

# National Safety Standards for Invasive Procedures (NatSSIPs)



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**Document Status**

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# **National Safety Standards for Invasive Procedures (NatSSIPs)**

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The National Health Service Commissioning Board was established on 1 October 2012 as an executive non-departmental public body. Since 1 April 2013, the National Health Service Commissioning Board has used the name NHS England for operational purposes.

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

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## **1 Preface from Dr Mike Durkin, Director of Patient Safety, NHS England**

Patient safety is not just important to what the NHS does; it lies at the very heart of what we do.

The last few years have seen great changes and challenges to the promotion and protection of the safety of patients. The NHS in England has responded to these challenges, driven by its commitment to the provision of high quality care for all, now and for future generations.

The introduction of the WHO Safer Surgery Checklist was a great step forward in the delivery of safer care for patients undergoing operations. Experience with its use has suggested that the benefits of a checklist approach can be extended beyond surgery towards all invasive procedures performed in hospitals. Experience with it has also made it evident that checklists in themselves cannot be fully effective in protecting patients from adverse incidents. The checklists must be conducted by teams of healthcare professionals who have trained together and who have received appropriate education in the human factors that underpin safe teamwork. Safety is not just about checklists, teamwork or human factors, it is about checklists AND teamwork AND human factors – and many other things beside.

These NatSSIPs are intended to provide a skeleton for the production of Local Safety Standards for Invasive Procedures (LocSSIPs) that are created by multiprofessional clinical teams and their patients, and are implemented against a background of education in human factors and working as teams. The NatSSIPs do not replace the WHO Safer Surgery Checklist. Rather, they build on it and extend it to more patients undergoing care in our hospitals. They will standardise key elements of procedural care, ensure that care is harmonised – not just within organisations delivering NHS-funded care but also between organisations – and will reinforce the importance of education to patient safety.

I am grateful to the members of the NatSSIPs Group who spent many hours creating these standards, and to the many patients and healthcare professionals whose testing and comments were a key part of their development. I am also grateful to NHS England's Surgical Services Patient Safety Expert Group, which has overseen the development of these standards.

However, it is the many healthcare organisations represented by the members of these groups who are the real owners of these standards. I am grateful to the many healthcare organisations, royal colleges, the regulatory bodies, and the system leadership of the NHS that have committed to endorse and support these standards, to build them into their own guidance and training, and to make sure that their implementation makes a real difference to patients.

The publication of these standards does not mark the end of a process but the beginning of an ongoing commitment to developing standardisation, harmonisation and education for the benefit of patient safety. I am sure that you will share with me a determination to see that these standards are translated into higher quality care for all – now and for future generations.



**Dr Mike Durkin**  
Director of Patient Safety  
NHS England

## 2 Foreword

*“Oh good – more standards!”*

This document presents what, on the face of it, appears to be a whole new set of care standards that those working in the NHS will be expected to follow, document and audit. My message to those who are about to read this document and fear another significant increase in the amount of form-filling expected of them is: “Don’t Panic”. Most of the steps these National Safety Standards for Invasive Procedures (NatSSIPs) require or suggest are already built into local standard operating procedures that exist in NHS hospitals throughout the UK. The NatSSIPs have been created to bring together national and local learning from the analysis of Never Events, Serious Incidents and near misses in a set of recommendations that will help NHS organisations to provide safer care to their patients. The idea is that hospitals will review their local standards and will ensure that they are harmonised with these national standards. Hospitals that have effective local standards will need to do little extra to comply with the requirements of this document. Some organisations will find that they will have to make more significant changes that will take some additional time. I hope that they will agree that this extra work is worth it.

*Keep it local*

The NatSSIPs presented here are meant to be modified for local use, i.e. used as the basis for the production of Local Safety Standards for Invasive Procedures (LocSSIPs). The local standards for a major surgical procedure performed under general anaesthesia in an operating theatre cannot and should not be identical to those supporting the safe insertion of a chest drain under local anaesthesia in a ward. Some steps outlined in the NatSSIPs will not be necessary, some can be combined and some details may need adapting to local circumstances, but these standards require that the NatSSIPs published here be taken into account in order to make sure that key safety steps are not omitted in the production of local standards. The NatSSIPs do not include every step that will need to be included in LocSSIPs, as they are meant to inform and harmonise the production and review of local standards, not to replace them or add to them. Several organisations publish guidance relevant to the safe performance of invasive procedures, for example the Association for Perioperative Practice’s (AfPP) “Standards and Recommendations for

Safe Perioperative Practice”<sup>1</sup>, and guidance such as this should be considered during the development of LocSSIPs and included where relevant to enhance safe patient care. Links to websites, and to guidance published by the organisations that contributed to the creation of the NatSSIPs are provided in Appendix A.

What does this mean for me?

- If you are a member of a Trust Board, you have responsibility for ensuring that LocSSIPs are created for all invasive procedures in your hospital and that they are harmonised with these NatSSIPs. You should also ensure that employees who are involved in the performance of invasive procedures are given adequate time and support to be educated in good safety practice, to train together as teams and to understand the human factors that underpin the delivery of ever safer patient care.
- If you are the Medical Director or Chief Nurse, you should create processes that identify all areas in your organisation in which invasive procedures are performed, and ensure that local standards exist that are compliant with these national standards. You should also ensure that audit of compliance is conducted regularly and that the results of this audit are reported to the Board and acted upon as appropriate.
- If you are a local governance or safety lead, you should ensure that, using local governance processes, arrangements are put in place to develop local standards for invasive procedures that are compatible with these NatSSIPs.
- If you are the leader of a Clinical Division or Directorate within a hospital, you should ensure that the healthcare professionals directly involved in the delivery of invasive procedures work together to create, adapt and adopt local standards (LocSSIPs) for their procedures that are compliant with NatSSIPs, and are committed to developing the standards and using them to deliver safe care.
- If you are the managerial or clinical leader of a service that performs invasive procedures, you should work with those healthcare professionals directly involved in the performance of invasive procedures to create LocSSIPs that are deliverable and practicable, and support safe patient care rather than distract people from it. You should ensure that time is available for team training in the delivery of safe care.
- If you are a healthcare professional who is a member of an invasive procedure team, you are the one who should feel a real sense of ownership of the local standards. You should contribute towards their creation, documentation, audit, review and development. You should participate fully in the safety checks and steps built into the standards. You are also the one who should speak up if they have any concerns at all about the care that the patient is getting. You are the one who makes safer patient care a reality.

Why is this document so long?

It could have been a lot longer! It has been kept as short as possible in the hope that all those involved in invasive procedures can take the time to read it. The number of references in the document has been kept small deliberately. These standards are based on recommendations in a report from the Surgical Never Events Taskforce

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<sup>1</sup> <http://www.afpp.org.uk/books-journals/books/book-123>

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entitled “Standardise, educate, harmonise: commissioning the conditions for safer surgery”<sup>2</sup>. This excellent report from a Never Events Taskforce led by Suzanne Shale has 15 pages of references that cover all aspects of the work behind this document, and interested readers should refer to the comprehensive literature base that they will find in the report. It is a document that is well worth reading.

### Whom should we thank for all this?

The people and organisations that contributed to the creation of these standards are listed in Appendix B.

### What do I do if I have any questions?

Please contact us on [patientsafety.enquiries@nhs.net](mailto:patientsafety.enquiries@nhs.net) if you have any comments, suggestions or questions. The answers to frequently asked questions will be provided on our website: [www.england.nhs.uk/ourwork/patientsafety/never-events/natssips/](http://www.england.nhs.uk/ourwork/patientsafety/never-events/natssips/).



**Will Harrop-Griffiths**  
*Chair, NatSSIPs Group*

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<sup>2</sup> <http://www.england.nhs.uk/wp-content/uploads/2014/02/sur-nev-ev-tf-rep.pdf>

## 3 Introduction

### 3.1 NatSSIPs and LocSSIPs

#### Standardise, harmonise, educate

This document presents **National Safety Standards for Invasive Procedures** (NatSSIPs) that have been developed by a multidisciplinary group of clinical practitioners, professional leaders, human factors experts and lay representatives brought together by NHS England. They set out the key steps necessary to deliver safe care for patients undergoing invasive procedures and will allow organisations delivering NHS-funded care to **standardise** the processes that underpin patient safety.

Organisations should develop **Local Safety Standards for Invasive Procedures** (LocSSIPs) that include the key steps outlined in the NatSSIPs and to **harmonise** practice across the organisation such that there is a consistent approach to the care of patients undergoing invasive procedures in any location. Put simply, the NatSSIPs in this document set out key elements of safe care, and should be used as a basis for the development of LocSSIPs by organisations providing NHS-funded care.

The development of LocSSIPs in itself cannot guarantee the safety of patients. Procedural teams must undergo regular, multidisciplinary training that promotes teamwork and includes clinical human factors considerations. Organisations must commit themselves to provide the time and resources to **educate** those who provide care for patients.

Most organisations providing NHS-funded care will already have local policies and standard operating procedures that encompass many or most of the steps outlined in these NatSSIPs. The aim is not to replace local policies, but to allow these organisations the opportunity to develop them and to benchmark them against both national standards and LocSSIPs developed by other organisations.

Continuous quality improvement in the delivery of safe care for patients undergoing invasive procedures will depend upon the audit of outcomes and compliance with LocSSIPs and NatSSIPs, and upon the ongoing development and refinement of safety standards in response to audit. Commissioners and regulators will look to organisations to provide evidence of audit and appropriate responses to the results, and of a commitment to standardise, harmonise and educate in order to promote patient safety.

## 3.2 The development of the NatSSIPs

### Surgical Never Events and patient safety

The concept of 'Never Events' was introduced into the UK in 2009, with a list of eight adverse patient safety events and a definition of "serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented". Amongst the original eight Never Events were two of the three core surgical Never Events: **wrong site surgery** and **retained instrument post-operation**. The 2010 Never Events Framework extended the scope of the latter Never Event to include retained swabs and throat packs. A 2012 document entitled "The Never Events policy framework" added a third core surgical Never Event (**wrong implant/prosthesis**) and redefined the retained instrument event as "**retained foreign object post-operation**".

