INVASIVE PROCEDURES POLICY

POLICY

Reference	CPG-TW-NatSSIP/LocSSIP		
Approving Body	Consent Group		
Date Approved	21st May 2021		
For publication to external SFH website	**Positive confirmation received from the approving body that the content does not risk the safety of patients or the public:**		
	YES	**NO**	**N/A**
	X		
Issue Date	31st May 2021		
Version	v2.0		
Summary of Changes from Previous Version	• Section 6.2: Additional detail added regarding process for adapted/ procedure specific forms • Section 7 (monitoring compliance): Amends made to clarify the current requirements to include use of highlight reports to consent group every 6 months. • Section 8 (education): updated to capture current requirements		
Supersedes	v1.2, Issued 31st May 2019 to Review Date May 2021 (ext[2])		
Document Category	• Clinical		
Consultation Undertaken	Members of the Consent Group		
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Date of Environmental Impact Assessment (if applicable)	January 2021		
Legal and/or Accreditation Implications	NHS England and CQC Regulatory requirements		
Target Audience	Trustwide		
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Sponsor (Position)	Medical Director		
Author (Position & Name)	Surgery Divisional Clinical Governance Lead, Mr K Bradrinath		
Lead Division/ Directorate	Surgery		
Lead Specialty/ Service/ Department	General Surgery		
Position of Person able to provide Further Guidance/Information	Divisional Clinical Governance Lead, Surgery Division		

Associated Documents/ Information	**Date Associated Documents/ Information was reviewed**
Not Applicable	Not Applicable
Template control	June 2020

CONTENTS

1.0 INTRODUCTION

The concept of 'Never Events' was introduced in the NHS in 2009 with a list of 8 serious and largely preventable adverse patient safety events which "should not occur if the available preventative measures have been implemented" (NPSA, 2009). Amongst these original eight Never Events were two surgical Never Events: wrong site surgery and retained instrument post-operation, subsequently extended to include retained swabs and throat packs. A third surgical Never Event, wrong implant / prosthesis, was added in 2012.

The WHO Surgical Safety Checklist was introduced in the NHS in 2010 with an expectation that it would reduce the incidence of surgical Never Events (de Vries et al, 2010). 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. It is also 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.

In September 2015 NHS England issued the National Safety Standards for Invasive Procedures (NatSSIPs), developed by a multidisciplinary group of clinical practitioners, professional leaders, human factors experts and lay representatives. The NatSSIPs set out key steps necessary to deliver safe care for patients undergoing invasive procedures and are designed to support organisations delivering NHS-funded care in standardising the processes that underpin patient safety.

Individual organisations are required to develop Local Safety Standards for Invasive Procedures (LocSSIPs) that include the key steps outlined in the NatSSIPs and to harmonise practice across the organisation so that there is a consistent approach to the care of patients undergoing invasive procedures in any location.

2.0 POLICY STATEMENT

The purpose of this policy is to define and standardise the approach taken by Sherwood Forest Hospitals NHS Foundation Trust to the implementation of LocSSIPs that are consistent with the principles and framework set out in the NatSSIPs.

This policy should be applied to all invasive procedures, wherever they are carried out.

An invasive procedure is defined in the NatSSIPs as a procedure that has the potential to be associated with a Never Event if safety standards are not set and followed, which includes:

- All surgical and interventional procedures performed in operating theatres, outpatient treatment areas, labour ward delivery rooms, and other procedural areas within the 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.

The process of safe care begins on the ward and this policy should be applied in conjunction with other policies and guidelines specific to the procedure being undertaken.

NatSSIPs include all 5 stages of the 5 Steps to Safer Surgery and are to be applied in clinical areas where 'lists' of invasive procedures are undertaken (ie where several patients attend pre-planned/ scheduled appointments) eg:

- Theatres
- Endoscopy Suite
- Cardiac Catheter Suite

LocSSIPs require a 3 stage WHO checklist to be applied in clinical areas where invasive procedures are undertaken on an individual/ ad-hoc/ case by case basis. Either a generic Invasive Procedure Safety Checklist (Appendix A) must be used or a local variation (which has been through the process described later in this policy) can be used.

