In the original NatSSIPs, organisations were required to write LocSSIPs for each procedure. There is a risk of over-complicating checklists and introducing bureaucracy. NatSSIPs now recommends that Standard Operating Procedures or LocSSIPs may be developed, based on this long version of NatSSIPs 2. These should be based on the local system and align where appropriate through standardisation, harmonisation and education.

LocSSIPs should include sequential and organisational review to be effective. For many procedures and contexts there will be no need to create completely new or bespoke standards or processes.
9. **Checklists;** Tools to support teams in following the NatSSIPs and LocSSIPs, and to support team behaviours. Checklists are not, and never have been, a solution in themselves and are dependent on the system and culture in which they are used.
10. **Teamwork behaviours;** Teamwork behaviours incorporate communication, situational awareness, leadership, and mutual support. A human factors perspective and recognition of the impact of these behaviours for effective delivery of the NatSSIPs in both Organisational and Sequential Standards is important.
11. **Standardise, Harmonise and Educate;** Standardise, Harmonise and Educate aims to reduce variation across specialties and organisations. Proportionate application of standardisation recognises that there are areas where the hazards are contextual, and standardisation may have unintended adverse consequences.

Table 1

	Organisational	Sequential ('The NatSSIPs Eight')
Standardise	Safety behaviours, processes, policies, insight, involvement and performance measures across organisations and specialties.	Expected behaviour, safety standards, checklists and format across invasive specialties.
Harmonise	Across groups of hospitals. Across IT systems.	Reduce variation across specialties.
Educate	Commit to safety education, human factors expertise and systems thinking. Create a safety infrastructure, leadership understanding and training in cultural change.	Teach and train in team behaviours, human factors, systems thinking learning / co-production with patients.

Scope

To whom does this apply?

The NatSSIPs apply to all providers of invasive procedures across the four nations delivered as part of NHS care. It is expected that they will be adopted in private settings also.

It includes regulatory, legal and national body expectations to ensure policy and inspection reflects the NatSSIPs Standards.

What should I do if my organisation is not delivering or engaging with NatSSIPs?

Report NatSSIPs issues via your line manager, governance system, site and organisations safety teams/leadership, Speak Up Guardian³⁶, Health Services Safety Investigations Body (HSSIB; formerly HSIB³⁷), the national regulators, and Colleges if you are concerned.

Organisational Standards

The Organisational Standards have been strengthened to support teams and patients and to indicate the foundation required for effective delivery of safe care in invasive areas. There is less focus on Local Standard (LocSSIPs) generation and more on the quality improvement and implementation strategy required to deliver and sustain the standards in a meaningful way.

The Organisational Standards now consist of three broad sections of **People**, **Processes** and **Performance**. Their interplay with the NHS Patient Safety Strategy⁹ categories of insight, involvement and improvement can be viewed in [Organisational Implementation Portal](#).

People

Patients

In summary: Patients should be involved in the safety pathway. Full information should be provided, and safety processes explained. Patients should understand the value of the checks and be encouraged to speak up/check if they have concerns. Patients having an invasive procedure may feel anxious, overwhelmed or not understand medical terms.

The NHS Patient Safety Strategy includes a framework⁹ for involving patients in patient safety. With reference to NatSSIPs 2:

- Patients should have sufficient, balanced information to support their decision-making about invasive care. Information should be written and communicated in plain language, without jargon, in line with Sequential Standard/Step 1 which includes consent and GMC consent [standards](#).³⁸ Patients should understand the information provided, have time to make an informed decision, and feel safe in communicating their needs and concerns.
- [Staff education](#) must include patient communication and listening skills. There are numerous examples where unsafe care could have been avoided had staff listened to their patients.
- Data related to staff safety training and associated safety benefits must be available to inform patients' decision making and choice.
- Questions asked of patients should be open and neutral whenever possible. Safe invasive procedures rely on partnership between patients and healthcare professionals. However, the nature of the clinical situation means that patients may not feel they are equal partners. From necessity, patients need to trust clinicians. While clinicians' confidence and professionalism are reassuring to patients, it is crucial to remain aware that they may also inhibit patients from raising concerns. In the operating theatre / procedural area the number of people present can be overwhelming. Patients can be vulnerable to suggestion, especially when anxious, distressed or in pain.
- Healthcare staff must encourage patients to ask questions by enquiring whether they have any concerns in a manner that conveys a sincere desire to hear from them. Patients are uniquely qualified to identify issues with their care because they are present and involved throughout the whole care pathway. Handovers are particularly important.
- Patients should be made aware that they also have an important and active role to play in safe practice and, where possible, be prepared/helped/trained to participate in checks and communication in the sequential pathway. Sequential Standards such as Consent and Procedural verification (includes site marking) and [Sign In](#) should involve the patient. These checks should reassure patients.
- Patients should be informed that 'a serious focus' is necessary during checks (equivalent to a legal proceeding or airport procedures). More relaxed conversation between the clinical team and patient can resume once checks are complete.
- Patients should not be relied upon to give detailed information to the clinical team. The British Association of Dermatology³⁹ has warned that risks of wrong site procedures may increase with patient specific factors such as impaired eyesight, hearing, understanding or lack of insight.

Box 1: Patient involvement during the Pathway Checks.

1. Be part of the conversation and shared decision making
2. Ask questions if something is not clear
3. Speak up if you have concerns
4. The checks are there to protect you and you can be part of them
5. During checks be serious and avoid jokes
6. Behave with respect and kindness towards healthcare professionals

- Patients have an interest in staff education, wellbeing and morale. Patients should be given clear opportunity to acknowledge excellent care and to offer feedback. This should be available in a variety of forms and language formats.
- Patients should be given clear opportunity to report concerns, complaints and harm. All concerns must be responded to with honesty, both to help patients understand what happened and for learning to occur. This is a priority for patients.
- Patients and/or their families and carers affected by a patient safety incident should be cared for with compassion, their questions addressed, and their needs met. When a learning response occurs they should be involved if they are able and wish to. They may provide valuable, informed insight critical to preventing a repeat, to support education and the action plans. This is central to the Patient Safety Incident Reporting Framework.^{40 41}
- The post incident process should reflect the Restorative Just Culture maxim of 'Who is hurt? What do they need? Whose obligation is it to meet those needs?'⁴²
- The Duty of Candour^{43 44 45 46} process is mandatory for all incidents resulting in moderate or more severe harm. Organisations must have systems to uphold the Duty of Candour in a sensitive and effective way. Professionals also have an individual Duty of Candour: organisations should train, encourage, and support their staff to apologise compassionately.
- Information should be available on how to access wider support networks related to patients' conditions and, if raising concerns, local independent advocacy services.
- Ongoing patient feedback, related to poor experience or harm as well as excellent care, should be routinely available to patients and analysed by organisational boards with patient involvement.
- Patients, local patient groups and interested public all need opportunity to input and advocate for safe systems and feedback on standards, policies, and local procedure. Patients have a different perspective, seeing issues and offering solutions that clinical or management staff may not have found.
- Supporting patients to be involved in their own safety means actively involving patients, their carers, family members or other lay people, in partnership with staff, to influence and improve the delivery, governance and leadership of safety within organisations.⁴⁷
- Creation of formal Patient Safety Partner⁴⁸ (PSP) roles for patients, carers, family members or other lay people in partnership with staff, can influence and improve organisational safety.
- A version of the standards should be accessible and understandable for all patients, including for patients with challenges in understanding, e.g. English is not first language or people with physical or learning difficulties, or with access only to basic or no technology.
- Communication is central to any strategy. Information campaigns must be continuous and use a variety of formats including email, post, apps and videos.
- Patient perspective, focus and involvement is a priority and should be embedded in every standard and throughout the pathway, not considered as an 'add on'. The standards should be continually reviewed and adapted as technology and circumstances change and new information becomes available. Patients may need to be helped or trained to use technology if necessary or required.
- The key message is that invasive areas are an overwhelming environment for patients, where it can be difficult to speak up. The team should be aware and compassionate to the patient needs.

Roles for NatSSIPs Delivery, Implementation and Sustainment

In summary: Every Trust/Healthcare Board must have an adequately resourced leadership team to deliver the NatSSIPs.

- Trusts / Healthcare Boards^b should have a named Board-member^c with NatSSIPs within their portfolio.
- There should be a named, substantive senior clinician^d, **practising clinically within the invasive procedures domain**, who is responsible for strategic direction and oversight of the implementation, development and improvements related to NatSSIPs.
 - This individual should have sufficient, transparently allocated time within their job-plan for this role, commensurate with the size of the organisation
 - This individual should have sufficient, transparently allocated administrative support for the role, commensurate with the size of the organisation
 - This individual should have the ability, and authority, to be able to obtain strategic and operational support from across the organisation including, but not limited to: Information Technology (IT); education; quality improvement support; and procurement
- Each Trust should have a formally constituted multidisciplinary steering group (to include all relevant professions and sites), chaired by the NatSSIPs lead, with responsibility for:
 - Strategic oversight
 - Review of relevant data / intelligence/ insight
 - Provision of assurance to the Board
 - Providing updates as a standing agenda item to Governance and Quality Boards
 - Organisational sign-off of NatSSIPs-related policies and procedures
 - Reinforcing that NatSSIPs are more than 'checklists' and that they require a strategy for organisational as well as Sequential Standards improvement
 - Embedding systems and human factors knowledge and understanding⁴⁹
 - Ensuring alignment of NatSSIPs with Trust Safety Strategy and Quality Objectives
- Every relevant specialty group within a Trust should have a named senior clinician^e, again practising clinically within invasive procedures with responsibility for specialty level governance of NatSSIPs and with representation on the Trust NatSSIPs group.
- In large Trusts, each site should have a NatSSIPs lead with allocated time to support the trust-wide remit.
- MDT members in training should be a formal part of these groups.
- The Trust NatSSIPs lead(s) should provide assurance to the Site and the Board on all aspects of NatSSIPs.
 - This assurance should include at a minimum an annual, publicly available account of progress and measurable outcomes related to NatSSIPs
- Boards should aim to include NatSSIPs within the strategic remit of patient safety specialists
 - Trust Boards should consider how NatSSIPs related activities will integrate with other key patient safety specialist roles (e.g. for maternity)

^b For brevity within the document, Trust will be used as shorthand for the variety of names across the four nations.

Similarly, Board should be understood as the level of the organisation with statutory responsibility for the organisation.

^c There will be different structures. It is the concept of leadership and ownership at the top of the organisation that is key.

^d Clinician deliberately includes medical, nursing, midwifery, pharmacy and Allied Health Professionals.

^e This individual may well have other governance roles within the specialty. The intention is to be clear who is responsible for NatSSIPs, not to create more jobs.

Invasive Area Staffing and Resources

In summary: Every Trust and service must have sufficiently skilled and knowledgeable teams to deliver invasive care safely.

Safety in invasive procedures relies upon:

- i. Having sufficient numbers of permanent staff vs agency staff.
- ii. Appropriately trained and competent staff (trained in specialty safety aspects).
- iii. Appropriate skill mix, and ratios of staff with relevant primary or postgraduate qualification (qualified in specialty).
- iv. Sufficiently rested staff who can take planned breaks during their shifts.
- v. Appropriate resources to plan for and perform the planned procedure.
- vi. List planning and scheduling that includes adequate preparation time.
- vii. Flow in and out of the invasive procedures (e.g. ward beds, critical care facilities).
- viii. A supportive culture and civil behaviour. Staff able to report safety concerns or exception reporting without fear of reprisal.
- ix. An understanding of how to support staff with building resilience, wellness and avoiding burnout.^{50 51}
- x. An understanding of the safety differences and risks between elective vs emergency patients.
- xi. Mechanisms, such as [Team Briefs](#) that can be used to share concerns with staff and build trust.

It is outside the scope of the NatSSIPs to directly quantify these needs, and they are intimately related with the processes, resources, and culture of the rest of the organisation and the wider healthcare system.

- The Trust NatSSIPs lead(s) should give an account of the state of these factors when describing the services within their organisation.
- Data relating to these aspects should inform the intelligence used by the NatSSIPs steering group. These may usefully include:
 - Performance measures such as agency staffing rates, staff leaving rates/retention/turnover
 - Cultural surveys (ability/opportunity to speak up, being listened to)
 - Specialty-based staffing algorithms for staffing
- There should be a clear procedure, risk assessment and escalation for when invasive procedures do not take place or are delayed due to safety concerns.

Staff Training and Education

In summary: Teams need to be trained in safety behaviours and practices. This needs to be supported via specialty bodies/examinations and regional integrated systems.

- The Board should provide sufficient time and resource for multidisciplinary, in person team-training. Online learning may have a supportive place in this education but is not sufficient on its own. This training should ensure that:
 - a. Every relevant member of staff understands the purpose, rationale, and practical implementation of the NatSSIPs and the risks relevant to their area
 - b. Team members understand and value each other's roles
 - c. Every relevant member of staff has an understanding of human factors application and systems thinking^{52 53}
 - d. All members of staff understand and model the importance of respectful and civil behaviour³³
 - e. The multidisciplinary team have clear processes which support safety (the team may not always know each other, are part of a wider specialty team and may be managed by different specialty leaders)
 - f. Senior members of the invasive procedures team understand how to model excellent team behaviours (communication, leadership, mutual support, and situational awareness) related to NatSSIPs, and support their teams in delivering these
 - i. Seniority, prior experience or competing pressures on time are not sufficient reason for not taking part in MDT training. It is more than learning and includes building trust and mutual support
- Multidisciplinary team training should involve rehearsal and analysis of typical and emergency scenarios and practice relevant to the team. e.g. a surgical fire. It should not be solely didactic teaching but should prioritise working in teams and breaking down professional barriers.
- Ongoing support for good practice within teams should be provided through team feedback such as quality performance data, feedback from debriefs and actions related to governance data.
- The organisation's NatSSIPs lead(s) will provide Trust-level assurance on the delivery of training. However, each specialty should have its own assurance and delivery plans and governance around training.
- Each specialty should be able to evidence the training and competence of their staff in relevant aspects of NatSSIPs, as should every member of staff involved in invasive procedures.
- Trusts should recognise when appropriate training and education has been undertaken within an appropriate timeframe within other organisations. Staff who rotate between organisations should not be duplicating training or assessments unnecessarily.
- Agency staff should have evidence of training and understanding of general NatSSIPs processes in the same way as substantive staff.

Wider health service

- Regional structures (e.g. ICS, place-based partnerships, provider collaboratives etc.) should consider how such training could be supported, harmonised, and standardised within geographic regions to reduce duplication and encourage sharing of good practice.
- The Royal Colleges, AfPP and other training bodies should ensure that safety risks, concepts and practical procedures within NatSSIPs are taught, examined and listed within their training curricula.^{8 54 55 56 57}
- The Royal Colleges, AfPP and other training bodies should ensure that their training materials are revised and updated to current best practice.
- All organisations within each of the UK nations that plan, commission and/or oversee education and training should consider how best to provide training, and repeat training, on invasive safety risks and NatSSIPs at all stages of training for medical, nursing, midwifery and Allied Health Professional colleagues.
- Accreditation / regulation bodies should have the capacity and capability to be able to meaningfully assess the quality and quantity of training within the organisation.
- The NHS should work towards the creation / accreditation of multi-disciplinary training programmes.