It was anticipated that the mandatory introduction of the WHO Surgical Safety Checklist in 2010 and the refinement of the three surgical Never Events would lead to a significant reduction in their incidence in the NHS in England. However, a marked decrease in these three Never Events was not seen and, in 2013, NHS England's Surgical Services Patient Safety Expert Group commissioned a Surgical Never Events Taskforce to examine the reasons for the persistence of these patient safety incidents, and to produce a report making recommendations on how their occurrence could be minimised.

The report, published in 2014<sup>1</sup>, advised the development of high-level national standards of operating department practice that would support all providers of NHS-funded care to develop and maintain their own, more detailed, standardised local procedures. The group tasked with creating these standards have named these **National Safety Standards for Invasive Procedures** (NatSSIPs) and **Local Safety Standards for Invasive Procedures** (LocSSIPs).

This document launches the concept of national and local safety standards, and sets out their rationale and place in the continuous improvement of the safety of care for patients undergoing invasive procedures. The aims of the creation of LocSSIPs are the standardisation and harmonisation of clinical practice throughout the NHS and the development of consistency in education, commissioning and regulation.

Most provider organisations will already have local policies for invasive procedures that can be used as a basis for the creation of LocSSIPs that are compliant with the NatSSIPs published in this document.

### Never Events and the Duty of Candour – new definitions, new guidance, new legislation

NHS England's Never Events Framework is modified and updated regularly to reflect feedback from organisations reporting and investigating Never Events. The latest update, published in March 2015<sup>3</sup>, details the 14 current Never Events and provides the following definition:

<sup>3</sup> <http://www.england.nhs.uk/ourwork/patientsafety/never-events/>

*Never Events are a particular type of serious incident that meet **all** the following criteria:*

- They are **wholly preventable**, where guidance or safety recommendations that provide strong systemic protective barriers **are available at a national level, and should** have been implemented by all healthcare providers.
- Each Never Event type **has the potential to cause serious patient harm or death**. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a Never Event.
- There is evidence that the category of Never Event **has occurred in the past**, for example through reports to the National Reporting and Learning System (NRLS), and a risk of recurrence remains.
- **Occurrence of the Never Event is easily recognised and clearly defined** – this requirement helps minimise disputes around classification, and ensures focus on learning and improving patient safety.

The introduction of a Statutory Duty of Candour, in the form of Regulation 20 of the 2014 Regulations of the Health and Social Care Act 2008<sup>4</sup>, was a direct response to recommendation 181 of the Francis Inquiry report into the Mid-Staffordshire NHS Foundation Trust<sup>5</sup>. This legislation places a statutory duty on healthcare providers in England to ensure that they are open and honest with patients when things go wrong with their care. Although the duty technically applies to organisations, all members of procedural teams, and indeed all healthcare professionals delivering care to patients, should understand and cooperate with their employers' relevant policies and procedures relating to the Duty of Candour. The concept of a Duty of Candour is built into these Safety Standards: if problems are identified that come within the remit of this professional duty, procedural team members should take the appropriate action.

Further guidance on the Duty of Candour is available, for example that published jointly by the General Medical Council and Nursing and Midwifery Council<sup>6</sup>, and that published by the Royal College of Surgeons of England<sup>7</sup>.

### 3.3 Why do Never Events happen?

#### *No one goes to work to make a mistake*

To try and understand why Never Events happen, it is necessary to take a systematic and wide ranging approach to the analysis of each incident. One way to understand the underlying influences on human behaviours that can lead to error is to apply a **clinical human factors** perspective. This means enhancing clinical performance through an understanding of the effects on human behaviour of teamwork, tasks, equipment, workspace, culture and organisation, with the application of that

<sup>4</sup> <http://www.legislation.gov.uk/ukdsi/2014/9780111117613>

<sup>5</sup> <http://www.midstaffpublicinquiry.com/sites/default/files/report/Executive%20summary.pdf>

<sup>6</sup> [http://www.gmc-uk.org/guidance/ethical\\_guidance/27233.asp](http://www.gmc-uk.org/guidance/ethical_guidance/27233.asp)

<sup>7</sup> <https://www.rcseng.ac.uk/publications/docs/duty-of-candour-guidance-for-surgeons-and-employers>

knowledge in clinical settings. Reviews of instances of wrong-site surgery have identified contributory factors that include:

- Workspace and environment.
- Work design.
- Organisation and culture.
- Task factors.
- Communication.
- Policies and procedures.

However, non-technical skills that include cognitive and social ability are also important. Most analysed incidents involve a combination of technical and non-technical factors. Human factors experts have concluded that many of the causes described in investigation reports cannot be adequately addressed by the resulting action plans that target each individual cause. Instead, the causes should be seen as a reflection of the current state of safety within an organisation, showing the underlying cultural and systems issues that need to be addressed at a wider level than that of the incident itself. Further, the response to new safety incidents should not be new policies and procedures, but the simplification and standardisation of existing policies, making sure that they are directly relevant to the areas in which they are used.

While team members may have perfect technical skills to perform the procedures, it is often failures in the non-technical skills that contribute to Never Events. Non-technical skills are 'the cognitive, social and personal resource skills that complement technical skills and contribute to safe and efficient task performance'. These include:

- **Situation awareness:** not gathering enough information; overlooking anomalies; not checking *mental pictures* with others; not recognising increased risks.
- **Decision-making:** proceeding with the task rather than checking when uncertain; an over-reliance on assumptions as to correct location such as prepositioned patients.
- **Teamwork:** failures in the team to speak up when the checklist was not followed; inadequate exchange of information to ensure a shared understanding of what was to be done.
- **Leadership:** not demonstrating procedural compliance, such as using the checklist; not ensuring the whole team had a shared awareness of the task.
- **Coping with stress:** not dealing effectively with work pressures; requiring staff to work faster.

Non-technical skills are taught in a number of safety-critical industries, most notably aviation, where this was first introduced in the form of Crew Resource Management (CRM) courses. Firstly, the relevant non-technical skills need to be identified, and then a training course is designed to improve understanding of the skills and to explain how they can influence safety and efficiency. These are usually classroom-based courses with exercises, demonstrations and opportunities for structured practice and feedback.

Common features in Never Events

Analysis of Never Events suggests some common clinical features. Risk factors associated with retained foreign objects in surgery are large blood loss procedures, long operations, multiple procedures, unexpected intra-operative events and lack of surgical counts, or incorrect surgical counts. Retained vaginal packs are a particular problem in obstetrics and gynaecology.

Common organisational and environmental failures leading to wrong site procedures or wrong implant/prosthesis include unplanned changes in list order, equipment problems, time pressures, interruptions, distractions, inadequate skill mix, and scheduling issues that result in essential team members not being present at critical times. Failures of standard operating procedures include failure to check the patient identity, the consent form or the site marking, particularly before the patient is anaesthetised or sedated. Contributing human factors include wrong site anaesthetic block, failure to take account of patient positioning, or multiple procedures on the same patient or involving different surgical teams. Hurrying, distraction and confirmation bias are also common antecedents. Documentation errors, for instance involving the medical record or the operating list, or incorrect labelling of specimens taken for diagnostic purposes have also been identified as risk factors for wrong site surgery. A single step time out immediately before the start of the procedure is the least reliable method to prevent wrong site procedures. Analysis of near misses suggests that the patient, or the nurses admitting the patient to the procedural area, are the people most likely to identify an error and to prevent a case of wrong site procedure from occurring.

Effective communication between clinical personnel before, during, and after procedures minimises the risk of adverse events. Many organisations have found that a 'briefing' at the start of the procedural list has been a key intervention to support team working, although this has not previously been mandated in England. Pre-procedure and post-procedure safety briefings improve compliance with essential processes, improve teamwork and communication in theatre, improve safety attitudes, situational awareness, and provide an opportunity for learning in a supportive and constructive environment. Low information sharing at post-procedure handover has been associated with an increased risk of complications, and standardised protocols for handover are recommended.

The WHO Surgical Safety Checklist has been shown to improve outcomes in surgery by standardising care, reinforcing safety processes, e.g. identifying patient and procedure, and fostering open communication. However, the checklist is only a lever to promote systemic change and prompt safer behaviour. Like all tools, its effectiveness depends on skilful use. There has been wide variation in adoption of the checklist between trusts, often reflecting the organisational safety culture and, in particular, the clinical leadership in the operating theatre. Where the Checklist is used well, it is as the result of professional leadership, organisational commitment, and time spent on local implementation.

## 3.4 About this document

### 3.4.1 Terminology

#### What the words “must” and “should” mean in this document

When used in this document, the word “**must**” implies that providers of NHS-funded care have to include this action or fulfil this recommendation in their LocSSIPs in order to be compliant with the NatSSIPs set out in this document. It is anticipated that Commissioners will include the development of LocSSIPs and their compliance with NatSSIPs in contracts with providers, and that the Care Quality Commission will use this document as a standards framework for use in assessments and visits.

The word “**should**” implies that it would be expected that providers of NHS-funded care would include this action or fulfil this recommendation in their LocSSIPs in order to be compliant with the NatSSIPs set out in this document. However, if a careful and documented risk analysis of local conditions confirms that the inclusion of a particular action or recommendation is not necessary for the delivery of safe care for patients undergoing invasive procedures in that organisation, a LocSSIP can be implemented that omits the action or recommendation provided its omission is regularly reviewed.

The phrase “**should consider**” implies that providers of NHS-funded care must consider the inclusion of this action or fulfilment of this recommendation in their LocSSIPs in order to be compliant with the standards set out in this document. The details of such considerations need not be documented, but organisations should be prepared to be challenged by regulatory agencies on decisions not to include such actions or recommendations.

### 3.4.2 Scope

#### What are **invasive procedures**?

The National Institute for Health and Care Excellence (NICE) defines an “interventional procedure” as a procedure used for diagnosis or for treatment that involves<sup>8</sup>:

- Making a cut or a hole to gain access to the inside of a patient's body - for example, when carrying out an operation or inserting a tube into a blood vessel, or
- Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body - for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth, or
- Using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) - for example, using a laser to treat eye problems.

