DRAFT FOR CONSULTATION

Centre for Perioperative Care

National Safety Standards for Invasive Procedures (NatSSIPs)

Contents

Thank you to our committee who have all contributed to discussion/debate and added content to build and write these standards.

Introduction

The NatSSIPs 1 (2015) were a great step forward in providing a system and standards to provide safe care to patients undergoing invasive procedures. Following the implementation of the WHO checklist in 2009, NatSSIPs 1, with associated Local Standards, provided the next steps in progression of checks and standards to enhance procedural safety culture, and the vision of harm free procedures. In addition, NatSSIPs 1 promoted the concept of evidenced based implementation using quality improvement and human factors methodology to engage and create a learning system that standardised, harmonised safety across silos, specialties and beyond traditional boundaries with education at its heart.

The new **National Safety standards for Invasive Procedures (NatSSIPs2/NS2)** represents the evolution of this document to include a UK wide remit, to be owned by the Centre for Perioperative Care (CPOC) and to represent 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. NS2 aims to reinforce safety themes to align with other current landmark safety papers including those from the four nations. These documents may include NHSE National Safety Syllabus, NHS Scotland Safety strategy, Royal College Syllabus, HSIB reports, highly profile review recommendations. E.g. Ockenden review and Pattinson inquiry, Safety Anaesthesia Liaison Group, Learning from Patient Safety Events LFPSE (previously NRLS).

All of our organisations and teams face the challenge of creating a proactive safety culture and learning safety system which delivers real improvement and doesn't focus on tick boxes or rare events, rather qualitative performance and the quest to learn from excellence. The SSIPs represents that evolution and the national and local learning that has occurred, with a view to simplify, rationalise and bolster processes to further procedural safety. There is a tension between standardised processes and rationalisation to a specific invasive area. The need for focus on organisational support to deliver the sequential steps and the relationship between the two sections is a central to these standards.

<u>What did we learn from NatSSIPs 1?</u>

According to the 2018 NatSSIPs implementation survey conducted by NHS Improvement, the existence and implementation of the NatSSIPs and associated LocSSIPs has been inconsistent and challenging. They found that the main barriers to embedding this important safety guidance are a) lack of time and staff not having protected time to do this work 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 this as priority e) lack of internal expertise as well as understanding of which areas / procedures qualify and whether this is at a trust or site level. These challenges are evident in trusts rated as inadequate or requires improvement as well as those rated as outstanding.

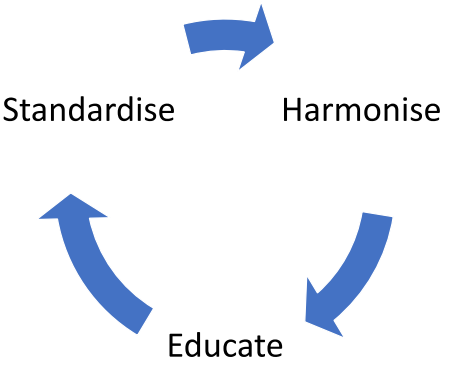
NatSSIPs2 in summary; organisational and sequential standards

Organisational Standards

People *for safety*
- Patients *as partners*
- Staff *to deliver*
  - Roles in safety
  - Training in safety
  - MDT Teams

Processes *for safety*
- Documentation
- Scheduling
- Induction
- Governance

Performance *for safety*
- Data on above for assurance and improvement



Sequential Standards (SSIPs 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. ***Musts and should.*** In accordance with standard terminology of regulators, colleges and 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. However, there will be completely legitimate occasions when a 'should' statement can, and 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**, may consider etc. are suggestions from the SSIPs 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. ***Core, Advanced, Aspirational***; within the standards there is an indication of what is seen a core safety practice that must be provided for every invasive procedure, with advanced aspects demonstrating a more mature safety practice and aspirational the intention for the future.
3. ***What is an invasive procedure?*** An invasive procedure is a procedure that is performed where a hole or incision is made in a patient and usually where consent is required. Invasive procedures can occur in many healthcare specialties including

surgery, radiology, medicine, maternity, emergency in theatres, wards and outpatient care.

4. ***Major and minor procedures;*** Within invasive procedure settings there are a wide range of procedures and specialties. In order to have proportional standards to the setting, the term major and minor procedures can ensure the standards are not a burden. (More detail is provided in the sequential standards)
5. ***Organisational Standards and Sequential Steps;*** The NatSSIPs include Organisational standards that an organisations must follow to provide the conditions to support teams in delivering safe patient care. Sequential steps are those safety steps (NatSSIPs 8) that are carried out by the team in the patient pathway and are based on proportional risk assessment and organisational learning to reduce harm
6. ***Local standards for invasive procedures;*** (LocSSIPs) should be based on this document, the SSIPs and represent the local system approach and insight to meet the standards. LocSSIPs should include sequential and organisational review to be effective.
7. ***Checklists;*** Tools to support teams in following the SSIPs and LocSSIPs and to support team behaviours.
8. ***Teamwork behaviours;*** Teamwork behaviours incorporate communication, situational awareness, leadership and mutual support. A human factors perspective and recognition of the impact on these behaviours for effective delivery of the SSIPs in both organisational and sequential standards is important.
9. ***Standardise, Harmonise and Educate;*** Standardise, Harmonise and Educate aims to reduce variation across specialties and organisations.

	Organisational	**Sequential (SSIPs 8)**
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 people safety education, human factors and systems thinking, safety infrastructure, leadership training and training in cultural change	Teach and train in team behaviours, human factors, systems thinking learning/ co-production with patients

Scope

Who does this apply to?

The NatSSIPs apply to all providers of invasive procedures across the four nations and in public and private settings. **Appendix I** indicates the specialties for which the NatSSIPs are applicable to.

How have the NatSSIPs been strengthened?

1. Bolstered organisational standard focus
2. Regulatory, legal and national body expectations to ensure policy and inspection reflects the SSIPs standards and to this purpose enhanced national and regional stakeholder level review and implementation. NatSSIPs 2 national safety alert, college inspections and/or visits, CQC inspections. ACSA. Colleges should include the principles of SSIPs in competence assessments and examinations eg DOPs

3. Local commissioning group expectation to assess SSIPs delivery by reporting on NatSSIPs 2 performance indicators.

What should I do if my organisation is failing to deliver on the NatSSIPs?
Report NatSSIPs failures via your line manager, governance system, site and trust safety teams/leadership, Speak Up Guardian, Healthcare Special Investigatory Branch and Colleges if you are concerned.

Organisational Standards

The organisational standards have been strengthened to support teams and patients and 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 the standards in a meaningful way.

The organisational standards now consist of 3 broad sections of People, Process and Performance. Their interface with the NHS safety strategy categories of Insight, involvement and Improvement can be viewed in **Appendix II**

Auditable performance standards / metrics are included in the Performance Standard.

Appendix III with resources including checklist examples

People

Patients

(The NHS Patient Safety Strategy includes a Framework for involving patients in patient safety. In reference to NatSSIPs 2, this requires acknowledging:)

- Patients should have sufficient, balanced information to be supported in their decision-making about invasive care. Information should be written and communicated in plain language, without jargon, in line with Sequential 1 consent and GMC consent standards (Hyperlink). 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. (Hyperlink to Training and Education) Data related to staff safety training and associated safety benefits must be available to inform patients decision making and choice.

- Patients are equal partners with 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 theatre the number of people present can be overwhelming. Patients can be vulnerable to suggestion, especially when anxious, distressed or in pain. Questions asked of patients should be open and neutral.

  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 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 responsibilities and, where possible, be prepared/helped/trained to participate in checks and communication in the sequential pathway. Steps such as Site marking and Sign In should involve the patient (Hyperlink). These checks should reassure patients.

  Patients should be informed that serious focus is necessary during checks (equivalent to a legal proceeding). More relaxed conversation between the clinical team and patient can resume once checks are complete.

  See box below on patient involvement and responsibility with the checks.

Patient Involvement and Responsibilities in 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 should be involved in the response to incidents, provided they are able and wish to. They may be valuable, informed witnesses and able to provide insight critical to preventing a repeat.

  Patient safety incidents can be psychologically distressing as well as physically harmful for patients. Organisations must create systems that ensure patients receive appropriate clinical and psychological care in the immediate term and on an ongoing basis, including during any investigation or other response to an incident.

  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?' (Hyperlink to Safety Processes)

- The Duty of Candour 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.

- 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.

- Supporting patients to be involved in their own safety requires creating patient safety partner (PSP) roles for patients, carers, family members or other lay people in partnership with staff, to influence and improve the delivery, governance, and leadership of safety within organisations.

- 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.

- A version of the standards must be simple/easy read, accessible and understandable by all patients, including language level, and for patients with challenges in understanding, e.g. English is not first language, physical and mental handicap and 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, 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.