Processes

Documentation processes

In summary: Proportionate checks for procedural safety are performed, recorded and reviewed regularly alongside governance, cultural aspects and IT integration.

- Invasive procedure checklists should be adapted from the WHO Safe Surgery Checklist.
 - Adaptation should be based on insights from local and national data
 - Staff, patients and safety specialists should be involved in this improvement process
 - There should be an organisational framework of standardisation, harmonisation, and education across all invasive checklists
- Specialty based procedural checklists can be used in dedicated specialty areas but checklists per procedure are not encouraged (unless a reliable IT solution which matches a checklist to a procedure appropriately is designed, tested and maintained).
- The NatSSIPs lead(s), in conjunction with relevant specialty groups should ensure that processes are designed and re-designed to support optimal safety and efficiency.
 - Paperwork and / or digital documentation should be reviewed regularly to ensure it is contemporary, without duplication, relevant to practice and closes the gap between work as imagined and work as done²⁹
 - The processes of patient flow before, during and after invasive procedures should be designed to balance deliberate redundancy of checks with unnecessary duplication
 - Checklists across the organisation should be reviewed to ensure they are harmonised in language, pattern of checks and appearance
 - The flow of information should be reviewed regularly to ensure there are 'versions of truth' that are reliable and accessible at all points of the patient journey
- IT solutions should be carefully designed and tested with partnership between IT and human-centred design experts and representatives of all members of the invasive procedures team. IT integration creates opportunities and risks for rationalisation and data analysis of Safety Standards.

Scheduling

In summary: Scheduling should include time for planning, and supports safe and efficient practice.

- Scheduling should provide adequate preparation time and provide maximum list information to support safe and efficient care.
- Scheduling should take into account realistic anticipated workload and the need to follow 'The NatSSIPs Eight'.
- The scheduling process should strive for continuous improvement through information, feedback, improvement and training.
- The information that accompanies the scheduling of a procedure should include as a minimum: name, identification number, date of birth, gender, planned procedure, site (and side) of procedure, source of patient e.g. ward or admissions lounge.
- Laterality must always be written in full on schedules, i.e. 'left' or 'right'.
- Further relevant information should be included such as urgency of the procedure (e.g. NCEPOD codes,⁵⁸ timeframe etc.), significant comorbidities, allergies, infection risk, any non-standard equipment requirements or type-specific implants, BMI, planned postprocedural care etc.
- The use of abbreviations should generally be avoided but, when common abbreviations are used, a list of locally approved abbreviations should be readily available to all staff. Senior or well-established staff should appreciate that an abbreviation well known to them may be not understood, or perhaps worse, misunderstood, by colleagues.
- Any list and / or order changes made after the deadline for the publication of a final version of the list must be agreed with the procedure team and should be discussed by all members at the Team Brief.
- A clear, effective mechanism must exist for removing old lists when a newer version has been published.
- The procedure list should be clearly displayed in the room in which the procedures are performed, and any other areas that are deemed important for the safe care of the patient.

Induction Processes

In summary: Staff should receive an appropriate induction covering local NatSSIPs processes before working in these clinical areas.

The induction process marks the start of a staff members safety journey within that organisation, and is critical to delivery of NatSSIPs.

- Induction of staff and students in both local and Organisational Standards should ensure NatSSIPs safety behaviour and processes/expectations are covered prior to work in a clinical or specialty area.
- Induction requires dedicated time, staffing, and space to enable delivery without any adverse effect on patient care.
- Temporary staff should receive a shortened, documented, role / site specific induction.

Governance Processes

In summary: Insight regarding NatSSIPs performance and risk should be tracked, acted upon and fed back to teams in invasive areas.

Governance processes should support:

- NatSSIPs Insight (multiple sources of data), learning and involvement.
- The insight sources of data should link UK-wide standards and benchmarking, reports with local insight based on both qualitative and quantitative data and reported incidents. National level data includes: Healthcare Safety Investigation Branch (HSIB) national investigations,¹³ reports from safety bodies (Confidential Reporting System in Surgery (CORESS),¹⁴ Safe Anaesthesia Liaison Group (SALG),¹⁵ Learn from patient safety events (LFPSE) service,¹⁶ National Reporting and Learning System (NRLS),¹⁷ the former National Patient Safety Agency (NPSA),¹⁸, Coroners' Preventing Future Deaths (PFD) reports,¹⁸ learning from excellence reports,⁵⁹ litigation, and patient complaints.
- Learning and action should be integrated into improvement, team induction and education opportunities.⁶⁰
- A restorative safety culture ('Just Culture') where staff and patients 'trust' organisations to investigate safety events for learning rather than blame.^{42 61 62 63}
- Proportionate responses and investigations to incidents with [patient involvement](#)⁶⁴ thematic analysis and a focus on learning in line with Patient Safety Incident Reporting Framework (PSIRF) recommendations⁴⁰
- An approach of analysing work system design, with human factors expertise and using models such as the [SEIPs model](#) (Systems Engineering Initiative for Patient Safety)³⁰, [Accimaps](#)⁶⁵ and [hierarchy of hazard control](#).⁶⁶
- Quality improvement methodology and implementation science to deliver meaningful and sustained change.
- Appropriate organisational roles and resource for the implementation of NatSSIPs.
- Risk assessment related to specific procedural harms in invasive areas. These include, but are not limited to:
 - Swab management (See [Sequential Step 6](#)) requires an organisational risk assessment and procurement alternatives/solutions to ensure swabs used for padding do not become an unknown risk to an accurate count
 - Fire Safety. Local policies should be in place to minimise risks, ensure safe laser management and ensure investigation of all fires:
 - Fires in airway surgery where laser is used are a known risk. A laser safety checklist is advised
 - Fires with surgical prep fluids, drapes and diathermy
- Procurement and tenders from contractors should also fall within this risk assessment and governance process to ensure quality and safety are matched to NatSSIPs requirements.
- Independent sector hospitals are encouraged to follow the same standards as NHS hospitals.

Performance

Measurement for improvement and assurance^f should go beyond measurement of the NatSSIPs for compliance and create a suite of measures which reflects qualitative and quantitative aspects.^{40 41 67 68}

Trusts

- Trusts should ensure regular collection, review and action upon data covering all aspects of implementation of NatSSIPs:
 - Metrics related to the Organisational and Sequential Standards performance
 - Data should include assessment of implementation and practice
 - Data should include behaviours (e.g. [safety culture/ climate and psychological safety](#)^{69 70}) and aspects of quality not quantity alone
 - Measurement for improvement concepts should be applied^{67 68 71 72}
 - Data from incidents including near misses, serious incidents, harm etc
 - Soft intelligence from teams via Team Brief and Debrief
 - Insight and action related to required actions from national and local reports⁵⁹ and from Organisational Standards
- The processes for collection of data should be standardised across the organisation as far as possible.
- The minimum standard for audit of NatSSIPs related practices and behaviours is intra-departmental peer-review accompanied by associated plans for improvement / innovation.
 - Peer review necessitates direct observation and assessment of quality of practice
 - Documentation audits are of little value on their own
 - Self-assessment may be a useful tool for teams to identify areas for improvement but does not constitute robust assurance

Wider NHS

- Regional structures (e.g. ICS, place-based partnerships, provider collaboratives etc.) should consider use of standardised tools to collect information about NatSSIPs implementation.
- The NHS (and equivalents) should consider provision of standardised tools to collect information about safety climate/culture and NatSSIPs implementation.
- Trusts may consider how to develop mutual relationships with neighbouring organisations to provide external review, and honest critique of practices.

Regulatory, legal and national body expectations

- The national regulators such as the [CQC](#) (England), [HIW](#) (Wales) and [HIS](#) (Scotland) and regional / local structures should use NatSSIPs as a framework for inspection and assurance. This should include both Organisational and Sequential Standards review.
- HSSIB (Healthcare Services Safety Investigations body) should use NatSSIPs as the reference for current expected standards for invasive procedure. This should include both Organisational and Sequential Standards.
- Central NHS bodies in the four nations including affiliated bodies related to commissioning, improvement, resolution and digitalisation should continue to promote the role of NatSSIPs in policy and strategy planning and documents.
- The GMC, GDC, NMC, HCPC and other standards bodies should include reference to Trusts' engagement and attainment of Organisational Standards if they are dealing with registrants who have been involved with incidents related to NatSSIPs.
- Royal Colleges, education and accreditation^{22 23 73 74} bodies should include NatSSIPs 2 in their policies and in their assessments (see Staff training and Education for inclusion into curricula) when they are reviewing services, including both Organisational and Sequential Standards.

^fThere is no intent or desire to create yet another auditing / incident review framework. These processes should be seamless and integrated with the rest of the organisation.



NatSSIPs 2

ORGANISATIONAL STANDARDS

Organisational Standards that enable teams to deliver safe care



People for safety

Patients as partners
Involve patients in their care and safety
Mutual respect and compassion

Staff to deliver
Roles in safety: resourced leadership to deliver
Training in safety: appropriate and skilled staffing
MDT Teams: have safety education with human factors



Processes for safety

Documentation:
User friendly checklists without duplication

Scheduling:
Provides necessary information for safe care

Induction:
Covers expectations for safe reliable care

Governance:
Provides insight, learning, involvement and improvement



Performance for safety

Data sources:
Sequential: peer review and qualitative performance with assurance data
Organisational: education and induction delivery measures

Use of data
Quality improvement focus

Visibility of data
Board to ward with expert support and challenge

Secure in safety

Local safety strategy is visible with infrastructure following NatSSIPs



Patient involvement

Patients involved in safety improvement, education, information and design



Leadership

Senior and substantive clinical leadership
Training in safety for leaders
Sufficient support and resource



Governance

Proportionate risk assessment, organisational resource, human factors expertise



Measurement for Improvement

Triangulation
Suites of measures
QI methodology



Systems design

Safe scheduling and list management
Local induction covers NatSSIPs
IT integration





The NatSSIPs Eight NatSSIPs 2 SEQUENTIAL STEPS

Delivery of safe invasive procedures by the MDT in the patient pathway



Consent and procedural verification

- Laterality in full
- Consent signed by operator
- Site marked by operator

Sign In

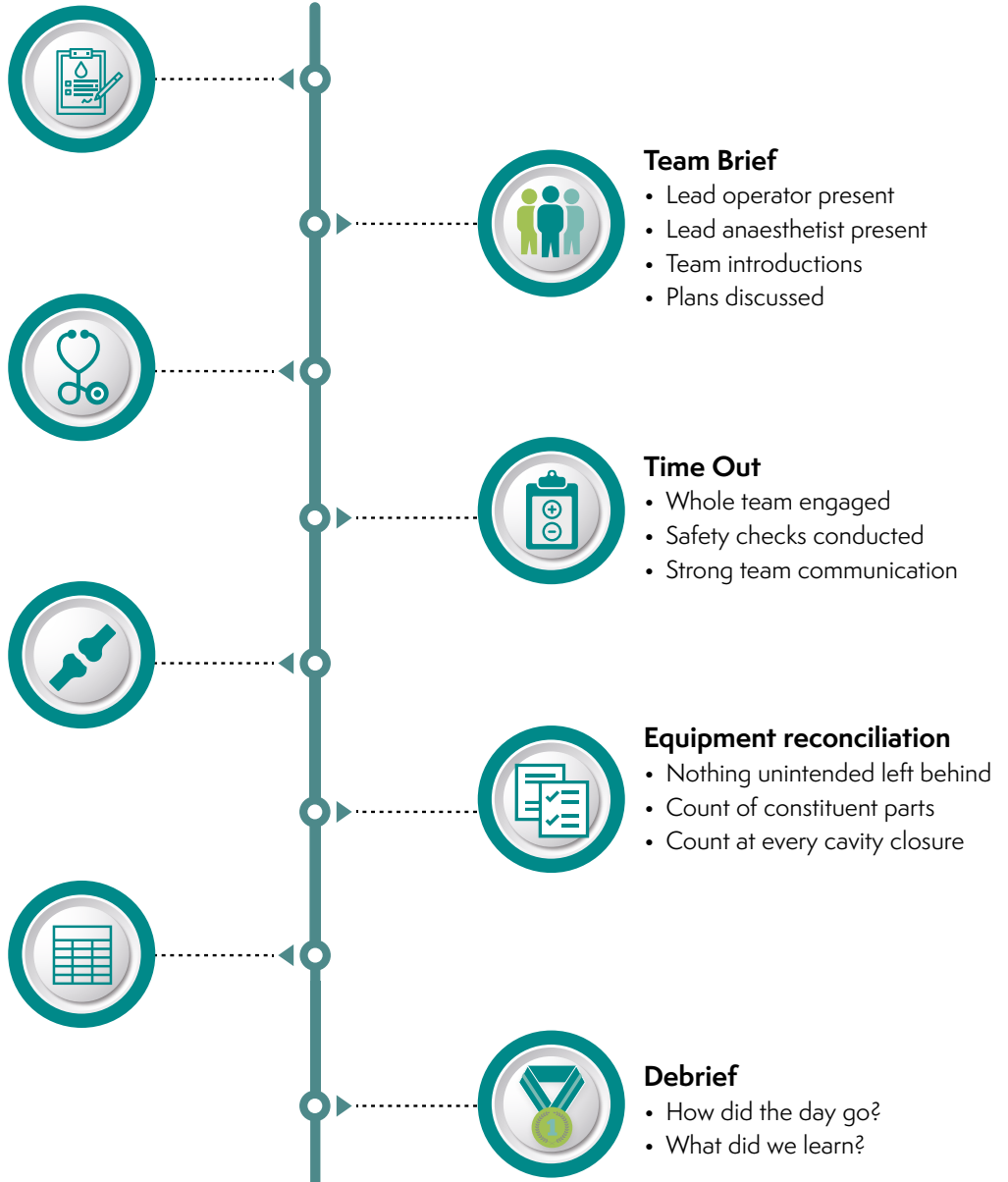
- Anaesthetic practitioner, anaesthetist with patient
- Checks including consent with patient

Implant check if required

- Check compatibility
- Record what is needed
- Team focus at checks
- Add to register
- Stock up

Sign Out

- Confirm count correct
- Flush IV lines
- Postoperative team instructions



Sequential Standards

The Sequential Standards or Steps are, as they suggest, performed in a sequence for every patient in their invasive procedure pathway. They form the basis of an 'enhanced local standard' WHO Checklist or specialty specific checklists in some settings.

Successful, sustained implementation of the Sequential Steps will only occur in the context of full engagement with Organisational Standards.

“Be great with The NatSSIPs Eight”

The Eight Steps provide safety checks to protect our patients and practice. The Five Steps to Safer Surgery were a great stride forward in invasive safety and are now seen as basic checks as we advance 'The NatSSIPs Eight' within NatSSIPs 2. In practice the vast majority of organisations undertake 'The NatSSIPs Eight' already – they are not new processes, rather clarification of expectation and bringing them all into one place. (**Harmonisation**).

Procedures that are performed in a dedicated area are suited to a specialty specific checklist which is proportionate to the risks and processes in that area. Based on the risk within that specialty (e.g. specialties which insert implants or prostheses, the type of anaesthesia: general vs regional vs local) and procedure (major vs minor procedure), particular checks may be more or less applicable.

