University Hospitals of Morecambe Bay NHS Foundation Trust

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Scope: Invasive procedures with implant surgery. (Excludes Intra Ocular Lens Implants Ophthalmology)	**Classification:** Departmental
Author / Title: Sue Wroe Governance Lead NatSsips Quality & Governance	**Responsibility:** Operating Clinicians Clinical Theatre Managers, Clinical Team Leaders, Scrub Practitioner Circulating Practitioner
Replaces: Version 1.1, (LocSsip) for: Verification and Opening of Prosthetic Implants in the Operating Theatre, Surg/LocsSip/002	**Head of Department:** Michael Thompson X Bay Theatre Manager. Daniel Bakey X Bay Theatre Manager
Validated By: Surgery & Critical Care DGAG	**Date:** 29/04/2016
Ratified By: Procedural Document and Information Leaflet Group	**Date:** 18/05/2016
Review dates may alter if any significant changes are made	**Review Date:** 01/04/2019
Which Principles of the NHS Constitution Apply? 1,2,3,4	**Which Staff Pledges of the NHS Constitution Apply?** 1,2,3
Does this document meet the requirements of the Equality Act 2010 in relation to Race, Religion and Belief, Age, Disability, Gender, Sexual Orientation, Gender Identity, Pregnancy & Maternity, Marriage and Civil Partnership, Carers, Human Rights and Social Economic Deprivation discrimination? **Yes**	
Document for Public Display: No	
Evidence Search/Check Completed by: Joanne Shawcross 06/04/2016 **To be completed by Library and Knowledge Services Staff**	

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BEHAVIOURAL STANDARDS FRAMEWORK

To help create a great place to work and a great place to be cared for, it is essential that our Trust policies, procedures and processes support our values and behaviours. This document, when used effectively, can help promote a workplace culture that values the contribution of everyone, shows support for staff as well as patients, recognises and celebrates the diversity of our staff, shows respect for everyone and ensures all our actions contribute to safe care and a safe working environment - all of which are principles of our Behavioural Standards Framework.

Behavioural Standards Framework – Expectations 'at a glance'

1. SUMMARY

Surgical systems are highly complex. In the operating theatre a high volume of care, tailored to individual patient needs, is delivered by differently trained staff working with specialised technology in a sometimes challenging environment.

Despite a genuine commitment to safe practice and a high degree of technical competence, there is ample scope for error.

Surgical placement of the wrong implant or prosthesis where the implant/prosthesis is fixed in the patient other than that specified in the surgical plan, either prior to or during the procedure, whereby the incident is detected at any time after the implant/prosthesis is placed in the patient is a 'Never Event' [1]

A 'Never Event'[1] has the potential to cause serious patient harm and can often, in cases of wrong prosthesis implantation cause disablement to the patient and instigate the need for further major surgery. An error of this type is both devastating to patient and staff and not without further risk to the patient.

2. PURPOSE

The UHMB Prosthesis Verification Safety Standards are part of the mandatory NHS NatSsips (National Safety Standards for Invasive Procedures directive)[2]. The standards in this document form an incremental checking process, when all the steps in the checking process are followed; they facilitate safety and assurance standards for correct prosthesis implantation into a patient.

The steps are simple and systematic; the operating surgeon and the theatre team involved in the surgical procedure must ensure the safety standards occur at the critical points prior to and during the invasive procedure.

These standards do not work in isolation but work in collaboration with the safety standards outlined in 'The 5 Steps to Safer Surgery' [3,] which is embraced at UHMB for all patients undergoing invasive procedures in the operating theatres.

3. SCOPE

The standards within this procedural document will be applicable to theatre patients and practiced without deviation by the operating surgeon and the theatre team staff when prosthesis is to be implanted during an invasive surgical procedure.

- The operating surgeon will retain the overall responsibility for ensuring that the correct type and size of prosthesis is implanted in the patient.
- The operating surgeon has overall responsibility for ensuring that no non retainable parts of the prosthesis are retained at implantation.
- The operating surgeon has accountability that any manufacturer's instructions and literature is fully understood and followed.