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<sup>8</sup> <http://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance>

In using a different term - “invasive procedure” – NatSSIPs proposes to address those procedures that have the potential to be associated with a Never Event if safety standards are not set and followed, to include:

- All surgical and interventional procedures performed in operating theatres, outpatient treatment areas, labour ward delivery rooms, and other procedural areas within an organisation.
- Surgical repair of episiotomy or genital tract trauma associated with vaginal delivery.
- Invasive cardiological procedures such as cardiac catheterisation, angioplasty and stent insertion.
- Endoscopic procedures such as gastroscopy and colonoscopy.
- Interventional radiological procedures.
- Thoracic interventions such as bronchoscopy and the insertion of chest drains.
- Biopsies and other invasive tissue sampling.

It is not intended that NatSSIPs and LocSSIPs address procedures that involve the simple penetration of the skin or entry of a body cavity, such as the insertion of an intravenous line or a urinary catheter, or the use of ionising radiation, such as the taking of a plain X-ray. Neither is it intended that every detail of the NatSSIPs be transposed into LocSSIPs for single-operator, ward-based procedures such as bone marrow aspiration, pleural biopsy and tapping of ascites. However, it is recommended that providers of NHS-funded care, when creating policies for the safe performance of all procedures that come under NICE’s definition of “interventional procedure”, but are not included in our definition of “invasive procedure”, take NatSSIPs guidance into consideration when developing local policies for safe patient care. This may be of particular importance to procedures such as the insertion of vascular lines, e.g. central venous catheters, as there have been Never Events relating to the accidental retention of guide wires<sup>9</sup>.

#### *What part of the patient pathway should LocSSIPs cover?*

LocSSIPs, and the NatSSIPs upon which they are based, are intended to cover the part of the patient pathway that pertains specifically to the performance of an invasive procedure. They start at the point at which a patient is admitted to the procedure area and end at the point at which the patient is discharged from the procedure area. However, it is appreciated that the delivery of safe patient care and the avoidance of Never Events starts well before the performance of the invasive procedure and ends well after it. Organisations providing NHS-funded care should consider the invasive procedure patient pathway as a whole, from referral, to the initial decision to treat, through assessment of the patient’s fitness and suitability for the procedure, the advance discussion and planning of admission, procedure, post-procedure care and discharge, the passage of key patient information between different parts of the organisation and other organisations, the consent process and documentation of the process, post-procedural management, review and surveillance after the procedure, and audit and clinical governance of the whole patient pathway. LocSSIPs should

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<sup>9</sup> <http://www.england.nhs.uk/wp-content/uploads/2015/04/prov-ne-data-apr-mar-15-fin.pdf>

therefore be considered a part of a larger patient pathway, and should be included in the continuum of care rather than becoming the sole focus of it.

### 3.4.3 Glossary

In order to extend the remit of invasive procedures to those performed outside of the operating theatres, this document uses the following terms:

**Procedure**, to include surgical operations, invasive cardiological procedures, endoscopy, interventional radiology, thoracic procedures and biopsies.

**Procedure area**, to include the operating theatres, cardiac catheter laboratories, endoscopy suites, labour ward and radiology department.

**Procedure room**, to include the individual procedural venue, e.g. operating theatre, delivery room and endoscopy room.

**Procedure team**, to include all those involved in the performance of the procedures, including doctors, nurses, midwives, operating department practitioners (ODPs), healthcare assistants (HCAs), technicians, scientists and any others directly involved in the performance of the procedure.

**Operator**, to include the surgeon, endoscopist, cardiologist, obstetrician, midwife, radiologist or other healthcare professional or practitioner performing the invasive procedure.

**Senior operator**, to imply the clinician with overall responsibility for the procedure.

**Operator team or clinical team**, to include the surgical or other team planning, scheduling and delivering care for the patient undergoing an invasive procedure.

**Operator's assistant**, to include any healthcare professional acting as first assistant to the operator.

**Scrub practitioner**, to include any healthcare professional taking the role of what would be traditionally held to be a "scrub nurse" in the operating theatre, i.e. managing the equipment and instruments during a procedure, ensuring sterility and participating in the reconciliation of swabs, needles, instruments and other items.

## 3.5 Governance of NatSSIPs and LocSSIPs

### 3.5.1 Implementation

#### Harmonised local standards based on shared national standards

The purpose of the development of NatSSIPs and LocSSIPs is the delivery of ever-safer care for patients undergoing invasive procedures, and the promotion of continuous quality improvement. The NatSSIPs in this document set out the key elements of safe care, and should be used as a basis for the development of LocSSIPs by organisations providing NHS-funded care. NatSSIPs represent the minimum standards considered necessary for the delivery of safe care during invasive procedures, and the multidisciplinary process that develops LocSSIPs within organisations must adapt these to match local conditions and circumstances while ensuring that all provisions in the NatSSIPs are fulfilled.

Organisations providing NHS-funded care should consider creating LocSSIP Implementation Groups with responsibility for the creation, governance, oversight, compliance, audit and review of LocSSIPs. LocSSIP Implementation Groups should set clear timelines for the creation and implementation of LocSSIPs that are compatible with implementation plans set out by NHS England.

LocSSIPs should be developed by procedural teams with the support of managers rather than simply being handed down by local managers to procedural teams. Different LocSSIPs can apply to different procedural areas within an organisation. For example, the LocSSIPs for obstetric procedures will differ markedly from those used for eye surgery. It is for individual organisations to produce their own LocSSIPs, implement them using improvement methodology, audit their implementation, compliance and performance, and modify their content based on continuous evaluation. The content of NatSSIPs will be reviewed regularly and will be adapted as necessary. Examples of good practice in the creation and implementation of LocSSIPs will be collated and placed on a dedicated website.

### 3.5.2 Record keeping

#### Documentation that supports the effective implementation of standards

The multidisciplinary group of experts that created NatSSIPs were unanimous in their belief that the implementation of electronic record keeping will support the correct, complete and sequential performance of the key safety checks in LocSSIPs, and will provide an accurate record of both the team performing the checks and the actual checks performed. Although many organisations providing NHS-funded care have made the transition to wholly electronic patient records and operating theatre or procedural management processes, many are in the process of implementing electronic record keeping and many are yet to embark on the transition. Those organisations that currently rely on paper records should make every effort to coordinate LocSSIP steps and to ensure that none is omitted. Organisations may wish to consider visual reminder aids such as large, laminate boards with the key

safety steps printed permanently upon them in addition to printed checklists to act as aide memoires and to ensure that every safety step in LocSSIPs is properly completed for every patient undergoing invasive procedures. Organisations do not need to document every detail of every step performed in every LocSSIP, as it is more important that the checks are conducted properly than that the performance of every step is recorded. Organisations should work with commissioners and regulators to determine an appropriate level of detail for records that will support audit and investigation while not placing an intolerable burden upon procedural teams.

### **3.5.3 Accountability and responsibility**

*Every team member is responsible for the delivery of safe care*

Organisational leaders, i.e. Trust Boards or equivalent, shall be ultimately responsible for the creation of LocSSIPs, their implementation, governance, audit and modification, and will be accountable for these to Clinical Commissioning Groups and to the Care Quality Commission. Multidisciplinary procedural teams, e.g. operating theatre teams, to include medically qualified, registered and non-registered practitioners, will be responsible for the development, implementation and continuous appraisal of the safety and efficacy of LocSSIPs, working with patient groups where appropriate. The line of accountability will pass up from these teams through clinical and non-clinical managers to the Trust Board or equivalent. However, the responsibility for ensuring that the LocSSIPs are followed accurately for every patient will be the responsibility of every member of the procedural team. Those members of the team who are registered healthcare professionals will be accountable both to their registering bodies and to their employers. Those members of the team who work in non-registered roles will be accountable to their employers. The fundamental basis of the delivery of LocSSIPs in the patient pathway is the sharing of responsibility between every member of the procedural team. When a document is signed as indicating that a step in a LocSSIP has been performed by a member of a procedural team, that member is signing on behalf of the whole team, and every member of the team therefore shares the responsibility for the performance of the LocSSIP, while sharing accountability for its full completion. The basis of safe care is teamwork, and the aim of both NatSSIPs and LocSSIPs is to promote and develop teamwork.

### **3.5.4 Organisational culture and teamwork**

*Effective teamwork in a supportive environment makes patient care safer*

Leaders of organisations providing NHS-funded care should take positive steps to ensure that LocSSIPs are introduced and managed within a culture of openness and transparency in which any member of any procedural team knows that they can speak up to express concerns about the process or patient safety at any time in the patient or procedural pathway. Although this document does not demand the implementation of a “Stop the Line” system similar to that used in vehicle manufacture, the implementation of such an approach, when it is safe, is encouraged within organisations. There must also be openness in the analysis of audit data of

compliance and use of metrics with LocSSIPs and NatSSIPs, and the learning derived from careful analysis of adverse patient safety incidents or “near misses”. The organisation must ensure that patient safety concerns are addressed and the recommendations or changes that result are fed back to procedural teams. Organisations should create local guidance that complies with current legislation for the sharing with patients the details of incidents or near misses occurring during their care.

Teamwork is fundamental to the safe delivery of patient care during the procedural pathway. Organisations should ensure as far as possible that procedural teams are consistent and coherent. Multidisciplinary teams that work together should train together, with a focus on human factors, effective communication and openness.

### **3.5.5 Education**

#### *Take time to train as teams*

Team members participating in any stage of any of the LocSSIPs must receive appropriate training to allow them to be able to fulfil their roles safely, effectively and consistently. The competence of individuals and teams in the performance of LocSSIPs should be regularly assessed. Organisations must accept that rapid developments can occur in procedural techniques and performance, and should ensure that the training of all team members is maintained and updated as appropriate. Training must not only be on an individual basis but must also include training as multidisciplinary and multiprofessional procedural teams – team members should train together in the delivery and development of LocSSIPs. Procedural teams must also receive regular training in human factors and non-technical skills. When new members join teams, particular care should be taken to introduce them to the teams and to ensure that their care is harmonised with that of other team members and teams. It is anticipated that undergraduate and postgraduate teaching will encompass training in NatSSIPs, and that appraisal, revalidation, performance development and review processes will include active participation in LocSSIPs and the learning deriving from the clinical governance of LocSSIP and NatSSIP processes.

