

UHL Policy on Safety Standards for Invasive Procedures

| | |
|--|--|
| Approved By: | Policy and Guideline Committee |
| Date Approved: | 16 December 2016 |
| Trust Reference: | B31/2016 |
| Version: | V3 |
| Supersedes: | V2 – July 2019 |
| Author / Originator(s): | Dr Colette Marshall, Deputy Medical Director |
| Name of Responsible Committee/Individual: | Medical Director |
| Latest Review Date | 29 July 2022 |
| Next Review Date: | October 2025 |

CONTENTS

| Section | | Page |
|---------|--|------|
| 1 | Introduction | 2 |
| 2 | Policy Aims | 3 |
| 3 | Policy Scope | 3 |
| 4 | Definitions | 3 |
| 5 | Roles and Responsibilities | 5 |
| 6 | Policy Standards | 7 |
| 7 | Education and Training | 9 |
| 8 | Process for Monitoring Compliance | 9 |
| 9 | Supporting References, Evidence Base and Related Policies | 10 |
| 10 | Process for Version Control, Document Archiving and Review | 10 |

| Appendices | | Page |
|------------|--|------|
| 1 | Policy monitoring table | 11 |
| 2 | LocSSIPs blank template with completion guidance | 12 |

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

Minor changes to reflect progress with implementation of framework.

KEY WORDS

NatSSIPPs, LocSSIPs, invasive procedures, never event, interventional procedures.

1 INTRODUCTION

- This document sets out the University Hospitals of Leicester (UHL) NHS Trust's Policy and Procedures for the development and implementation of local patient safety standards for invasive procedures (LocSSIPs). LocSSIPs are Standard Operating Procedures (SOPs) that ensure safe care is delivered to patients undergoing invasive procedures.
- A report, published in 2014 commissioned by NHS England on "Surgical Never Events", recommended the development of high-level national standards that would support all providers of NHS-funded care to develop and maintain their own, more detailed, local standards. This led to the development of National Safety Standards for Invasive Procedures (NatSSIPs)¹ which sets out the standards that LocSSIPs should be based upon.
- There is a NHS-wide programme of work, in which each trust is required to develop their own LocSSIPs based upon the high-level national standards. Organisations must also ensure compliance with the LocSSIPs they develop.

2 POLICY AIMS

- The aim of this policy is to provide:
 - guidance on how to develop (or update) and implement a LocSSIP
 - a list of the key items that must be included in a LocSSIP to make it compliant with NatSSIPs
 - a description of the expected LocSSIP sign-off process
 - a description of the expected compliance monitoring processes for LocSSIPs
 - a description of the trust's assurance processes that give assurance that LocSSIPs are being followed and hence that invasive procedures are being performed safely according to nationally set standards.

3 POLICY SCOPE

- This policy applies to all invasive procedures performed in UHL (including the Alliance) with the exception of:
- Procedures performed within the main theatre complexes – these procedures will be subject to the "UHL Safer Surgery Policy"²
- This policy should be followed for all SOPs that are for invasive procedures.
- 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, LocSSIPs should 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.
- Whilst the focus of NatSSIPs is to prevent Never Events, LocSSIPs should also include guidance on how to prevent other safety incidents (e.g. prevention of hospital acquired infections, air embolus, bleeding).

- NatSSIPs or LocSSIPs do not replace the WHO Safer Surgery Checklist. Rather, they build on it and extend it to more patients undergoing care in UHL.
- The NatSSIPs document states: 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. These simple procedures are therefore excluded from LocSSIPs. In these cases the relevant trust policy applies.

4 DEFINITIONS

- **Standard Operating Procedure:**

An SOP is a document that sets out in step by step detail how a procedure or process is to be performed according to pre-determined quality and safety criteria.

- **LocSSIP:**

A LocSSIP is a written SOP that sets out the critical safety and quality steps required for invasive procedures. A LocSSIP should be created by multi-professional clinical teams and their patients; and is implemented against a background of education in human factors and working as teams. They are designed to state how a procedure is carried out safely. LocSSIPs must be compliant with the National Safety Standards for Invasive Procedures¹ and draw on other relevant national guidance. A LocSSIP will contain an example of the procedural documentation (e.g. checklists and care pathways) to be used in the clinical area.