This clinical document applies to:

Staff group(s)

- All staff involved in either developing or approving a local variation checklist
- All staff caring for and treating patients requiring invasive procedures

Clinical area(s)

- Trustwide application across all relevant sites
- All clinical areas where invasive procedures are undertaken

3.0 DEFINITIONS/ ABBREVIATIONS

Trust	Sherwood Forest Hospitals NHS Foundation Trust
Staff	All employees of the Trust including those managed by a third party on behalf of the Trust
Invasive procedure	A procedure that has the potential to be associated with a Never Event if safety standards are not set and followed
NatSSIPs	National Safety Standards for Invasive Procedures: • A procedure that has the potential to be associated with a Never Event if safety standards are not set and followed, which includes all surgical and interventional procedures performed in operating theatres, outpatient treatment areas, labour ward delivery rooms, and other procedural areas within the organisation.
LocSSIPs	Local Safety Standards for Invasive Procedures • An invasive procedure which has the potential for a 'Never Event' performed in a clinical area not designated as a NatSSIPs location.
WHO	World Health Organisation
NPSA	National Patient Safety Agency

4.0 ROLES AND RESPONSIBILITIES

4.1 Divisional Clinical Chairs

Divisional Clinical Chairs will be responsible for ensuring their anaesthetists, surgeons and physicians carry out the instructions within this policy.

4.2 Senior Anaesthetist/ Operator

The most senior anaesthetist/ operator present during the invasive procedure will be responsible for ensuring that sign in on the Surgical Safety Checklist (or approved variation) is read aloud and completed. The most senior anaesthetist/ operator must ensure the sign in section of the checklist has been signed before induction of anaesthesia.

4.3 Senior Nurse

The most senior member of the nursing team should ensure that a briefing and debriefing take place at the start and finish of the operating list.

4.4 All Operating Theatre/Procedure Room Staff

- The Five Steps to Safer Surgery process is a team function and all team members should contribute and feel empowered to speak out if they have a concern.
- Where it has been identified that a patient has been put at risk by failure to follow the Five Steps (a near miss has occurred) staff should raise/ submit an incident on Datix.
- Where an incident has occurred due to failure to follow the policy staff must alert the theatre manager/ senior manager of production area and relevant Head of Service, in addition to raising/ submitting an incident on Datix.
- Any concerns regarding the practice of individuals in relation to implementation of this policy should be escalated appropriately to an individual's line manager and/or professional lead.

5.0 APPROVAL

Following appropriate consultation, this policy (v2.0) has been approved by the Consent Group

6.0 DOCUMENT REQUIREMENTS

6.1 The Process

6.1.1 The Five Steps to Safer Surgery

The key elements to the "Five Steps to Safer Surgery" are the Brief, Sign-in, Time-out, Sign-out and Debrief. The original WHO Checklist did not mandate Brief and Debrief, but the evidence base supports the importance of these steps from a safety point of view and the time spent ensuring everyone is briefed at the start of a list will often save time later.

6.1.2 Safety briefing

A ***safety briefing*** must be performed at the start of all elective procedure sessions wherever the procedures are taking place. A briefing should also be performed before all 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.

The safety briefing should take place in a discreet location in which patient confidentially can be maintained, while enabling inclusivity and contribution from all team members. As many members of the procedural team as possible should attend the briefing, but as a minimum it must include the operator and anaesthetist who have seen and consented the patient(s) shortly before the procedural session and the theatre nursing staff/ procedural area support staff.

The safety briefing should consider each patient on the procedural list from an operator, anaesthetic and practitioner perspective and the list order should be confirmed.

For each patient, the discussion should include:

- Diagnosis and planned procedure.
- Availability of prosthesis when relevant.
- Site and side of procedure.
- Infection risk, e.g. MRSA status.
- Allergies.
- Relevant comorbidities or complications.
- Need for antibiotic prophylaxis.
- Likely need for blood or blood products.
- Patient positioning.
- Equipment requirements and availability, including special equipment or ‘extras’.
- Post-procedure destination for the patient, e.g. ward or critical care unit.

6.1.3 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***. Participation of the patient (and/or parent, guardian, carer or birth partner) in the sign in should be encouraged when possible.

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 full resolved except in extreme emergencies. The necessary checks as part of the sign in process are detailed in the relevant procedural checklist.

The sign in must be performed by at least two people involved in the procedure. For procedures performed under general or regional anaesthesia, these should include the anaesthetist and anaesthetic assistant. For procedures not involving an anaesthetist, the operator and an assistant should perform the sign in. The sign in section of the procedural checklist must be signed and dated.