Continuous safety improvement depends on continuous audit of outcome and compliance with safety standards, and on the collection and analysis of data on adverse patient events and near misses. It is important that team members are given regular opportunities to suggest improvements in LocSSIPs and patient care. The drive for greater efficiency in the delivery of NHS care has in many organisations been associated with a decrease in the time devoted to regular meetings that address adverse patient events and training for procedural teams. Such meetings have had names such as Morbidity and Mortality (M&M) Meetings, Audit Meetings or Clinical Governance Meetings. Providers of NHS-funded care should, as part of their commitment to the development, implementation and ongoing management of LocSSIPs, schedule regular Safety Meetings for multidisciplinary procedural teams of adequate length and frequency to allow training, analysis of adverse incidents and near misses, review of audits of compliance with LocSSIPs, and teamwork development and practice.

### 3.5.6 Patient involvement

*The patient is the most important member of the team*

It is recommended that patients and patient groups be involved in the creation, development, implementation, review, modification and governance of LocSSIPs. Patients, and/or their parent, guardian, carer or birth partner, should be actively involved in the individual safety steps in LocSSIPs when feasible. For instance, a patient with capacity can participate in the handover to the procedure team from the ward or admission area, in addition to the sign in. If the procedure is performed under regional or local anaesthesia without sedation, it is also possible for the patient to participate in the time out, sign out and other handovers within the patient pathway.

### 3.5.7 Audit and review

*Not just “what we did” but “how well did we do it?”*

At the heart of the NatSSIPs and LocSSIPs processes and pathways is continual audit of compliance with the safety standards and review of patient safety incidents, “near misses” and suggestions from procedure teams for ways of improving patient safety. Both NatSSIPs and LocSSIPs will be part of iterative processes that will allow review of the current standards, suggestions for changes and improvement, careful implementation of modified standards, and audit of the effects of changes. This continuous quality improvement cycle conducted on a local basis will be mirrored nationally, with organisations being able to feed back to the organisations who created the NatSSIPs, with changes being made as appropriate to the standards.

Organisations should not only audit the fact of the performance of LocSSIPs, but should also audit the quality of their performance, e.g. it is not sufficient simply to record that a Time Out occurred, but that the Time Out included the active involvement of all staff involved in the procedure. Organisations could develop scoring systems that allow those involved in invasive procedures to grade the quality of the performance of LocSSIPs.

## 3.6 Structure and content of the NatSSIPs

The NatSSIPs presented in this document are in two groups: organisational (the standards that underpin the safe delivery of procedural care) and sequential (a logical sequence of steps that should be performed for every procedure session or operating list, and every patient):

#### **Organisational**

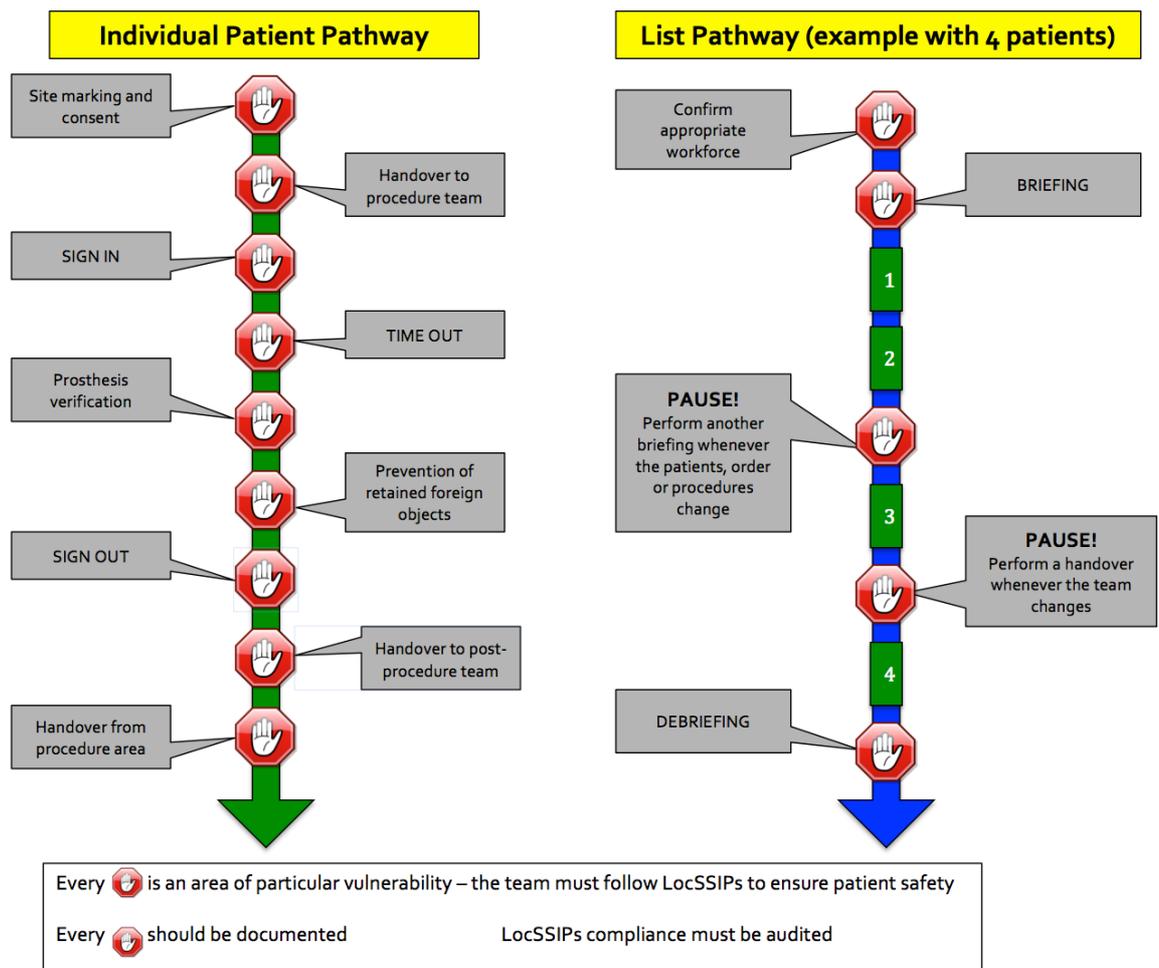
- 1 Governance and audit
- 2 Documentation of invasive procedures
- 3 Workforce
- 4 Scheduling and list management
- 5 Handovers and information transfer

**Sequential**

- 6 Procedural verification and site marking
- 7 Safety briefing
- 8 Sign in
- 9 Time out
- 10 Prosthesis verification
- 11 Prevention of retained foreign objects
- 12 Sign out
- 13 Debriefing

It is accepted that in some procedural environments, the combination of two sequential steps may be logical, e.g. performing a simultaneous Sign In and Time Out for procedures for which sedation is not used and for which the operator provides local anaesthesia. If two steps are combined, the key safety elements of both steps as set out in this document should be retained in the single, combined step.

The following diagram illustrates the role of these NatSSIPs within individual patient pathways and the conduct of a list of procedures.



## 4 National Safety Standards for Invasive Procedures

### Sabeena's story

Sabeena is a 36-year-old woman suffering from advanced endometriosis. It was agreed that the best course of treatment for Sabeena would be the removal of her ovary, fallopian tube and uterus, which could be performed laparoscopically.

Because of her age, she was keen to preserve one of her ovaries so that she would not require hormone replacement therapy. Sabeena consented to total laparoscopic hysterectomy and left salpingo-oophorectomy, with excision of endometriosis and adhesiolysis if necessary (removal of the uterus, cervix, left ovary and fallopian tube, along with treatment for adhesions and scarring). It was agreed that the right ovary and fallopian tube would be preserved, as the left ovary was more affected by the disease.

The consent form was completed correctly and Sabeena mentioned to the anaesthetist during the "Sign In" that she was only having one ovary removed. The printed theatre list stated the procedure as "Total laparoscopic hysterectomy + LSO + excision of endometriosis".

As this was complex surgery, the procedure was carried out by an experienced consultant gynaecologist who specialises in treating severe endometriosis, supported by a specialist registrar. The registrar attended the briefing, participated in the Time Out and started the procedure. However, he experienced problems inserting the Verres needle (a small needle inserted near the umbilicus that allows gas to be introduced into the abdomen), and asked the consultant to assist him. The consultant joined the theatre team and began the procedure.

There were problems with the light leads and camera stack, and it took a few minutes to find replacement equipment, during which time the registrar, who was on call for the wards, had to leave the theatre to answer his bleep. By the time the consultant restarted the procedure, most of the team present at the briefing were not in the theatre: the circulating practitioner was outside looking for equipment, the HCA was working in another theatre that was short-staffed, and the registrar was on the 'phone in the corridor. With a new camera stack that was working properly, the consultant continued with the procedure, but started by dividing the blood supply to the right ovary. He quickly realised his error, stopped the operation and informed the procedural team. The surgeon considered saving the left ovary, but felt this was not possible due to the endometriosis, and carried on with the procedure, as it was felt to be in Sabeena's best interests.

Sabeena was told the next day that she had had both of her ovaries removed and received a full explanation and an apology from the surgeon. Although she understood what had happened, she was upset that she would have to take hormone replacement therapy and asked that a full enquiry be conducted and changes made so that the mistake could not happen to other patients. The hospital conducted a Serious Incident enquiry as required by the organisation's Never Events policy and made changes based on the root cause analysis that is part of the enquiry.

**Comments from the NatSSIPs Group:**

“This is a really unfortunate case and, although it is good that Sabeena received a quick and full apology, in line with the Duty of Candour, several errors were made that should not have occurred:

- The operating list should not have contained any abbreviations such as “LSO” – this should have been written out in full as: “Left salpingo-oophorectomy”.
- The senior operating surgeon who was going to do the procedure should have been present at the Briefing and Time Out.
- The registrar should not have had other commitments that may take him out of the operating theatre during a procedure.
- Staff shortages should not lead to procedural teams changing during a list.
- If the procedural team changes during a case, a handover should be performed that includes reconfirming the planned procedure and a discussion of any issues raised at the Briefing, Sign In and Time Out”.

