University Hospitals of Morecambe Bay NHS Foundation Trust

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Document Title: **UHMB LocSsips Patient Safety Standards Procedural Document for:** **The verification and opening of devices for endoscopic implantation**	**Version Number:** 1 **Status:** Ratified
Scope: Endoscopists (The Operator) Clinical unit Managers All nurses and support staff working in the endoscopy unit.	**Classification:** Departmental
Author / Title: Sue Wroe,Governance Lead NatSsips Quality & Governance	**Responsibility:** Endoscopy
Replaces: New	**Head of Department:** Matron: - Simon Glover Lindsey Kelsall – Clinical Lead for Endoscopy X-Bay
Validated By: Medicine DPDG	**Date:** 03/11/2016
Ratified By: Medicine DGAG	**Date:** 30/11/2016
Review dates may alter if any significant changes are made	**Review Date:** 01/11/2019
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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1. SUMMARY

In the endoscopic unit a high volume of care, tailored to individual patient needs, is delivered by differently trained staff working with specialised technology in a busy and sometimes challenging environment.

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

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

A 'Never Event' has the potential to cause serious patient harm and can often, in cases of wrong device implantation cause disablement to the patient and instigate the need for a further interventional procedure. An error of this type is both devastating to patient and staff and not without further risk to the patient.

2. PURPOSE

The UHMB LocSsips for Endoscopic Device Verification Safety Standards are congruent with the NHS NatSsips (National Safety Standards for Invasive Procedures directive) . The standards in this LocSsip form an incremental checking process, when all the steps in the checking process are followed; they facilitate both assurance of the correct device and traceability standards for the correct device to be implanted into the correct patient.

The steps are simple and systematic; the Operator performing the endoscopic procedure and the procedural support team must ensure that 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 Safe Endoscopy Standards' (see Section 6 for link) which is embraced at UHMB for all patients undergoing endoscopic procedures in the unit.

3. SCOPE

The standards within this procedural document will be applicable to those endoscopic patients and practiced without deviation by the endoscopist (the Operator) and the procedural team when a device is to be implanted.

- The Endoscopist will retain the overall responsibility for ensuring that the correct type and size of device is implanted in the patient.
- The Endoscopist has overall responsibility for ensuring that no non retainable parts of the device are retained at implantation.
- The Endoscopist has accountability that any manufacturer's instructions and literature is fully understood and followed.
- The lead nurse in the procedural support team has overall responsibility to ensure that tracking, traceability and re ordering occurs.

4. PROCEDURE

Local Safety Standards for device selection and verification
Device and Implant stock should be safely stored as close to the procedural room as possible, If practicable they can be stored on a moveable stock retaining trolley. This can then be move in and out of procedural rooms as required.

4.1 STEP 1: Prior to the commencement of the endoscopic list

- Stock reconciliation must be undertaken on a regular basis by the team and a record or log kept to demonstrate it has occurred..
- Discussion regarding device availability must occur on the day of scheduled lists and prior to the list start at the list Safety Briefing.
- It is the responsibility of the Operator to confirm that the implants present are suitable for the patients scheduled on the list.

4.2 STEP 2: Device size confirmation and initial verification during the endoscopic procedure

The following must be verbally stated in a clear auditable tone by the operator:
- The device name
- The device size
- The side if relevant
- A support member of the eam must confirm the implant request and log it on a white board along side the patients name and RTX number in the procedural room..
- The Operator must acknowledge and confirm this is the correct requested implant/device that they have requested.before they are selected

4.3 STEP 3: Final device Verification prior to implantation

The Operator must confirm that the boxed implant before it is opened is the required device/implant and the log on the white board should be used as a cross check.

This verification check must also include integrity of the prosthesis packaging for:
- Sterility including the Expiry date of sterility
- Red Gamma Dot identification where appropriate
- Size, type and side if applicable

4.4 CHECK 4: Traceability, Record Keeping & Reordering of Prosthesis implanted

- In each procedural room where devices are implanted, a traceability implant book must be maintained.
- 1 set of stickers from the device must be secured in the procedural room 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 if required.
- 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).
- The device size/s will also be logged into patients electronic care record where systems allow.
- The white board in the procedural room is cleaned for subsequent patients.

4.5 Endoscopic Devices List

The manufacturer or device may change; the standards for implantation remain the same.

- Oesophageal stents -CareFusion
- Rectal stents -Boston Scientific
- Biliary stents- Cook
- Endoclips- Boston Scientific
- Polyloops -Olympus

4.6 Errors, Discrepancies, untoward events

- Errors, discrepancies or near misses are untoward incidents.
- Detection of a wrongly implanted device is not exclusively limited to the time of insertion. It can be after or at clinic follow up upon realising any device implanted 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 Trust's Policy for the management of incidents (see Section 6 for link).
- Always ensure that Duty of Candour if to be applied is followed according to policy (see Section 6 for link to 'Being Open' policy).