Proportionate and professional application of the standards should fit the case based on the identified, known risks and previous incidents in that specialty or other related specialties performing procedures. Proportionality is key to engagement, organisational and team uptake.

Forcing teams to undertake checks that have no perceived relevance or safety benefit to their context is likely to be detrimental to patient safety overall. Carrying out full checks in an emergency such as Category 1 Caesarean section⁷⁵ or a trauma patient may be detrimental to the patient. Conversely, such emergencies are predictable, and are associated with increased risks, so organisations should design, and train for, processes that ensure appropriate checks can and do occur.

All staff should appreciate that although an individual item or process may not appear immediately relevant to them, or to that particular case, there may be wider reasons for including that check or step (**Education**).

The steps and associated checks work best in the presence of an engaged team who understand human factors and error and want to keep their patient safe.

The 'proportionate count' (Reconciliation Standard 6) is a change to the NatSSIPs which recognises that in some settings such as most minor procedures and interventional procedures a full count is not required since the procedure is performed via a needle and hole, rather than an incision.

[Patients](#) want to feel safe, can find the checks reassuring and should be involved with them.

The checks should form a team conversation and plan, which, where applicable, includes the patient. They should allow an opportunity for any member of the team or the patient to speak up. They should integrate and understand human factors, behaviour and safety knowledge.

Linking data based on the team performance in quality of checks (appropriate to the procedure) is a method for measurement of service quality and measure for improvement.

Each standard has suggested performance measures which are integrated into '[Performance Indicators NatSSIPs](#)'. These can be observed at performance reviews, safety visits and external body safety accreditation/evaluation. In specialties with caveats, the data collected can be adjusted to meet locally agreed standard. Linking organisational and sequential performance is important for sustained implementation.

Table 2: ‘The NatSSIPs Eight’ Sequential Step Standards

1	Consent, Procedural verification, and Site marking
2	Team Brief
3	Sign In
4	Time Out
5	Safe and efficient use of implants (where relevant)
6	Reconciliation of items in the prevention of retained foreign objects
7	Sign Out
8	Handover/Debrief

Major and Minor Procedures

These standards cover all invasive procedures and all settings, including hospital-based theatres, clinics, treatment centres and primary care, and invasive investigations in outpatient departments. Some areas do not currently have a culture of using a checklist or the Sequential Steps. NatSSIPs 2 has developed the new concept of minor or major procedures and organisations should decide which type of checks are required in each area, based on the risks:

- Major procedures require more checks and generally a full count (except for interventional radiology areas).
- Minor procedures require fewer checks (Sign In and Time Out can be combined) and generally a proportionate count.

Table 3: Procedure characteristics to help decide whether a procedure is minor or major

	Minor procedures	Major procedures
Location	Outpatient or Emergency Department procedures that are performed without entering cavities and with small incisions under local anaesthesia in non-theatre areas, e.g. treatment rooms	Any procedure in operating theatre settings (includes surgical hubs)
Anaesthesia/ Sedation	Minimal or conscious sedation with local anaesthesia given by proceduralist (not general anaesthesia) ⁷⁶	Procedure occurring under general, regional or local anaesthesia or sedation (minimal, conscious and deep sedation)
Procedure site / access	Skin or natural orifice, sometimes needle puncture	Surgical incisions, sometimes via needle
Example procedures	<ul style="list-style-type: none"> • ‘-oscopies • Skin biopsy in clinic • Vasectomy in primary care • Most radiologically guided procedures 	<ul style="list-style-type: none"> • ‘-ectomies, e.g. tonsillectomy, endarterectomy • ‘-otomies, e.g. craniotomy • Replacements • Repairs • Interventional radiology procedures • Catheter lab procedures
Procedures that require caution	Dermatology skin lesions ³⁹	<ul style="list-style-type: none"> • Multiple teams • Large incisions • Cavities • Implants • Delivery room procedures • Emergency situations where ‘priority’ or time critical checks are necessary
The count	Proportionate count	Full count for all procedures (except most in Interventional Radiology procedures)

Table 4: Which checks should occur?

	Minor procedures	Major procedures
Essential initial Basic checks	<ul style="list-style-type: none"> • Patient states name and date of birth • Medical record number check against list, notes and consent • Consent form checked for procedure, which is confirmed with patient • Site marking, if applicable, to be cross-checked with the patient, consent form and procedure list • Allergy status 	<ul style="list-style-type: none"> • Same as minor basic but checked against the patient identity band, nursing documentation/care plan and procedure list • Priority checks for emergency situations e.g. blood management plan
Advanced / Additional checks	<ul style="list-style-type: none"> • Departments should add standard checks relevant to the risk within that specialty, for example, checking renal function or coagulation will be relevant to some minor procedures but not all • Pregnancy status if radiology is required / anticipated 	<ul style="list-style-type: none"> • Pregnancy status • Infection risk to staff • Starvation time • VTE risk assessment and prophylaxis • Anaesthetic and emergency equipment/ drugs check • Airway strategies and preparedness • Confirmation of patient blood management plan • Regional anaesthesia 'Stop Before You Block/Prep Stop Block'⁷⁷ checks • Availability of essential instrumentation • Availability of implants, stents, prostheses • Implants (surgical metalwork, pacemakers, etc.) • Availability of essential staff • Other checks to be decided locally as appropriate for specialty • For procedures involving ionising radiation, the processes should be designed to ensure IR(ME)R⁷⁸ and NatSSIPs requirements are met without unnecessary duplication.
'The NatSSIPs Eight' requirements	<ol style="list-style-type: none"> 1. Site marking required where relevant 2. Team Brief appropriate to context 3. Sign In and 4. Time Out can be combined 5. Implant checks should be performed where relevant 6. Count can be proportionate if site accessed via a needle or surface incision. If guidewires are used, they should be counted for reconciliation of items 7. Sign Out may be concise 8. Debrief if required 	<ol style="list-style-type: none"> 1. Site marking required where relevant 2. Team Brief with full team in attendance 3. Sign In and 4. Time Out should be completed separately 5. Implant checks should be performed where relevant 6. Full count procedure required and reconciliation except for IR, catheter labs 7. Sign Out 8. Debrief should be carried out

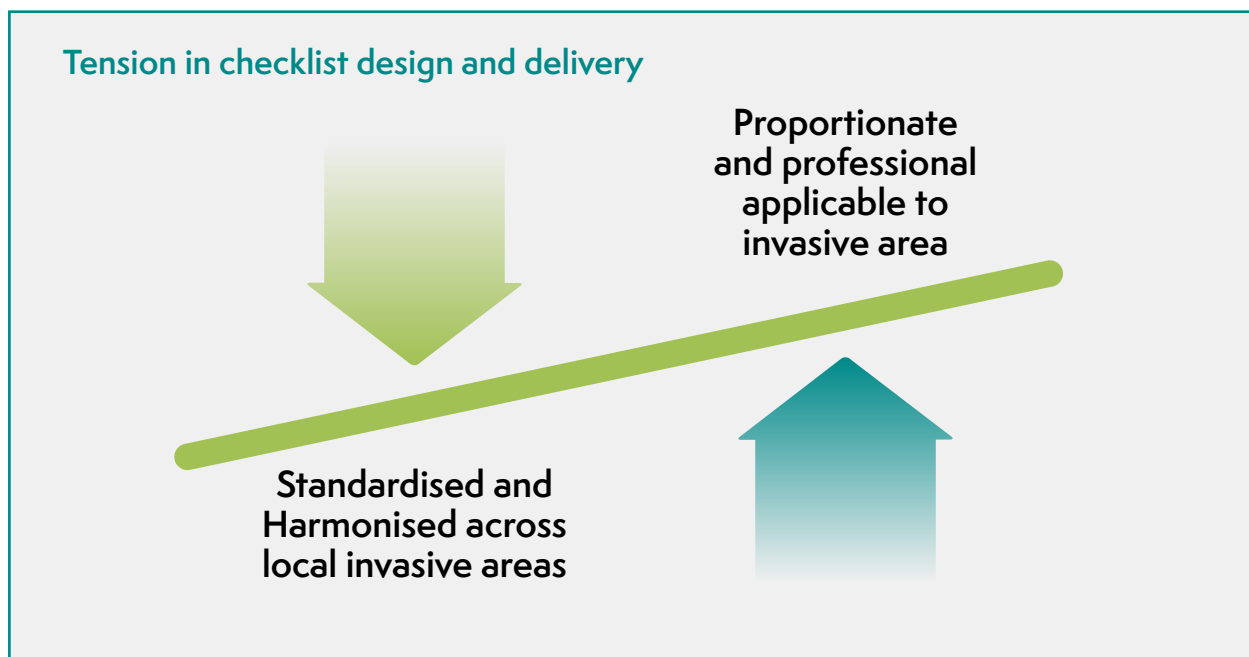
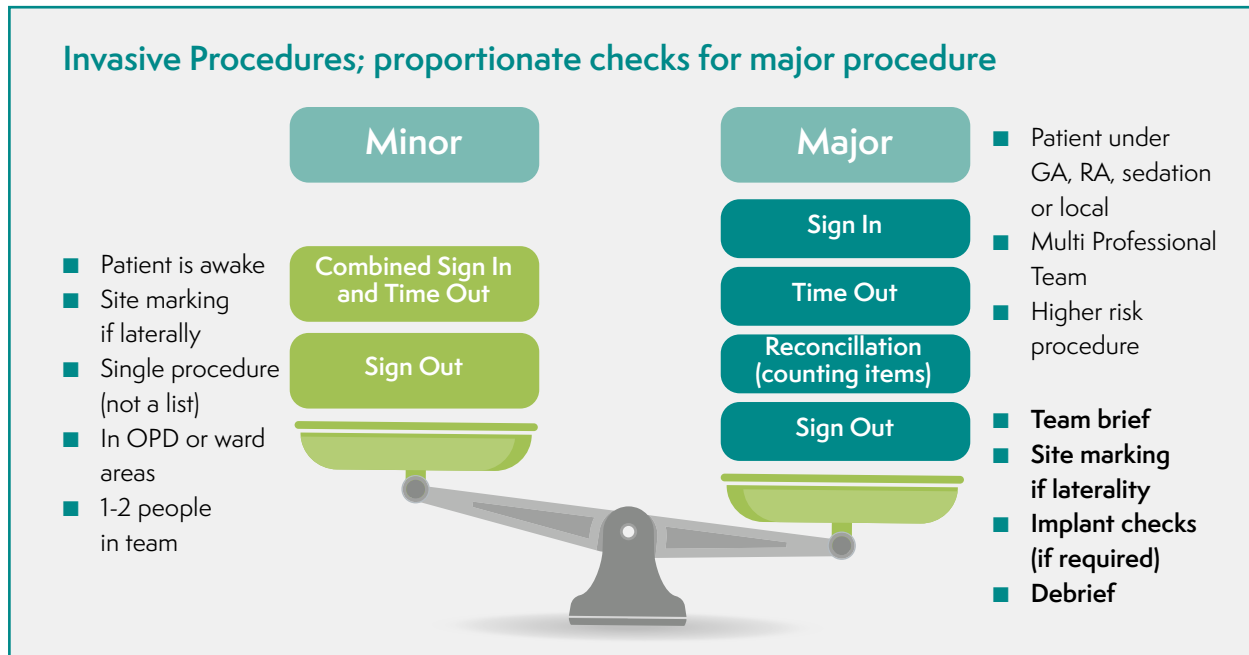


Table 5: In Summary: regarding Sign In and Time Out Checks

Type of check	What is checked?	When appropriate
Basic	<ul style="list-style-type: none"> • Patient states name and date of birth • Medical record number check against list, notes, consent +/- identity band • Consent form checked for procedure, which is confirmed with patient • Site marking, if applicable, to be cross-checked with the patient, consent form and operating list • Allergy status 	All procedures
Advanced/ Additional	<ul style="list-style-type: none"> • Pregnancy status • Infection risk to staff • Starvation time • VTE risk assessment and prophylaxis • Anaesthetic and emergency equipment/ drugs check • Airway strategies and preparedness • Confirmation of patient blood management plan • Regional anaesthesia 'Stop Before You Block/Prep Stop Block' checks⁷⁷ • Availability of essential instrumentation • Availability of implants, stents, prostheses • Implants (surgical metalwork, pacemakers, etc.) • Availability of essential staff <p>Other checks to be decided locally as appropriate for specialty</p>	All major procedures and some minor
Priority	<ul style="list-style-type: none"> • Command and control from team lead and role allocation • Blood management plan • Other emergency checks depending on specialty 	<p>Always major</p> <p>Life threatening/time critical surgery</p> <p>Whole team including operator(s) present at Sign In and Time Out</p>

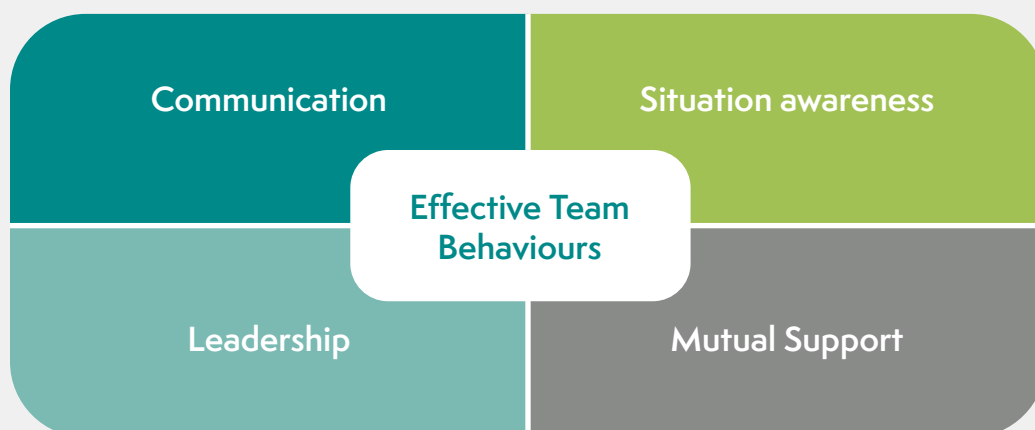
Example procedures

- | | |
|---|---|
| <ul style="list-style-type: none"> • '-oscopies • Skin biopsy in clinic • Vasectomy in primary care • Most radiologically guided procedures | <ul style="list-style-type: none"> • '-ectomies, e.g. tonsillectomy, endarterectomy • '-otomies, e.g. craniotomy • Replacements • Repairs • Interventional radiology procedures • Catheter lab procedures |
|---|---|

Sequential Step Standards - Overarching Standards

- Patients should be involved in the checking process whenever possible and appropriate.
- All staff should engage with the Sequential Steps in a professional manner.
- Behaviour should be respectful, honest and civil.³³
- Staff should never undermine the checking processes with phrases such as ‘just some paperwork’.
- Failure to attend / engage with any or all the relevant Sequential Steps at individual or team level should be addressed constructively but should be viewed as a risk and a performance concern.
- The checks should be performed using a paper, poster, electronic or laminated checklist around and by the side of the patient. They should never be filled out retrospectively, by memory or across distance/behind equipment of a procedural room.
- Specialty specific checklists should follow a format, simple language, and structure consistent with other checklists within the organisation.
- Specialty specific checklists should be formally agreed, and risk assessed for use in specific, usually localised, settings.
- Training should be provided for teams using specialty-specific checklists and generic checklists.
- Checklist adaptations should be integrated with local risk assessment and management processes.⁷⁹
- Checklists should be used as tools to assist colleagues in establishing a shared mental model of the hazards associated with procedures they are to undertake and to encourage colleagues to engage the team and establish teamwork/metacognition.^{80 81}
- Each of the relevant Sequential Steps should be conducted and completed in an environment that is free from distractions, including music, interruptions, phone/device use, or non-essential or other conversation.
- Other important clinical activities – such as application of monitoring, scrubbing, positioning – should be done before or after the Sequential Steps, not during, in order to allow full attention to be given.
- Any team member is empowered to challenge others to respect the expected silent focus.
- Every team member should be encouraged to ask questions, seek clarification or raise concerns about any aspect of patient care or the planned procedure.
- Teamwork behaviours, with an understanding of human fallibility and using checklists and standards to enable safe care should be understood by all teams.
- The minor and major procedures split recognises that some invasive procedures may require less detailed checks that are proportionate to the processes involved.
- Emergency situations e.g. Category 1 Caesarean section⁷⁵ or trauma may require adapted ‘Priority’ checks.
- Teams should ensure that external and internal factors that affect performance and communication in invasive areas are recognised, addressed and mitigated. These include noise levels⁸² (music, laminar flow systems), protective clothing (gowns, masks, hoods) and fatigue.⁸³

Checklists and Standards support Effective Team Behaviours



Consent, Procedural Verification and Site Marking

The process of obtaining consent and shared decision making with the patient is 'an ongoing process' focussed on meaningful dialogue: the exchange of relevant information specific to the individual patient. Full GMC guidance on obtaining consent is available⁸⁴. Similar guidance is available from the Royal College of Surgeons⁸⁵, the Royal College of Anaesthetists⁸⁶ and the Association of Anaesthetists⁸⁷. The patient gives consent - it is not taken.