#### **4.1 Governance and Audit**

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

1. The organisation must ensure that LocSSIPs are compliant with all National Safety Standards for Invasive Procedures (NatSSIPs).
2. The organisation must identify sufficient time and human resources to support full implementation and audit of all LocSSIPs. This will include regular multidisciplinary meetings of the workforce.
3. The organisation’s clinical governance processes must include the requirement for regular audit of compliance with all LocSSIPs. This should include:
  - Compliance of LocSSIPs with NatSSIPs.
  - Compliance of local practice with LocSSIPs.
  - Evidence of action plans incorporating timescales for addressing non-compliance.
  - Evidence of regular review of LocSSIPs and their adjustment as required.
4. Governance processes should support proactive improvement of safety systems as well as reactive responses to reported incidents.

5. All patient safety incidents and near misses should be documented and reported to the organisation's incident reporting system. These should be analysed, investigated as appropriate, and learning should be fed back to staff for continuous improvement. This should be in accordance with organisational policy, ensuring compliance with the Serious Incident Framework and Never Event Framework.
6. The organisation must promote transparency and openness when near misses or patient safety incidents occur, in line with the statutory Duty of Candour.
7. The organisation should ensure that outcomes of its governance activities in relation to LocSSIPs, such as audit of compliance, are disseminated to staff and commissioners.
8. Each procedure team should have an identified team member responsible for collating relevant briefing and debriefing documentation, e.g. reviewing action logs and sharing information with local governance and management systems on a regular basis.
9. There must be arrangements that promote the escalation of issues identified that may have implications for the safety of services in other parts of the organisation. Organisations must comply with local and national processes that promote the sharing of information about safety issues with other organisations that provide NHS-funded care.
10. The organisations that created NatSSIPs will disseminate learning from the development, implementation and audit of LocSSIPs to organisations providing NHS-funded care. Organisations should develop ways of learning from this process and should work with NatSSIPs and other groups to share best practice and learning in relation to LocSSIPs and NatSSIPs.
11. When safety processes for invasive procedures are being introduced or changed, the organisation must assess the impact on compliance with these standards.

## 4.2 Documentation of Invasive Procedures

Organisations must create standardised documentation for patients undergoing invasive procedures that promotes the sharing of patient information between individuals and teams at points of handover, and forms a record for future reference. This standard outlines the minimum expectations for this documentation. It recognises that the structure of the documentation can in itself contribute to safe working practices. Both electronic and paper documentation must be designed in such a way that key safety checks in the patient pathway are performed in sequence and are documented.

1. Standardised documentation for invasive procedures performed in all areas within an organisation must ensure the recording of essential information throughout the patient pathway, to include pre-procedural assessment and planning, the conduct of anaesthesia or sedation, the invasive procedure itself and post-procedural care.

2. The documentation should promote the implementation and audit of, and record compliance with or variation from, other LocSSIPs, to include handovers of care, safety briefing, sign in, time out, checks to ensure correct site surgery, the insertion of the correct prosthesis, prevention of the retention of foreign objects, the sign out at the end of the procedure and debriefing.
3. Invasive procedure documentation should allow the identification of the members of the team present at each stage in the patient pathway.
4. Documentation must be complete, legible and contemporaneous, and must use locally agreed standardised terminology, avoiding the use of abbreviations or jargon.
5. A record should be kept of the performance of the key safety checks in the patient pathway. Local organisations can decide whether this is simply confirmation that the check has been performed by the procedure team, or whether a particular individual or individuals should be responsible for confirming, on the team's behalf, that the check has been performed.
6. The time and author of any alterations to the documentation must be recorded.
7. The documentation will include records made by responsible persons:
  - Administering anaesthesia or sedation.
  - Performing the procedure.
  - Providing other care during the procedure.
8. Organisations must ensure that there is a standardised process for documenting adverse incidents, near misses and unexpected outcomes.
9. When paper and electronic documentation are both in use, both systems should be aligned such that there is no unnecessary duplication of data entry or inconsistency. The organisation must identify which is the primary information source for later reference.

### **4.3 Workforce**

This standard supports the principle that the safe care of patients undergoing invasive procedures depends upon having the correct numbers of appropriately trained, skilled and experienced staff members who work together effectively in a team.

1. Organisations must develop LocSSIPs that clearly identify the workforce necessary to deliver safe patient care in every operating theatre and invasive procedural area in the organisation. These should be developed and agreed with appropriate staff representatives.
2. The LocSSIPs must account for the full scope of local services, e.g. the needs of different clinical specialties and factors such as complexity, technology, elective and non-elective activity, and variability in demand and capacity.

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3. Job plans and establishments must take into account the time required to set up, calibrate and perform safety checks on specialist equipment, and for staff to participate in briefing, debriefing and other key safety steps in LocSSIPs.
4. Day-to-day workforce plans must be based upon the expected duration of the activity, and the LocSSIPs must be specific about processes for members leaving or joining the clinical team part way through an activity, and the steps necessary to ensure patient safety when teams hand over care.
5. The LocSSIPs should ensure that all members of the procedural team practise within the limits of their proven and agreed competence.
6. The LocSSIPs must define the number and skill-mix of staff, with an appropriate ratio holding a specific primary or postgraduate practice qualification applicable to the procedural area, for example a qualification in perioperative practice. This may not necessarily reflect current staffing and, if it does not, a documented action plan must be created in order to achieve and maintain the stated number and skill-mix within a reasonable time.
7. The LocSSIPs must address workforce needs for procedures that take place outside of normal working hours. The workforce standards set for out-of-hours work should be no less than those set for equivalent procedures performed during standard working hours. The LocSSIPs should provide guidance on escalation processes and actions to be taken should a clinical situation overwhelm available resources.
8. The LocSSIPs must take into account the supervision of students and trainees, including:
  - Doctors in training
  - Student ODPs
  - Undergraduate and postgraduate nurses and midwives
  - Learners in other supporting roles
9. The LocSSIPs must specifically address the induction requirements of non-substantive staff in the procedure team. Allocation of staff to clinical duties must reflect a risk-managed mix of substantive (or familiar and experienced staff) and non-substantive staff.
10. The theatre manager, or equivalent individual for each procedural area, should confirm the availability of an appropriate workforce for each operating theatre or invasive procedural area before the start of any list or session. It may occasionally be necessary to perform an emergency procedure with a workforce that does not comply with the LocSSIP. When this happens, it should be reported as a safety incident and should be reviewed through local governance processes.
11. If any member of the procedure team is concerned about whether the assigned workforce is sufficient in number or skill-mix for the safe conduct of the proposed clinical activity, they should bring this to the attention of the theatre manager or equivalent individual for the procedural area. The theatre manager or equivalent should respond to such concerns and assess the situation, and

should only advise that the procedure be performed if he or she is satisfied that the workforce is appropriate to support safe patient care. When this happens, it should be reported as a safety incident and should be reviewed through local governance processes.

12. When members of the workforce have clinical responsibilities outside of the procedural area, the potential for competing and irreconcilable clinical demands must be addressed. This is most commonly an issue outside of normal working hours, and examples include theatre staff allocated to the designated emergency theatres also covering the obstetric theatre or cardiac arrest teams, or medical staff covering both theatres and emergency departments or wards. LocSSIPs should include a requirement to risk assess and monitor the incidences of competing priorities to provide assurance that appropriate workforce levels are maintained.
13. There should be an agreed process for the provision of non-medical team members acting as procedural first assistants that ensures that they have the appropriate competences and that their performance of this task does not deplete the procedural team.
14. Clinical practice and technology relating to invasive procedures are subject to constant development and change. All members of the workforce must receive regular updates and continuous professional development.
15. Nationally, Colleges, Professional Bodies and Specialty Associations may define workforce standards for specific clinical specialties or activities. Where these exist or become available, it is appropriate to use these to inform workforce LocSSIPs.

#### **4.4 Scheduling and list management**

Patient safety during the performance of invasive procedures is dependent upon adequate preparation, the accurate scheduling of procedures and the management of procedure lists. This standard supports procedure teams in ensuring that lists accurately reflect the plans for patients and the procedures they are scheduled to undergo.

1. Organisations must develop LocSSIPs that dictate how clinical teams schedule both elective and emergency procedures, and communicate key patient and procedure information to procedure teams using agreed, standardised data sets. An organisation's scheduling processes should when possible be consistent such that different clinical services use similar processes to schedule invasive procedures in different locations.
2. LocSSIPs must include the unambiguous use of language in all communications relating to the scheduling and listing of procedures. Laterality must always be written in full, i.e. 'left' or 'right'. The use of abbreviations should be avoided but, when common abbreviations are used, it must not be assumed that all personnel will be familiar with the abbreviation. A list of locally approved abbreviations should be readily available to all staff. Special consideration should be given to the use of abbreviations that could be confusing or misread

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across specialties, examples of which might include TAH for Total Abdominal Hysterectomy versus THR for Total Hip Replacement, and ERPC for Evacuation of Retained Products of Conception versus ERCP for Endoscopic Retrograde Cholangio-Pancreatography.

3. The information that accompanies the scheduling of a procedure should include when relevant, but is not limited to:
  - Patient name.
  - Identification numbers, i.e. NHS number with or without hospital number.
  - Date of birth.
  - Gender.
  - Planned procedure.
  - Site and side of procedure if relevant.
  - Source of patient, e.g. ward or admissions lounge.
  - Further information that can be provided when relevant may include:
    - NCEPOD classification of intervention.
    - Significant comorbidities.
    - Allergies, e.g. to latex or iodine.
    - Infection risk.
    - Any non-standard equipment requirements or non-stock prostheses.
    - Body mass index.
    - Planned post-procedural admission to high dependency or intensive care facility.
4. Although the clinical team performing the procedure is primarily responsible for its accurate scheduling, it must when appropriate involve other clinical disciplines such as anaesthesia and radiology to ensure that all healthcare professionals necessary for the safe performance of the procedure are available at the correct time.
5. The clinical team performing the procedures is responsible for deciding the order of procedures within a list of cases. In determining the order of a list, priority should be given to clinical criteria, e.g. urgency, extremes of age, allergies such as latex allergy, and medical conditions that make early or predictable start times desirable, e.g. diabetes or sleep apnoea.
6. The scheduling of a list must take into account the expected workload, taking into consideration other factors that include:
  - Team briefing and debriefing, and other key safety steps in LocSSIPs.
  - Induction of and emergence from anaesthesia, and the time taken for anaesthetic procedures.
  - Patient positioning and preparation.
  - Preparation of all necessary equipment and instrumentation.

