National Safety Standards for Invasive Dermatology Skin Procedures

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British Association of Dermatologists

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Foreword

The last few years have seen great changes and challenges to the promotion and protection of the safety of dermatology patients. The commitment to the provision of high quality care for all, now and for future generations is fraught with many challenges which need to be addressed both at a national and local level.

The introduction of the WHO Safer Surgery Checklist[1] was a great step forward in the delivery of safer care for patients undergoing operations. Experience with it has 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.

National Safety Standards for Invasive Procedures (NatSSIPs) is 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. Their purpose is to 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.

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.

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.

Several organisations publish guidance relevant to the safe performance of invasive procedures, which should be considered during the development of LocSSIPs and included where relevant to enhance safe patient care.

This guidance has been developed by the BAD and it surgical stakeholders to provide national standards to all healthcare professionals who are a member of an invasive dermatology procedure team. It describes the expected procedure when managing surgical and skin cancer patients in Dermatology departments and across multi-professional teams.

We hope these standards empower dermatology healthcare professionals to take ownership of their local standards and to:

- Contribute towards their creation, documentation, audit, review and development;
- Participate fully in the safety checks and steps built into the standards;
- Speak up if they have any concerns at all about the care that the patient is getting.

1 Introduction

This document presents National Standards for Invasive Dermatology Procedures that have been developed by a multidisciplinary group of clinical stakeholders, professional leaders, patients and lay representatives brought together by the BAD. They should be used to inform on the development of LocSSIPs to deliver safe care for patients undergoing invasive dermatology procedures and standardise the processes that underpin patient safety.

Organisations should develop Local Safety Standards for Invasive Procedures (LocSSIPs) that include the key steps outlined in NSSIDPs 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.

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.

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.

1.1 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.

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[2] launched 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.

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 published NSSIDPs.

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[3] 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[4], and that published by the Royal College of Surgeons of England[5].

1.2 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[6]:

- 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;
- 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;
- Using electromagnetic radiation (which includes X-rays, lasers, gamma- rays and ultraviolet light) - for example, using a laser to treat eye problems.

In using a different term - “invasive procedure” – NatSSIPs proposed 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, and other procedural areas within an organisation;
- Interventional radiological procedures;
- 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.

1.3 What Part of the Patient Pathway Should LocSSIPs Cover?

LocSSIPs 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 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.

1.4 Record Keeping

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.

1.5 Accountability and Responsibility

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.

1.6 Education

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.

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.

1.7 Audit and Review

At the heart of NSSIDPs 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.

2 Core Standards

2.1 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.

2.2 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, 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.

2.3 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.
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, 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 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.
9. 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.

2.4 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 across specialties.
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;
    - NCEPOD classification of intervention;
    - Significant comorbidities;
    - Allergies, e.g. to latex or iodine;
    - Infection risk;
    - Any non-standard equipment requirements.
4. Although the clinical team performing the procedure is primarily responsible for its accurate scheduling, it must when appropriate involve other clinical disciplines 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;
- Patient 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 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.

2.5 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.

2.5.1 All Handovers

1. Organisations should consider the use of structured handover forms as a prompt for all handover conversations.

2. 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.

3. 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.

4. Participation of the patient (and/or parent, guardian, carer or birth partner) in handovers should be encouraged when feasible.

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.

2.5.2 Handovers to Procedure Teams

1. There must be a formal handover process from the ward or admission team to the practitioner receiving the patient in the procedure room or designated location in the procedural area.
2. 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;
    - Allergies;
    - Procedure, and site or side if appropriate;
    - Site marking if relevant;
    - Relevant clinical features, e.g. blood sugar for diabetic patients;
    - An appropriate patient record;
    - A properly completed consent form.
3. 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.

2.5.3 Handovers during Procedural Care

1. 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.
2. 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.

2.5.4 Post-Procedure Handovers

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:

2.5.4.1 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.

2.5.4.2 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.

2.6 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. This takes place when the patient attends for their procedural appointment.

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. Check against surgery booking form, written clinical notes, clinic letter and photograph (if taken).

5. The procedure site must be marked shortly before the procedure.
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. The non-operative side must never be marked - not even with statements such as "not this side".
11. 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.
12. Documentation of sign in, time out and sign out should include procedure and surgical site and side.

2.7 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[1]. 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. Team members should understand their roles, names should be known, and all members of the team should be encouraged to speak up, if they have concerns.
3. The total time set aside for the procedure or list of procedures should include the time taken to conduct the safety briefing.

2.8 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.

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.

The sign in must be performed by at least two people involved in the procedure. For procedures not involving an anaesthetist, the operator and an assistant should perform the sign in.

2.9 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.
3. 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;
- 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.

4. 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.
5. Any omissions, discrepancies or uncertainties identified during the time out should be resolved before the procedure starts

2.10 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.

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.

1 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.

