University Hospitals of Morecambe Bay NHS Foundation Trust

Document Type: **Procedure**	**Unique Identifier:** CARDIO/LOCSSIP/001
Document Title: **Local Safety Standards for Invasive Procedures (LocSsips) for:** **The Verification and Opening of Devices for Cardiac Implantation (Cardiac Catheter Lab)**	**Version Number:** 1 **Status:** Ratified
Scope: Patients undergoing a cardiological procedure where a specified item or device is to be implanted.	**Classification:** Departmental
Author / Title: 1. Sue Wroe, Governance Lead NatSsips Quality & Governance 2. Alison Capps-Nevett, Lead Radiographer Cardiac Catheter Lab	**Responsibility:** Cardiologists (The operator) Cardiac Physiologists Clinical unit Manager All nurses, radiographers and support staff working in the cardiology unit.
Replaces: New	**Head of Department:** Sarah Hunter Ward Manager MBCC
Validated By: Medicine Divisional Procedural Documents Group	**Date:** 07/07/2016
Ratified By: Medicine Divisional Governance and Assurance Group	**Date:** 16/09/2016
Review dates may alter if any significant changes are made	**Review Date:** 01/08/2019
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 cardiac catheterisation 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 of the wrong cardiac device or requested size 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 Cardiac Verification Safety Standards, are congruent with the NHS NatSsips (National Safety Standards for Invasive Proceedures directive) . The standards in this LocSsip form an incremental checking process, when all the steps in the checking process are followed; they facilitate safety and assurance standards for the correct device to be implanted into the correct patient.

The steps are simple and systematic; the Operator performing the cardiogical 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 of the 'cardiac safety checklist ' which is embraced at UHMB for all patients undergoing cardiac procedures /stentings in the unit.

3. SCOPE

The standards within this procedural document will be applicable to those cardiac patients and practiced without deviation by the operator and the procedural team when a device is to be implanted.

- The operator will retain the overall responsibility for ensuring that the correct type and size of device is implanted in the patient.
- The operator has overall responsibility for ensuring that no non retainable parts of the device are retained at implantation.
- The operator has accountability that any manufacturer's instructions and literature is fully understood and followed.
- The clinical lead in the procedural support team has overall responsibility for ensuring that recording of the implant for traceability is undertaken and for documenting the device type used to facilitate the ordering process.

4. PROCEDURE

4.1 Check 1

- Device availability for the forthcoming list must have occured at the list Safety Brief which is undertaken on the day prior to the start of the scheduled list..
- Clinical indications determine the type of implant device for each patient. This is assessed and verified by the Operator in collaboration with the Cardiac Physiologist and the support team.

4.2 Check 2: Device size confirmation and initial verification during the cardiological procedure

- When surgical/vascular access has been sucessfully established, the operator must confirm the device required for implantation for that patient.
- In a clear and auditable tone the operator states the device required and includes the following:

    - Device name,
    - Device accessories and other relevant implant information
    - Device size and other relevant implant information,
    - Device side if appliciable

- A runner in the support team ensures this information is written on the procedural room white board.
- The operator must read the recorded information on the white board and confirm this is his request.
- The written information is patient specific and should not be removed until the procedure for that patient is completed and sign out has occurred, but before a new patient enters the procedural room

4.3 Check 3: Final device Verification prior to procedural implantation

- The runner ensures that the device selected matches the requested device on the white board.
- At the appropriate time the device is visualy confirmed bythe operator and the following checks are made:

    - The integrity of the packaging is checked.
    - Make/Manufacturer
    - Size
    - Sterility date or expiry is checked to ensure the device is in date of its sterilisation life cycle.
    - Red Gamma Dot identification where appropriate.

4.4 Traceability, Record Keeping & Reordering of Implant/Device implanted

- A traceability log of all devices implanted must be kept in each procedural room where devices are implanted in patients.
- 1 set of stickers from the device must be secured in the device 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 the implant device is recorded onto a National data base NICOR (National Institute for Cardiovascular Outcomes Research).
- Records of the implant device are logged for each patient on a local spreadsheet which serves as a local traceability tool as well as a means of managing stock control for reordering purposes**.**

4.5 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 Trusts 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).

4.6 Procedure/Devices Currently in use at UHMB

- Insertable Cardiac Monitor System
  - Medtronic Reveal XT 9529/9539
- Single Chamber Pacemaker
  - Boston Scientific Essentio MRI SR Ref L100 (Magnetic Resonance Imaging compatible
- Dual Chamber Pacemaker
  - Boston Scientific Essentio MRI DR Ref L111 (Magnetic Resonance Imaging compatible)
- Cardiac Resynchronisation Therapy Pacemaker
  - Boston Scientific Visionist X4 CRT-P Ref U228
  - Boston Scientific Visionist CRT-P Ref U225
- Coronary Stent System for using in Emergency Setting only
  - Abbott Xcience Pro Everolimus Eluting Coronary Stent System
    - 2.15mm/18mm
    - 3.50mm/12mm
    - 3.50mm/18mm

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**
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**
N/A	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

8 DEFINITIONS / GLOSSARY OF TERMS	
Abbreviation or Term	**Definition**
Operator	Term identified by NatSsips recommended to be used to describe the clinician or practitioner undertaking the procedure.
C.I.R.	Clinical Incident Report
I.C.P.	Integrated Care Pathway
UHMB	University Hospitals Morecambe Bay
M.B.H.T.	Morecambe Bay Hospital Trust
N.I.C.O.R.	National Institute for Cardiovascular Outcomes Research
MDT	Multi-Disciplinary Team

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**
Adrian Brodison	Consultant Cardiologist UHMB
Sasalu Deepak	Consultant Cardiologist UHMB
Michael Coupe	Consultant Cardiologist UHMB
Sarah Hunter	Ward Manager MBCC
Suzanne Collett	Clinical Leader MBCC
Jerzy Wojciuk	Consultant Cardiologist UHMB
Kay Smith	Team Leader Clinical Investigations Cross Bay
Dawn Kirkpatrick	Senior Cardiac Physiologist
Lucy Gomersall	Senior Cardiac Physiologist
Gail Vickers	Deputy Lead Radiographer Cath lab

10 DISTRIBUTION PLAN	
Dissemination lead:	Alison Capps-Nevett
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:	Include in the UHMB Weekly News; New documents uploaded to the Document Library Include in the Divisional Monthly Newsletter Share with Leads of Services within the Multi-Disciplinary Team for dissemination to individual clinical staff groups

11 TRAINING Is training required to be given due to the introduction of this procedural document? Yes		
Action by	**Action required**	**Implementation Date**
Alison Capps-Nevett MDT Cardiology Leads of Service	To present and discuss at Staff meetings to capture all MDT staff groups	December 2016

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 device required	Primary Operator Cardiologist	Standard 4 4.1 check 1 bullet points 1 to 4.	Yes
The operator must visually inspect and confirm the devices with the team prior to the patient being sent to the procedural area.	Primary Operator Cardiologist	Standard 4 4.1 check 1 bullet point 5	Yes
A record of implants must be made which facilitates tracking and traceability of devices to patients.	All Cardiac MDT	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 Cardiac MDT	As above	Yes
Reconciliation of item used during invasive procedure	Cardiac 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:**		
	• 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.