Immediately before the insertion of a regional anaesthetic, the anaesthetist and anaesthetic assistant must simultaneously check the surgical site marking and the site and side of the block (Stop Before You Block).

6.1.4 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***. A time out must be conducted immediately before the start of the procedure and the relevant checks are listed in the procedural checklist. 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.

Any member of the procedure team may lead the time out. All team members involved in the procedure should be present at the time out and, except in extreme emergencies, all team members must stop what they are doing and participate. Asking all team members to introduce themselves is an effective way of doing this and is the first step of the time out process.

It is mandated that the primary operator is present at time out; in the exceptional event that he/she is not present (perhaps due to an emergency in another theatre / procedural area) he/she must confirm the identity of the patient, planned procedure and site before scrubbing in.

Any omissions, discrepancies or uncertainties identified during the time out should be resolved before the procedure starts. Consideration should also be given to other safety guidelines that may apply to the specific procedure being carried out.

6.1.5 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 before handover to the post-procedure care team: ***the sign out***. For general anaesthetic cases the sign out checks should be conducted before the patient is awoken. The necessary checks are detailed in the relevant checklist.

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.

The senior operator must sign the sign out section of the checklist.

6.1.6 Debriefing

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 should occur in a manner and location that ensures patient confidentially, while enabling inclusivity and contribution from all team members.

Every member of the procedural team should take part in the debriefing. Any team member may lead the debriefing, but the operator and anaesthetist must be present.

If any team member, and especially the senior operator, scrub practitioner or anaesthetist, has to leave before the debriefing is conducted, they should record any positive feedback and raise any issues they would like discussed during the debriefing.

The content of the team debriefing can 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.

Any problems identified or issues that need to be corrected should be communicated to theatre managers / managers of procedural area.

6.2 Process and Printing for Local Variations/ Adaptations

Adapted specialty/ procedure specific checklists which have been approved for use are listed in Appendix B ***(or can be found in the appendices of the individual divisional implementation SOPs)***

There should be no other checklists in use other than those listed in Appendix B ***(or appendix of the divisional SOPs),*** and as a default; the generic Invasive Procedure Safety Checklist should be used (Appendix A).

If a member of staff feels that none of the approved checklists relate to their area of practice yet invasive procedures are taking place, they should seek clarification from their line manager. If he/she feels that there is a good reason why a particular clinical area should adopt a different checklist, this would require appropriate agreement, development and consultation at specialty level (or wider as applicable eg multi-specialty/ divisional/ cross-divisional) with subsequent/ final approval by the Consent Group, which has been delegated authority for this purpose by the Quality Assurance Safety Cabinet (QASC).

Adapted specialty/ procedure specific checklists must be developed in the approved standard template (Appendix A). An editable WORD file can be requested for the purpose from the Governance Support Unit (GSU).

Approved checklists will be published by the Governance Support Unit (GSU) in the relevant section of the Policies, Procedures and Guidelines intranet. Once published, GSU will update and list/ link the checklist in Appendix B ***(or in the appendix of the relevant divisional implementation SOP)*** as having been approved for use in practice.

Checklists are subject to periodic reviews in-line with other centrally maintained clinical documents.

- Minor wording amendments can be approved at specialty level (with escalation to Division level if deemed necessary)

- Moderate/ Significant amendments need to be agreed/ consulted at specialty level with escalation to Division level if deemed necessary followed by subsequent/ final approval by the Consent Group.

Printing: For smaller volumes, checklists should be printed for use on a case by case basis from the intranet as needed. For larger quantities, either contact Clinical Illustration to support the requirement or raise an order in the usual manner via the e-Series process for procurement.

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Use of NatSSIPs and LocSSIPs must be monitored by specialties/ clinical areas to ensure safe practice. Any issues/ good practice should be shared accordingly for learning and where necessary action plans should be devised to support improvements.

