NHS England

National Safety Standards for Invasive Procedures (NatSSIPs)

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Contact Details for further information	NHS England Patient Safety Domain 6th Floor Skipton House 80 London Road London SE1 6LH

Document Status

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National Safety Standards for Invasive Procedures (NatSSIPs)

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- 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 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.

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 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

- 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

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.

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***".

The report, published in 2014[1], 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).

*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.*

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 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.

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.

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.

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

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. 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..

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[9].

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.

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.

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

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.. 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. 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.

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.

3.5.4 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.
It is important that team members are given regular opportunities to suggest improvements in LocSSIPs and patient care., 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.

3.5.5 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.

3.5.6 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 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

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

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.

4.2 Documentation of Invasive Procedures

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.

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.

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.

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.

4.6 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.

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[10]. Noise and interruptions should be minimised during the safety briefing.

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.

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.

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 AFTER THE PROCEDURE

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.

4.12 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.

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.

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

Royal College of Surgeons of England (RCSE)	Website	Good Surgical Practice Duty of candour guidance
Surgical Services Patient Safety Expert Group (SSPSEG)	Website	

Appendix B - Contributors

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

Chair	William Harrop-Griffiths
Association for Perioperative Practice (AfPP)	Tracey Williams*
Association of Anaesthetists of Great Britain & Ireland (AAGBI)	Isabeau Walker*
Care quality Commission (CQC)	Paula Mansell
Clinical Human Factors Group (CHFG)	Nick Toff
College of Operating Department Practitioners (CODP)	Bill Kilvington*, Marita Kirkham
Ethics and patient safety expert Faculty of Dental Surgery, Royal College of Surgeons	Suzanne Shale Tara Renton
General Medical Council (GMC)	Toby Reynolds
Health and Care Professions Council (HCPC)	Michael Guthrie (corresponding member)
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
Nursing and Midwifery Council (NMC)	Anne Trotter
Patient and lay representatives	Archie Naughton, Cate Quinn
Royal College of Anaesthetists (RCoA)	Peter Venn, Richard Marks
Royal College of Obstetricians and Gynaecologists (RCOG)	Edward Morris
Royal College of Radiologists (RCR)	Patricia Woodhead
Royal College of Surgeons of England (RCSE)	Frank Smith*, Paul McArdle
Surgical Services Patient Safety Expert Group (SSPSEG)	Clare Marx (Chair)

*** Indicates Writing Group Lead**

Writing group members:

Isabeau Walker	**Bill Kilvington**	**Frank Smith**	**Tracey Williams**
Paul Barker	Nikki Grimmett	Tom Clutton-Brock	Mark Cheetham
Bryn Baxendale	Natasha Hare	Chris Davies	Amy Gass
Mahmood Bhutta	Debra Morris	Jonathan Frost	Susan Hall
Ben Davies	Stavros Prineas	Grey Giddins	Richard Marks
Paul Eyers	Julie Saunders	Andrew Hollowood	Guy McClelland
Julie Johnson	Sian Weller	Terry Irwin	Sandra Phillips
Julie Plumridge	Stephen Wordsworth	Paul McArdle	Julie Pierce-Jones
Marc Wittenberg		Tracey Radcliffe	Toby Reynolds
		Timothy Rimmer	
		Debbi Scotting	
		Francesca Stedman	
		Michele Upton	
		Denis Wilkins	