- Familiarity, skill-mix and expertise of all members of the procedure team.
  - In assessing the likely time needed for common procedures, review of existing theatre usage records may be valuable.
7. LocSSIPs should dictate the processes by which the final version of a list is signed off for publication by the operator team. Deadlines for the publication of a final version of a list should be set and adhered to.
  8. List changes should be avoided if possible. Any list changes made after the deadline for the publication of a final version of the list must be agreed with identified key members of the procedure team, and should be discussed by all members of the procedure team at the safety briefing.
  9. Organisations must ensure that all relevant personnel are made aware of any late changes to a list. In the absence of electronic list scheduling, the organisation must have clear processes for managing lists and an effective mechanism for version control that ensures that different versions of lists are not available.
  10. LocSSIPs should include specific safeguards and clear responsibility for ensuring that patients are not deprived of oral nutrition or hydration for unnecessarily long periods due to delays or list changes.
  11. 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. The final version of the list should be available at the safety briefing.

## 4.5 Handovers and information transfer

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. This standard sets out the basis of the LocSSIPs that organisations should develop for handovers. Not all items in the comprehensive bulleted lists given below will be necessary for all handovers but are included for completeness and to allow organisations to devise locally relevant handover documentation.

### 4.5.1 All handovers

- i. Organisations should consider the use of structured handover forms as a prompt for all handover conversations.
- ii. Handovers should be both verbal and written, and should be documented. On rare occasions, the immediate urgency of a procedure may mean that there is only time for a verbal handover. Under these circumstances, documentation can be retrospective.
- iii. Organisations should specify which team members should be present at each handover. Surgeons or operators must participate in handovers in which the

patient's care pathway has deviated from that planned and when patients are handed over to critical care teams after procedures.

- iv. Participation of the patient (and/or parent, guardian, carer or birth partner) in handovers should be encouraged when feasible.
- v. During handovers, only one person should speak at a time, and the conversation during the handover should relate only to the patient. Non-handover activities should cease during the handover. Each team member should be given the opportunity to ask questions and clarify information.

#### **4.5.2 Handovers to procedure teams**

- i. There must be a formal handover process from the ward or admission team to the practitioner receiving the patient in the anaesthetic room, procedure room or designated location in the procedural area.
- ii. The handover should include when relevant, but is not limited to, a check of:
  - Patient name, with patients identifying themselves, checked against an identity band.
  - Correct documentation of weight.
  - Allergies.
  - Procedure, and site or side if appropriate.
  - Site marking if relevant.
  - Fasting status.
  - Relevant clinical features, e.g. blood sugar for diabetic patients.
  - An appropriate patient record.
  - A properly completed consent form.
- iii. If there are any omissions, discrepancies or uncertainties identified, these must be resolved before the next stage of the patient pathway, i.e. the sign in. On rare occasions, the immediate urgency of a procedure may mean that the handover may have to be completed without full resolution of any omissions, discrepancies or uncertainties.

#### **4.5.3 Handovers during procedural care**

- i. Handover between any members of the procedural team during a procedure should be avoided if possible. When lengthy procedures can be predicted, working and shift arrangements should be adjusted to minimise changes in staff. If staff changes during a procedure cannot be avoided, they should be scheduled when possible and communicated at the team brief.
- ii. When there is a change in team members during a procedure or between procedures, the outgoing and incoming team members must ensure that they hand over all relevant information, including any issues arising from the team brief, sign in and time out, and they should inform the rest of the team about the

change. If the handover takes place during a procedure, relevant patient and procedure information must also be exchanged.

- iii. When there is a change of scrub practitioners, the outgoing and incoming practitioners must ensure that all items identified at the beginning or during the procedure, e.g. swabs, needles and instruments, are accounted for. This must include items on the operating tray, in the operative field and inside body cavities. Once completed, the incoming practitioner must communicate this verification to the operator.
- iv. If there is a change in the operator during a procedure, there must be a handover to include all relevant information, including the number and location of any swabs or other foreign objects in body cavities at the point of handover. This must be verified by the scrub practitioner.
- v. On occasion, there may be a change in venue during a procedure, for instance when a pregnant woman is transferred from a delivery room to an operating theatre for an instrumental or operative delivery. Such a transfer should be treated as a handover of care, and there must be effective communication about changes in team members during the process, and any instruments, swabs or packs transferred between venues either with or inside the patient.

#### **4.5.4 Post-procedure handovers**

- i. There must be a formal handover from the procedure team to the post-procedure care area, e.g. the Recovery Room or Post-Anaesthesia Care Unit (PACU). Such handovers should only happen when the patient is monitored appropriately and they are clinically stable. There must be a further handover from the post-procedure care area to the ward or critical care area. On occasion, a patient will be transferred directly from the procedure room to a ward or critical care area or team. Post-procedure handovers may include when relevant, but are not limited to:

##### **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.

### Information about surgical care

- 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.

### Information about anaesthetic care

- ASA physical status.
- 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

### Juan's story\*

Juan is a 68-year-old man who underwent a total hip replacement. The surgical team who cared for him work together regularly and are strong supporters of the Five Steps to Safer Surgery. During the Safety Briefing, the hip implant sizes were discussed. The implant consists of three components: socket (inserted into the pelvis), stem (inserted into the femur) and head (placed on top of the stem). Each component is packed separately in its own labelled box. Each component can be of a different size to suit the patient, and each has specific measurements. However, the head has two measurements: the head diameter, which must fit snugly with the socket component, and the length, which is an independent variable. One combination of these implant sizes was considered most likely to suit the patient, but another was brought into theatre as a contingency.

The surgeon made the final size decisions regarding size during a visual examination after the start of surgery. She was passed the correct size socket, which she put in place. When ready for the head of the implant, the surgeon asked for a "+5" - a reference to the length, not the diameter of the head. The diameter is not normally specified at that point as it is automatically defined by the size of the socket, which has already been implanted by that time. It was seen as a given by all involved. The circulating practitioner passed the head to the scrub practitioner, who confirmed the length as "+5" but did not read out the diameter. The surgeon assumed that she was being passed a head that matched the socket, but this was not the case – the socket and head were different diameters. The operation was completed; the sticker from the implants was attached to the operation notes and entered into the computerised national register.

The error came to light about a year later when the patient was reviewed in the outpatient clinic. He reported some discomfort and looseness of the joint when walking downstairs. While investigating the possible causes, the surgeon reviewed the operation notes. She noticed that the implant stickers showed that the diameters of the socket and the head were not compatible. The surgeon disclosed the error to the patient and apologised, in line with the Duty of Candour. The patient was upset and unhappy. The team felt devastated that their error had caused harm, especially given the high priority they place on safety in their practice.

\* Adapted from a story in the NHS England Never Events Taskforce [Report](#)

**Comments from the NatSSIPs Group:**

“It is wholly understandable that Juan is upset by the procedural team’s mistake. He would naturally have expected to have compatible components inserted and will not have understood why he had a socket and head that didn’t match. Analysis of the incident showed that the circulating practitioner thought the scrub practitioner would check the diameter of the head, the scrub practitioner thought the circulating practitioner had checked it, and the surgeon thought the scrub practitioner had checked it. In practice, no one had checked it. The surgeon genuinely thought she was being passed the correct component. Three points are worth making:

- The procedural team rightly used the Safety Briefing to discuss the range of implants that would be needed.
- The Prosthesis Verification Standard suggests that once the prosthesis has been selected, any prostheses not to be used for that patient should be clearly separated from the correct prosthesis. In this case, two sets of components were retained in the operating theatre, and this may in part have led to the mistake.
- The procedural team’s standard procedures did not identify which member of the team was going to check all the characteristics of all three components. The Prosthesis Verification Standard suggests that the operator should confirm all the characteristics of the prostheses with the rest of the procedural team before removing them from their packing prior to their insertion”.

## 4.6 Procedural verification of site marking

Organisations must develop and implement LocSSIPs that ensure that patients undergo the correct procedures on the correct sites and sides.

1. All patients undergoing invasive procedures under general, regional or local anaesthesia, or under sedation, must undergo safety checks that confirm the procedure to be performed and the site and side of the procedure. These checks must be performed at least during the sign in and time out.
2. All patients admitted to procedural areas must be accompanied by a valid consent form completed in accordance with national and local guidance.
3. Surgical site marking is mandatory for all procedures for which it is possible.
4. Reliable marking of surgical 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 surgical site error, the correct procedure must be verified by full review to ensure consistency of the clinical record, diagnosis, treatment plan, investigation results, written consent, intraoral surgical site check and confirmation by with the patient. Reference to radiological imaging may be useful.
5. The procedure site must be marked shortly before the procedure but not in the anaesthetic room or the procedure room.
6. The marking must be performed by the operator or a nominated deputy who will be present during the procedure.
7. The mark must be made with an indelible marker, the ink of which is not easily removed with alcoholic solutions.
8. The mark must be placed such that it will remain visible in the operative field after preparation of the patient and application of drapes.
9. 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 surgical site should be reverified and the surgical mark checked.
10. Stoma sites should be marked by a professional experienced in siting stomas, and an indication of the planned stoma position must be maintained during the procedure.
11. The non-operative side must never be marked - not even with statements such as "not this side".
12. The planned procedure must be confirmed and the surgical site marking checked at both sign in and time out. At sign out, confirmation that the procedure has been performed on the correct site and side should be obtained.
13. Documentation of sign in, time out and sign out should include procedure and surgical site and side.

## 4.7 Safety briefing

Procedural team briefing is a key element of practice in the delivery of safe patient care during invasive procedures, and forms part of both the WHO Surgical Safety Checklist and the Five Steps to Safer Surgery<sup>10</sup>. Noise and interruptions should be minimised during the safety briefing.