- **Procedural documentation:**

In this policy the term “procedural documentation” refers to the paperwork used in the clinical area that supports implementation of the LocSSIPs. Examples include (but are not limited to):

- Safety checklists
- Proformas for recording an invasive procedure
- Care pathway documentation
- Team briefing and debriefing proformas

- **Interventional 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:

- 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.

- **Invasive procedures:**

In using a different term - “invasive procedure” – NatSSIPs propose to address those procedures that have the potential to be associated with a Never Event (see below) 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.

- **Never Events**

The concept of ‘Never Events’ was introduced into the UK in 2009, with a list of eight adverse patient safety events. Never Events are defined as “serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented”. The current Never Event list (January 2018) includes:

- Wrong site surgery
- Retained foreign object post-procedure
- Wrong prosthesis or implant
- Mis-selection of strong potassium solution
- Wrong route administration of medication
- Overdose of insulin due to misuse of abbreviations or wrong device
- Overdose of methotrexate for non-cancer treatment
- Mis-selection of high strength midazolam solution during conscious sedation

5 ROLES AND RESPONSIBILITIES

5.1 Medical Director:

The Medical Director is the executive board member responsible for this policy.

5.2 Deputy Medical Director with responsibility for Safety Standards involving Interventional Procedures

- Trust-wide implementation of this policy.
- Quality assurance checks of draft LocSSIPs to ensure that they meet the guidance in this document.
- Ensuring, where necessary, that draft LocSSIPs have a wide consultation with all relevant stakeholders and in particular with the Alliance.
- Regular assurance updates to the Executive Quality & Performance Board.
- Overseeing a corporate quality visit schedule to give further independent assurance that LocSSIPs are followed.

5.3 CMG management teams (Clinical Directors, Heads of Nursing, and Heads of Operations):

It is the responsibility of the CMG management teams to ensure that:

- Procedures in their areas of responsibility that require LocSSIPs to be written are systematically identified
- Lead clinicians or managers are identified for each LocSSIP
- LocSSIPs are signed off at the CMG Quality and Safety Board
- LocSSIPs are regularly reviewed to ensure that they remain up to date
- Regular audits of compliance are carried out and presented to the CMG Quality and Safety Board with onward reporting to the Executive Quality & Performance Board by exception.
- Dissemination of LocSSIPs to relevant team members
- Archiving of LocSSIPs on the intranet

5.4 Heads of Service:

It is the responsibility of Heads of Services to ensure that:

- LocSSIPs are covered in local induction programmes for all new incoming staff to their specialty (including locums and agency workers)
- Suitable training for staff members occurs within their specialty
- LocSSIPs are consistently used for invasive procedures in their specialty
- Regular audits of compliance are carried out in each area that undertakes invasive procedures
- Draft LocSSIPs are disseminated for consultation prior to sign off
- LocSSIPs are piloted before becoming finalised
- LocSSIPs are disseminated to all team members

5.5 Ward managers/procedure area managers/Heads of Service:

It is the responsibility of the ward managers/procedure area managers working in conjunction with the Heads of Service to ensure that:

- LocSSIPs are covered in local induction programmes for all new incoming staff to their area (including locums and agency workers)
- Suitable training for staff members occurs
- LocSSIPs are consistently used by all relevant staff for invasive procedures in their area
- Compliance audits are regularly performed
- Themes from briefing and debriefing are regularly collated and used for quality improvement work.

5.6 Clinicians:

It is the responsibility of clinicians involved with invasive procedures:

- To ensure that LocSSIPs are followed and used consistently
- To highlight any modifications to LocSSIPs that are needed in order to improve the safety of care for patients
- To ensure that other team members are encouraged to use LocSSIPs
- To use the Datix reporting system for significant deviations from LocSSIPs that have resulted in patient harm or could have resulted in patient harm (nearmiss).
- To ensure that clinical procedural documentation is filed in the Patient's medical record.