Within NatSSIPs 2 the consent process and procedural verification are linked, and there are a few particular areas where clarity and reinforcement are required.

Who

- The person obtaining consent should have clear knowledge of the procedure and the potential risks and complications.

When

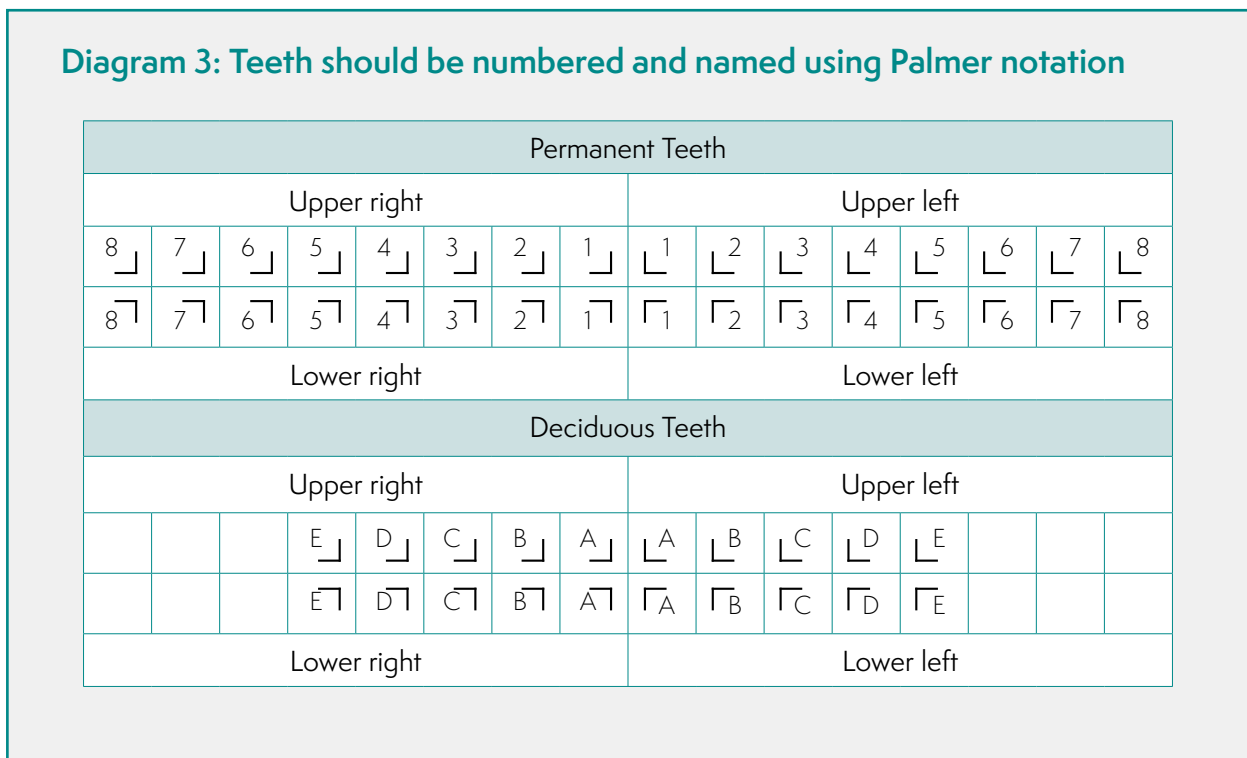
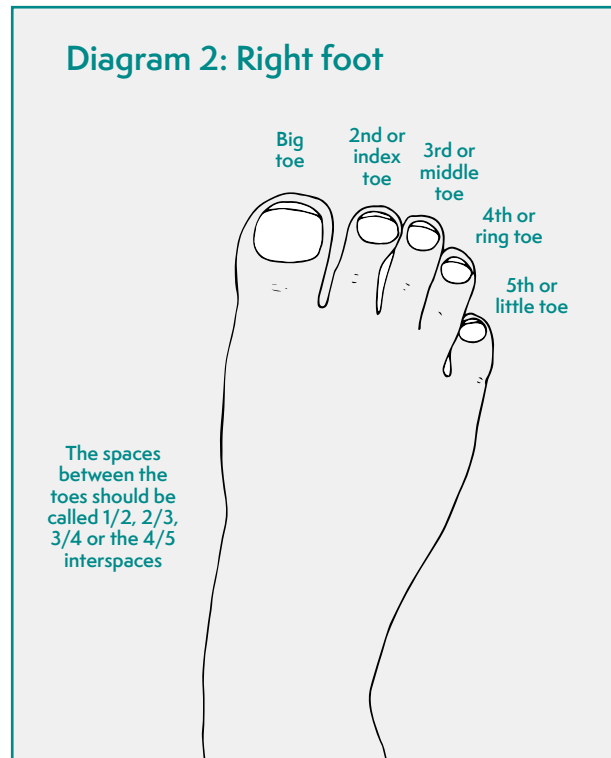
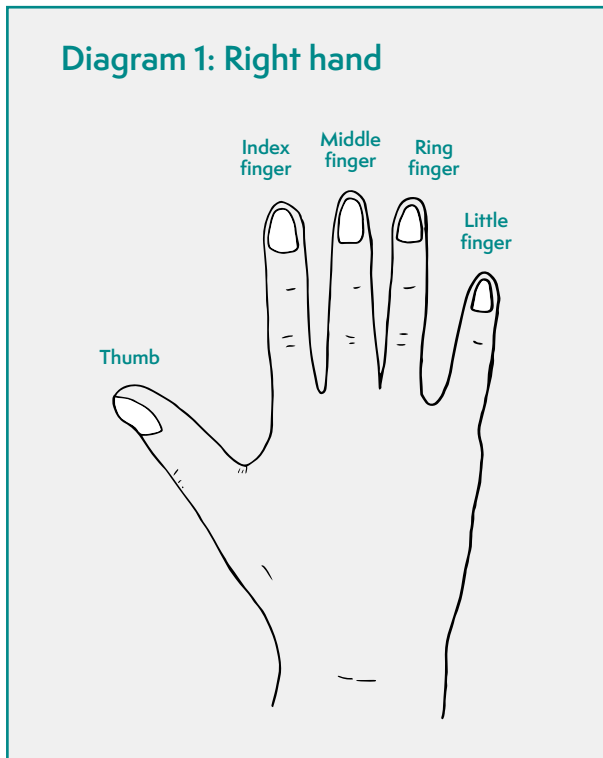
- Consent may be obtained in advance and verified/confirmed on the day of the procedure. The verification and confirmation must include checking the records, including relevant images, biopsy results and investigations, and consent form rather than relying solely on the printed operating list for the procedure being performed.
- Consent verification and surgical/procedural site marking should occur at the same time, by a suitably trained clinician.
- Wherever possible verification of consent and marking should involve the patient.
- Except for life / limb threatening emergencies, a patient's primary consent should never be taken in the anaesthetic room.
- Patient **confirmation** of understanding consent is part of the Sign In process.

Documentation

- Procedures involving anatomical sites that have laterality, the word(s) Right, Left or Bilateral should be documented on the operating list, consent form and all other relevant documentation in full. The use of the abbreviations R / L to indicate laterality is not acceptable.
- In services where electronic notes are in use, measures must be in place to ensure that written information (consent form, printed operating list, body maps and/or photographs etc) is available to the operator or their deputy at the theatre trolley/bedside.
- To ensure accuracy, the consent form and waiting list entry card/request should be completed with the patient present in clinic. Dictated notes or electronic note entries should be completed while the patient is present, or before the next patient (and not saved until the end of clinic).

Recommendations for naming and marking the digits of the hand and feet

- The digits on the hand must be named thumb, index, middle, ring and little. **Diagram 1**
- Toes should be named with either of these names: hallux or big toe, 2nd or index toe, 3rd or middle toe, 4th or ring toe or 5th or little toe.⁸⁸ **Diagram 2**
- The spaces between the toes should be named as 1/2, 2/3, 3/4 or the 4/5 interspaces.
- Any digit for amputation must have a preoperative arrow on the digit itself. There will be rare occasions where this is physically impossible due to pathology and clinical teams should be mindful of the risks of marks further away from the site of surgery.
- The digit names must be indicated on the consent form and similarly marked with a marking pen with the patient's agreement while they are awake.



Site Marking

The purpose of site marking is to provide a visual cue to the whole team of the intended procedural site that has been agreed with the patient. Team awareness and engagement with correct site is an important aspect of safety. Site marking cannot guarantee correct site procedures in and of itself.

A key aspect of site marking is consistency such that the same process is followed within an organisation. Inevitably, this will, on occasion, mean that site marking may appear superfluous but the need for consistency over-rides this.

If the operator has not met the patient prior to the procedure this creates an increased risk of a wrong site procedure.

Who

- The marking should be performed by the operator, a nominated deputy who will be present during the procedure or, in the case of emergency procedures, by a member of the clinical team (staff) who is familiar with the patient and capable of performing the procedure. This fits with the requirement that the operator should meet the patient prior to the procedure.
- There may be particular contexts where this process needs adapting. These include:
 - Emergency work e.g. marking of affected limbs by on-call staff in orthopaedic trauma. In these cases, units must have a risk-assessed, locally agreed process proportionate to the service and work. In emergency and urgent work for example, the risk may be mitigated by having the operator present at Sign In and a second confirmatory arrow over the first
 - Marking of stoma sites is usually carried out by specialist nurses⁸⁹

When

- Site marking must be performed for all procedures for which variation is possible. i.e. where there is laterality, level or more than one operating site.
- The procedure site must be marked shortly before the procedure but not in the anaesthetic room or the procedure room. This should be done with the patient's agreement while the patient is awake and prior to premedication.
- Marking should be performed in parallel with signing the re-confirmation of consent by the operator if a primary consent is made in clinic or on another date.

How (with information and the patient)

- The mark should be applied after confirming the procedure to be undertaken by verifying the procedure with the records, including images and previous investigations and in conjunction with confirming the consent form and, where possible and most importantly, with discussion with the patient.
- The scheduled printed / electronic operating list must not be relied upon as it may not be accurate for the site of the procedure being performed.

How to make the mark

- The mark must be made with an indelible marker, the ink of which is not easily removed with alcoholic solutions.
- An arrow should mark the operative site.
- In addition, if digits are involved, they may be marked with an extra arrow placed on the nail of the digit or at the base of the digit. ([See diagram digits above.](#))
- Do not mark with an 'X'.
- The non-operative side must never be marked - not even with statements such as "not this side".
- If the procedure involves multiple sides/sites during the same procedure, each site and side should be marked as indicated on the consent.
- Text or other markings are discouraged except for when deemed necessary for procedural planning and safety such as a procedure where there are:
 - i) Multiple teams and multiple procedures/scenarios (e.g. 'OSTEOTOMY' on one limb, 'REDUCT' on one breast) or if the operator wishes to add clarity.

- ii) Markings for the procedure e.g. plastics and breast lines.
 - iii) To indicate medial, lateral, posterior, anterior if positioning requires it.
- In scenarios where text is required for the procedure:
- iv) The marks should either be made after Sign In and be considered part of the procedure or text should be written in block capital, legible and read aloud at Time Out.
 - v) The operator is the only clinician who should write text.
 - vi) Text should be agreed per specialty and should always still include a clear arrow to denote the side. It should be recognised that text is error prone.
 - vii) Initials, messages or other symbols should not be used.
- A circle may be added (in addition to the arrow) if the operator requires this to target an abscess, ganglion, lesion, deformity or similar.
 - Other markings may be needed to identify particular procedural sites such as pacemakers, generators or stomas.⁸⁹
 - The mark must not include a date or operator's initials.
 - 'Single use' marker pens should be used in patients with a known infection or in the immunocompromised.
 - The colour of the marking pen is irrelevant provided it is clearly visible on the skin. Pens which have had the cap kept on are safe to use between patients who do not pose an infection risk.
 - A ballpoint pen should not be used; ballpoint pens on skin are painful.
 - Organisations should have risk-assessed, agreed systems for specific contexts. e.g. the use of markers in certain oncology procedures. These systems should conform to the principles outlined in these standards.

Where

- The mark must be placed such that it will remain visible in the procedure field after preparation of the patient and application of drapes. For procedures during which the patient's position may be changed, marking must be applied such that it is visible at all times. When the patient's position is changed during a procedure, the site should be re-verified and the mark checked. An exception is when marking is limited by a dressing or cast; the mark should be made as close to the operative site as possible.

Cautions and Amendments

Reliable marking of procedural sites such as teeth, which may be small, broken down, filled or buried, may not be possible.