Supporting patients to be involved in their own safety means actively creating patient safety partner (PSP) roles for patients, carers, family members or other lay people in partnership with staff, to influence and improve the delivery, governance and leadership of safety within organisations. 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 a resourced leadership team to deliver the NatSSIPs (job plans, committees, structured agenda and minutes)

- Hospitals / trusts / equivalent names[1] should have a named Board-member with NatSSIPs within their portfolio.
- There should be a named, senior clinician[2], clinically active 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

[1] Going to use Trust from now on for ease of typing in draft

[2] Clinician deliberately includes medical staff, nursing, midwifery and AHPs.

    - 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: IT; education; quality improvement support; procurement.
- Each Trust should have a formally constituted multidisciplinary steering group (to include all relevant professions), chaired by the NatSSIPs lead, with responsibility for:
    - Strategic oversight
    - Review of relevant data / intelligence/insight
    - Provision of assurance to the Board
    - Provide updates as a standing agenda item to Governance and Quality Boards
    - Organisational sign-off of NatSSIPs related policies and procedures
    - To ensure aligns with Trust Safety Strategy and Quality Objectives
- Every relevant specialty group should have a named senior clinician[3] with responsibility for specialty level governance of SSIPs and with representation on the NatSSIPs group.
- Doctors in training should be a formal part of this group
- The Trust lead should provide assurance to the Board on all aspects of NatSSIPs.
    - This assurance should include at least an annual, publicly available account of progress and measurable outcomes related to SSIPs.
- Trusts should aim to include NatSSIPs within the direct remit of patient safety specialists
    - Trusts should consider how NatSSIPs related activities will integrate with other key patient safety specialist roles (e.g. for maternity)

INVASIVE AREA STAFFING AND RESOURCES

- 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 allows 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 the safety differences and risks between elective vs emergency patients
    x. Team Brief (Hyperlink with sequential) can be used to share concerns with staff and build trust

It is outside the scope of the SSIPs 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 NatSSIPs lead should give some 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.
- Link to performance measures such as agency staffing rates, staff leaving rates/retention/turnover, cultural surveys (ability/opportunity to speak up), listened to Specialty based staffing algorithms for staffing
- NatSSIPs leads should influence governance by ensuring that risk management decisions are made by management and clinicians

[3] This individual may well have other governance roles within the specialty.

- There should be a clear procedure, risk assessment and escalation for when procedures do not take place due to safety concerns and how prioritisation is carried out.

STAFF TRAINING AND EDUCATION

- The Trust should provide sufficient time and resource for multidisciplinary, in person team-training to ensure that:
    a. Every relevant member of staff understands the purpose, rationale and practical implementation of the sequential steps relevant to their area
    b. An understanding of human factors and systems thinking
    c. 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 team training. It is more than learning but rather building trust and mutual support
    d. Online learning may have a supportive place in this education but is not sufficient on its own.
- Multidisciplinary team training should involve rehearsal and analysis of typical and emergency scenarios and practice relevant to the team.
- Not didactic teaching, working in teams and breaking professional barriers
- Every member of staff involved in invasive procedures should be able to evidence their training and competence in relevant aspects of NatSSIPs.
- Team feedback should be provided in the form of quality performance data, action related to governance data and debrief feedback
- Regional structures (e.g. ICS, place-based partnerships, provider collaboratives etc.) should aspirationally consider how such training could be supported, harmonised, and standardised within geographic regions to reduce duplication and encourage sharing of good practice.
- Although it is the organisational SSIPs lead who can provide assurance on the delivery of training, 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.
- Trusts should recognise, where appropriate training and education that has been undertaken within an appropriate timeframe within other organisations. Staff who rotate between organisations should not be duplicating training or assessments unnecessarily.
- The Royal Colleges and other training bodies should ensure that concepts and practical procedures within NatSSIPs are taught and examined within their training curricula.
- The Royal Colleges and other training bodies should ensure that their training materials are revised and updated to current best practice.
- Health Education England / equivalent bodies should consider how best to provide training, and repeat training, on NatSSIPs at all stages of training for medical, nursing, midwifery and AHP 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

- A LocSSIPs or NatSSIPs WHO checklist is an invasive checklist that has been adapted from WHO based on local insight with standardisation, harmonisation, and education in addition to insight, involvement and improvement to create a local safety solution. Specialty based procedural checklists can be used in dedicated specialty areas but checklists per procedure are not encouraged (unless a reliable IT solution to drop down based on booked procedure appropriate checklists is provided)
- The Trust should ensure that processes are designed and re-designed to support optimal safety and efficiency.
    - Trusts should regularly review 'paperwork' to ensure it is contemporary, without duplication, relevant to practice and closes the gap between work as imagined and work as done.
    - Trusts should regularly review how patients flow through the process to balance redundancy of checks with unnecessary duplication
    - Trusts should regularly review the flow of information to ensure there are 'versions of truth' that are reliable and accessible at all points of the patient journey
    - IT integration poses opportunities for rationalisation and data analysis of SSIPs

SCHEDULING

- Scheduling should provide adequate preparation time and provide maximum list information to allow for safe care.
- Scheduling should take into account workload and the need to follow the 'NatSSIPs Eight'.
- The scheduling team should improve the clinical teams' scheduling through information, feedback, improvement and training.
- The information that accompanies the scheduling of a procedure should include: name, 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 schedule, i.e. 'left' or 'right'.
- Further information should be included when relevant: NCEPOD urgency, significant comorbidities, allergies, infection risk, any non-standard equipment requirements or type specific implants, BMI, planned postprocedural care.
- 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.
- Any list and 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

- Induction both local and organisational should support 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.

- The induction process marks the start of a staff members safety journey within that organisation and is critical to delivery of NatSSIPs.
- Agency staff should receive a shortened induction and an appropriate checklist completed.

GOVERNANCE PROCESSES should support

- NatSSIPs Insight (multiple sources of data), learning and involvement. The insight sources of data should link UK wide standards, benchmarking, reports with local insight based on data both qualitative and quantitative, reported incidents and SIs, LFD reports, learning from excellence reports, litigation, patient complaints. Learning should be integrated into team induction and education opportunities. Incident investigation should be approached with systems thinking and just culture in line with PSIRF recommendations.
    - Involvement and improvement opportunity should be encouraged by every team member.
    - Role and development opportunity to support the SSIPs
- Governance of the implementation of NatSSIPs via appropriate organisational Roles Hyperlink
- Risk assessment and following of related to specific procedural harms in invasive areas
    - Swab management (See sequential step 6) requires an organisational risk assessment and procurement alternatives/solutions to ensure swabs used for padding don't 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 preparation and diathermy
- Tenders from contracted companies should follow risk assessment and governance procedure to ensure quality and safety fit with NatSSIPs requirements
- Private hospitals should follow the same standards as NHS hospitals.

Performance

Measurement for improvement and assurance[4] should go beyond measurement of the NatSSIPs for compliance and create a suite of measures which reflects qualitative and quantitative aspects

- Trusts should collect, review and act upon data covering all aspects of implementation of NatSSIPs on a regular basis.
    - Metrics related to the organisational and sequential standards performance
    - Data should include assessment of implementation and practice
    - Data should include behaviours (Safety culture/climate/psychological safety) and aspects of quality not quantity alone
    - Data from incidents including near misses, serious incidents
    - Soft intelligence from team via Team Brief and Debrief
    - Insight and action related to required actions from national and local reports, learning from excellence and from organisational standards
- The processes for collecting should be standardised across the organisation as far as possible
- Aspirationally, regional structures (e.g. ICS, place-based partnerships, provider collaboratives etc.) should consider use of standardised tools to collect information about SSIPs implementation

[4] There 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.

- Aspirationally, the NHS (and equivalents) should consider provision of standardised tools to collect information about safety climate/culture and SSIPs implementation
- The minimum standard for audit of SSIPs related practices and behaviours is intra-departmental peer-review.
  - Self-assessment may be a useful tool for teams to identify areas for improvement but does not constitute robust assurance.
  - Aspirationally, Trusts should develop mutual relationships with neighbouring organisations to provide external review, and honest critique of practices.
  - The CQC should use SSIPs as a framework for inspection

Sequential Steps

Redesign infographic with CPOC

GENERAL PRINCIPLES

General principles explanatory statements are set in red font throughout. Standards are in black font.

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 based on risk and harm to protect our patients and practice. The 5 steps to Safer Surgery were a great step forward in invasive safety and are now seen as Basic Checks, as we advance the 'NatSSIPs Eight' within NatSSIPs (version 2 from NatSSIPs version 1).

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

Proportional and professional application of the standards to fit the case based on the identified, known risks and previous incidents in that specialty or other related specialties performing procedures, 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.

Conversely, all staff should appreciate that although an individual item or process may not appear immediately relevant to them, or in their particular case, there may be wider reasons for including that check step.

The steps and associated checks are useful in the presence of an engaged team who understand human factors, error and want to keep the patient safe.

The 'proportional 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 and can find the checks reassuring and should be involved with them. Hyperlink Patient Section within organisational.