6 POLICY STATEMENTS, STANDARDS*, PROCESSES*, PROCEDURES* AND ASSOCIATED DOCUMENTS

6.1 Developing a LocSSIP:

6.1.1 LocSIPPs must be developed and written by a member of staff with the expertise and knowledge to be able to design a document that is fit for purpose. Development must be in consultation with clinical team members; and where possible with patients.

6.1.2 LocSSIPs must be based on the guidance in the NatSSIPs document¹ and cover the following key areas:

| Organisational (the standards that underpin the safe delivery of procedural care) | Sequential (a logical sequence of steps that should be performed for every procedure session or operating list, and every patient) |
|---|---|
| 1 Governance and audit 2 Documentation of invasive procedures 3 Workforce 4 Scheduling and list management 5 Handovers and information transfer | 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 |

A reduced version of the above list can be used for single operator ward-based procedures.

6.1.3 LocSSIPs must include (in appendices) examples of the procedural documentation used for implementation of the LocSSIPs. Such documentation will include checklists or care pathways. These documents must be standardised and 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. The documentation must also record the performance of the key safety checks in the patient pathway.

6.1.4 Procedural documentation must be designed to ensure the recording of essential information throughout the patient pathway.

6.1.5 Procedural documentation must be designed to promote audit of the pathway and compliance with the LocSSIP.

6.1.6 Procedural documentation must be designed to allow identification of the team members involved in the invasive procedure and in other relevant steps in the patient

pathway.

6.1.7 Procedural documentation must be complete, legible and contemporaneous, and must use locally agreed standardised terminology, avoiding the use of abbreviations or jargon.

6.1.8 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 LocSSIP must identify which is the primary information source for later reference.

6.1.9 If there are several very similar procedures done in one area then they can be covered by a single LocSSIP for that area.

6.1.10 There are a number of resources that can be used in the development of LocSSIPs e.g.:

- Appendix 2 to this policy has a copy of the blank template. This template provides guidance that can be deleted and procedure-specific guidance inserted. Irrelevant sections can be deleted.
- Royal College or specialty societies may have their own templates for checklists and these must be used as the basis of a LocSSIP or documentation when they are available. NHS improvement provide examples of LocSSIPs from elsewhere and these can be used for as a basis for a UHL LocSSIP.
- Existing SOPs can be used as the basis for a LocSSIP provided that they are updated to bring them into line with this policy and NatSSIPs.

6.2 Signing off a LocSSIP:

6.2.1 Sign off of LocSSIPs is important to ensure that the documents are fit for purpose and meet the national standards set out in NatSSIPs. Sign off has a CMG element and a corporate element to ensure that these criteria are met.

6.2.2 LocSSIP sign-off occurs in three stages:

1. Draft LocSIPP developed by specialty and sent for feedback from the relevant clinical team members and ideally with patients.
2. Draft (with feedback acted upon as necessary) sent to the Deputy Medical Director with responsibility for Safety Standards involving Interventional Procedures to check against the national standards.
3. Agreed final draft sent for sign-off to the relevant CMG Quality and SafetyBoard.

6.2.3 LocSSIPs are to be stored in the Policy and Guideline Library as Category C trust documents. If a LocSSIP applies trust-wide then they will be a Category B document and must be reviewed by the Policy and Guideline Committee.

6.2.4 It is the responsibility of CMG Clinical Directors to ensure that LocSSIPs are archived and made available to staff members.

6.3 Updating a LoCSSIP and version control:

6.3.1 Changes to a LocSSIP can be made at any time to ensure that the content remains current and up to date.

6.3.2 The time and author of any alterations to the documentation must be recorded in the footer and the changes signed off by the CMG Quality and SafetyBoard.

6.3.3 A clear indication of the version number must be made in the footer of the

document.

6.3.4 Clinical users of the LocSSIP must be informed of any changes; and if procedural documentation is changed the CMG must ensure that all copies of the old version are removed from the clinical area and replaced with the new version.