1. A safety briefing must be performed at the start of all elective, unscheduled or emergency procedure sessions. The briefing may need to be conducted on a case-by-case basis if there is a change in key team members during a procedure session.
2. The total time set aside for the procedure or list of procedures should include the time taken to conduct the safety briefing.
3. The safety briefing 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.
4. As many members of the procedural team as possible should attend the briefing, to include the operator and anaesthetist who have seen and consented the patient(s) shortly before the procedural session. These should include when relevant, but are not limited to:
  - The senior operator and trainee(s)/assistant(s).
  - The senior anaesthetist and trainee(s).
  - The anaesthetic assistant.
  - Scrub and circulating practitioners or other procedural assistants.
  - Any other healthcare professional involved in the procedure, e.g. radiographer or perfusionist, when this is practicable.
  - The clinical manager of the procedural area if appropriate.
5. Any team member may lead the safety briefing.
6. Each member of the procedural team expected to be involved in the scheduled session must be named and this list made easily visible throughout the session. The operator, scrub practitioner and anaesthetist if relevant must be identified for each case listed. Any changes to the team members during the day should also be recorded in this document or notice, and should be the subject of an appropriate briefing if anticipated.
7. The safety briefing should consider each patient on the procedural list in order from an operator, anaesthetic and practitioner perspective. A process must be in place to update the procedural team with relevant information in the case of staggered admissions, i.e. if patients are admitted after the start of the list. The

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<sup>10</sup> <http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=93286>

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content of the safety briefing should be modified locally, and must be relevant to the patient and procedure.

8. Team members should introduce themselves to ensure that their roles and names are known and to encourage people to speak up.
9. For each patient, the discussion should include when relevant, but is not limited to:
  - Diagnosis and planned procedure.
  - Availability of prosthesis.
  - Site and side of procedure.
  - Infection risk, e.g. MRSA status.
  - Allergies.
  - Relevant comorbidities or complications.
  - Need for antibiotic prophylaxis.
  - Likely need for blood or blood products.
  - Patient positioning.
  - Equipment requirements and availability, including special equipment or 'extras'.
  - Postoperative destination for the patient, e.g. ward or critical care unit.
10. The expected duration of each procedure, to include anaesthetic procedures, should be identified. This should promote a discussion about agreed plans if it appears that the duration of the planned procedures will exceed the time allocated.
11. Any additional concerns from an operator, anaesthetic or practitioner perspective must be discussed, and contingency plans made.
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. A record should be made of the team briefing, and should be displayed in the procedural area for reference during the procedure list. If a significant issue about the care of a patient arises during the briefing, a clear and contemporaneous note of this should be made in the patient's records. Any issues raised in the briefing 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.

### 4.8 Sign in

All patients undergoing invasive procedures under general, regional or local anaesthesia, or under sedation, must undergo safety checks on arrival at the procedure area: the sign in. Along with the time out and sign out, this is based on the checks in the WHO Surgical Safety Checklist and forms part of the Five Steps to Safer Surgery. Noise and interruptions should be minimised during the sign in.

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1. Participation of the patient (and/or parent, guardian, carer or birth partner) in the sign in should be encouraged when possible.
2. The sign in should not be performed 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.
3. A sign in must be completed and documented on arrival at the procedure area or anaesthetic room. The checks performed during the sign in should include when relevant, but are not limited to:
  - Patient name checked against the identity band.
  - Consent form.
  - Surgical site marking if applicable.
  - Operating list.
  - Anaesthetic safety checks: machine, monitoring, medications.
  - Allergies.
  - Aspiration risk.
  - Potential airway problems.
  - Arrangements in case of blood loss.
4. The sign in must be performed by at least two people involved in the procedure. For procedures performed under general or regional anaesthesia, these should include the anaesthetist and anaesthetic assistant. For procedures not involving an anaesthetist, the operator and an assistant should perform the sign in.
5. Any omissions, discrepancies or uncertainties identified during the sign in should be resolved before the time out is performed or any procedure starts. 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.
6. Immediately before the insertion of a regional anaesthetic, the anaesthetist and anaesthetic assistant must simultaneously check the surgical site marking and the site and side of the block (Stop Before You Block<sup>11</sup>).

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<sup>11</sup> <http://www.rcoa.ac.uk/standards-of-clinical-practice/wrong-site-block>

## 4.9 Time out

All patients undergoing invasive procedures under general, regional or local anaesthesia, or under sedation, must undergo safety checks immediately before the start of the procedure: the time out. Along with the sign in and sign out, this is based on the checks in the WHO Surgical Safety Checklist and forms part of the Five Steps to Safer Surgery. Noise and interruptions should be minimised during the time out.

1. Participation of the patient (and/or parent, guardian, carer or birth partner) in the time out should be encouraged when possible.
2. The time out should not be performed until any omissions, discrepancies or uncertainties identified in the sign in 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.
3. Any member of the procedure team may lead the time out. All team members involved in the procedure should be present at the time out. The team member leading the time out should verify that all team members are participating. This will usually require that they stop all other tasks and face the time out lead.
4. A time out must be conducted immediately before skin incision or the start of the procedure. It should include when relevant, but is not limited to, checks of:
  - Patient's name and identity band against the consent form.
  - The results of any relevant tests that must be present and available in theatre, e.g. imaging, hearing tests and eye tests.
  - The procedure to be performed.
  - Verification of surgical site marking.
  - Operator:
    - The anticipated blood loss.
    - Any specific equipment requirements or special investigations.
    - Any critical or unexpected steps.
  - Anaesthetist:
    - Any patient specific concerns.
    - Patient's ASA Physical Status.
    - Monitoring equipment and other specific support, e.g. blood availability.
  - Scrub practitioner or operator's assistant:
    - Confirmation of sterility of instruments and equipment.
    - Any equipment issues or concerns.
  - Surgical site infection:
    - Antibiotic prophylaxis.
    - Patient warming.
    - Glycaemic control.
    - Hair removal.
  - VTE prophylaxis.
  - Patient allergies.

5. When different operator teams are performing separate, sequential procedures on the same patient, a time out should be performed before each new procedure is started. This may be a modified version of the initial time out.
6. Any omissions, discrepancies or uncertainties identified during the time out should be resolved before the procedure starts.

## 4.10 Prosthesis verification

A prosthesis is defined as an internal or external medical device for artificial replacement of an absent or impaired structure. Verification is essential for correct surgical placement of the appropriate prosthesis. Deleterious effects arising from incorrect prosthesis selection may include patient factors, e.g. mortality, morbidity and further procedures, surgical factors, e.g. substandard clinical outcome, and financial costs, e.g. discarded prostheses, medicolegal repercussions, cancelled cases due to lack of prosthesis availability. The terms *prosthesis* and *implant* are synonymous in these standards.

### 4.10.1 BEFORE THE PROCEDURE

- i. LocSSIPs should define how specific prosthesis requirements are communicated by surgical and other clinical teams to operating theatre and procedural teams.
- ii. When a prosthesis is non-standard or is not included in an agreed permanent prosthesis stock, i.e. a “non-stock” prosthesis, the operator must ensure that the prosthesis requirements are communicated effectively to the procedural team in sufficient time for the prosthesis to be ordered and received.
- iii. A named team member should be responsible for ordering and checking correct implant delivery before the procedure. This information should be available to the rest of the team.
- iv. When permanent stocks of prostheses are maintained in the organisation, a named individual should be responsible for checking stocks, ordering, and ensuring that expiry dates are checked regularly and that any prostheses that have passed their expiry dates cannot be used.
- v. The operator must use the safety briefing before the start of a procedural list to confirm with the procedural team that the required prostheses, or range of implantable material such as may be needed for fracture fixation, for every patient in the procedural list, and any relevant equipment associated with their insertion, are present in the procedural area.
- vi. The operator must inspect the available prostheses and confirm that the correct prosthesis or range of prostheses, or range of implantable material such as may be needed for fracture fixation, is available before arranging for the patient to be brought to the procedural area, i.e. before the patient is “sent for”.

#### 4.10.2 DURING THE PROCEDURE

- i. Before removal of the prosthesis from its packaging, the operator should confirm the following prosthesis characteristics with the procedural team:
  - Type, design, style or material.
  - Size.
  - Laterality.
  - Manufacturer.
  - Expiry date.
  - Sterility.
  - Dioptre for lens implants.
  - Compatibility of multi-component prostheses.
  - Any other required characteristics.
- ii. Once the correct prosthesis has been selected, any prostheses not to be used for that patient should be clearly separated from the correct prosthesis to minimise the risk of confusion between prostheses at the time of implantation.

#### 4.10.3 AFTER THE PROCEDURE

- i. A record of the implants used must be made in the patient's notes and appropriate details should be shared with the patient after the procedure. When a manufacturer's label is available, this should be placed in the notes. When it is not, the following should be recorded:
  - Manufacturer.
  - Style.
  - Size.
  - Manufacturer's unique identifier for the prosthesis, e.g. the serial number.
- ii. Compliance with local, national and international implant registries is encouraged, and in certain cases may be a mandatory legal requirement.
- iii. The organisation must have a process in place for recording which prostheses are used for which patients.
- iv. The organisation must ensure that appropriate and agreed stock levels of prostheses are maintained.
- v. Instances of failed prosthesis verification, wrong prosthesis insertion and "near misses" 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.
- vi. Audit of prosthesis verification data must be performed.
- vii. When manufacturers' labelling, packaging or implant defects contribute to failure of prosthesis verification, a process must be in place through which both the manufacturers and the MHRA (Devices) are informed.

## 4.11 Prevention of retained foreign objects

This standard supports safe and consistent practice in accounting for all items used during invasive procedures and in minimising the risk of them being retained unintentionally. The processes outlined in LocSSIPs should ensure that all items are accounted for and that no item is unintentionally retained at the surgical site, in a body cavity, on the surface of the body, or in the patient's clothing or bedding. LocSSIPs should cover 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.

### 4.11.1 ORGANISATIONAL RESPONSIBILITIES

- i. Organisations must have LocSSIPs in place to ensure the accurate reconciliation of items used during all invasive procedures.
- ii. The methods detailed in the LocSSIPs for counting and reconciliation should be consistent in all areas in which invasive procedures are performed within the organisation, and should use accepted and published methodologies when they are available.
- iii. The LocSSIPs must specify the process of reconciliation, including what should be counted and at what point during the invasive procedure, and should identify which items must be reconciled at the start and finish of the procedure. When body cavities are entered, reconciliation must occur before the closure of each cavity.
- iv. The organisation should agree a generic list of items to be included in the count. This list should be changed in line with local circumstances after the analysis of risk and safety incidents, e.g. the inclusion of specimen retrieval bags; liver retraction devices; vaginal swabs and tampons; radiological sheaths, catheters and guide wires.
- v. Specific processes for the management of sharps should be detailed.
- vi. There must be standardised methods for recording the items in use during a procedure, whether electronic, paper, whiteboard or a combination.