- Tooth notation: must be standardised such that only the Palmer notation is used. This must be clearly documented on the consent form, checklist, and whiteboard for verification by the team. To minimise the risk of a procedural site error, the correct procedure should be verified by full review to ensure consistency of the initial request, clinical record, diagnosis, treatment plan, investigation results, written consent, intraoral procedural site check and confirmation with the patient. Reference to radiological imaging should be used when appropriate.
- Stoma sites: should be marked⁸⁹ (and consent taken) by a professional experienced in siting stomas, and an indication of the planned stoma position must be maintained during the procedure.
- Regional anaesthesia: the mark should be used to check side during Prep Stop Block Checks⁷⁷ for regional anaesthesia after Sign In and immediately prior to block insertion.
- Remote access: for procedures where access is remote from the lesion. e.g. interventional radiology, ureteric access etc. an arrow should be drawn relevant to the correct side. This arrow is to aid team awareness at Sign In / Time Out / during the procedure.
- For some procedures it may be useful to use clear drapes to allow visibility of the arrow or to mark the drapes with a sterile marker. If these practices are adopted, they should be consistently applied (e.g. the same approach for all patients within an interventional radiology unit).
- Wrist bands to indicate laterality are not recommended. They have invisibility issues and are liable to being removed and replaced on another limb.
- In cases where the procedure is required following referral from another specialty, there should be easy access to a specialist. For example, if a patient is undergoing excision of a dermatological lesion the operator should have received education in skin conditions and the referring dermatology team should be available, in case of any ambiguity.³⁹

Exclusions

- Patient refusal (try to explain the reason for the site marking).
- Religious or cultural beliefs that exclude site marking.
- Intravenous access.
- Insertion of Hickman lines, central venous catheters (CVC) as the site may change. However, where a specific site is needed or should be avoided this should be explicitly stated on the consent form and procedure list.
- Cardiac catheters and interventional neuroradiology as imaging is used to guide the procedure on table and the entry point will be in artery.
- Critical emergencies where delay due to marking could have an adverse effect on the patient's condition. This is at the discretion of the lead consultant(s).
- Cases of bilateral internal procedures (e.g. bilateral tonsillectomy, oophorectomy) if bilateral is indicated in the consent.

Check Points of Consent and Site Marking

Checking of consent and site marking is a team process to aid team understanding and to support the team's ability to challenge discrepancy. At some points these checks are more concerned with ensuring that correct documentation has been transferred with the patient (e.g. notes, displayed imaging) than (re)identifying the patient per se. Particular caution is needed with patients presenting for repeat procedures, where more than one body part is affected, or where ability to communicate is impaired.

On the ward or admission area

- The consent is checked to be valid.
- A registered Healthcare Professional (HCP) checks the presence of the site mark prior to the patient leaving the ward / admission area and that the side matches the consent and the patient expectation.
- The procedure site mark should be recorded as meeting these standards in the patient's peri-operative patient care plan.

At Sign In (Sequential step 3)

- The planned procedure is confirmed with the patient and their valid consent, against their identity band and by checking the site marking (2 practitioners. See Sign In standards).

At Time Out (Sequential step 4)

- The consent form should be checked by the team against the printed / electronic operation / procedure list as well as against the patient's identity band.

At Sign Out (Sequential step 7)

- Confirmation that the procedure has been performed on the correct site and side occurs.
- If there are multiple procedures, confirmation they have been completed.
- Marks may be erased or crossed off at the end of the procedure if another procedure is planned or likely to occur on the same patient within the same admission.
- Removing previous arrows prior to a new mark is advised.

Caution moments during consent and site marking

Emergency and urgent work

Confused patients

Casts covering the operative site

Multiple operative sites

A rare or less commonly performed procedure

A newly formed team

Unfamiliar environment

Please see the '[Performance Indicators NatSSIPs](#)'

Team Brief

The procedural multidisciplinary Team Brief is a key element of practice in the delivery of safe patient care in invasive procedure pathways, and forms part of the WHO Surgical Safety Checklist² the Five Steps to Safer Surgery and now 'The NatSSIPs Eight'.

Engagement with the Team Brief is a required behaviour in the delivery of safe care and is a demonstration of mutual respect to the multidisciplinary team and an aspect of professionalism. It shows a commitment to the importance of communication for patients, staff and patient safety.

Good leadership will ensure all members of the team feel comfortable, valued and empowered so that any issues of safety can be volunteered and this will encourage an environment of openness and flattened hierarchy. Continuing with tasks and trying to listen is a distraction for the individual, it is a distraction for the rest of the team, and it is a poor example to the rest of the team.

Who

- Organisations must support job plans and timetables to facilitate attendance at Team Brief.

When

- A Team Brief must be performed at the start of all procedural sessions whether elective, scheduled, urgent/unscheduled or emergency procedures.
- Any MDT staff member who will undertake an active role in the invasive procedure should be present. The team should confirm their names and roles. These should always include (in major procedures) but are not limited to: the senior operator and trainee(s)/assistant(s), the senior anaesthetist, and trainee(s), the anaesthetic practitioner, scrub and circulating practitioners or other procedural assistants, including those in training. Other healthcare professionals involved in the procedure should be involved at this communication point as appropriate.
- Radiographers can attend Team Brief, but their absence should not delay it. It is unlikely in most settings that the same in-theatre radiographer will be present during a list.
- The team members' names and roles should be written on a team whiteboard.
- Organisations may consider whether theatre hats with names are a useful aid to communication.⁹⁰
- The senior responsible clinicians should always be involved. Key decisions and knowledge of potential safety issues need to be conveyed by and shared with the team by senior clinicians involved in the case / list. If a clinician intends to have an active role in the case, they should participate in the Team Brief from a safety perspective and as a sign of respect to the team.
- In elective settings, total time set aside for the procedure or list of procedures should include the time taken to conduct the Team Brief.
- The Team Brief should occur at a locally agreed set time and the team should respect this agreed time.
- Staff should not be expected to be undertaking Team Brief whilst simultaneously doing other clinical or managerial tasks.
- In emergency or life-threatening procedures covered by on-call teams, a Team Brief may not always be possible. In exceptional circumstances, where responsibility may need to be delegated, the colleague must be able to perform the procedure independently and must be able to convey the lead's requirements and plan to the procedural team.
- In some scenarios, use of technology such as video conferencing may be a useful complementary approach but should not be used solely for the convenience of team members. There may be situations where, for instance, an operator is involved only with a case later in the day, and video conferencing may promote safe and efficient teamwork.
- Any team member may lead/facilitate the Team Brief and this opportunity can encourage an open culture. The lead should ensure the whole team is listening and participating, and that interruptions are avoided.
- The Team Brief should take place in a discreet location in which patient confidentiality can be maintained, while enabling inclusivity and contribution from all team members. The Team Brief should usually be conducted before the first patient arrives in the procedural area. For operating theatres, Team Brief generally should occur within the anaesthetic room or theatre itself so that detail can be added to a team board and patient confidentiality can be maintained. This location should be modified locally for other procedural areas but should not occur in public areas.

- The Team Brief may need to be conducted on a case-by-case basis if there are changes in key team members during a procedure session, list changes due to other factors or staggered patient admissions. Any changes to the team members during the day should be recorded and trigger a re-brief where appropriate.
- For robotic cases, communication and human factors are important in planning. Safety with robot deployment needs to be considered.
- The Team Brief should occur with the correct and agreed list order and each patient discussed. A process should be in place to update the procedural team with relevant information in the case of staggered admissions or emergency lists. If the order is unclear at the start of a session, or the potential list of patients may change depending on various factors such as test results, a provisional list should be discussed.
- Each patient should be discussed in list order from the perspective of the operator, operator's assistant, the anaesthetist (if appropriate), scrub team and other key team members.
 - Diagnosis, consent, planned procedure and laterality (Sequential Step 1)
 - Relevant comorbidities or complications
 - Airway management plans if applicable
 - Additional monitoring or equipment needed
 - Patient communication issues or disability
 - Allergy status
 - Blood management plans should be confirmed as appropriate to the patient and procedure (e.g. tourniquets, tranexamic acid, cell salvage, availability of blood products)³⁵
 - Patient positioning
 - Infection Prevention and Control issues
 - Implant, prosthesis, stent availability (Sequential Step 5)
 - Equipment requirements/Special equipment and extras (Sequential Standard 6 Equipment Reconciliation)
 - Antibiotics and / or other drugs required
 - Other risks e.g. lasers, fire risk and management plan
 - Postoperative destination e.g. ward or critical care unit
- The Team Brief should provide an opportunity to open up communication channels to discuss, where appropriate:
 - drinks / food for patients later in the list
 - additional cases
 - planned breaks
 - changes in personnel
 - student and trainee needs
 - staff familiarity with the procedures
 - expected behaviour/culture/non-tolerance of bullying
- A specialty-specific Team Brief checklist may be locally developed and used to ensure essential information is shared. [See Online Sequential Step Implementation portal](#)
- For situations where there is only one invasive procedure, the concept of a Team Brief is still important. Although it may be concise, it still provides an opportunity to discuss important aspects – enhancing safe, efficient, reliable care.
- A record of Team Brief should be kept to guide the list and feedback to management.
- Organisations should develop systems that can use information gathered at Team Briefs (and Debriefs) to address issues and support quality improvements. The record can be kept on paper or electronically with local theatre management systems. This can help identify failures and opportunities for learning especially if used in conjunction with the Debrief (Sequential Step 8).
- Any issues raised in the Team Brief that may have relevance for the care given to other patients by the organisation should be reported to local governance systems by an identified team member.

Caution moments during Team Brief

- Emergency and urgent work
- Confused patients
- Altered list order
- Lack of senior engagement with Team Brief

Please see the ['Performance Indicators NatSSIPs'](#)

Sign In

Sign In is the point at which the team checks that it is safe and appropriate to commence anaesthesia. In minor procedures Sign In can be combined with Time Out. Sign In is not a replacement for safe and efficient processes in admissions and ward areas.

- All patients must undergo Sign In using a checklist.
- Sign In must take place for all patients undergoing invasive procedures with general, regional or local anaesthesia, with or without sedation.
- Patient participation in the Sign In should be routine (when possible).
- Staff should treat the Sign In process as a safety critical moment. Completing other tasks, referring to the process as 'just some paperwork', 'more tick boxes' etc. is not reflective of a positive safety culture.
- Questions to the patient should be open, such as:
 - 'Can you confirm your name and date of birth?' Not 'Your name is XXX, is that correct?'
 - 'Tell us in your own words what procedure you are expecting and which side?' (where relevant) Not 'The form says we are fixing your right ankle, is that right?'
 - 'Do you have any allergies?' Not 'no allergies?'
- Specialty-specific checklists and checklists for minor procedures should be used where these have been risk assessed and agreed, e.g. in an outpatient setting Sign In and Time Out may be merged for speed and ease of use.
- The minimum documents (online or paper) required are valid consent, operating list and a robust form of patient identification.
- At least two people should complete the Sign In process, alongside the patient. For procedures performed under sedation or general /regional anaesthesia, this should be the anaesthetist and anaesthetic practitioner. For procedures not involving an anaesthetist, the operator and a registered member of staff should perform Sign In.
- Organisations should have agreed, risk-assessed approaches to whether a scrub team member and / or the operator should be present. These processes should be consistent within a specialty, and not varied by the preference of individual clinicians.
- The Sign In should not be completed until any omissions, discrepancies or uncertainties identified in the handover from the ward or admission area to the receiving practitioner in the procedure area or anaesthetic room have been fully resolved. On rare occasions, the immediate urgency of a procedure may mean that it may have to be performed without full resolution of omissions, discrepancies, or uncertainties. Such occurrences should be reported as safety incidents.
- Provision must be made for patients who cannot speak English / Welsh or have other communication difficulties: interpreters should come into the anaesthetic room or procedure area, or an adult family member if this is not possible. Otherwise, the person confirming consent should be present to confirm prior comprehension via the interpreter.
- Organisations should develop processes to ensure transfer of patients from admissions areas / wards are safe and efficient, without unnecessary duplication of checks. Sign In is the key check at this point, and repeated checks of paperwork and patient identification around this time (e.g. in holding bays) are likely to detract from, rather than enhance, safety.
- Safety checks should include the following for any invasive procedures: (Basic)
 - Patient name, date of birth and medical record number check with the patient and the consent form. In major procedure areas, it must also be checked against the printed identity band, nursing documentation / perioperative care plan and operating list
 - In areas where ID bands are not used routinely (e.g. primary care, outpatient areas) organisations must have a robust standard identification process in place
 - The consent form should be checked to confirm the absence of abbreviations, understanding of patient and date of consent
 - Site marking, if applicable, to be cross-checked with the patient, consent and operating list
- Allergy status should be checked and indicated by a red identity band.⁹¹

■ Safety checks should also include the following where appropriate: (Advanced/additional)

- Pregnancy status
- Infection risk to staff
- Starvation time
- Anaesthetic and emergency equipment/drugs checks
- Airway strategies and preparedness
- A re-cap on the plan for management of blood loss. This goes beyond the previously used question about expected volume of blood loss and includes (where appropriate) questions around tourniquet, anticoagulant use, tranexamic acid, cell salvage etc³⁵. This should be planned at the Team Brief
- Regional anaesthesia ‘Stop Before You Block/Prep Stop Block’ checks⁷⁷
- Availability of essential instrumentation
- Availability of implants, stents, prostheses
- Implants (surgical metalwork, pacemakers etc.)
- Availability of additional staff e.g. radiographers
- Others to be decided locally as appropriate for speciality

Priority checks are appropriate in life threatening situations and by nature are always major procedures and include command and control from team lead and role allocation, and blood management plan.

Caution moments during Sign In

Emergency and urgent work

Confused patients or those less fluent

Patients presenting for second procedures

Disengagement of staff

Risks

Infection including Covid

Pregnancy

DVT

Pressure sores

Metalwork

Availability

Regional block kit

Anaesthetic kit and emergency drugs

Implants

Instrument trays

Blood

Staff/Experts

Please see the [‘Performance Indicators NatSSIPs’](#)

Time Out

Time Out is the most critical check in the WHO Surgical Safety Checklist and is the final check before the procedure. Time Out is a checking opportunity to support the whole team in providing safe, effective and efficient patient care. Time Out is a team process that relies on engagement of the whole team throughout. Some aspects of the Time Out process may appear more relevant to some team members than others, but all are important.

Good leadership will ensure all members of the team feel comfortable, valued and empowered so that any issues of safety will be volunteered. The Time Out is important for training and education.

The key decisions and knowledge of potential safety issues need to be conveyed by and shared with the senior clinicians involved in the case / list.

This helps to bring the team together, raise situation awareness and ensure the essential equipment/prostheses/kit is readily available.

Who

- All patients undergoing invasive procedures under general, regional or local anaesthesia, with or without sedation, must undergo team Time Out immediately before the start of the procedure.
- The lead/senior named responsible operator holds responsibility to ensure Time Out meets the standards.
- Leadership of the Time Out checks can be delegated to any team member, but the operator carries responsibility: they should ensure the whole team is listening and participating.
- If a clinician wishes to perform a procedure there is an expectation that they are present and engaged at Time Out. There are few exceptions to this rule e.g. emergency out of hours work, on-table specialist input.
- The primary operator should summarise the key events/steps/safety issues of the procedure planned, particularly in complex procedures or if some members of the team may be unfamiliar with the steps of the case.
- The primary operator, if not the responsible consultant, should know who and how to call for assistance.

When

- The Time Out should be performed as close as possible to skin incision. This will usually be just before skin prep and draping.

Time Out should take place only when:

- Every team member is giving the process their full attention.
- When the lead operator (and lead anaesthetist) is present.
- All other activities have stopped (e.g. side/other conversations, scrubbing, patient positioning).