2.11 Debriefing

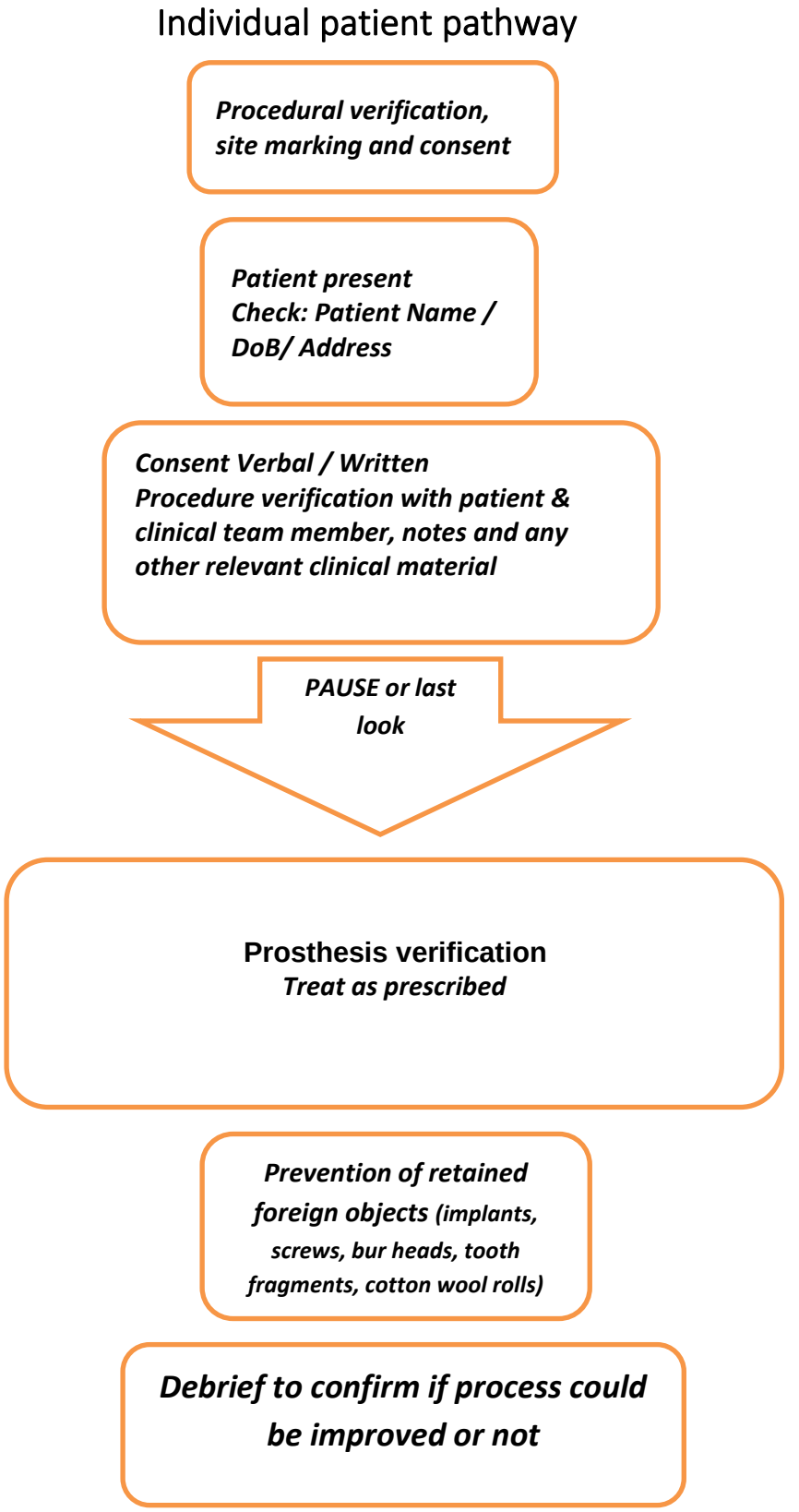
Procedural team debriefing is a key element of practice in the delivery of safe patient care during invasive procedures, and forms part of both the WHO Surgical Safety Checklist and the Five Steps to Safer Surgery. The debriefing should be seen as being as important a part of the safe performance of an invasive procedure as any of the other steps outlined in this document.

1. 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.
2. 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.
3. The total time set aside for the procedure or list of procedures should include the time taken to conduct the debriefing.
4. 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.
5. Every member of the procedural team should take part in the debriefing. Any team member may lead the debriefing, but the operator must be present. If any team member, and especially the senior operator, 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.
6. 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.
7. 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.
8. 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.

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.

The following template (Figure 1) provides a summary example of the role of these NatSSIPs within individual patient pathways and the conduct of a list of procedures.



Appendix 1 – 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 NSSIDPs. 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 Resolution	Website	
Nursing and Midwifery Council (NMC)	Website	
Royal College of Anaesthetists (RCoA)	Website	Safety, standards and quality
Royal College of Nursing	Website	
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	

Appendix 2 – Learning from Never Events – Wrong site surgery, including Reflective learning Log for Appraisal

How does the team learn from a Wrong site surgery?

Investigation and analysis of a Wrong site surgery should collect information regarding not only the technical aspects of what went wrong but also the human factors that may have contributed to the WSE. Managing the response to Never Events is a critical component of corporate and clinical governance.