### 4.11.2 EQUIPMENT MANAGEMENT

- i. Instrument sets and equipment should be periodically risk-assessed to minimise the risk to patients from retained foreign objects. This process should ensure that instrument sets are rationalised to contain minimum amounts of required equipment, and that equipment is appropriately maintained. An up-to-date list of the instruments in the sets should be maintained.
- ii. Instrument sets containing swabs should be regularly reviewed to ensure that the swabs are fit for purpose. Consideration should be given to standardising the type of swabs available for specific procedures, e.g. small swabs may not be routinely required on a standard maternity delivery pack.

- iii. Equipment trays must contain a comprehensive list of the instruments present to enable checking before and after use. Photographs may be helpful to provide a clear, visual representation of complex or unfamiliar equipment.
- iv. 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.
- v. The integrity of all items must be checked before and after use, including component parts of equipment and instrumentation.
- vi. All swabs used for invasive procedures should contain radio opaque markers, e.g. "Raytec" swabs.
- vii. LocSSIPs should determine the size, colour and number of swabs to be included in standard packs for procedures, and locally agreed and standardised terminology should be used for swabs of different sizes.
- viii. LocSSIPs should identify when it is acceptable for non-radio-opaque swabs to be used, and should define the size and colour of swabs that can be used for this purpose, e.g. for urinary catheterisation and anaesthetic use. Non-radio-opaque swabs should only be placed in the sterile field when the surgical wound has been closed.

#### **4.11.3 DURING THE PROCEDURE**

- i. The process of counting and reconciliation should be performed by the same two members of the procedure team; both should have received appropriate training and competence assessment, and both should be experienced in counting and reconciliation.
- ii. If a change in the team is required during the procedure, the LocSSIP must identify how this should be managed, e.g. a reconciliation of all items at the point of handover.
- iii. A reconciliation must be undertaken before the closure of each body cavity, and a final reconciliation must be undertaken before the final closure of the operative site and before the sign out.
- iv. Operators should check the wound carefully for foreign objects before closure.
- v. When an item is intentionally retained, with plans for later removal, e.g. wound or vaginal pack, drain or catheter, LocSSIPs must identify how this should be documented to ensure removal – see below.

#### **4.11.4 FAILED RECONCILIATION**

- i. LocSSIPs should include a clear process to be followed in the event that an item is unaccounted for during or at the end of the procedure that should avoid unnecessary exposure of the patient to ionising radiation without good cause, or subject the patient to additional surgery. This process should include:
  - Consideration of a further count.
  - Immediate communication to the lead surgeon or operator, and the procedure team, identifying the discrepancy.
  - Undertaking a thorough search for the missing item.

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- Not moving the patient out of the procedure room until the missing item is accounted for if possible.

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 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.

Comprehensive documentation relating to unaccounted for items should be added to the patient’s record and the patient should be informed.

- ii. Patients must be made aware of any unintentional retention of a foreign object and what impact this may have on their health.

### **4.11.5 INTENTIONAL RETENTION OF OBJECTS**

- i. Patients must be made aware of any object intentionally retained after a procedure and what the plan is for its removal. The use of written information for patients who have intentionally retained items requiring removal at a specified time other than at the time of insertion should be considered.
- ii. On occasion items are intentionally left permanently in place. For example, the 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 it. These decisions and subsequent explanations to the patient must be documented in the patient record.

### **4.11.6 AFTER THE PROCEDURE**

- i. The points at which the care of a patient is transferred between professionals, i.e. handovers, are recognised as being high risk in relation to the retention of foreign objects. It is therefore essential that the handover process for patients with retained foreign objects is specified in LocSSIPs.
- ii. Organisations must ensure that there is a process to identify the presence, and planned removal, of an item that is intentionally left in the patient with a requirement for removal at a later date. This should include at least:
  - Clear documentation of the item left behind and the plan for its removal.
  - Specific inclusion of this information in the handover process at any point of transfer of care.
  - Consideration of the use of a visual marker worn by the patient of the consequent incomplete reconciliation and the intended date of its removal.
  - Consideration of standardisation of items often left in place after a procedure, e.g. vaginal packs.

## 4.12 Sign out

All patients undergoing invasive procedures under general, regional or local anaesthesia, or under sedation, must undergo safety checks at the end of the procedure but before the handover to the post-procedure care team: the sign out. Along with the sign in and time out, this is based on the checks in the WHO Surgical Safety Checklist and forms part of the Five Steps to Safer Surgery. Noise and interruptions should be minimised during the sign out.

1. Any member of the procedure team may lead the sign out. All team members involved in the procedure should be present at the sign out. The team member leading the sign out should verify that all team members are participating. This will usually require that they stop all other tasks and face the sign out lead.
2. Sign out checks should be conducted 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. These checks should include when relevant, but are not limited to:
  - Confirmation of the procedure performed, to include site and side if appropriate.
  - Confirmation that instruments, sharps and swab counts are complete (or not applicable).
  - Confirmation that any specimens have been labelled correctly, to include the patient's name and site or side when relevant.
  - Discussion of post-procedural care, to include any patient-specific concerns.
  - Equipment problems for inclusion in the debriefing.

## 4.13 Debriefing

Procedural team debriefing is a key element of practice in the delivery of safe patient care during invasive procedures, and forms part of both the WHO Surgical Safety Checklist and the Five Steps to Safer Surgery. The debriefing should be seen as being as important a part of the safe performance of an invasive procedure as any of the other steps outlined in this document. Organisations should ensure that the job plans and working patterns of those involved in invasive procedures should allow and oblige them to attend debriefings in all but exceptional circumstances. Noise and interruptions should be minimised during the debriefing.

1. A debriefing should be performed at the end of all elective procedure sessions. A debriefing should also be performed after all unscheduled or emergency procedure sessions. The debriefing may need to be conducted on a case-by-case basis if there is a change in key team members during a procedure session.

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2. The total time set aside for the procedure or list of procedures should include the time taken to conduct the debriefing.
3. The debriefing should occur in a manner and location that ensures patient confidentiality, while enabling inclusivity and contribution from all team members. This should be agreed at the team briefing.
4. Every member of the procedural team should take part in the debriefing. Any team member may lead the debriefing, but the operator and anaesthetist (if an anaesthetist has been involved) must be present. If any team member, and especially the senior operator, scrub practitioner or anaesthetist, has to leave before the debriefing is conducted, they should have the opportunity to comment and document any positive feedback or issues for improvement they wish to see addressed during the debriefing. In this circumstance, their absence from the debriefing should be recorded and included in routine audit of compliance with LocSSIPs.
5. Members of the procedural team must note any key points for consideration at the debriefing as the procedure list progresses. This can be on a personal record or annotated in the team briefing record.
6. The content of the team debriefing should be modified locally and must be relevant to the patient and procedure. For each patient, the discussion should include, but is not limited to:
  - Things that went well.
  - Any problems with equipment or other issues that occurred.
  - Any areas for improvement.
7. Records of debriefings should include an action log that can be used to communicate examples of good practice and any problems or errors that occurred. Each procedural team should have an identified member who is responsible for feeding this information into local governance processes.
8. If a significant issue about the care of a patient arises during the debriefing, a clear and contemporaneous note of this should be made in the patient's records. Local governance processes must ensure that issues identified in debriefing action logs are communicated at an appropriate level within the organisation, and that there is a mechanism to capture and promote learning.

## Appendix A – Published guidance

The guidance included in this document is based in part on existing standards and guidelines published by the organisations that contributed to the creation of the NatSSIPs. Links to the organisations' websites and published guidance are given below.

Association for Perioperative Practice (AfPP)	<a href="#">Website</a>	<a href="#">Standards and guidance</a>
Association of Anaesthetists of Great Britain & Ireland (AAGBI)	<a href="#">Website</a>	<a href="#">Guidelines</a>
Care Quality Commission (CQC)	<a href="#">Website</a>	
Clinical Human Factors Group (CHFG)	<a href="#">Website</a>	
College of Operating Department Practitioners (CODP)	<a href="#">Website</a>	The CODP provides curricula and guidance on staffing - please email <a href="mailto:codp@unison.co.uk">codp@unison.co.uk</a>
Faculty of Dental Surgery of the Royal College of Surgeons (FDS)	<a href="#">Website</a>	
General Medical Council (GMC)	<a href="#">Website</a>	
Health and Care Professions Council (HCPC)	<a href="#">Website</a>	<a href="#">Standards of proficiency - Operating department practitioners</a>
Health Education England (HEE)	<a href="#">Website</a>	
NHS England (NHSE)	<a href="#">Website</a>	
NHS Litigation Authority (NHSLA)	<a href="#">Website</a>	
NHS Trust Development Authority (NHS TDA)	<a href="#">Website</a>	
Nursing and Midwifery Council (NMC)	<a href="#">Website</a>	
Royal College of Anaesthetists (RCOA)	<a href="#">Website</a>	<a href="#">Clinical Quality, Standards and Safety</a>
Royal College of Nursing	<a href="#">Website</a>	<a href="#">Patients Undergoing Minor Interventional Procedures such as Biopsy, Drain insertion and Aspiration</a>
Royal College of Midwives	<a href="#">Website</a>	
Royal College of Obstetricians and Gynaecologists (RCOG)	<a href="#">Website</a>	<a href="#">Green-top guidelines</a>
Royal College of Ophthalmologists	<a href="#">Website</a>	<a href="#">Patient safety information</a> <a href="#">Quality standards</a>
Royal College of Radiologists (RCR)	<a href="#">Website</a>	

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Royal College of Surgeons of England (RCSE)	<a href="#">Website</a>	<a href="#">Good Surgical Practice</a> <a href="#">Duty of candour guidance</a>
Surgical Services Patient Safety Expert Group (SSPSEG)	<a href="#">Website</a>	

## Appendix B - Contributors

The following organisations and individuals contributed to the creation of these standards

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Health Education England (HEE)	Lisa Hughes, Anna Lee
Human factor experts	Susan Burnett, Charles Vincent
NHS England	Joan Russell, Fran Watts, Laura Johnson
NHS Litigation Authority (NHSLA)	Tracy Coates
NHS Trust Development Authority (NHS TDA)	Stanley Silverman, Rowan Wathes
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