Procedure/Prosthesis Examples (not exhaustive current at time of standard formulation)

- Total Hip Arthroplasty
- Hemi Hip Arthroplasty
- Knee Arthroplasty
- Ankle Arthroplasty
- Shoulder Arthroplasty
- Elbow Arthroplasty
- Breast Implants
- B.A.H.A. (Bone anchored hearing aid) Implants
- Titanium tooth implants
- Testicular Implants
- Penile Implants
- Trauma Implants

- Errors, discrepancies or near misses are untoward incidents.
- Detection of a wrongly implanted prosthesis is not exclusively limited to surgical implantation in theatres. Upon realising any prosthesis is incorrect; firstly ensure any immediate appropriate actions have been taken.
- The incident must be escalated and reported on the Trusts Patient Safety Module (Safeguard) by the raising of a Clinical Incident Report (CIR).
- The incident will be then be managed and investigated in line with the Trusts Policy for the management of incidents.
- Always ensure that Duty of candour according to policy occurs.

4. PROCEDURE

4.1 Check 1: Confirmation of Prosthesis availability. This must be discussed at Step 1 of the 5 Steps to Safer Surgery (List Pre- Brief)

- The theatre scrub & circulating team are responsible for the pre-operative checking of instruments and prosthesis required for implantation for each operating list before it commences.
- At Step **1** from the 5 Steps to Safer Surgery process (Pre-List Briefing) the responsible operating surgeon must specify by name the prosthesis and system type to be used for the surgical operation, if the prosthesis is side specific this must also be confirmed at this stage.
- It is critical at Pre Briefing that the prosthesis of choice are confirmed as **available**, or **not** by the team to the operating surgeon.
- This check must include presence of implant sizes and that the integrity of the implants in a system i.e. sterility, along with availability of all instrumentation in the required system being present and drapes and sterility markers are confirmed as intact.
- Before the patient is transferred from the ward to theatre, and before any sign in or

anaesthetic commencement if the patient has arrived, the operating surgeon must be informed of any unavailable implants or instrumentation problems. The patient must not be anaesthetised until a decision is made.

- If there is unavailability of implants or compromised instrument integrity. It is ultimately the operating surgeon's decision to continue with the surgery, change systems, or cancel the patient if that is most appropriate.
- **NB:** On the day cancellations should be avoided at all costs. In some instances the surgeon may have templated / pre-sized the patient and consider the missing size not to be a risk, nor jeopardise the patient outcome. Only the surgeon after careful consideration of these facts can take the decision to continue without a full set of implants.
- If the missing implant or instruments to complete the set can be sourced from one of the Trust other sites, then a change in the list order to allow arrival of the transfer of the missing prosthesis must be considered, and the list order change safety standards followed.
- The patients' surgery or anaesthesia must never be commenced if prosthetic implants and or instruments are not available and transfer of their arrival is awaited.

- Incomplete sets of implants whether or not the operation occurs must be raised as a CIR and recorded as a near miss.
- Problems with instrument integrity must be raised as a CIR for investigation by the Sterile Services Department.
- Discussion of a cancellation if it occurs due to any of the above must be discussed at Step 5 of Safer Surgery[3] (Debrief) for learning and improvement

4.2 Check 2: Prosthesis size confirmation and initial verification during the surgical procedure

Prosthesis stock should be safely stored as close to the operating theatre as possible, If practicable they can be stored on a moveable stock retaining trolley. This storage method allows transfer into, or close access to the implants by the theatre where the surgery is being performed.

- Once known during the surgical procedure, the operating surgeon informs the scrub practitioner of the prosthetic implant required.

<u>The Following must be stated in a clear audible manner by the operating surgeon:</u>

- The implant name/s
- The implant/s size
- The side if relevant
- The scrub practitioner confirms with the circulating practitioner the required implants and the circulator immediately writes them on the theatre yellow board.
- The written implants sizes should not be removed from the yellow board until the case is complete and the theatre is re-prepped for the next patient.

The operating surgeon must verify the implants wrote on the yellow board are correct and

agree this is what he has requested.