6.3.5 LocSSIPs must be reviewed annually and signed off at the CMG Quality and Safety Board.

6.4 Implementation of a LocSSIP:

6.4.1 Implementation must involve all team members to ensure that familiarisation with the LocSSIP is able to occur; and, where necessary training can be delivered.

6.4.2 It is recommended that procedural documentation from safety debriefs is regularly collated to examine emerging themes that can then be fed back into quality improvement work.

6.4.3 Where possible it is recommended that team training with a human factors approach is used to embed the use of LocSSIPs in clinical areas.

7 EDUCATION AND TRAINING REQUIREMENTS

7.1 LocSSIPs must clearly identify the workforce necessary to deliver safe patient care in every operating theatre and invasive procedural area in the organisation.

7.2 LocSSIPs must take into account the supervision of students and trainees, including:

- Doctors in training
- Student ODPs
- Undergraduate and postgraduate nurses and midwives and Nursing Associates
- Learners in other supporting roles

7.3 LocSSIPs must specifically address the induction requirements of new staff in the procedural area including locums, bank staff, agency staff and substantive staff.

7.4 Training in how to use a LocSSIP will be carried out in the clinical area by the manager/clinical supervisor of that area to ensure that all staff are aware of the safety processes and are able to use them consistently.

8 PROCESS FOR MONITORING COMPLIANCE/ESCALATION

8.1 Monitoring and audit of compliance with LocSSIPs

8.1.1 Compliance with LocSSIPs should be monitored on a monthly basis by each area that undertakes invasive procedures using the audit tool provided by the safe surgery team. This can be accessed on insite here: <http://insite.xuhl-tr.nhs.uk/homepage/management/corporate-directorates/medical/patient-safety/locssips/safe-surgery-accreditation>

8.1.2 The trust has a Quality Assurance and Accreditation programme for areas undertaking invasive procedures. The results from this programme will be reported to CMGs and it is expected that this will be an agenda item on their Quality and Safety board meetings. Results will also feed into CMG Performance Review Meetings.

- 8.1.3** Gaps in compliance identified by the quality assurance process must generate an action plan that is monitored by the CMG Quality and Safety Board. LocSSIPs should be part of the reporting cycle for the relevant Quality and Safety Boards to ensure that invasive procedures are given adequate coverage and scrutiny.
- 8.1.4** All patient safety incidents and near misses must be documented and reported on Datix. These should be analysed, investigated as appropriate, and learning should be fed back to staff for continuous improvement.

8.2 Providing assurance to the trust:

Reports will be reported to the EQB to provide assurance to the trust that safety procedures are being implemented and followed. Action plans targeting areas for improvement will be monitored through the CMG Q&S Boards and EQB by exception.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

1. NatSSIPs available at: <https://www.england.nhs.uk/patientsafety/never-events/natssips/>
2. Never Events: available at: <https://www.england.nhs.uk/patientsafety/never-events/>

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

This document will be uploaded onto SharePoint and available for access by Staff through INsite. It will be stored and archived through this system.

POLICY MONITORING TABLE: APPENDIX 1

The top row of the table provides information and descriptors and is to be removed in the final version of the document

| Element to be monitored | Lead | Tool | Frequency | Reporting arrangements | Lead(s) for acting on recommendations | Change in practice and lessons to be shared |
|---------------------------------------|--|-------------------------|---|-----------------------------------|---|--|
| Compliance against LocSSIPs standards | Lead for each LocSSIP | Audit, PSI reporting | Annual as minimum; or as defined in individual LocSSIPs | CMG Quality and Safety Board; EQB | Clinical Directors delegating to LocSSIP leads/Ward managers/Procedural area managers | Via usual audit processes – sharing via patient safety newsletters, M+M meetings, safety boards, e-mail etc. |
| Compliance against LocSSIPs standards | Corporate Medical Team (Deputy Medical Director) | Quality visit checklist | Risk-based approach when concerns | CMG Quality and Safety Board; EQB | Clinical Directors delegating to LocSSIP leads/Ward managers/Procedural area managers | Via usual audit processes – sharing via patient safety newsletters, M+M meetings, safety boards, e-mail etc. |

Insert name of procedure(s)
Standard Operating Procedure
UHL Department (LocSSIPs)