How

- A safety checklist must be used to ensure all the steps are followed. Specialty-specific, emergency and minor procedure checklists can be used where appropriate.
- Every member of the team must participate in the Time Out process.
- When all checks are confirmed and addressed the lead should declare Time Out is complete and that the procedure can commence.
- A record of Time Out should be kept; the senior lead operator should take responsibility and they are accountable for the completion of Time Out. There are various ways to validate checklist completion; using a paper, electronic, laminated checklist or poster followed by an electronic or actual signature.
- If any problems or concerns are raised at Time Out the procedure should not begin until they are resolved. The senior operator and / or anaesthetist should always acknowledge these concerns. If these are not resolved and are creating a risk in themselves (e.g. due to excessive delay), the lead operator should assess the situation and discuss the options with the team. If a decision is taken to proceed at risk with a workaround, it should be reported as a safety incident and the rationale documented in the notes.

Basic checks for any invasive procedure

- Confirmation that the team members know each other's names. This should occur for the first patient on the list. If any staff changes occur after Team Brief, and if team members subsequently change, the team introductions should be repeated.
- Confirmation of concordance of patient identity, verbal or written consent, relevant imaging and / or test, site(s) of procedure. It is important that the team understands that this is as much a check of documentation, imaging etc. as of the patient per se. It is also an opportunity to ensure that the whole team understands exactly what procedure is planned.
- Confirmation of any allergies or intolerances indicated via a red wrist band.^{65 66}
- Confirmation that whole team is aware of any key/critical or unusual/potentially unexpected aspects of the procedure and any specific equipment or investigation requirement.
- Confirmation that all equipment, including implants and drugs, needed are present, working and sterile.

Advanced/additional checks relevant to more involved or specialty specific procedures

- Confirmation of the agreed blood loss management plan.
- Confirmation of a diabetes management plan.
- Confirmation of an individualised patient risk assessment using tools such as ASA, generic scores such as SORT, or surgery / procedure specific tools.
- Confirmation of anaesthetic concerns and readiness.
- Confirmation of management plan in event of a surgical fire.
- Confirmation of appropriate infection prevention measures and infection risk from patient.
- Confirmation of warming and temperature monitoring.
- Confirmation of antibiotic administration if appropriate.
- Confirmation of appropriate VTE prophylaxis in place.
- Confirmation of relevant medications e.g. anticoagulants, insulin, steroids, DDAVP.
- Confirmation of any existing intentional foreign objects in situ, e.g. packs.
- Others to be decided locally as appropriate, e.g. perfusion checks.

Additional points of clarification

- There may be legitimate reasons to perform Time Out earlier (e.g. complex positioning) or later (after draping) but the same standards of performance apply.
- If the patient is moved significantly after Time Out, an abbreviated check for correct site and procedure must take place.
- More than one Time Out is required if multiple procedures or multiple teams are involved. e.g. sequential procedures on the same patient with different operating teams.
- In minor procedure areas, e.g. OPD procedures where there is minimal sedation⁷⁶ and no general anaesthesia, Sign In and Time Out can be merged for efficiency and to avoid unnecessary duplication.

The awake patient

- The team should encourage the patient/parent to be involved if appropriate. Only relevant introductions need to be made to the patient and this can be judged on an individual basis, i.e. there is no need for every team member for every procedure to identify themselves to the patient as this can be intimidating and overwhelming.
- Reassurance for the patient is most important. Teams should allocate one team member for that role and where appropriate and respectful they should provide reassuring hand hold / gestures / conversation.
- The patient's dignity should be maintained at all times, e.g. avoiding unnecessary skin exposure.

Consent discrepancy

- If there is discrepancy between the consent form and the procedure expected / proposed by the operator or the medical record in an anaesthetised patient the procedure should **STOP**.
 - Where possible seek advice from senior clinical staff not directly involved
 - Review all the relevant medical records, relevant results and imaging
 - In cases of children or adults unable to consent for themselves, it may be possible to confirm the correct procedure with the person who provided consent
 - In cases of adults who gave their own consent, it is not appropriate to seek consent from a relative
 - If there is any doubt as to the correct procedure, the patient should be woken up, followed by explanation by senior clinicians and completion of Duty of Candour^{43 44 45 46}

Specialty specific requirements

There may be highly localised requirements for Time Out where specific processes are needed related to risk. However, too many variations may cause a risk in itself. This is a key role for the Trust and specialty NatSSIPs leads to make locally informed decisions on the balance between standardisation and rationalisation.

Caution moments during Time Out

Emergency and urgent work

Multiple procedures and / or teams

Lack of appropriate conduct for Time Out

Lack of senior clinical engagement with Time Out

Please see the '[Performance Indicators NatSSIPs](#)'

Implant Verification

Insertion of an implant is a key procedural event. It is important that the correct patient receives the correct implant(s) and that this is achieved safely and efficiently.

These simple safety standards aim to minimise errors and take away some of the cognitive burden, helping teams to insert implants safely by providing standardised pre- and peri-procedural processes for checking that the correct implant is selected for use.

The implant checks should be brief/minimal in duration, to reduce the risk of a wrong implant and keep in perspective the actual level of risk. Lengthy checks may introduce new risks by over burden of checks, checking fatigue and unnecessary delay.

Planning in advance of the procedure, standardisation of processes and education of all staff are important elements in ensuring that the correct implant is chosen.

These processes aim to increase understanding of risk and to strike a balance between a rigid checklist and the avoidance of automaticity which may lead to error.

Technological / engineered solutions may be of benefit, but currently, and for the foreseeable future, there will be human involvement in selection and checking processes. HSIB have completed relevant investigations to this standard with a systems perspective.^{92 93}

Definition of an implant

An implant is an item intended to remain within the patient's body long term. The term prosthesis is sometimes used, but this usually implies a replacement part. The term implant is used here as it is broader and includes stents, pacemakers and similar devices.

What is not an implant?

An item which is intended to be removed, e.g. a wire to hold a fracture that will be removed in clinic in a few weeks. An item which is left in the body that was not intended to be an implant, e.g. the tip of a drill bit which breaks in a bone and a decision is made that it would be better to leave it in the body than to retrieve it.

Sometimes a device or kit is used to insert an implant, such as a stapling device in bowel surgery. An understanding of the component parts is important to avoid a retained foreign object and should be subject to count procedure (See standard 6 Reconciliation of items). If an implant is used, a full count procedure is required in any invasive setting e.g. pacemakers, knee replacement.

Types of Implant Terminology

Type specific implant - chosen for laterality, power, size e.g. knee, breast, lens, coils, stents

Custom implant - made for the patient e.g. cranioplasty

Biological implant - from a human or animal e.g. rib in rhinoplasty or valve in cardiac

Electrical implant - e.g. generator or pacemaker

Multi-part implant - compatible parts fit together

Onyx/Glue Implant - is an injectable substance that hardens into an implant

Standards dependent on timing of implant decision

In general, the choice of implant is made at one of three times, and this will affect the process for checking the implant(s) before implantation:

- a) **Known implant.** When the exact implant(s) is known before the procedure. This includes custom-made or biological implants. It also includes batteries / generators for an in-situ device that need changing, a lens in eye surgery or a custom cranioplasty implant.
- b) **Restricted/evolving decision/choice.** When the exact size or type of implant is decided upon during the procedure. e.g. joint prostheses.
- c) **Unplanned or unexpected implant insertion.** Local practice will determine whether on table measurement or templating is required to guide which intended implant is requested, for example, endovascular stents or knee replacement.

The requested implant details should be written down in any situations where there is an appreciable time gap between request and implantation, or where implants are in a different physical location. Local units must agree on a process that meets these standards, taking into account local practices and environment.

Standards dependent on the number of implants

- If there is only one implant, the minimum information that should be checked is:
 - Type of implant/prosthesis/device
 - Laterality (when applicable)
 - Size (all relevant dimensions)
 - Expiry date
 - Sterility
- In addition, if the implant is custom-made, the name, date of birth, and a unique number (NHS number and/or hospital number) should be cross-checked with the patient's identity band. Some specialties will specify additional items.

Standards dependent on more than one implant (including screws)

- The key additional factor for the second and subsequent implants that should be checked is compatibility. Some specialties will have additional items, for example, an orthopaedic operation which involves the use of different screws may wish to add "size 40, four zero" on giving and receiving each. Compatibility will be context specific, e.g. type of material, size of implant relative to other components. The key question for the operator and those giving the implant is simply, 'Is this the correct implant to be used in this situation?' There will be occasions when the operator deliberately and appropriately chooses to use implants that are not intended to be used together. This is a justifiable clinical decision.

Standards for organisations

- When permanent stocks of implants are maintained in the organisation, a named individual should be responsible for: checking stocks, ordering, organised storage, ensuring that expiry dates are checked regularly, and that any implants that have passed their expiry dates are removed and cannot be used.
- Some organisations use scanning technology to track and reconcile equipment, prostheses and implants, and procedures for each patient. This could be extended to more implants and / or provide an alert when there is a patient/product mismatch,^{92,93} in addition to providing up to date stock information.
- The organisation must have a process in place for recording which implants/prostheses are used for which patients. For most implants this documentation is a national requirement, e.g. breast and joint implants.
- The organisation should ensure that appropriate and agreed stock levels of implants/prostheses are maintained.
- Errors or near misses with correct implant insertion should be reported, recorded and openly discussed at the Debrief, and fed into local governance processes to act as the basis for learning and the development of new or altered procedures to promote patient safety.
- When manufacturers' labelling, packaging or implant defects contribute to failure of implant verification, a process should be in place through which both the manufacturers and the MHRA (Devices) are informed.⁹⁴
 - Access MHRA reporting via this link <https://yellowcard.mhra.gov.uk/>

Before the procedure

- When the patient is scheduled for an invasive procedure, the waiting list or scheduled list information should be clear and detail whether or not an implant(s) is required. This is of particular relevance to custom or type specific implants.
- Implants should be kept adjacent to the procedure room. Local units should ensure that excessive numbers of unneeded implants are not in the theatre/room.
- Elective lists, within reason, should have information of which implants are required before the day of the procedures. Emergency or Trauma list information will enable implant stock checks or decisions on the day.
- A named team member, usually a senior practitioner or team lead, should be responsible for ordering the implant(s) and checking that the correct implant has been delivered and stored before the procedure. This information should be available to the rest of the team. This team-member should check sterility and expiry dates.

At Team Brief

- The operator should confirm whether or not an implant is required, if the type of implant is known, or if the specific implant will be decided during the procedure.
- If other implants are needed for foreseeable back-up, this should also be discussed and checked.
- If the exact implant is not known, confirm with the runner that they know where each possible required implant is; and which are compatible with each other.
- One member of the team should check that the implant is available, or that the expected range of implants from which the final choice will be made is available.

At Time Out

- If the implant is known, the team should confirm the type of implant and write it down (on paper or a whiteboard in the theatre). The requested implant details must be written down in any situations where there is an appreciable gap between request and implantation, or where implants are in a different physical location. Local units must agree on a process that meets these standards, taking into account local practices and environment.
- If the exact implant is not known, confirm with the runner that they know where each possible required implant is; and which are compatible with each other.
- Any operator sight issues and the need for spectacles to assist checking should be declared and acknowledged.

During the procedure

- Only a named regular member of staff (e.g. the runner) should receive the request, obtain and hand over an implant. A company representative must not do this task.
- Dependent on the context, when the operator requests the implant it may be appropriate for the runner (or another team member) to write down the requested implant on the whiteboard (or on paper). This Implant check step is sometimes called an 'Implant Time Out' or 'surgical pause for implant'⁹³ and helps refocus the team in theatre. The runner obtains the implant and shows it to the operator, who 'reads aloud' the implant details:
 - Type
 - Laterality (when applicable)
 - Size
 - Expiry date
 - Sterility
- If it is a custom-made implant, the name, date of birth and another identifier (NHS number or hospital number) should be cross-checked with the patient's identity band.
- The runner then opens the implant, and the operator or scrub practitioner receives it. All packaging is kept. Labels are placed in the theatre record and the patient notes, or electronic equivalent.
- If there are subsequent implants:
 - The same process is followed
 - In addition the operator should check:
 - i) Is this compatible with the previous implant?
 - ii) Any other information relevant to this specialty, e.g. size

- At Sign Out the operator confirms the implant.
- A record of the implants used must be made in the patient's records. Appropriate details should be shared with the patient after the procedure. When a manufacturer's label is available, this should be placed in the notes. When it is not, for example with electronic patient records, the following should be recorded:
 - Manufacturer
 - Style
 - Size
 - Manufacturer's unique identifier for the implant, or the serial number
 - Expiry date
- Compliance with local, national and international implant registries is encouraged, and in certain cases may be a mandatory legal requirement.

In summary

Implants checks are required for all specialties that insert implants

Before starting: Formally verify that expected implants are available

On requesting: Write it down if there is a time gap between request and implantation

Before implanting:

Formal verification by operator

Always confirm compatibility for multiple implants

After implantation:

Ensure details are recorded in an auditable process

Please see the ['Performance Indicators NatSSIPs'](#)

Reconciliation of Items in the Prevention of Retained Foreign Objects

This standard supports safe, consistent and efficient practice in accounting for all items used during invasive procedures and in minimising the risk of them being retained unintentionally.

The processes outlined in this standard should ensure that all items are accounted for and that no item is unintentionally retained at the invasive site, in a body cavity, on the surface of the body, or in the patient's clothing or bedding. This standard represents the gold standard in count procedure and practice. The need to prevent the rare occurrence of unintentional retention of items must be balanced against the need to support timely and efficient surgery and other procedures. Enforcing counting procedures where the possibility of retained objects is unlikely, will be counter-productive to engagement with safety procedures and may make processes less efficient.

The prevention of retained foreign objects is a shared responsibility and the risk of occurrence is reduced through education, effective teamwork and processes.

These standards apply wherever and whenever invasive procedures are carried out. This includes all aspects of maternity care, outpatient and ward-based procedures.

This standard includes all potentially retainable items used in procedures, as well as those used as part of anaesthesia and sedation, e.g. throat packs placed by the anaesthetist during oral or nasal surgery. The AfPP Standards do not extend to all invasive areas and so remains aligned.⁷³

Full Count procedures:

For all invasive procedures in any environment where swabs, sharps and instruments are used and where there is a cavity large enough to retain them, e.g. operating theatres; labour suite rooms; and in areas where the procedure provides a surgical cavity in scenarios such as interventional radiology hybrid procedures, pacemaker insertion or the emergency department.

Type of count	Which procedure?
Full Count	Major procedures (other than interventional radiology (IR)) All maternity areas including delivery room Any procedure where a cavity is entered
Proportionate Count	IR areas and minor procedures

A full count may not be necessary in some settings, for example procedures performed via incisions too small to retain objects, via needle punctures, or via natural orifices without the insertion of swabs. Whilst it is still essential to prevent retained foreign objects in these settings (e.g. wire count), the complexity is less, and a full count would be irrelevant and time-consuming.

Standards for organisations

- Organisations must have processes in place to ensure the appropriate reconciliation of all items and equipment used during invasive procedures.
- The methods and documentation used for counting should be both consistent and standardised within an organisation for all count procedures.
- All team members involved in counting and reconciliation should have received appropriate training and competency assessment.
- Organisations should agree a generic list of items to be included in the counts in specialty areas. This list should be adapted, reviewed, and revised in line with local circumstances and the specialty, taking into account analysis of benefits, risks and local, national and international safety incidents, e.g. the inclusion of specimen retrieval bags; liver retraction devices; vaginal swabs and tampons; radiological sheaths, catheters and guide wires.