4.3 Check 3 Final Prosthesis Verification prior to surgical implantation

- It is the circulating practitioner's responsibility to collate and verify the prosthesis requested from stock and gather them for checking by the scrub team.
- Once the requested prosthesis from stock are selected, prior to interrupting the scrub practitioner, the circulating practitioner should make an initial 'unified' check to ensure that their selection matches the request recorded on the yellow board.
- At the appropriate time the circulator interrupts the scrub practitioner. The circulating practitioner and scrub practitioner together will then verify that the prosthesis match the information for requested prosthesis recorded on the theatre yellow board.
- This verification check must include integrity of the prosthesis packaging for:
    - Sterility
    - Red Gamma Dot identification where appropriate
    - Expiry date of sterility
    - Size, type and side if applicable
- When confirmed that the prosthesis is correct the scrub practitioner when appropriate and safe will interrupt the surgeon.
- Both the surgeon and scrub practitioner at this point will pause and focus on checking the prosthesis.
- Both must repeat the verification process which was undertaken between the scrub and circulating practitioner again.
- It must be the surgeon who verbally confirms accuracy of the prosthesis and authorises for them to be opened.
- Using strict aseptic technique the circulator will open the outer packaging of the prosthesis for acceptance by the scrub practitioner.
- It is the scrub practitioner's responsibility to ensure the prosthesis is kept in a secure manner, placing it in an unused sterile receiver and storing it in uncluttered area on the sterile trolley will assist with minimal handling of the prosthesis until required for implantation.
- When a prosthesis is implanted from the operative field, the surgeon and scrub practitioner must ensure that any non-retainable packaging is disposed of and not a risk to the patient by being retained.

4.4 Traceability, Record Keeping & Reordering of Prosthesis implanted

- In each theatre where implant surgery occurs, a traceability implant book must be maintained.
- 1 set of stickers from the prosthesis must be secured in the theatre implant traceability book, along with a patient identification label – from which the re-ordering of the used implant can cross referenced as a check for the re-order process.
- At least 1 set of stickers must be secured in the patient's own notes in the appropriate section, i.e. the designated section on the I.C.P. (Integrated Care Pathway) in orthopaedic surgery and the operative surgical record for other specialities.'
- The implant/s size/s will also be logged into patients electronic care record in the field for prosthesis on O.R.M.I.S. (Operating Room Management Information System). 'Please note this item must **not** be entered as a high cost disposable'.
- In the case of arthroplasty surgery, 1 set of stickers must be secured to the N.J.R.

form (National Joint Register); this form should be present with the patients' notes.

5. ATTACHMENTS	
Number	**Title**
1	Description of NatSsips
2	Equality & Diversity Impact Assessment tool

6. OTHER RELEVANT / ASSOCIATED DOCUMENTS	
Unique Identifier	**Title and web links from the document library**
Corp/LocSsip/001	LocSsip for: •Surgical Site Marking •5 Steps to Safer Surgery using the W.H.O. 'Theatre Time Out' Checklist http://uhmb/cs/tpdl/Documents/CORP-LOCSSIP-001.docx
Surg/LocSsip/003	LocSsip for: Counts of Swabs, Instruments and Non-Retainable Items for Invasive Procedures. http://uhmb/cs/tpdl/Documents/SURG-LOCSSIP-003.docx

7. SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS **References in full**	
Number	**References**
1	NHS England. Never Events. Available from: https://www.england.nhs.uk/patientsafety/never-events/ (accessed 28.4.16)
2	NHS England. National Safety Standards for Invasive Procedures (NatSSIPs) Available at: https://www.england.nhs.uk/patientsafety/never-events/natssips/ (accessed 28.4.16)
3	National Patient Safety Agency (NPSA) (2010) How to guide to the five steps to safer surgery. Available at: http://www.nrls.npsa.nhs.uk/resources/?EntryId45=92901 (accessed 27.4.16)
Bibliography	
NHS England. (2014) Standardise, educate, harmonise Commissioning the conditions for safer surgery. Report of the NHS England Never Events Taskforce. [Online] Available at: https://www.england.nhs.uk/wp-content/uploads/2014/02/sur-nev-ev-tf-rep.pdf (accessed 27.4.16)	