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 to measure for improvement.

Each standard has suggested performance measures which are integrated into the Performance Standard which can be observed at performance reviews, safety visits and external body safety accreditation/evaluation. Hyperlink to Performance

The 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

Proportionality/Rationalisation to procedure type

Minor Procedures	**Major Procedures**
Outpatient or ED procedures that occur under local anaesthesia in non-theatre areas e.g. Treatment room	Any procedure occurring under general anaesthesia
A procedure where there are only 2 practitioners	Any procedure where the team is greater than 2 people
Sign In and Time Out can be combined	Sign in and Time out should be done separately

A procedure that does not open into a cavity or involve an orifice where a foreign object could be retained	Any procedure involving a cavity or an orifice where a swab or other foreign object could be retained. E.g. vaginal swabs
Proportional count usually applies	Full count procedure is required except in Interventional Radiology To be linked to full count p40

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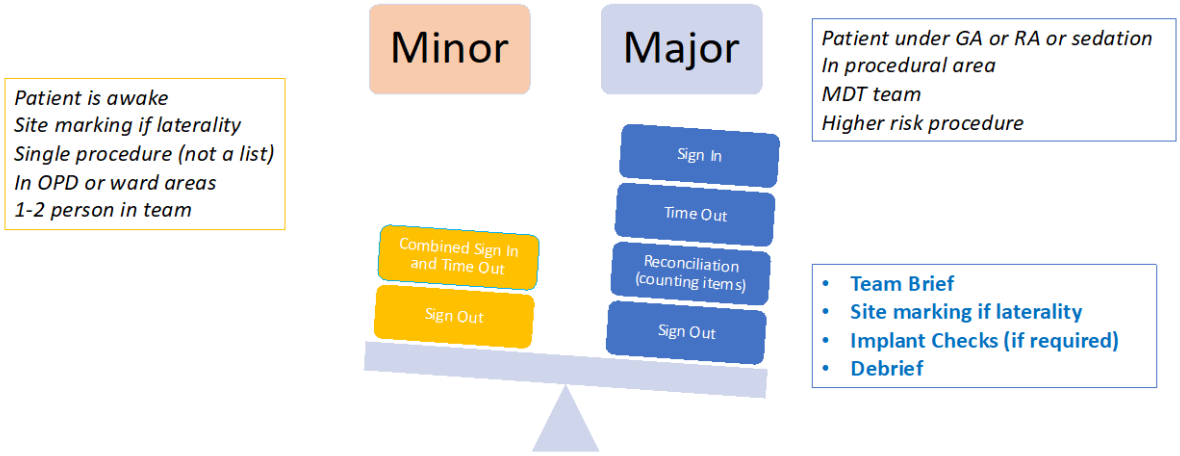
Invasive Procedures; proportional checks for major procedures



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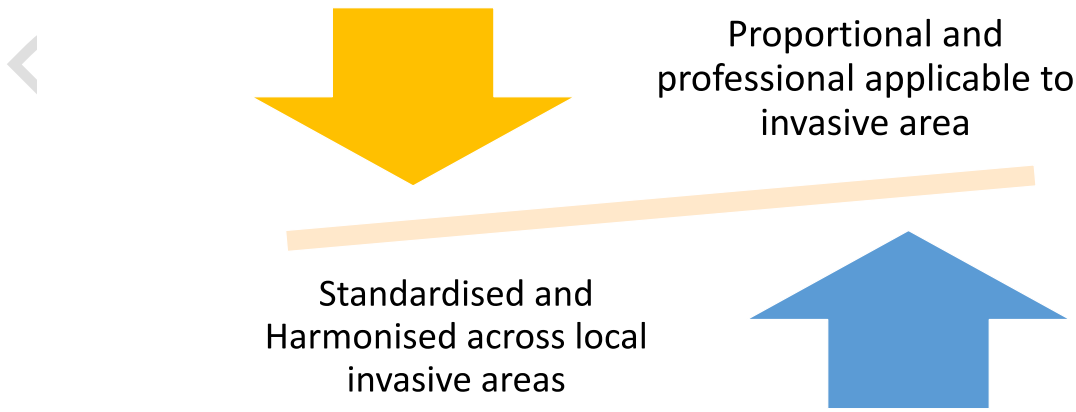
Tension in checklist design and delivery



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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.

Sequential Step Standards- Overarching standards

1) Patients should be involved in the checking process whenever possible and appropriate.
2) All staff should engage with the sequential steps in a professional manner.
3) Staff should never undermine the checking processes with phrases such as 'just some paperwork'.
4) Failure to attend / engage with any or all of the relevant sequential steps at individual or team level should be addressed constructively but should be viewed as a risk and a performance concern.
5) 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.
6) Specialty specific checklists should follow a format, simple language, and structure consistent with other checklists within that organisation.
7) Specialty specific checklists should be agreed, and risk assessed for use in specific, usually localised, settings.
8) Training for teams using specialty specific checklists should be provided to the same standard as for generic checklists.
9) Each of the 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.
10) 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.
11) Any team member is empowered to challenge others to respect the expected *silent focus*.
12) Every team member should be encouraged to ask questions, seek clarification or raise concerns about any aspect of patient care or the planned procedure.
13) Teamwork behaviours with an understanding of human fallibility and using a checklists and standards to enable safe care should be understood by all teams.

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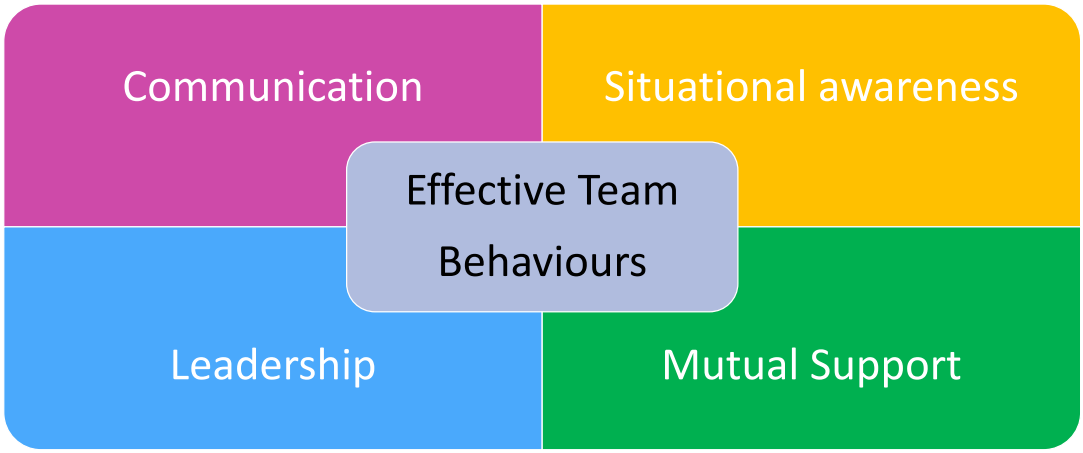
Checklists and Standards support Effective Team Behaviours