- Instrumentation and new equipment must be risk assessed. This includes an understanding of the labelling/ names, parts and integrity of all instruments/items/equipment used in invasive procedures. These must be checked in a proportionate manner before and after use by staff with appropriate training.

What

- The count should include any item that enters the procedural field, including swabs, sharps, disposable items and instruments and their constituent parts.

Who

- Two trained staff should perform the count. One should be GMC (General Medical Council), GDC (General Dental Council), NMC (Nursing and Midwifery Council) or HCPC (Health and Care Professions Council) registered; any unregistered staff should be assessed as competent.
- Count competencies should be maintained. [See Online Sequential Step Implementation portal](#)
- All scrub practitioners / operators' assistants and operators in the full count areas must be familiar with the count as it applies to their area. Other members of staff need an understanding of the basic count method outlined below to support those performing the count.

When

- A pre-procedure count should be performed prior to commencing a procedure to establish a baseline. This should include any existing intentional foreign objects in situ and anaesthetic packs.
- An intra-procedure count should be performed when appropriate: before intentionally packing a cavity and when there is a change in scrub personnel.
- A first count should be performed (as appropriate to the procedure):
 - Before closure of a cavity or major organs
 - Before closure of the first layer of muscle, e.g. during spinal and joint replacement surgery
 - Before wound closure begins
- The final count should occur at the beginning of closure of the skin or before the end of the procedure. This point should be identified to the team (e.g. 'pause for gauze') as a point when the scrub team need time and concentration to count carefully. The end is when 'final count complete' is announced. This is confirmed at Sign Out (Sequential Step 7).
- A count should be performed any time a discrepancy is suspected that cannot be readily checked.
- A count should be performed if there is a changeover of either the scrub or circulating practitioner.

How

- Staff should be allowed to count without distraction unless there is urgent, unforeseen clinical need.
- If the count is interrupted, it should restart from a point before the interruption.
- The members of staff should ideally be the same throughout the procedure, but changes of scrub practitioner or operator's assistant may be required. In the event of a staff handover being necessary, a full count should be undertaken to account for all items at that point.
- In the event of failed reconciliation, the operator must be informed, the count repeated, and the theatre and operating site searched. If unsuccessful, locally agreed procedures on the use, and interpretation of x-rays must be followed.
- A count board must be used, with standard notation and documentation.
- Count boards should be of sufficient size and positioning to be readily visible and salient at all times.
- Locally adapted count boards should be used in specialist areas to include specialty specific items.
- Organisations should have systems in place to avoid unnecessary duplication of documentation.
- The count marks should be easily visible, legible, and written horizontally on the board. The count board marking, and symbol practice should be consistent across the organisation.
- The total number of items currently in use and those counted out, should be always clearly legible and understandable. No extraneous/additional markings in the running total should be made.
- All items should be visually inspected to ensure they are intact after removal from the body.
- The count board must have specific areas for noting the numbers of each type of item in use and the count (both in and out) should follow a standardised order.

Swabs

- Swabs should be counted in and out in multiples of five and should include the red tag used to bundle the swabs into packs of five.
- If present the integrity of tapes or tails that are part of swabs or packs must be visually checked when the items are being counted.
- Instrument sets should not contain swabs.
- All packs and swabs used in invasive procedure fields must contain a radio-opaque strip.
- Throat packs placed by the anaesthetist must be in the count and have a radio-opaque strip. The tail may be used to secure the pack to the tube and a throat pack sticker should be used. The presence of a throat pack must be communicated to the team following insertion and its removal confirmed at the end of the procedure.

Green swabs or gauze are used in anaesthesia for a) pressure padding (e.g. around 3 way taps or tube ties) b) absorption (e.g. failed cannulation, saliva, ultrasound gel) and c) to stop a drape sticking to a tracheal tube. Green swabs represent a risk as they do not have a radio-opaque line and they can end up mixed in the count.

Local risk assessment should take place to reduce risk of green gauze retention. Using other items designed for purpose, e.g. soft band tube ties should be procured/considered.

- The mouth represents a danger zone. Green gauze should never be used to stabilise an airway.
- Overzealous use of green swabs is discouraged.
- Blue swabs should be used for surface dressings or on a closed wound.
- Packs and swabs should NEVER be cut.
- The size, colour and number of swabs to be included in standard packs for procedures should be locally agreed.
- Standardised terminology should be used for swabs and packs.
- A 'Pack' used as a packing material usually has a tail and is bigger than a large swab. Packs must never be tied together. e.g. trauma and maternity.
- A dressing pack is a pre-prepared sterile pack used for some procedures. Dressing packs should always contain radio-opaque swabs and initiate a count whether proportionate or full.
- The dry weight of swabs and packs should be known by weighing dry in order to accurately calculate estimated blood loss.
- Risk assessment should identify when and if it is acceptable for non-radio-opaque swabs to be used in invasive areas and should define the size and colour of swabs that can be used for this purpose, e.g. for urinary catheterisation and anaesthetic use.
- Only the minimum number of items necessary, including swabs, should be opened prior to any procedure.
- Some packing materials are absorbed by the body. These should be documented but do not need to be counted. See [Online Sequential Step Implementation portal](#) for materials/items used for packing.

Table 6: Details on types of swabs, how they differ and their subsequent risks. This is a guide, as local procurement may vary.

Type of swab	Radio-opaque	Use	Routinely counted	Risks
White Radio opaque swabs Small Swabs 15x10cm Med Swabs 30x30cm Large Swabs 45x45cm	Yes - which allows detection in the event of failed reconciliation. Radio-opaque swabs are more expensive. This is still reliant on a robust count process to identify missing items	In all cavity or invasive procedures	Counted in 5s	Should never be cut. Large numbers may be used that all require counting.
Large Pack with radio-opaque line (has a tail)	Yes - which allows detection in the event of failed reconciliation. Radio-opaque swabs are more expensive. This is still reliant on a robust count process to identify missing items	In all cavity (maternity/trauma/HPB) or invasive surgery	Counted	Should never be cut. or tied together. Used in high blood loss situations e.g. trauma or obstetrics Should follow process for intentionally retained pack if packing is left in situ
Green pack with radio-opaque line (has a tail)	Yes - which allows detection in the event of failed reconciliation. Radio-opaque swabs are more expensive. This is still reliant on a robust count process to identify missing items	As a throat pack for some surgeries	Counted	Airway obstruction
Lintines and patties	Yes- which allows detection in the event of failed reconciliation. This is still reliant on a robust count process to identify missing items	Neurosurgical and spinal surgery	Counted in 5s or 10s.	Should never be cut. or tied together. Large numbers may be used
White swabs	No- radio-opaque line Must never be used in a cavity or major surgical procedure. If in procedural field, risk assessment must be completed	When the procedure is performed outside the operating theatre and through a needle, small wound or natural orifice (e.g. for Interventional Radiology or flexible cystoscopy in outpatients).	Not counted - these are areas where a proportionate count is used	If a bigger incision is made or cavity entered - they are not radio-opaque and radio-opaque swabs should be used
Blue swabs	No- radio-opaque line Must never be used in the surgical/ procedural field until wound closed	Surface wound dressings (e.g. ortho and plastics)	Not counted	If mixed with the count, they are not radio-opaque and cannot be detected with x-ray
Green swabs	No- radio-opaque line Must never be used in the surgical/ procedural field.	Anaesthesia a) pressure padding e.g. around 3 way taps or tube ties and b) absorption e.g. failed cannulation, saliva, ultrasound gel. C) To stop a drape sticking to a tracheal tube.	Not counted	If mixed with the count, they are not radio-opaque and cannot be detected with x-ray

Sharps

- Suture and hypodermic needles should all be counted.
- Suture packs should be retained for cross-checking and should be included in the count.
- Organisations must have adequate processes in place for safe management of sharps.

Instruments and disposable items

- Instruments should be counted using the checklist for that set when they are part of a set.
- Supplementary single-packed instruments should be counted separately.
- Instruments with multiple parts should be counted as one instrument (but confirmed to be intact).
- Disposable items, e.g. Bert bags for laparoscopic surgery, should be counted on and off the procedure field in the same way as instruments and sharps.
- Both single use and re-usable items should be counted.

Proportionate count procedures

- When procedures are performed outside of theatres, via incisions too small to retain objects, via needle punctures, or via natural orifices without the insertion of swabs; a proportionate count to confirm the presence of intact equipment and the removal of any wire and ancillary equipment, such as sheaths, may be sufficient. This will apply to the majority of radiology, cardiology, endoscopy, wards, outpatient areas, emergency department and minor procedures.
- However, if a procedure in this area involves a cavity large enough to retain an item, such a proportionate count will be insufficient.
- There is no requirement to use a count board, but the completion of these checks must be documented in the patient notes.

The principal risk in this situation is the retention of guide wires and the detachment of parts of instruments or other devices during use. Verbal checks should be performed for an abbreviated count.

- A two-person verbal confirmation of the removal of any wires used should occur.
- Lone insertion of lines should not occur. An assistant is always needed. It is a quality standard to insert lines with two practitioners to assure sterility, so this will assist in the required checks.
- A two-person verbal confirmation that any equipment used is intact.
- This check should be modified or augmented by individual areas as necessary to mitigate their particular risks for retained objects.
- Any other check(s) which local areas feel necessary to mitigate their particular risks.
- Physical and human factor design aids to force guidewire removal exist. Organisations should consider where and when such aids may be beneficial, e.g. Wiresafe™.⁹⁵

Equipment and instrument management

- The generic list of items to be included in the count must be agreed locally and continuously updated in line with analysis of local risks and safety incidents.
- Instrument sets and equipment should be periodically risk-assessed and rationalised to ensure that they contain minimum amounts of required equipment, and that the equipment is appropriately maintained.
- New equipment should be risk assessed and broken into component parts before use. A manual should be available, alongside training and a company representative when appropriate prior to first use.
- There must be a local traceability system of all instruments used during the procedure. These should be recorded in the patient record.
- An up-to-date list of the instruments that are present in each set/tray must be maintained. These must be included in the sterile set management by decontamination and sterilisation services so that incomplete sets and missing equipment are highlighted.
- Equipment that can be disassembled, e.g. for cleaning purposes, must be clearly described on the instrument list, including the number of parts, e.g. retractors. The integrity of all items must be visually checked before and after use, including component parts of equipment and instrumentation. The use of photographs can sometimes be helpful for complex instrumentation.

- Where possible and appropriate kit and other items should have radio-opacity.
- Organisations should consider implementation of technological solutions to tracking of swabs and instruments as they become available.

Intentionally retained foreign items

- Patients and healthcare staff must be made aware of any item intentionally or deliberately retained after a procedure and what the plan is for its removal.
- A locally agreed process should be followed whenever foreign items, such as swabs, packs, or any other objects are intentionally retained. There is currently no strong barrier, but strategies may include:
 - A coloured alert wristband indicating a retained item to clinical staff and the patient
 - A patient information leaflet with sufficient information of the site, nature, number and purpose of the retained items for the patient and any other healthcare providers
 - An alert in the notes and clear documentation on the procedural note as to the site, nature, number and purpose of retained objects
 - Confirmation of the above before Sign Out is complete
- On occasion, items which were not intended to be implanted may appropriately be intentionally left permanently in place. For example, a surgeon may on balance decide that it is safer to leave a fragment of broken screw in a bone than to risk further injury or damage in an attempt to retrieve. When this occurs, this must be clearly documented in the medical record and the patient informed.
- Absorbable packing. Some packing material is deliberately retained and is absorbed over time into the patient. It is not necessary for this to be included in the process for deliberately retained items or subsequent count.
- The receiving ward (or theatre) nurse / practitioner must confirm the presence of any intentionally retained items at the time of handover.
- The nurse / practitioner must ensure that the intentionally retained item is clearly documented and that a patient information leaflet is given.
- If the patient returns to an operating theatre / procedure room for removal of an intentionally retained foreign item the site, nature, number, and purpose of the items to be removed must be confirmed during Time Out.
- On removal of the item(s), any patient-held indicators of the item (e.g. wristbands) must be removed with clear plans to discuss the current status with the patient. Documentation of removal of items must be clear in the notes. If multiple items retained in the patient, a removed (in vs out) count check with the documentation and patient should occur.

Ward process for discharging with intentionally retained items

- The discharging nurse should ensure that the item is discussed as part of the discharge checks and the patient information leaflet is given.
- The discharging operator should ensure that the intentionally retained item is documented in the notes and the discharge summary.
- If the item is due to be removed in the outpatient department, the discharging nurse must ensure that the patient has their outpatient department appointment booked before leaving the hospital / clinic.
- The ward nurse should ensure a district nurse, general practitioner or other appropriate referral is made for items which are due to be removed in the community and the referring consultant must be informed that this has been done. A record should be kept of all patients with intentionally retained items going to the community.
- Commonly retained items include negative pressure wound dressings (e.g. VAC-dressings). An agreed system must be in place between operating theatres, wards (including on patient transfer) and the local community teams as to how dressings are accounted for. Dressing changes on the ward, in outpatients or the community must follow the same rigorous counting in and out process. Count risk and processes should be shared with tissue viability and district nursing with agreement of when a wound becomes a cavity.

Transfer of women from labour suite to maternity theatres is a particular risk.

- Maternity units should have a rigorous process for ensuring handover of any vaginal swabs between the labour suite and theatres or wards. The often-urgent nature of these transfers places the woman at higher risk of inadvertent retention and is reason to follow a robust process.

Failed reconciliation

- There should be a clear, agreed local process to follow in the event that an item is unaccounted for during or at the end of the procedure. This should balance avoiding unnecessary exposure of the patient to ionising radiation without good cause, with the risk of subjecting the patient to additional procedures.
- In the event of failed reconciliation, the operator should be informed. The operator must stop wound closure, if safe to do so, whilst the count is repeated, and the theatre and operating site searched. If unsuccessful, this process should include:
 - Immediate communication to the lead operator, and the procedure team, identifying the discrepancy
 - A full further count
 - Undertaking a thorough search for the missing item
 - Not moving the patient out of the procedure room until the missing item is accounted for
 - X-ray in the theatre should be used in accordance with local policy. A risk-benefit decision should then be made as to the need for the item's retrieval
 - If x-ray is used it should be (wherever possible) whilst the patient remains under anaesthesia and in the procedure room
 - An x-ray in the recovery room ('just in case') is not appropriate and is too late
 - Staff should never assume that missing items are not somewhere in the room
- There will be occasions on which there is a failed reconciliation but when the operator is certain that there is no foreign object remaining in the patient. Under these circumstances, the agreed processes for failed reconciliation should proceed unless and until the whole procedural team is agreed that there can be no foreign objects left in the patient.
- The operator must listen to and acknowledge the concerns of the team.
- The local process for use of x-rays must involve discussion and agreement with radiography and radiology departments to ensure the correct images are used in the correct context.
- The failed reconciliation process should specify when an image intensifier or plain x-ray is used, and when the opinion of a radiologist concerning the image should be sought. It should be noted that x-ray visible or "Raytec™" swabs cannot be reliably identified with an image intensifier, nor can needles less than 10mm. Comprehensive documentation relating to unaccounted for items should be added to the patient's record and the patient should be informed.
- Patients must be made aware of any unintentional retention of a foreign object and what impact this may have on their health. This is aside from any obligations under Duty of Candour legislation.