Blank template: delete guidance and populate with your statements.

| | |
|--|--|
| Change Description <input type="checkbox"/> Change in format | Reason for Change <input type="checkbox"/> Trust requirement |
|--|--|

| APPROVERS | POSITION | NAME |
|-----------------------------------|----------|------|
| Person Responsible for Procedure: | | |
| SOP Owner: | | |
| Sub-group Lead: | | |

| |
|---|
| Appendices in this document: |
| <p>Appendix 1: UHL Safer Surgery Department Checklist. Appendix 2 : Patient Information Leaflet for Procedure Available at:</p> |
| Introduction and Background: |
| <p>Include some narrative about what this LocSSIP covers (area -where it happens, and procedure types) and what national guidance it is based on. Similar procedures can be grouped together under one LocSIPP Specifically reference the National Safety Standards for Invasive Procedures. Include some description of the indications and contraindications for the procedure Referral process – include a description</p> |
| Never Events: |
| <p>Describe what Never Events could occur in your area and what specific measures are addressed in this LocSSIP to prevent these from occurring.</p> |
| List management and scheduling: |

Describe how patients are booked for a list
List the minimum dataset required for scheduling a patient on the list State who can sign off the list and when this should happen
State who is responsible for ordering the list
Describe how the list is published and who is informed Describe how list changes are communicated
State that abbreviations of laterality (i.e. L and R for left and right) will not be used Describe any special arrangements that need to happen at list booking stage (e.g. ensuring a lab technician is available to process sample)
Describe how DNAs are handled to prevent loss to follow-up Flow charts might be useful

Patient preparation:

Describe COVID risks and PPE precautions where appropriate
Describe the fasting and hydration arrangements for patients pre-operatively Describe what information patients will be provided with (note: patient information should be available on YourHealth which is the UHL repository for patient information)
Describe what pre-procedural investigations and work-up are required e.g.
Blood tests – and list any critical parameters for proceeding (e.g. INR<1.5, platelets >50 etc.)
Imaging requirements
ECG, lung function tests etc.
Describe any special requirements
Describe how you handle patients with special requirements such as:
Diabetes
Use of anti-platelet agents

- Use of anticoagulants (refer to Anticoagulant Bridging therapy Policy – see refs)

Describe pre-operative MDT involvement in the patient pathway
Describe how shared decision making will be considered as per GMC
Describe how patients will be consented and by whom
Describe the requirements for delegated consent for this procedure and how this is recorded, audited and monitored for compliance (if relevant)
Describe the specific complications and mortality risks that patients should be informed of in the consent process
Describe infection prevention strategies – e.g. hair removal, warming, antibiotic prophylaxis, use of gowns, drapes, skin preparation required
Describe any special steps for prevention of safety incidents e.g. ensuring stoppers/bungs are in an “off” position to prevent air embolism; ensuring antiseptic preparations are not kept in open Gallipots to prevent inadvertent injection etc.
Include reference to the trust venothrombo-embolism policy and policy for diabetic patients undergoing surgery
Provide a copy of the patient pathway or any associated checklists in an Appendix
Describe how patients with disabilities will be managed
Describe how patients requiring translation or interpretations will be managed
Describe the patient identification used in the area in line with the UHL Patient Identification Band Policy B43/2007

Workforce – staffing requirements:

State minimum safe staffing standards for a procedure list.
Define number and skill-mix of staff, including specific practice qualifications where applicable.
Define for in hours and out of hours (NB. Out of hours standards should be no less than the minimum for in hours)
State escalation procedures if a clinical situation overwhelms available resources
State how learners or students will be supervised in area
State how newcomers to area have an induction and summarise what this induction includes
State how workforce levels will be maintained and monitored to provide assurance that procedures can safely proceed

Ward checklist, and ward to procedure room handover:

Describe the formal handover process from the ward to the procedure team
List the content of this handover
Provide a copy of the checklist required in an Appendix to this SOP

Procedural Verification of Site Marking:

Make clear what site and side marking is required for this procedure.
If none is required justify why not and what other procedures are to be used instead
Surgical site marking is mandatory for all procedure for which it is possible.
Site marking should be performed with an indelible marker designed for that purpose and must be:

- Performed shortly before the procedure by the operator or nominated deputy
- Must remain visible in the operative field and not be obscured by drapes
- State how site marking is documented

Team Safety Briefing:

The Team Safety Briefing must occur at the start of any elective, unscheduled or emergency procedure session. Use this section to:
Define who must be present at the team safety briefing, where it will happen and at what time.
Provide a copy of the team briefing documentation showing the content as an appendix to this SOP.
Describe the process for archiving, storing and collating information from team briefings.
Describe how this information will feedback into improving safety and processes
List the content of the team brief

Sign In:

Sign in refers to the checklist completed at the patient's arrival into the procedure area. In this section please state:

- Where the Sign In will happen
- Who will perform it – minimum of two people required (if under GA anaesthetist and anaesthetic assistant must take part)
- That the patient will be encouraged to participate where possible
- That omissions, discrepancies or uncertainties must be resolved before proceeding

List the components of the check

Add in a "Stop Before you Block" reminder if the procedure is performed under regional anaesthesia

Provide a copy of the checklist in an Appendix to this SOP

Time Out:

Time out is the final safety check that must be completed for all patients undergoing invasive procedures just before the start of the procedure. The WHO checklist is the Gold Standard and may be adapted for local use with the deletion or addition of elements to suit the procedural requirements. Some Royal Colleges or other national bodies have checklists for their specialties.

This section should have a description of your Time Out procedures:

State:

- That the patient will be encouraged to participate where possible
- Who will lead it (any member can)
- That all team members must be present and engaged as it is happening
- That it will occur immediately before the procedure start
- That separate time out checklist will be completed if there is a separate or sequential procedure happening on the same patient
- That any omissions, discrepancies or uncertainties must be resolved before starting the procedure

List the components of the time out checklist (see example on page 38 of the NatSSIPs guidance)

Provide a copy of the checklist in the appendices to this SOP.

Include reference to UHL's antimicrobial policy in relation to antimicrobial prophylaxis required.

NB. For procedures under local anaesthetic where the patient is fully conscious Time Out can be combined with the Sign In in one checklist.

Performing the procedure:

Describe any special safety features that are important for performing the procedure e.g. positioning of the patient, technique, equipment used etc.

Monitoring:

Describe how the patient will be monitored throughout the time in the procedural area.

Consider:

- O2 Sats
- ECG
- Blood Pressure
- Pulse rate
- Respiratory rate
- GCS
- Temp
- BMs

Ensure that this is compliant with the UHL Sedation Policy if relevant (see below)

Prosthesis verification:

In this section you must document the procedures required to ensure that the correct implants or prostheses are selected and used for an invasive procedure. The safety procedures that need to be followed can be broken down into before, during and after surgery. Your summary of these procedures must include where relevant:

Before:

- How stock is ordered
- How specific requirements are communicated to the operating theatre or procedural team in good time to ensure stock is present (e.g. on operating list, by e-mail)
- How stock is checked, ordered and expiry dates maintained appropriately
- How the safety team briefing is used to highlight the need for prostheses
- The need for inspection of the prosthesis by the operator prior to the patient being sent for

During:

- How the implant is confirmed with the operator to be the correct one – this should include a check of type, design, style, material, size, laterality, manufacturer, expiry date, sterility, compatibility with other multi-component prostheses and any other required characteristics (sometimes called a Critical Prosthetic Pause)
- How this verification check is documented
- State that all prostheses not destined for use in the patient will be removed from the immediate area to avoid the wrong implants being selected

After:

- How a record of the implant is made, including how it will be recorded in any registry

Prevention of retained Foreign Objects:

Describe in this section the procedures that are followed to prevent foreign objects being retained unintentionally. You may refer to over-arching SOPs on safe practice. Describe the equipment used:

- Use of lists of equipment
- Equipment and how often it is checked for loose parts etc., how many component parts there are
- Type of swabs used - size, colour, number and whether radio-opaque markers are used
- Sharps used