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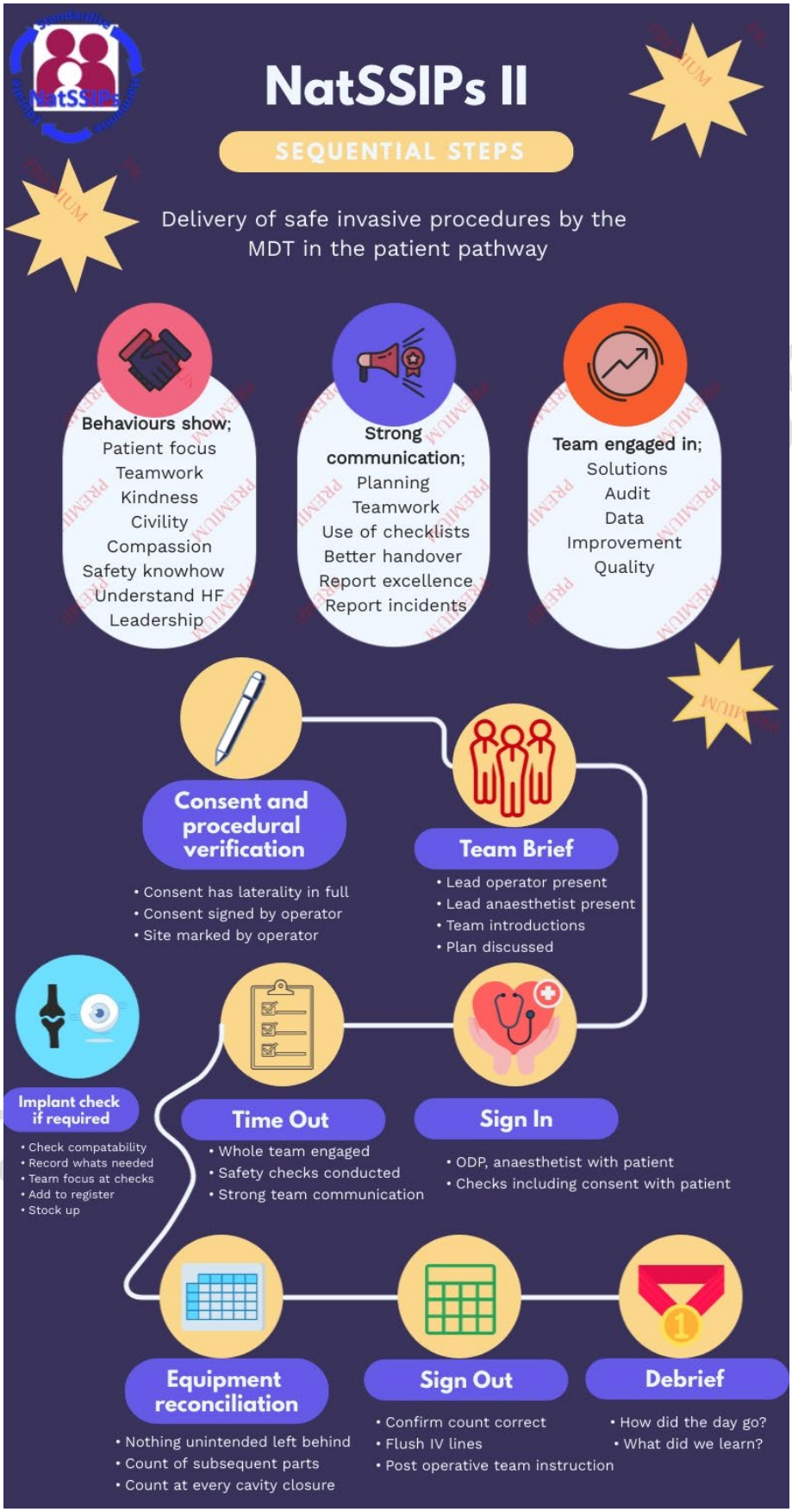
NatSSIPs II
SEQUENTIAL STEPS
Delivery of safe invasive procedures by the MDT in the patient pathway
Behaviours show;
Patient focus
Teamwork
Kindness
Civility
Compassion
Safety knowhow
Understand HF
Leadership
Strong communication;
Planning
Teamwork
Use of checklists
Better handover
Report excellence
Report incidents
Team engaged in;
Solutions
Audit
Data
Improvement
Quality
Consent and procedural verification
• Consent has laterality in full
• Consent signed by operator
• Site marked by operator
Team Brief
• Lead operator present
• Lead anaesthetist present
• Team introductions
• Plan discussed
Implant check if required
• Check compatability
• Record whats needed
• Team focus at checks
• Add to register
• Stock up
Time Out
• Whole team engaged
• Safety checks conducted
• Strong team communication
Sign In
• ODP, anaesthetist with patient
• Checks including consent with patient
Equipment reconciliation
• Nothing unintended left behind
• Count of subsequent parts
• Count at every cavity closure
Sign Out
• Confirm count correct
• Flush IV lines
• Post operative team instruction
Debrief
• How did the day go?
• What did we learn?

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CONSENT, PROCEDURAL VERIFICATION AND SITE MARKING

The process of obtaining consent and shared decision making with the patient is 'an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient' Full GMC guidance on obtaining consent is available. [REF: GMC 2020 https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent]. Similar guidance is available from the Royal College of Surgeons and the Association of Anaesthetists.

Within SSIPs the consent process and procedural verification are linked, and there 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. [RCSEng]

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 and, where possible, with the patient, rather than relying solely on the printed operating list for the procedure being performed [RCSEng].
- 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.
- The consent process must not start in the anaesthetic room; patient **confirmation** of understanding consent is part of the Sign-In process.
- Except for life threatening emergencies a patient's primary consent should never be taken in the anaesthetic room. [RCSEng]

Documentation

- Procedures involving anatomical sites that have laterality, the word(s) Right, Left or Bilateral will 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 from, printed operating list, etc) is available to the operator or their deputy at the theatre trolley/bedside.
- The digits on the hand must be named little, ring, middle, index and thumb, (Diagram 1) and on the foot numbered (Diagram 2) and this should be indicated on the consent form and similarly marked with a marking pen with the patient's agreement while they are awake and prior to premedication.

Diagram 1: Hands

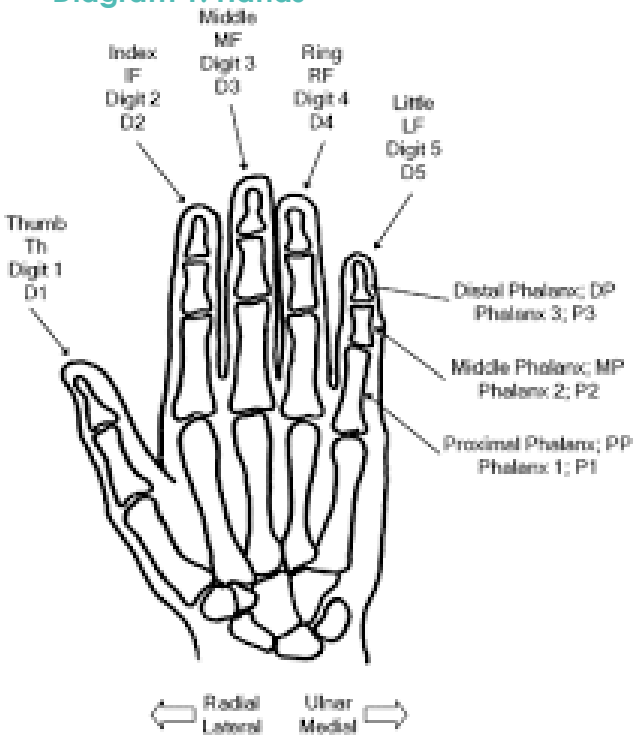
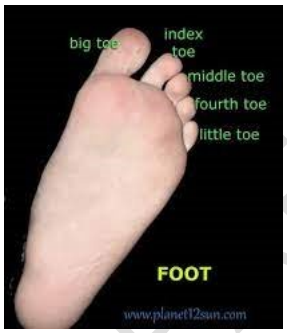


Diagram 2: Feet



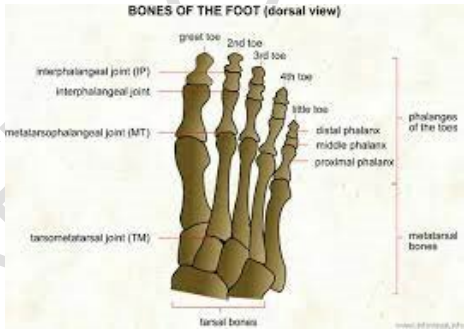
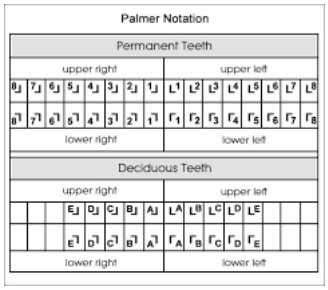


Diagram 3: Teeth should be named using Palmer notation



Site marking:

General principles

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 surgery 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.

- 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.

WHEN

- 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 surgeon if a primary consent is made in clinic or on another date. REF: https://www.rcseng.ac.uk/-/media/files/rcs/library-and-publications/non-journal-publications/consent_2016_combined-p2.pdf

WHO

- The marking should be performed by the operator, or a nominated deputy who will be present during the procedure or in the case of emergency surgery: 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 surgery.
- 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, local 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 surgeon present at Sign In and a second confirmatory arrow over the first.
- Marking of stoma sites is usually carried out by specialist nurses.

HOW, WITH INFORMATION AND THE PATIENT:

- The mark should be applied after verifying 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 may not be accurate for the site of the procedure being performed and must not be relied upon.

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.
  - The mark should be an arrow, except for Palmer notation for teeth (see maxillofacial).
  - In addition, if digits are involved, they may be marked with a dot placed on the nail of the digit if the skin is intact or at the base of the digit.
  - 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.
  - An arrow should mark the operative site
  - Text or other markings are discouraged except for when deemed absolutely 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 eg, plastics and breast lines.
    iii) To indicate medial, lateral, posterior, anterior if positioning requires it
    In these scenarios
    iv) The marks should 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) Agreed text per specialty? Clear arrow to denote the side. 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 surgical sites such as pacemakers/neurobrain/batteries generators and stomas.
  - The mark must not include a date or surgeons initials.
  - 'Single use' marker pens should be used in patients with a known infection or in the immunocompromised.
  - A ballpoint should not be used

The colour of the marking pen is irrelevant provided it is clearly visible on the skin. Ball point pens on the skin are painful.

Pens which have had the cap kept on, are safe to use between patients who do not pose an infection risk.