	Minimum Requirement to be Monitored **(WHAT – element of compliance or effectiveness within the document will be monitored)**	**Responsible Individual** **(WHO – is going to monitor this element)**	**Process for Monitoring e.g. Audit** **(HOW – will this element be monitored (method used))**	**Frequency of Monitoring** **(WHEN – will this element be monitored (frequency/ how often))**	**Responsible Individual or Committee/ Group for Review of Results** **(WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)**
1	Patient safety incidents associated with invasive procedures	Heads of Service	Review of patient safety incident reports raised/ submitted on Datix.	As they occur	Specialty Clinical Governance Group with escalation as required through governance structure.
2	Use and completion of invasive procedure checklists (NatSSIPs and LocSSIPs) – generic and specialty/ procedure specific.	Heads of Service/ Department Lead	Data Collection/ observational audit/ completed checklists. *(eg audit via BlueSpier in Theatres or using audit tool on AMaT in Medicine Division)* Information from the above to be included in Divisional Highlight Report to Consent Group	Minimum 20 patients/ sets of notes every 6 months Every 6 months	Specialty Clinical Governance Group with escalation as required through governance structure. Consent Group via Divisional Representative on the Group

8.0 TRAINING AND IMPLEMENTATION

Staff will be appropriately trained in the various procedures requiring the use of a checklist (5 steps/ 3 steps). This will be undertaken at specialty level, usually at induction.

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix C
- This document is not subject to an Environmental Impact Assessment

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence Base:

- De Vries EN, PrinsHA, Crolla RMPH, et al. (2010) "Effect of a comprehensive surgical safety system on patient outcomes". N Engl J Med; 363:1928-37.
- NHS England (2015) Revised Never Events Policy & Framework
- NHS England (2015) National Safety Standards for Invasive Procedures (NatSSIPs).

Related SFHFT Documents:

- Health Records Management Policy (regarding standards for documentation to be retained in medical notes)

11.0 KEYWORDS

WHO checklist; Never events; NatSSIPs; LocSSIPs; Surgical safety checklist; natsip; locsip; natsipp; locsipp;

12.0 APPENDICES

Appendix A – Invasive Procedure Safety Checklist (hyperlinked to intranet)
Appendix B – List of approved variations of Invasive Procedure Safety Checklists
Appendix C – Equality Impact Assessment Form

Appendix B – List of approved variations of Invasive Procedure Safety Checklists
(last updated: ***February 2023***)

Please also see the following divisional SOPs which also indicate "Procedures requiring use of procedure specific safety checklist" as well as those requiring use of generic safety checklist accessed/ printed from the intranet

- CSTO: SOP for the implementation of the SFH Invasive Procedures Policy within the division of Clinical Support, Therapies and Outpatients
- Medicine: SOP for the implementation of the SFH Invasive Procedures Policy in the Division of Medicine
- Surgery: SOP for the implementation of the Invasive Procedures Policy in the Division of Surgery, Critical Care and Anaesthesia
- U&EC: SOP for the implementation of the SFH Invasive Procedures Policy in the Division of Urgent & Emergency Care

Title of checklist (hyperlinked to document on intranet)	**Date initially approved**	**Owning Specialty**	**Intranet Location:**
Maternity - Invasive Procedure Safety Checklist	July 2017 Consent Steering Group	Maternity	➢ Policies, Procedures & Guidelines ➢ CLINICAL (Specialty/ Department) ➢ Maternity ➢ Theatres (maternity)
Gynaecology Outpatient Procedures – Invasive Procedure Safety Checklist	Sept 2019 Consent Group	Gynaecology	➢ Policies, Procedures & Guidelines ➢ CLINICAL (Specialty/ Department) ➢ Gynaecology

APPENDIX C – EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: Invasive Procedure Policy			
New or existing service/policy/procedure: Existing			
Date of Assessment: January 2021			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed:			
Race and Ethnicity	None	N/A	N/A
Gender	None	N/A	N/A
Age	None	N/A	N/A
Religion	None	N/A	N/A
Disability	None	N/A	N/A
Sexuality	None	N/A	N/A
Pregnancy and Maternity	None	N/A	N/A
Gender Reassignment	None	N/A	N/A
Marriage and Civil Partnership	None	N/A	N/A

Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation)	None	N/A	N/A

What consultation with protected characteristic groups including patient groups have you carried out?

- As part of consultation for the policy

What data or information did you use in support of this EqIA?

- Authors knowledge of subject and information provided within the policy

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

- None known

Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

High Level of Impact/Medium Level of Impact/***Low Level of Impact*** *(Delete as appropriate)*

For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.

Name of Responsible Person undertaking this assessment: Mr K Badrinath

Signature:

Date: January 2021