Describe how counts are done

- Two staff members
- Use of whiteboard
- Staff changes
- Reconciliation before closure of a body cavity

Describe procedures to follow if items are unaccounted for

Describe how patients and other staff will be made aware of the intentional retention of a foreign object (e.g. Vaginal swab) and how this will be handed over and documented

Describe any special standardisation that is aimed at minimising error – e.g. standardisation of vaginal packs

Radiography:

Include a section on radiography and how this is used safely in the area if this is relevant

Describe how contrast will be used safely without having open Gallipots as a reservoir

Sign Out:

Sign out must occur before the patient leaves the operative/procedure area. In this section include a description of the content of the sign out which should include:

- Confirmation of procedure
- Confirmation that counts (instruments, sharps and swabs) are complete
- Confirmation that specimens have been labelled correctly
- Discussion of post-procedural care and any concerns
- Equipment problems to include in team debriefing

Describe how this is documented and provide a copy of the checklist in an Appendix.

Handover:

Describe content required for handover to post-procedural team or ward

Team Debrief:

A team debrief should occur at the end of all procedure sessions.

State where and when it will occur

State who should be present (all team members) Describe the content of the debrief which should include:

- Things that went well
- Any problems with equipment or other issues
- Areas for improvement
- An action log
- A named person for escalating issues

Provide a copy of the debrief checklist as an Appendix to this SOP

State how the team debrief will be documented

Describe the process for archiving, storing and collating information from team debriefings.

Describe how this information will feedback into improving safety and processes

Post-procedural aftercare:

Describe monitoring arrangements

Describe possible complications and how to recognise them

Describe where patients will be nursed

Discharge:

Describe criteria for discharge (including nurse led discharge)

Describe discharge letter requirements

Describe follow-up

Describe how any results will be communicated

Governance and Audit:

Define what constitutes a safety incident in this area

State that all incidents will be reported on Datix

State the procedures for review, investigation, dissemination, and learning from incidents after a Datix is submitted

State how will this SOP be audited – how often, where will results be presented and acted upon?

Include a table of standards and KPIs that will be monitored

To submit monthly Safe Surgery Audit and WHOBARS assessment as per Safe Surgery Quality Assurance & Accreditation programme

Training:

State how staff will be trained in this SOP

State how you will incorporate a Human Factors approach into training

State how the multidisciplinary team will be trained together

Documentation:

Describe how this pathway is documented in the patient record
Describe any other records that will be kept e.g. theatre management system
Provide a copy as an Appendix to this SOP

References to other standards, alerts and procedures:

Insert reference to all other trust SOPs that are relevant
Insert references to national standards that apply e.g. Royal College standards
Insert references to any CAS alerts that apply to the procedure
For procedures involving sedation please reference the sedation policy
For all procedures include reference to NatSSIPs and the UHL Safer Surgery Policy:

National Safety Standards for Invasive Procedures, NHS England 2015:

<https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/09/natssips-safety-standards.pdf>

UHL Safer Surgery Policy: B40/2010

Other relevant UHL policies that may need to be cited:

UHL Sedation Policy: Safety and Sedation of Patients Undergoing Diagnostic and Therapeutic Procedures B10/2005

UHL Consent to Treatment or Examination Policy A16/2002

UHL Delegated Consent Policy B10/2013

UHL Patient Identification Band Policy B43/2007

UHL Guideline: Anticoagulation management (“bridging”) at the time of elective surgery and invasive procedures (adult) B30/2016

UHL Guideline: Management of adult patients with diabetes undergoing elective surgery and procedures B3/2013

UHL Guideline: Venous thromboembolism risk assessment B9/2016

UHL Guideline: Antibiotic guide for surgical prophylaxis in adults B14/2007 (or other relevant guideline)

Shared decision making for doctors: [Decision making and consent \(gmc-uk.org\)](http://www.gmc-uk.org)

COVID and PPE: [UHL PPE for Transmission Based Precautions - A Visual Guide](#)

COVID and PPE: [UHL PPE for Aerosol Generating Procedures \(AGPs\) - A Visual Guide](#)

END