- 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, and 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 surgical site check and confirmation with the patient. Reference to radiological imaging should be used when appropriate.
- Stoma sites: should be marked (and consented) by a professional experienced in siting stomas, and an indication of the planned stoma position must be maintained during the procedure. https://ascnuk.com/_userfiles/pages/files/finalascnstandardsnew.pdf
- 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 (i.e. same approach for all patients within an interventional radiology unit.)
- Wrist bands to indicate laterality are not recommended. They have the same invisibility issues and are liable to being removed and replaced on another limb.

EXCLUSIONS

- Patient refusal (try to explain the reason for the site marking)
- Intravenous access
- Insertion of Hickman lines, CVP lines as 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 on table and 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 surgery (e.g. bilateral tonsillectomy) if bilateral is indicated in the consent

Details of specialty specific guidance is given in **Appendix 1**

Check points of consent and site marking: Pathway schematic?

GENERAL PRINCIPLES

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).

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

- A registered HCP or nurse should check 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 presence of the operation site mark must be recorded as meeting these standards on the patient's peri-operative patient care plan.
- Organisations should have an agreed process for managing discrepancies in a proportionate, safe and efficient manner.

AT SIGN IN (Sequential step 3)

- The planned procedure must be confirmed with the patient, with a valid consent, and the site marking checked.

AT TIME OUT (Sequential step 4)

- The consent form should be checked against the printed / electronic operation / procedure list as well as against the patient's wrist band.
- If there are multiple procedures, it may be helpful to write these on a white-board and check through each when this is done.

AT SIGN OUT (Sequential step 7)

- Confirmation that the procedure has been performed on the correct site and side should be obtained.
- If there are multiple procedures, it should be confirmed that all 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. This cannot be relied upon.
- Removing previous arrows prior to a new mark is advised

Caution moments in this standard

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

Performance Standard Assessment

Local observational snapshot audits and QI projects can be carried out to drive improvement to meet the NatSSIPs. A driver diagram can be used to plan interventions to improve meeting standard. In specialties with caveats, the data collected can be adjusted to meet locally agreed standard. Linking to organisational standard including that this standard

Sequential measures
Consent is taken or reconfirmed by surgeon who is present in theatre
Patient is marked before arriving in theatre
Patient understands need for mark
Marked by the primary surgeon
Marked with an indelible marker
Mark visible after draping
Emergency pts sign in includes surgeon
Organisational measures
Consent, Procedural Verification and site marking local standard in policy *Included at local induction and performance review*

Team Brief

Procedural multidisciplinary team briefing 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 Checklist, 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 in 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 will be volunteered and will encourage an environment of openness and flattened hierarchy. Continuing with tasks and trying to listen is a distraction for the individual, secondly it is a distraction for the rest of the team, thirdly it is a bad example to the rest of the team.

- 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. 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.
- 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 but also as a matter of courtesy.
- 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, a surgeon 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 that 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, and 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

915 can be maintained. This location should be modified locally for other procedural areas as
916 appropriate but should not occur in public areas.

917 • The Team Brief may need to be conducted on a case-by-case basis if there are change
918 in key team members during a procedure session, list changes due to other factors or
919 staggered patient admissions. Any changes to the team members during the day should
920 also be recorded and should be the subject of an appropriate re-brief if anticipated.

921 • The Team Brief should occur with the correct and agreed list order and each patient
922 discussed. A process should be in place to update the procedural team with relevant
923 information in the case of staggered admissions or emergency lists. If the order is unclear
924 at the start of a session, or the potential list of patients may change depending on
925 various factors such as test results, a provisional list should be discussed.

926 • Each patient should be discussed in list order from the perspective of the operator,
927 operator's assistant, the anaesthetist (if appropriate), scrub team and other key team
928 members.

929 ▪ Diagnosis, consent, planned procedure and laterality *(Sequential Standard 1)*
930 ▪ Relevant comorbidities or complications
931 ▪ Airway management plans if applicable
932 ▪ Additional monitoring or equipment needed
933 ▪ Patient communication issues or disability
934 ▪ Allergy status
935 ▪ Blood loss management plans should be confirmed (e.g. tourniquets, tranexamic
936 acid, cell salvage)
937 ▪ Patient positioning
938 ▪ Infection Prevention and Control issues
939 ▪ Implant, prosthesis, stent availability *(Sequential Standard 5)*
940 ▪ Equipment requirements/Special equipment and extras *(Sequential Standard 6*
941 *Equipment Reconciliation)*
942 ▪ Antibiotics required/prophylaxis
943 ▪ Other risks e.g. lasers, fire risk
944 ▪ Postoperative destination e.g. ward or critical care unit

945 • The Team Brief should provide an opportunity to open up communication channels to
946 discuss, where appropriate;

947 ▪ drinks / food for patients later in the list
948 ▪ additional cases
949 ▪ planned breaks
950 ▪ changes in personnel
951 ▪ student and trainee needs
952 ▪ staff familiarity with the procedures,
953 ▪ expected behaviour/culture/non-tolerance of bullying

954 • A specialty-specific Team Brief checklist may be locally developed and used to ensure
955 essential information is shared. See Appendix IV

956 • A record of Team Brief should be kept to guide the list

957 • Organisations should consider development of systems that can use information
958 gathered at Team Briefs (and debriefs) to address issues and support quality
959 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 standard 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 in this standard

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

Performance Standard Assessment

Sequential measures
The Team Brief starts on time
The senior clinicians are present
All team members present
All team members are engaged in Team Brief 'Silent Focus'
A Team Brief record is kept
The Team Brief allows feedback of information for systems management
Organisational measures
Team Brief standard included at local induction and performance review

Sign In

GENERAL PRINCIPLES

Sign in is the point at which the team checks that it is safe and appropriate to commence anaesthesia

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 general, regional or local anaesthesia, with or without sedation
- Patient Participation in the Sign In should be routine (when possible.)
- Questions to the patient should be open in form.
    - 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. Not 'The form says are fixing your left ankle, is that correct?'
    - 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.
    a. For procedures performed under sedation or general /regional anaesthesia, this should be the anaesthetist and anaesthetic practitioner.
    b. For procedures not involving an anaesthetist, the operator or a practitioner and an assistant should perform Sign In.
- 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 any 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 taking consent should be present to confirm prior comprehension via the interpreter
- 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 preference of the individual clinicians.
- Organisations should develop processes to ensure transfer of patients from admissions areas / wards do 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 in 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/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.
  - Consent form checks 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

- Safety checks should also include the following where appropriate: (Advanced)
  - Pregnancy status.
  - Infection risk to staff
  - Starvation time.
  - VTE risk and management
  - Anaesthetic and emergency equipment/drugs checks.
  - Airway strategies and preparedness
  - A recap 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) question around tourniquet, anticoagulant use, tranexamic acid, cell salvage etc. This should be planned at Team Brief.
  - Regional anaesthesia 'Stop Before You Block/Prep Stop Block' checks.
  - Availability of essential instrumentation.
  - Availability of implants, stents, prostheses
  - Implants (surgical metalwork, pacemakers etc.)
  - Availability of additional staff.
  - Others to be decided locally as appropriate for specialty

Caution moments in this standard

Emergency and urgent work
Confused patients or those less fluent
Patients presenting for second procedures
Disengagement of staff

Alternatively could organise like this:

Risks
Infection inc Covid
Pregnancy
DVT
Pressure sores
Metalwork

Availability
Regional block kit
Anaesthetic kit and emergency drugs
Implants
Instrument trays
Blood
Staff/Experts

Performance Measures

1. Consent correct; no abbreviations, in date, patient understanding hyperlink to Site marking standard but checked at this point
2. Marking correct

Time Out

GENERAL PRINCIPLES

Time Out is the most critical check in 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 Team Brief 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 situational awareness and ensure the essential equipment/prostheses/kit is readily available.

1) 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 operating consultant holds responsibility to ensure Time Out meets the standards

2) The Time Out checks leadership can be delegated to any team member but the operator carries responsibility: they should ensure the whole team is listening and participating.

- Any delegation of responsibility of the entire list and associated Time Outs, to a primary operator, needs to be documented and risk assessed by the service with associated competence and workplace-based assessments
- If a surgeon wishes to operate 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 a complex procedure 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 how to call for assistance.

WHEN

Time Out should take place only when:

1) 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)
- Every member of the team must participate in the Time Out process

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.
- 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

MINIMUM ITEMS 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 are repeated.
- Confirmation of concordance of patient identity, verbal or written consent, relevant imaging, 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
- Confirmation that whole team is aware of any key/critical or unusual/unexpected aspects of the procedure. Any specific equipment requirements or special investigations. Relevant imaging / tests / implants available

- Confirmation that all equipment, including implants, needed are present, working and sterile

ADDITIONAL STANDARDS RELEVANT TO MORE INVOLVED 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 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 any existing intentional foreign objects in situ, e.g. packs.
- Confirmation of sterility of instruments and equipment. Any equipment issues or concerns.
- Others to be decided locally as appropriate, e.g. perfusion checks
- 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 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.