Maternity services

Maternity remains the highest risk area for retained foreign objects. This is in part due to a number of caregivers in the pathway, a series of handovers, the urgent nature of some interventions and the desire to avoid unnecessary medicalisation of the process.

- The count procedure in obstetric theatre or delivery room should be as in any theatre with a full count procedure and use of a count board.
- The standards of counting, equipment reconciliation, training in the count and count handover detailed above apply in full to birthing / labour suite rooms.

Emergency procedures

On occasion procedures may be of such urgency that following every standard above would pose a greater risk to the patient than providing immediate care. This is fully justifiable and supported by NatSSIPs. However, organisations should strive to have processes to reduce the risks even when certain checks cannot be performed. These include pre-prepared emergency kits, allocation of staff to specifically address equipment issues etc.

Training, competency assessment in counting and item reconciliation

- Organisations must have a robust and proportionate (risk-based) approach to training, assessment and ongoing competence for the processes described above. Details of standards expected are given in [Online Sequential Step Implementation portal](#).
- AfPP Standards⁷³ expect the whole MDT to receive training and assessment in count procedure.
- AfPP Stanadards⁷³ do not yet include the proportionate count concept although this change in practice is intended for non-perioperative areas such as interventional radiology or minor procedures in OPD.

Caution moments during reconciliation of items in prevention of retained foreign objects

Emergency and urgent work

Multiple operative sites or cavities

Multiple trays, teams, and handovers

Maternity services

White swabs without a radio-opaque line in dressing packs

Green swabs near mouth or cavity areas

Please see the Performance Indicators 'NatSSIPs'

- **Count competencies.** [Example of count competency framework](#).
- **Materials used for packing.** There are a [number of materials](#) which are used for packing wounds. Those which are absorbable do not need to be counted.

Sign Out

Sign out is a specific set of checks which: supports safe completion of the invasive procedure, including relevant documentation; starts the process of safe and efficient handover of care; and identifies patient, equipment, staff or process concerns that need addressing.

Standards

- All patients must undergo Sign Out using a checklist: all patients who have had procedures under general, regional, or local anaesthesia, or under sedation, must undergo Sign Out. Specialty-specific and minor procedure checklists are available and should be used where appropriate.
- All team members should still be present: as a minimum, this must include the operator, the operator's assistant, the anaesthetist (if applicable) and the member of staff who will be handing over to the post-procedure team (if different).
- Any team member can lead, but the operator carries responsibility: they should ensure the whole team is listening and participating. This will usually require that the team stop all other tasks and face the Sign Out lead.
 - Sign Out should occur once the count is complete, but before the patient leaves the theatre or procedure room and prior to handover to post procedure care team
- Safety checks should include the following:
 - Confirmation of the exact name of the procedure, site and side; this may have been altered or expanded
 - Estimated blood loss if relevant
 - Explicitly checking that specimens are labelled correctly and in the correct container
 - Confirmation of a correct count including instruments, swabs, throat packs and sharps. All items must be confirmed to be intact
 - Confirmation of any intentionally retained items (if appropriate)
 - Implant check if applicable
 - Key procedural / surgical and anaesthetic plans for recovery and postprocedural management including level of care and any patient-specific concerns
 - Equipment or process problems for inclusion in the Debrief
 - Confirmation that VTE risk assessment is completed and actioned
 - IV lines are flushed, and unnecessary extensions removed in preparation to handover to recovery. Timing may depend on procedure and the situation
 - The patient is still wearing identity bands when appropriate
- Sign Out should also include the following where appropriate:
 - Drain and clamp instructions
 - Responsibility assigned for talking to the patient and / or family
 - Others to be decided locally as appropriate
- Sign Out should not end until all steps to prevent retained foreign objects are complete. Sign Out should stop and wait for reconciliation tasks to be done.
- Notes should be completed as soon as feasible.
- Organisations should consider how the Sign Out can support safe and efficient processes for early discharge of suitable patients such as prescription of take-home medication, completion of discharge letters or criteria for discharge.
- Please see the 'Performance Indicators NatSSIPs'.

Handover/Debrief

Handover

There are formal handover points in the patient pathway at which professional responsibility and accountability is transferred between individuals or teams. There will also be planned or unplanned changes in the members of a procedural team that occur during procedures or lists of procedures. Handovers may occur pre-operatively, during the procedure and post procedure.

- Handovers should follow a structured format to convey key procedural information. Structure may involve use of a format such as SBAR⁹⁶ (Situation, Background, Assessment Recommendation). Handover may include:

Basic

- General information
- Name of patient, checked against identity band
- Relevant comorbidities
- Allergies
- Planned and actual procedure(s) performed, with site and side if relevant, and procedural course
- Post-procedure management plan, to include provision of analgesia
- Relevant intraoperative medications, including opioids, anti-emetics and antibiotics

Advanced/Additional

- Target range for physiological variables
- Course of anticipated recovery and problems anticipated
- Plan for oral or intravenous intake
- Medications
- VTE prophylaxis
- Early warning scores when in use in the organisation
- Information given to the patient about the procedure, or any plans for information to be given after the procedure
- Any patient safety incidents
- Procedural complications and interventions to correct these
- Procedural site dressings, tubes, drains or packs
- Any further information or instructions in relation to drains, e.g. whether suction should be applied or not
- Any intentionally retained objects and plans for their removal, if relevant
- Anaesthesia information; ASA physical status / Risk assessment
- Anaesthetic complications and interventions to correct these
- Any problems related to the airway
- Confirmation that intravenous lines and cannulae have been flushed
- Confirmation that the lumens of multi-lumen catheters have been both clamped shut and occluded with caps or needleless connectors
- Confirmation that any throat pack has been removed
- Intravenous fluids and blood products given, with estimated losses
- Participation of the patient (and/or parent, guardian, carer or birth partner) in handovers should be encouraged when feasible.
- The participants should be focussed on the handover and ensure the team are actively listening.
- Handover should take place before or after monitoring is applied. Handover should not be attempted whilst staff are performing other tasks.
- Read back can be used to confirm understanding.
- Each team member should be given the opportunity to ask questions and clarify information.

Debrief

The Debrief is an opportunity to confirm the recording of good practice, incidents and near misses to ensure that information is input in a timely manner to improve data quality and accuracy of reporting.

All elective major procedure sessions should end with a Debrief. A Debrief is encouraged if feasible after emergency cases. Although it is sometimes logistically difficult to arrange, the Debrief allows the team to provide feedback and take actions on the session before facts are forgotten. This feedback can be used to improve future work and should thus be prioritised.

- Debrief should occur on a case-by-case basis during emergency sessions or one-off minor procedures: a flexible approach is needed when the composition of the team is constantly changing.
- Debrief also applies to minor procedure sessions: local modifications as necessary should be encouraged to make it practical and useful for individual areas.
- Points of interest should be captured during the session to ensure they are not forgotten at the end: issues should be identified during the list and captured for summary and discussion at the end.
- Dedicated time: job plans, scheduling and working patterns should allow and oblige staff to participate in Debrief.
- Involve the whole team: every member of the procedural team should be encouraged to take part and offer suggestions for future improvement.
- Key elements to discuss:
 - Things that went well
 - Problems identified and plans to address these
 - Areas for improvement
 - Maintain a debrief action log: problems identified; action taking place to resolve the issue; named member of staff leading on the action, timeframe for action
 - Share and learn from themes in the Debrief: these should be openly available
 - and shared with the wider procedural team. Local governance processes must ensure that any issues identified lead to learning and improvement
- If there are further debrief is needed the After Action Review (AAR) model can be considered to help team learning.^{97 98}

Please see the '[Performance Indicators NatSSIPs](#)'

Table 7: NatSSIPs on a page Performance Indicators

	Standard	Generic organisational measures	Specific organisational measures	Team level measures	
1	Consent, Procedural verification, and Site marking	<ul style="list-style-type: none"> Standards are explicitly addressed in trust-wide and local (e.g. site / specialty) policies and procedures. Standards are addressed at induction. Governance reviews for all standards. Team-based training and education for each standard. Human factors and systems thinking education and governance approach. Processes in place for qualitative assessment and review of engagement with all standards. 	Number of recognised episodes of actual or near miss incorrect site procedures	Consent is taken or reconfirmed by an operator who is present in theatre	
2	Team Brief			Scheduling includes Team Brief time	Patient is marked before arriving in theatre
					Patient understands need for mark
Marked by the primary operator					
Marked with an indelible marker					
Mark visible after draping					
Emergency patients Sign In includes operator					
3	Sign In		<ul style="list-style-type: none"> Standards are explicitly addressed in trust-wide and local (e.g. site / specialty) policies and procedures. Standards are addressed at induction. Governance reviews for all standards. Team-based training and education for each standard. Human factors and systems thinking education and governance approach. Processes in place for qualitative assessment and review of engagement with all standards. 	<ul style="list-style-type: none"> Delays / cancellations / workarounds due to problems in implant processes Number of actual / near miss wrong implant events 	Registered practitioner (and Anaesthetist if relevant) undertake Sign In
4	Time Out	Provision made for patients who don't speak English or Welsh			
		Open questions are used			
		Patient is involved			
		Consent is correct; no abbreviations, in date, patient understanding			
		Marking is correct			
		Appropriate safety checks occur (Basic, Advanced and Priority)			
5	Safe and efficient use of implants	<ul style="list-style-type: none"> Human factors and systems thinking education and governance approach. Processes in place for qualitative assessment and review of engagement with all standards. 			<ul style="list-style-type: none"> New equipment risk assessment and ratification processes in place Number of recognised failed reconciliation events Count boards standardised across areas with standardised documentation and symbols
6	Reconciliation of items in the prevention of retained foreign objects		Minimum checks and checks for planned implant (including custom), multi-implant, evolving and unplanned implants are defined		
			Maternity system for 'count' in birthing rooms/delivery suite and evidence of improvement support		
			Specialty count lists and up-to-date tray lists		
7	Sign Out		A checklist is used		
			The count is declared correct or resolved		
		Completed before the patient leaves the procedure room			
8	Handover/ Debrief	Structured handover format in place	Structured handover format used		
		Debrief log and action log is kept			

Glossary

	Meaning	Further information
AAR	After Action Review	https://openwho.org/courses/AAR-en
AffP	Association for Perioperative Practice	https://www.afpp.org.uk
AHP	Allied Health Professional	https://www.healthcareers.nhs.uk/explore-roles/explore-roles
AoMRC	Academy of Medical Royal Colleges	https://www.aomrc.org.uk/
ASA	American Society of Anesthesiologists Classification	https://www.ncbi.nlm.nih.gov/books/NBK441940/
BAD	British Association of Dermatologists	https://www.bad.org.uk/
BADS	British Association Of Day Surgery	https://bads.co.uk/
BMI	Body Mass Index	BMI = kg/m ² (weight / height squared). https://www.nhs.uk/live-well/healthy-weight/bmi-calculator/
Category 1	Emergency Caesarean Section	https://www.nice.org.uk/guidance/ng192/
CORESS	Confidential Reporting System in Surgery	https://coress.org.uk/
CPOC	Centre for Perioperative Care	https://cpoc.org.uk/
CQC	Care Quality Commission	[England] https://www.cqc.org.uk/
CRM	Crisis Resource Management	
CVC	Central Venous Catheter	
DDAVP	Desmopressin	
FTSU	Freedom To Speak Up Guardian	https://nationalguardian.org.uk/
GDC	General Dental Council	
GMC	General Medical Council	https://www.gmc-uk.org/
HCP	Health Care Professional	
HCPC	Health and Care Professions Council	https://www.hcpc-uk.org/
HIS	Healthcare Improvement Scotland	https://www.healthcareimprovementscotland.org/
HIW	Healthcare Inspectorate Wales	https://www.hiw.org.uk/

National Safety Standards for Invasive Procedures (NatSSIPs) 2

HSIB	Healthcare Safety Investigation Branch	[Till 2022]. https://www.hsib.org.uk/
HSSIB	Health Services Safety Investigations Body	New organisation from HSIB. https://www.hsib.org.uk/
ICS	Integrated Care Systems (in England)	
ID	Identity (eg identity band)	(Often white for no allergies; red for allergies).
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations	https://www.rcr.ac.uk/publication/irmer-implications-diagnostic-imaging-interventional-radiology-diagnostic-nuclear-medicine
LFPSE	Learn from patient safety events	https://www.england.nhs.uk/patient-safety/learn-from-patient-safety-events-service/
LocSSIPs	Local Safety Standards for Invasive Procedures	
MDT	Multi-Disciplinary Team	Means the same as Multi-Professional Teams. https://www.aomrc.org.uk/wp-content/uploads/2020/05/Developing_professional_identity_in_multi-professional_teams_0520.pdf
MHRA	Medicines & Healthcare products Regulatory Agency	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
NatSSIPs	National Safety Standards for Invasive Procedures	https://www.cpoc.org.uk/guidelines-and-resources
NatSSIPs 2	Second edition of NatSSIPs	
NCEPOD	National Confidential Enquiry into Patient Outcome and Death	https://www.ncepod.org.uk/
NHSE	NHS England	
NHSEI	NHS England and Improvement	
NICE	National Institute for Health and Care Excellence	https://www.nice.org.uk/
NMC	Nursing and Midwifery Council	https://www.nmc.org.uk/
NPSA	National Patient Safety Agency	
PFD	Prevent Future Deaths	[To 2019] https://www.england.nhs.uk/patient-safety/patient-safety-alerts/
PPP	People Processes Performance	https://www.judiciary.uk/courts-and-tribunals/coroners-courts/reports-to-prevent-future-deaths/
PSP	Patient Safety Partners	New NatSSIPs 2 concept

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Prep Stop Block	[before regional anaesthesia]	https://www.england.nhs.uk/patient-safety/framework-for-involving-patients-in-patient-safety/
Proportionate count	Count of items proportionate to risk of retained foreign materials (eg if puncture wound)	https://www.salg.ac.uk/salg-publications/stop-before-you-block/
PSIRF	Patient Safety Investigation Response Framework	https://www.england.nhs.uk/patient-safety/incident-response-framework/
SALG	The Safe Anaesthesia Liaison Group	https://www.salg.ac.uk/
SBAR	Situation-Background-Assessment-Recommendation	https://www.england.nhs.uk/improvement-hub/wp-content/uploads/sites/44/2017/11/SBAR-Implementation-and-Training-Guide.pdf
SEIPs	Systems Engineering Initiative for Patient Safety	http://doi.org/10.1136/qshc.2005.015842
SHE	Standardise, Harmonise, Educate	New NatSSIPs 2 concept
SI	Serious Incident	https://www.england.nhs.uk/patient-safety/serious-incident-framework/
SORT	Surgical Outcome Risk Tool v2 (SORT)	http://www.sortsurgery.com/
VTE	Venous ThromboEmbolism	

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