8. DEFINITIONS / GLOSSARY OF TERMS	
Abbreviation or Term	**Definition**
ORMIS	Operating Room Management Information System
NJR	National Joint Register
CIR	Clinical Incident Report
ICP.	Integrated Care Pathway
UHMB	University Hospitals Morecambe Bay
MBHT	Morecambe Bay Hospital Trust
DGAG	Divisional Governance and Assurance Group

9. CONSULTATION WITH STAFF AND PATIENTS Enter the names and job titles of staff and stakeholders that have contributed to the document	
Name	**Job Title**
Wendy Akrigg	Clinical Leader WGH Operating Theatres
Daniel Bakey	Cross Bay Matron Theatres UHMB
Michael Thompson	Cross Bay Theatre Performance Manager UHMB
Pamela Calder	Performance Lead Surgery & Critical Care UHMB
Sarah Cullen	Assistant Chief Nurse Surgery & Critical Care
Laura Armitstead	Acting Governance Lead Surgery & Critical Care

10. DISTRIBUTION PLAN	
Dissemination lead:	Daniel Bakey
Previous document already being used?	No
If yes, in what format and where?	N/A
Proposed action to retrieve out-of-date copies of the document:	N/A N/A
To be disseminated to:	
Document Library	Sue Wroe
Proposed actions to communicate the document contents to staff:	Briefing to Clinical Theatre Managers at monthly meeting Face to face briefing to staff during monthly audit session Email communication to multi-disiplinary teams including clinicians Printed copy on each site during initial implementation (Can remove this point as slightly outdated method and old ones are stored incorrectly)

11. TRAINING Is training required to be given due to the introduction of this procedural document? No		
Action by	**Action required**	**Implementation Date**
Daniel Bakey to delegate to Clinical Leaders and Clinical Theatre Managers	Audit day training session to clinical leaders Clinical Leaders to train their specific teams who they hold immediate line management responsibilities for	1 month within ratification

12. AMENDMENT HISTORY				
Revision No.	**Date of Issue**	**Page/Selection Changed**	**Description of Change**	**Review Date**
1.1	01/02/2017	Throughout	Surgery boards now yellow – were white.	01/04/2019
1.2	13/11/2017	Page 3	BSF page added	April 2019

Appendix 1: Description of NatSsips

Description of NatSsips which are mandatory inclusion in this LocSsip. The mandatory standards in this document are not all the standards required for prosthesis verification , the only inclusion is what is relevant to this particular standard	By Whom	Where identified	Inclusion achieved
The operator must use the safety briefing before the start of the procedural list to confirm the range/type prostheses required	Primary Operating Surgeon	Standard 4 4.1 check 1 bullet points 1 to 4.	Yes
The operator must visually inspect and confirm the prosthesis with the team prior to the patient being sent to the operating area.	Primary Operating Surgeon	Standard 4 4.1 check 1 bullet point 5	Yes
A record of implants must be made	All Theatre MDT (Surgical)	Standard 4.4 Traceability & Recording – all bullet points	Yes
The organisation must have in place a process for recording which prosthesis are used for which patients.	All Theatre MDT (Surgical)	As above	Yes
Reconciliation of item used during invasive procedure	Theatre Team	4.4 Reordering	Yes

Appendix 2: Equality & Diversity Impact Assessment Tool

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**	No	
	• Age	No	
	• Disability	No	
	• Race	No	
	• Sex	No	
	• Religious belief – including no belief	No	
	• Sexual Orientation	No	
	• Gender reassignment	No	
	• Marriage and civil partnership	No	
	• Pregnancy and maternity	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination are there any exceptions - valid, legal and/or justifiable?**	No	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
4a	**If so can the impact be avoided?**	No	
4b	**What alternative are there to achieving the policy/guidance without the impact?**	No	
4c	**Can we reduce the impact by taking different action?**	No	

For advice in respect of answering the above questions, and / or if you have identified a potential discriminatory impact of this procedural document, please contact the relevant person (see below), together with any suggestions as to the action required to avoid/reduce this impact.

For Service related procedural documents: Lynne Wyre, Deputy Chief Nurse & Lead for Service Inclusion and Diversity

For Workforce related procedural documents: Karmini McCann, Workforce Business Partner & Lead for Workforce Inclusion and Diversity.