ADDITIONS POINTS OF CLARIFICATION

- The Time Out should be performed as close as possible to skin incision. This will usually be just before skin prep and draping.
- 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 no sedation or anaesthesia, Sign In and Time Out should 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 which can be intimidating and overwhelming.

- Reassurance for the patient is most important. Teams should allocate one team member allocated for that role and where appropriate and respectful may providing 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, investigation etc.

SPECIALTY SPECIFIC REQUIREMENTS

There may be highly localised requirements for Time Out where specific processes are needed related to risk. However, too many variations can cause a risk in itself.

Caution moments in this standard

Emergency and urgent work
Multiple procedures and / or teams
Lack of appropriate conduct for Time Out
Lack of senior clinical engagement with Time Out

Performance Measures

1. Team engagement/attention qualitative measure at Time Out

Implant Verification

GENERAL PRINCIPLES

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 time, 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, check fatigue and unnecessary delay.

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

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

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 (for example, 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, where an understanding of the subsequent 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- with batteries 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.
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, EVAR stent or knee replacement.

- The requested implant details should 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.

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
  - 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 wrist band. Some specialties will specify additional items.

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.

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 trusts use scanning technology to track and reconcile equipment, prostheses and implants, and procedures for each patient. This could be extended to certain implants and provide an alert when there is a patient/product mismatch.

www.hsib.org.uk/investigations-and-reports/insertion-of-an-incorrect-intraocular-lens/ in addition to providing up to date stock information.

BEFORE THE PROCEDURE

- When the patient is scheduled for an invasive procedure, the waiting list or scheduled list information should be clear and list whether or not an implant (s) is required. This is of particular relevance to custom or type specific implants.
- Implants should be kept implants adjacent to the procedure room and it should be ensured 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 must also be discussed and checked
- 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.
- The operator requests an implant.
- If the surgeon requests, the runner (or another team member) writes down the requested implant on the whiteboard (or on paper).
- This Implant check step is sometimes called an 'Implant Time Out' 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 wrist band.
- The runner then opens the implant, and the surgeon 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 operator requests an implant.
  - If the surgeon requests, the runner (or another team member) writes down this information on the whiteboard (or a piece of paper.)
  - The runner gets the implant and shows it to the operator, who "reads back" about the implant:
    i) Is this compatible with the previous implant?
    ii) Any other information relevant to this specialty, e.g. size.
- The runner then opens the implant, and the surgeon or scrub practitioner receives it. All packaging is kept. Labels are placed in the theatre record and the patient notes, or electronic equivalent.
- At Sign Out (at the end of the procedure and before the patient is awoken from general anaesthesia or, when general anaesthesia is not used, before the patient leaves the procedure room) the operator confirms the implant.

SUMMARY:

Before case	At booking – will an implant be used?	The operator (or person booking the list) should communicate the type of implant to theatre staff. If it is a "non-stock" implant, the operator must ensure that the implant requirements are communicated effectively to the procedural team in sufficient time for the implant to be ordered and received. There should be a procedure for storage of custom implants. The implant should be listed in the equipment or comments section, so that it appears on the printed scheduled list.
		Named person checks stocks, expiry dates and sterility and feeds back to operator.
		A senior member of staff should consider whether a company representative should be present, or particular members of staff.
At Team Brief	Is an implant likely?	Is implant type/laterality/size already decided?
		Or will implant(s) be decided during the case, if so what is likely?
		Are other team-members familiar with the type of implant? (This may affect times of staff breaks.)
At Sign In	Is the implant available?	A named team member will confirm the implant or range of options is available.

		Confirm that runner knows where implants are located and which are compatible.
At Time Out	Confirm if an implant is expected	Write down which implant is expected, if known, on the theatre white board.
At Implant insertion	Operator confirms type or size of first implant	If requested, the runner writes information down. The runner shows operator implant before opening. Operator "reads aloud": - Type - Laterality (if applicable) - Size - Expiry date - Sterility This may be checked against the written request. This is a key procedural safety step, and it is a team event. It is expected that the whole team will focus and be quiet to allow implant insertion checks to occur. This is sometimes called an Implant Time Out?
	Operator confirms type or size of second or subsequent implant	If requested, the runner writes information down. The runner shows operator implant before opening. Operator reads aloud information. The critical issue is: - Compatibility
At Sign out	Confirm implant(s) inserted	
After operation	Record implant in notes and theatre record.	

Other points to note:

- 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 recorded 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.
- Compliance with local, national and international implant registries is encouraged, and in certain cases may be a mandatory legal requirement.
- 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.
- On the occasion of an error, with incorrect implant insertion or a "near miss" this should be reported, recorded and openly discussed at the debriefing, 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.
- Audit of implant verification data must be performed where the record implants inserted are checked against the stock used.
- 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.

Specialties where Implants are used

Specialty	Implants	
Anaesthesia	See Pain	
Breast	Yes	inject blue dye after induction of anaesthesia. We have a separate time out for this again – after the inappropriate administration of blue dye to a patient that did not need it. This alerts the team to the injection – confirms the side and the need for the injection and also the anaesthetist as there is a 1:1000 risk of significant reaction (inc anaphylaxis).
Cardiology	Yes- pacemakers	
Cardiothoracic	Yes- valves	
Critical Care		
Dental	Yes	
Dermatology	?	
ENT and Head and Neck	Yes	Biological implants in nose e.g. rib T tubes
Endoscopy	No	
Endocrine surgery	No	
General	Yes	
Gynaecology		
Haematology		
HPB		
Interventional Radiology and Radiology OP and IP		
IVF	No	
Maxillofacial	Yes	
Neurosurgery	Yes- cranioplasty	
Neurosurgery spinal		
Neurology		
Obstetrics	No	
Oncology?		
Opthalmology	Yes	
Orthopaedics	Yes	
Orthopaedics Spinal	Yes	
Paediatrics?		
Pain	Yes	
Plastics	Yes	
Radiotherapy		
Renal		
Respiratory		
Urology		
Vascular		

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 any gap between request and implantation
Before implanting:
Formal verification by operator
Always confirm compatibility for multiple implants

Performance Measures

1. Evidence of audited process with implants
2. Quality of implant checks

Reconciliation of items in 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. The standard covers 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. 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 makes processes less efficient.

General Principles

The prevention of retained foreign objects is a shared responsibility and that 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.

Full count procedure; any item that enters the surgical field must be counted. This is for all invasive procedures in any environment where swabs, sharps and instruments are used where there is a cavity large enough to retain them.

Type of Count	Which procedure?
Full Count	Major procedures (other than IR) All maternity areas including delivery room

Proportional count	IR areas and minor procedures

A full count may not be necessary in some settings. such as 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.

- 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 and 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.
- The organisation 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, risk 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.

FULL COUNT PROCEDURES: for all invasive procedures in any environment where swabs, sharps and instruments are used 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 some scenarios such as interventional radiology hybrid procedures (involving a surgical specialty like vascular or cardiac and radiology. Starts off interventional but may become open. Two teams), pacemaker insertion or the emergency department

WHAT

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

WHO

Two trained staff should perform the count. One should be NMC (Nursing and Midwifery Council) or HCPC (Health and Care Professionals Council) registered; any unregistered staff should be assessed as competent)

- Count competencies should be maintained. See Appendix VI
- All scrub practitioners / operator's 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 The count must be performed

- 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.
- 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. This count should not usually be interrupted. 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.
- 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, 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 5.
- 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. Usually bright green. The tail may be used to secure the pack to the tube and a throat pack sticker should be used.
- Green swabs or gauze are used in anaesthesia for 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 an ETT. Green swabs represent a risk as

  i)they do not have a radio-opaque line and

  ii) they can end up mixed in the count. There is no benefit to green swabs being having a radio-opaque line as they are not expected to be missing.

Local risk assessment to reduce risk of green gauze retention and 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. Making all swabs used in invasive areas are X-Ray Detectable unless included in the count will not solve the issue.

- Blue swabs 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
- Different size swabs. E.g. Large, Medium, Small

  Large 10 x 10 cm

  Medium 7.5 x 7.5 cm

  Small 5 x 5 cm
- 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-filled sterile pack used for some procedures. Dressing packs should always contain radio-opaque swabs and initiate a count whether proportionate or full.

Some packing materials are absorbed by the body. Table in appendix of materials/items used for packing

- 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.

Mydiasert (Mydriasert is an insoluble ophthalmic insert indicated for mydriasis prior to cataract surgery, which gradually releases the active ingredients: tropicamide and phenylephrine) pellets put under the eyelid before surgery and not removed during the procedure should be counted

SHARPS

- Suture and hypodermic needles should 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 sheathes 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 wire used should occur.
- Lone insertion of lines should not occur. An assistant is always needed. It is a quality standard to insert lines with 2 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

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 subsequent parts before use. A manual should be available, training and a company representative 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 is 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 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 local 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
- When the item (s)is removed, any patient-held identifiers (e.g. wristbands, patient information) must be removed or updated. Documentation of removal of items must be clearly documented. 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.
- 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 when 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 not a reason to not 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 surgery.