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

6 OTHER RELEVANT / ASSOCIATED DOCUMENTS	
Unique Identifier	**Title and web links from the document library**
Endo/LocSsip/002	LocSsip for: 4 Steps for Patient Safety (Endoscopy) http://uhmb/cs/tpdl/Documents/ENDO-LOCSSIP-002.docx
Corp/Proc/022	Reporting and Investigation of Incidents including Serious Incidents http://uhmb/cs/tpdl/Documents/CORP-PROC-022.docx
Corp/Pol/023	Being Open http://uhmb/cs/tpdl/Documents/CORP-POL-023.docx

7 SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS **References in full**	
Number	**References**
1	Revised Never Events Policy and Framework – NHS England 2016/17 https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/never-evnts-pol-framwrk-apr2.pdf
Bibliography	
	National Safety Standards for Invasive Procedures (NatSsips) Standardise, educate, harmonise, Commissioning the conditions for safer surgery Report of the NHS England Never Events Taskforce February 2014 https://www.england.nhs.uk/wp-content/uploads/2015/09/natssips-safety-standards.pdf

8 DEFINITIONS / GLOSSARY OF TERMS	
Abbreviation or Term	**Definition**
CIR	Clinical Incident Report
ICP	Integrated Care Pathway
UHMB	University Hospitals Morecambe Bay
MBHT	Morecambe Bay Hospital Trust

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**	**Date Consulted**
Rosalind Fawcett	Endoscopy Unit Manager	
Suzanne Langley	Endoscopy Unit Manager	

10 DISTRIBUTION PLAN	
Dissemination lead:	Sue Wroe
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	
Proposed actions to communicate the document contents to staff:	Include in the UHMB Weekly News – New documents uploaded to the Document Library

11 TRAINING		
Is training required to be given due to the introduction of this procedural document? No		
Action by	**Action required**	**Implementation Date**

12 AMENDMENT HISTORY				
Revision No.	**Date of Issue**	**Page/Selection Changed**	**Description of Change**	**Review Date**

Appendix 1: Description of NatSsip

Description of NatSsip 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		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.		Standard 4 4.1 check 1 bullet point 5	Yes
A record of implants must be made		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.		As above	Yes
Reconciliation of item used during invasive procedure		4.4 Reordering	Yes

Appendix 2: Equality & Diversity Impact Assessment Tool

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Equality Impact Assessment Form

Department/Function	Endoscopy			
Lead Assessor	Sue Wroe			
What is being assessed?	Local Safety Standard for Invasive Procedures (LocSsip) for: The verification and opening of devices for endoscopic implantation			
Date of assessment	17/11/2016			
What groups have you consulted with? Include details of involvement in the Equality Impact Assessment process.	Equality of Access to Health Group	☐	Staff Side Colleagues	☐
	Service Users	☐	Staff Inclusion Network/s	☐
	Personal Fair Diverse Champions	☐	Other (Inc. external orgs)	☐
	Please give details:			

1) What is the impact on the following equality groups?

Positive:	**Negative:**	**Neutral:**
➢ Advance Equality of opportunity ➢ Foster good relations between different groups ➢ Address explicit needs of Equality target groups	➢ Unlawful discrimination, harassment and victimisation ➢ Failure to address explicit needs of Equality target groups	➢ It is quite acceptable for the assessment to come out as Neutral Impact. ➢ Be sure you can justify this decision with clear reasons and evidence if you are challenged

Equality Groups	**Impact** (Positive / Negative / Neutral)	**Comments** ➢ Provide brief description of the positive / negative impact identified benefits to the equality group. ➢ Is any impact identified intended or legal?
Race (All ethnic groups)	Neutral	
Disability (Including physical and mental impairments)	Neutral	
Sex	Neutral	
Gender reassignment	Neutral	
Religion or Belief	Neutral	
Sexual orientation	Neutral	
Age	Neutral	
Marriage and Civil Partnership	Neutral	
Pregnancy and maternity	Neutral	
Other (e.g. caring, human rights)	Neutral	

2) In what ways does any impact identified contribute to or hinder promoting equality and diversity across the organisation?	

3) If your assessment identifies a negative impact on Equality Groups you must develop an action plan **to avoid discrimination and ensure opportunities for promoting equality diversity and inclusion are maximised.**

- This should include where it has been identified that further work will be undertaken to further explore the impact on equality groups
- This should be reviewed annually.

Action Plan Summary

Action	**Lead**	**Timescale**

This form will be automatically submitted for review for Policies and Procedures once approved by Policy Group. For all other assessments, please return an electronic copy to EIA.forms@mbht.nhs.uk once completed.