An open and supportive culture is essential to facilitate and enable open reporting and learning from Never Events.

Providers must establish effective governance mechanisms to ensure that:

- There is early, meaningful and sensitive engagement with the affected patients and/or their families/carers from the point that the WSE is identified, throughout the investigation and action planning, to closure of the incident. Details of the conversation must be documented in the patient records, and disclosure must not be delayed whilst the Never Event status is being determined. All staff should be familiar with related requirements of Being Open 2 and the Duty of Candour3 and information should be shared in line with this Guidance;
- Investigations are undertaken by appropriately trained and resourced staff and/or teams that are sufficiently removed from the incident to be able to provide an objective view;
- Never Events are investigated via root cause analysis by specific dedicated and trained staff. Investigations should follow a systems-based methodology to ensure identification of all the possible contributory factors and root causes;
- The investigation will also identify focused actions, including those which relate directly to the patient and their family/carer, plus clear learning outcomes.

Effective governance mechanisms should be established to ensure:

- timely reporting and liaison with their commissioning bodies.
- the incident is reported to the CQC.
- compliance with reporting and liaison requirements with agencies such as: NHS Improvement ; the Care Quality Commission (CQC); Public Health England and the Health and Safety Executive.
- commissioners are encouraged to publish information relating to all serious incidents, including Never Events, within annual reports and other public facing documents such as governing body reports, including data on the numbers and types of incidents, ensuring patient confidentiality is respected. Incidence of Never Events must be

identified in the commissioner's annual report and the provider's quality accounts, again ensuring patient confidentiality. This should include, where possible:

- data on the type and number of Never Events, including historical context and related incidents;
- a summary of each Never Event;
- the learning derived from the incident(s), with a particular focus on the system changes that have been made to reduce the probability of recurrence;
- how learning has been shared at all levels within the organisation, and also, externally.
- A strong and supportive culture, which supports the team involved in a Never Event, will enable the required learning from the incident and facilitate improvements in the quality of practice. The support provided is critical if we are to avoid 'second victims' amongst those members of staff involved in a Never Event such as wrong site extraction.
- At an individual level, the practitioner should be logging the incident and providing a reflection with learning outcomes for their Appraisal documents.

Reflective Learning Log - for Appraisal

Patient Identifier:
Age & sex of patient:
Medical and relevant Social History:
Brief summary of Never Event, including: • Risk Factors
Effect of never event on patient: • How will the outcome be managed?
How did the clinical team manage the never event? • What went well? • What did not go well?
What has been learnt from the never event? • Root causes • Mitigation of risk factors • What will be done differently next time? • How will it influence your future approach to similar cases?
How has the learning been shared amongst the team/service? Has the learning been reflected in updated operational procedures/training? Have the members of the team who were involved in the never event, received adequate and appropriate support?

Appendix 3 – Exemplar

Scenario	A patient was seen in the 2 WW and referred for a biopsy of lesion, which was marked and photographed. On return to the dermatology department the consultant noticed the lesion which the biopsy was booked looked clinically benign. Consultant also noticed a slightly irregular pigmented lesion on the tip of the patient's nose and decided to take an incisional biopsy of this area instead which was duly marked.
History	1. Medical history: N/A 2. Social history: N/A
Risk Factors	1. The pictures from the referral, showed that both lesions are very close and the marking could be misinterpreted. 2. The change in clinical decision was not recorded in the clinical records. 3. A dressing was in place and patient could not see which one had been biopsied. 4. The correct protocol of offering a mirror was not followed.
Error	The error was noticed during suture removal at the GP and patient escalates her concerns to the hospital.
Actions	Immediate steps in relation to patient: Explanation to patient: 1. There is a prompt response following the detection of the issue. 2. Consultant gives a complete and honest explanation of the error in accordance with 'Being Open' and 'Duty of Candour'. 3. Consultant gives a full apology. 4. Consultant explains next clinical steps. 5. The correct lesion is marked, and biopsy is performed. Immediate steps in relation to administrative Process: 1. A different consultant to be asked to review the photographs of the original marked site. 2. Decision making to change biopsy sites to be fully documented in the clinical records. 3. The WHO checklist for Dermatology to be reviewed, with version numbers and explicit instructions. 4. Terminology for the explanation of site to be clarified. 5. Review Biopsy Request SOP and Surgical SOP as not formalised 6. An appropriate senior manager is designated to carry out an investigation. Investigation: 1. A full investigation is instigated including a Root Cause Analysis. 2. All processes/systems and protocols within the practice, are reviewed. 3. All Contributory Risks factors are considered as part of the investigation.

	4. An Action Plan is developed. 5. Preventive measures are put in place to reduce the risk of a repeat occurrence, including use of WHO surgical checklist. 6. Learning outcomes are shared across dermatology sites run by the same group. 7. Any training needs within the practice are identified and implemented. 8. A culture of safety is promoted within the practice. 9. The patient is informed of outcomes of the investigation as part of the Trust's *Being Open* policy