- In the event of failed reconciliation, the operator should be informed who must stop wound closure if safe to do whilst the count is repeated, and the theatre and operating site searched. If unsuccessful, this process should include:
  - Immediate communication to the lead surgeon or 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 wherever possible be 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 "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.

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 section XX.
- AFPP guidance expects the whole MDT team to receive training and assessment in count procedure

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.
- These 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.

Caution situations in this standard

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

Key Performance Indicators

1. Audits in full count and proportionate count areas
2. Maternity system for 'count' in birthing rooms/delivery suite and evidence of improvement support
3. Specialty count lists and up-to-date tray lists
4. Count boards standardised across areas with standardised documentation and symbols
5. Staff training in count competencies; evidence and process
6. Wider team understanding/education in this standard and counting process
7. Policy and Process for deliberately retained items and failed reconcilitaion
8. New equipment risk assessment, ratification count and process; evidence
9. Number of recognised failed reconciliation events
10. Number of never events related to retained foreign object

Appendices

Count competencies Example of count competency framework. Link to appendix 6

Materials used for packing. There are a number of materials which are used for packing wounds. Those which are absorable do not need to be counted.

Specialty	Material	Trade name	Radio-opaque	Absorbable	Not Absorbable	To be removed later
All	Alginate	Kaltostat			x	As a dressing, **NO.** Inside cavity, **YES**
All	Carboxymethylcellulose	Aquacel			x	Yes
All	Ribbon gauze		Must be		x	Yes
All	Proflavine dressing				x	As a dressing, **NO.** Inside cavity, **YES**
All	Heamostatic gelatin sponge	Spongostan		x		No
All	Bandage roll	Kerlix			x	As a dressing, **NO.** Inside cavity, **YES**
All	Silver impregnated dressing	Atrauman			x	As a dressing, **NO.** Inside cavity, **YES**
Maxfax	Dental Packs- with string hanging out		Yes		x	No but need to be accounted for in handover
ENT	Nasal polyvinyl alcohol tampon	Merocel			x	Yes
ENT	(DL-lactide-co-E-caprolactone) urethane	Nasopore		x		No
ENT	Bismuth Subnitrate & Iodoform paste impreg gauze	BIPP	Yes		x	Yes
O and G	Vaginal pack		Yes		x	Yes
O and G	Tampon- with string hanging out		No		x	Yes if inserted by surgeon or midwife
O and G	Perineal pads		No		x	Not used as a packing material

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.

- 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, and the anaesthetist (if applicable).
- 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 be completed before the patient leaves the procedure room:
  - Sign Out should occur once wound dressings are in place and the count is complete, but before the patient leaves the theatre 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
  - Check 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 surgical and anaesthetic plans for recovery and postoperative management including level of care. Discussion of post-procedural care, to include any patient-specific concerns.
  - Equipment or process problems for inclusion in the debriefing.
  - Confirmation that VTE risk assessment is completed or is has been done at Sign In
  - IV lines are flushed, and unnecessary extensions removed Flushing in preparation to handover to recovery. *HSIB has advised CPOC to take responsibility to ensure this type of incident will not occur*. Disconnection requires flush. Timing depends on procedure and the situation
  - The patient is still wearing electronic wrist bands.
- Sign Out should also include the following where appropriate:
  - Drain and clamp instructions
  - VTE prophylaxis prescription
  - 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 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.

Performance Measures

1. Team attention at Sign Out Qualitative measure

Handover/Debrief

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.

Pre-operative

During the procedure

Post procedure

- Handover should follow a structured format to convey key procedural information. This can include:
  - 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 surgical course.
  - Relevant intraoperative medications, including opioids, anti-emetics and antibiotics.
  - Target range for physiological variables.
  - Course of anticipated recovery and problems anticipated.
  - Postoperative management plan, to include provision of analgesia.
  - 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.
  - Surgical complications and interventions to correct these.
  - Surgical 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 focused 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.
- All elective major procedure sessions should end with a Debrief and if feasible after emergency cases: although in 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.

Performance Measures

1. Handover format
2. Debrief log and action log

Appendix 1: Specialty list with risk and linked specialties

Specialty	Major/Minor examples	Linked risk	Linked specialty
Anaesthesia		Wrong site	
Breast		Wrong site Prostheses	Ophthalmology Orthopaedics
Cardiology		Prostheses	
Cardiac		Prostheses	
Critical Care		Wrong site	
Dental		Wrong site	
Dermatology		Wrong site	
Endoscopy		Wrong site	
Gynaecology		Wrong site	
Haematology			
Interventional Radiology		Wrong site	
IVF			
Maxillofacial			
Neurosurgery		Wrong site Prostheses	
Neurology			
Obstetrics		Retained FO	
Opthalmology		Prostheses	
Orthopaedics		Prostheses	
Plastics		Wrong site	
Renal		Wrong site, Prostheses	
Respiratory		Wrong site	
Urology		Prostheses	
Vascular			
SPECIAL Emergency checks e.g. Code red/Code black emergency			

1958 **Appendix 1b: Site Marking**
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Specialty	When specifically?	Marks recommended	Text permitted	Specialty guidance links/Caveats
Anaesthesia	Regional blocks	Arrow		Prep Stop Block checks with surgical mark
Breast	To indicate which breast	Arrow, localisation devices? Wires/clips With localised excisions there at seeds and or wires or nuclear medicine injections and they are all part of the site/side identification process as patients agree which side they are having surgery	*In some scenarios based on surgical practice and following cosmetic discussion with the patient marks are used but note that marks can be seen as insensitive to the patient and is a detailed visible sign of the operation that the patient is having.*	
Cardiology				
Cardiothoracic	Thoracics	Arrow		
Critical Care	Chest drains, regional blocks, not required for access as site may change	Arrow – as respiratory		
Dental	To ensure correct tooth removal	Palmer notation on consent and whiteboard Arrow on skin can be used		
Dermatology	To indicate which skin lesion (s)	Arrow and circle around lesion if multiple		
ENT and Head and Neck	If laterality in parathyroid, thyroid plus ear, unilateral tonsil, other neck masses	Arrow. Circle may be needed for some masses / nodes.		
Endoscopy	Consent to indicate			
Endocrine surgery	If laterality e.g. adrenals			
General	Stoma site marking, hernia side, abscesses	Pen markings for stoma, arrow for laterality and ring with arrow for abscesses		

Gynaecology	Labia, Ovaries	Labia; Mark to inner/upper thigh		Laparoscopic laterality decision making can be intraoperative and if consent does not indicate laterality, then a mark is not required
Haematology				
HPB				
Interventional Radiology and Radiology OP and IP	Renal intervention (e.g. nephrostomy, ureteric stenting, renal biopsy, renal tumour ablation) Arterio-venous fistulogram + proceed Angioplasty if laterality indicated, Joint injections, Biopsy of lesion	Arrow and clear drapes		
IVF	Laterality for egg harvest?	Arrow		
Maxillofacial	Mandible ORIF laterality	Arrow		
Neurosurgery	Craniotomy, cranioplasty Stealth guided	Arrow on neck / shoulder, or redo scalp mark after shaving		
Neurosurgery spinal	Can we link with ortho spinal?	Arrow	Anterior Posterior Left Right	Skin marking for spinal surgery may be a 2-stage process: Pre-operatively: The skin will be marked at the level of the procedure. The skin mark should indicate anterior vs. posterior and right vs. left Intra-operatively:

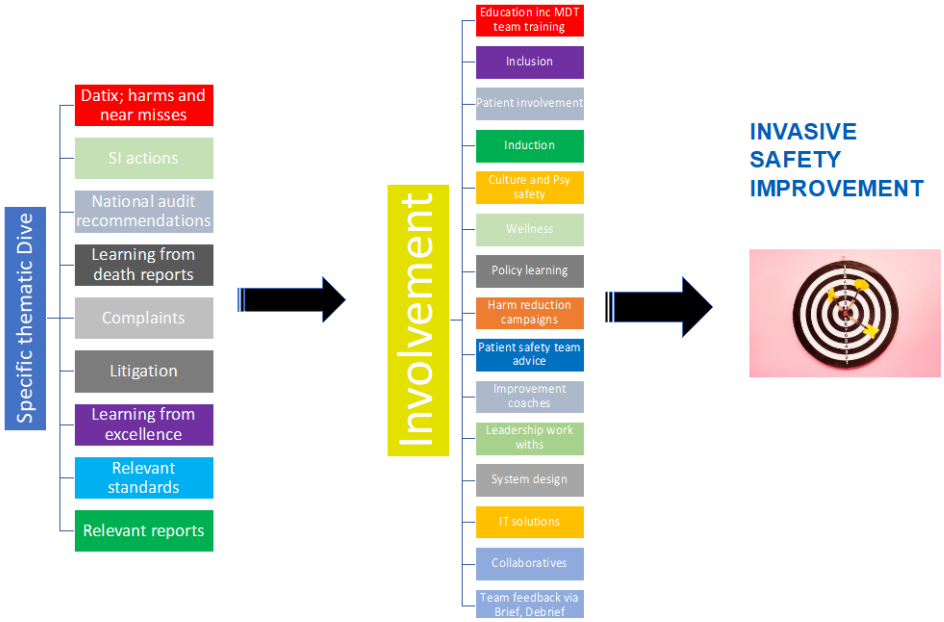
				X-rays will be used to determine exact location and level of surgery and the site marked with a sterile permanent marker by the operating surgeon.
Neurology				
Obstetrics				
Oncology?				
Ophthalmology	To indicate which eye	Arrow above the eyebrow (not covered by hat)		
Orthopaedics	To indicate limb	Arrow		
Orthopaedics Spinal	Link to neuro spinal		Anterior Posterior Left Right	
Paediatrics?	As per other specialties. No specific extra / different requirements			
Pain	To indicate site of block or implant	Arrow	Additional marks to plan surgery	
Plastics	To indicate laterality, digit and plan surgical approach	Arrow and circle around lesion if multiple	Additional marks to plan surgery	
Radiotherapy				
Renal	To indicate which kidney	Arrow		
Respiratory	Chest drain	Arrow		
Urology	Testicular surgery Stent	Arrow		
Vascular	Angioplasty	Arrow		
SPECIAL Emergency checks e.g. Lifesaving surgery (Code	In life saving			

red/Code black emergency)				
Laparoscopic / endoscopic surgery through non-lateralising entry				Laparoscopic operative laterality decision making can be intraprocedural and if consent does not indicate laterality, then a mark is not required

Appendix 2

Insight, Involvement, and Improvement form a framework which can be used to follow recognised strategy for safety improvement which is required for SSIPs implementation. Safety is a complex as it involves humans, their behaviour, culture, and systems thinking. Multi-faceted approaches at implementation are evident in resilient systems.

		Insight	Involvement	Improvement
People	Staff	Measure culture	Build psychological safety Focus on staff; wellbeing Communication formats Education of the team Induction of new staff Inclusion and equity	Leadership, civility training Staffing level review MDT team training in QI and safety methodology including HF, simulation and teamwork
	Patients	Listen to patients, feedback,	Involved on safety and improvements groups	Safety information for patients
Processes		Governance related learning; Understand insight sources Understand invasive risks Thematic harm analysis Scheduling Contracted services Policies and standards	Infrastructure Board; named executive lead, minutes, patient safety specialist; HF specialist appointment Learn from excellence as well as from harm Checklists created by teams NatSSIIPs governance	IT capability Documentation, information transfer and IT system integration Scheduling and list management Governance and safety systems investigations Standardise checklists
Performance		Data sources for NatSSIPs ☐ sequential and orgnisational ☐ quality measures ☐ Outcome measures in context (NEs with Harm to incident ratio)	Work withs not walkarounds Full benchmarking and performance evaluation appendix - Linked to performance dashboard at end of each standard. - Meeting national safety alerts	Measure for improvement and sustain IT intelligence, system flags



Appendix 3

Checklist principles

Principles of checklist design for invasive procedures

- Organisations should invest time and resources into the design and revision of checklists combining theoretical concepts with understanding of how checklists are used (and misused) in local environments.
- End-users should be always involved in checklist (re)design.
- Checklists are fundamentally a tool to support well-trained, motivated staff to perform their roles.
    - Checklists are not an end in themselves.
    - Unthinking use of checklists is potentially harmful to patients and staff
- Staff should be trained in the use (and potential misuse) of checklists relevant to their environment.
- Checklists in used around the time of invasive procedures are generally some combination of:
    - Decision aids: focussing attention towards one, important, issue at a time; reducing the influence of cognitive biases (such as familiarity); identifying / rectifying individual or team knowledge gaps
    - Memory aids: adding to innate working memory, particularly in the context of distraction and / or familiarity and internal / external stressors; enabling sequential steps to be undertaken in the correct order.
- Checklist items may prompt:
    - information giving
    - planning
    - checking
- The checklists and their individual items should be designed with awareness of their primary purpose(s).
- The purpose and scope of a checklist should be clear.
- The actions to be taken in response to each item of a checklist should be clear
    - A check always requires a response
- The actions to be taken if a checklist item cannot be resolved should be clear
- Checklist items should be brief, concise with sufficient detail to prompt a professional with appropriate training to undertake the correct action.
    - They should not be verbose statements attempting to explain how to do something.
    - Multiple conditions within a single item should be avoided
- Checklist items can be ordered in different ways.
    - Items on which other questions depend should come first (e.g. patient identification comes before airway plans)
    - For items that have no particular priority / precedence, moving through in a sequence that relates to the team, physical layout of the room / procedure, physiological systems may help with efficient flow.
    - Key items may be given greater salience by ordering them first or last
- Fonts should be of sufficient size and design as to be easily read
- Highlighting of key elements with CAPITALS or **bold** or boxes may help improve salience
- The number of items in an individual checklist should be limited.
    - Checklist items should focus on items that are of major importance and / or easily missed
    - Checklists should not become a dumping ground for every risk
    - Just because an incident has occurred or a risk identified this does not mean a checklist is an appropriate solution.
- The principles of checklist design within electronic health records are similar, but specialists in user-interface should be involved in their (re)design.

- Checklists should undergo regular review and revision.

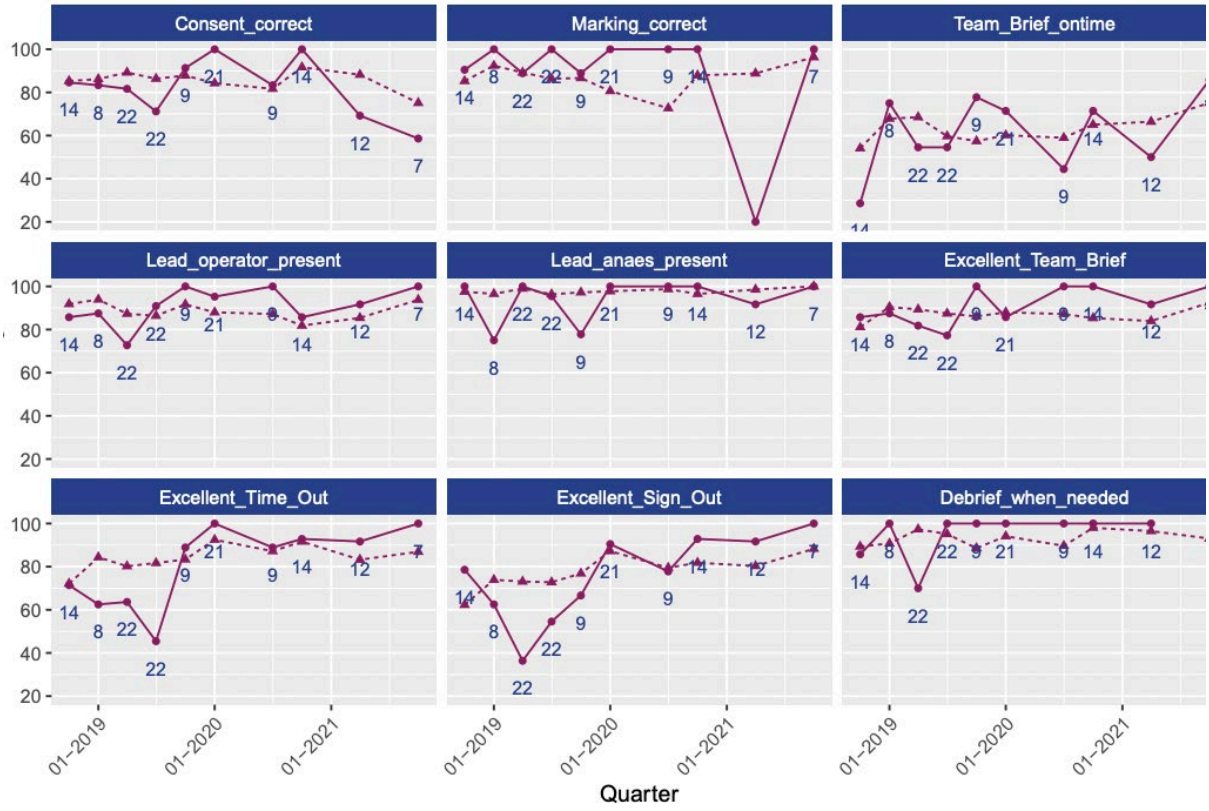
Checklist examples will be included

Appendix 4

Specialty Team Brief examples will be included

Appendix 5

Qualitative data examples will be included



Appendix 6

Count competencies example will be provided

References

TBC