Worcestershire Acute Hospitals NHS Trust

Local Safety Standards for Implant Verification in Theatre

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

- Insertion of an implant is a key procedural event. It is important that the correct patient receives the correct implant and that this is achieved safely and efficiently.
- All prosthetic implants should be checked prior to use by the surgeon and scrub practitioner.
- Nationally, wrong prosthetic implant is one of the most frequently occurring 'Never Events'.
- Following the described local safety standards should help reduce the risk of wrong implant insertion.

This guideline is for use by the following staff groups :

Surgeons
Theatre team members (registered and non-registered staff)
Procurement and stores teams

Lead Clinician(s)

James Hutchinson	Consultant Anaesthetist
Approved by *TACCSS* ……. on:	17th January 2024
Review Date	17th January 2027

This is the most current document and should be used until a revised version is in place:

Key amendments to this guideline

Date	Amendment	Approved by:
17th Jan 24	Document approved	TACCSS

Local Safety Standards for Implant Verification

Summary of Guideline

Before the procedure

Operating list should contain details of whether or not an implant is required.

A named team member should be responsible for ordering the implant and checking it is correct before the procedure.

At Team Brief

The surgeon should confirm the implant if possible. Otherwise, they should confirm that the specific implant will be decided during the procedure.

If the exact implant is unknown, confirm with the runner that they know where each possible implant is.

One member of the team should check implant is available (or range is available from which the final choice will be made).

At Sign In

Availability of required implant should be confirmed.

At Time Out

Implant requirements and availability should be confirmed at the Time Out.

Where implant is known the type of implant should be written down (i.e. on whiteboard or paper). If exact implant is unknown, the runner should be asked to confirm they know the location of each possible implant.

'Implant Time Out' - during the procedure

When known, the specifications of the implant should have been written down (i.e. on the theatre whiteboard or paper).

Only a regular member of staff should obtain and handover an implant (a company representative should not do this task).

The runner should show the surgeon the implant who should read aloud the details. The following specifications should be checked, when relevant:

- Type
- Laterality
- Size
- Expiry date

- Sterility

If there are subsequent implants the same process is followed. *Compatibility* should also be confirmed.

Customised implants should be cross-checked with the patient's wrist band.

At Sign Out
The Surgeon should confirm the implant used and a record of the implants must be made in the patient records.

Introduction

An implant is an item intended to remain in the patient's body long term. The term 'Prosthesis' implies a replacement part. It includes stents, pacemakers and mesh.

Any item which is intended to be removed (e.g. a wire to hold a fracture which will be removed in a few weeks) is not described as an implant.

Wrong implant insertion remains one of the more common 'Never Events'. Following the described local safety standards should help reduce the risk of wrong implant insertion.

Organisational Standards.

A named individual should be responsible for checking stocks, ordering, organised storage, ensuring expiry dates are checked regularly and removing implants past their expiry date.

The organisation should have a process in place for recording which implants are used for which patients. For most implants this is a national requirement (e.g. breast and joint implants).

Appropriate and agreed stock levels should be maintained.

Errors or near misses with implant insertion should be reported and discussed at de-brief and fed into local governance processes, i.e. by datix completion.

Before the procedure

When the patient is scheduled the list information should include whether or not an implant(s) is required. This is of particular relevance to custom implants.

Implants should be kept adjacent to the procedure area. Ensure that excessive numbers of unneeded implants are not in the theatre.

Elective lists, within reason, should have information of which implants are required before the day of the procedures. Emergency / Trauma list information will enable implant stock checks on the day.

A named team member, usually a senior practitioner, should order the implants and check that the correct implant has been delivered before the procedure. This information should be available to the rest of the team. This team-member should check sterility and expiry dates.

At Team Brief

The operator should confirm whether or not an implant is required, if the type of implant is known, or if the specific implant will be decided during the procedure.

If other implants are needed for fore-seeable back-up, this should also be discussed and checked.

If the exact implant is not known, confirm with the runner that they know where each possible required implant is.

One member of the team should check that the implant is available, or that the expected range of implants from which the final choice will be made is available.

At Time Out

If the implant is known, the team should confirm the type of implant and write it down (on paper or a whiteboard in the theatre). The requested implant details must be written down in any situations where there is an appreciable gap between request and implantation, or where implants are in a different physical location.

If the exact implant is not known, confirm with the runner that they know where each possible required implant is; and which are compatible with each other.

Implant Time Out - during the procedure

Only a named regular member of staff (e.g. the runner) should receive the request, obtain, and hand over an implant. A company representative must not do this task.

Dependent on the context, when the operator requests the implant, it may be appropriate for the runner (or another team member) to write down the requested implant on the whiteboard (or on paper).

The runner obtains the implant and shows it to the surgeon, who 'reads aloud' the implant details:

- Type
- Laterality (when applicable)
- Size
- Expiry date
- Sterility

If it is a custom-made implant the implant details should be cross-checked with the patient's wrist band.

The runner then opens the implant, and the operator or scrub practitioner receives it. All packaging is kept.

Labels are placed in the theatre record and the patient notes, or electronic equivalent.

If there are subsequent implants the same process is followed. In addition, the operator should check *is this compatible with the previous implant*?

Sign Out

At Sign Out the operator confirms the implant.

A record of the implants used must be made in the patient's records. Appropriate details should be shared with the patient after the procedure. When a manufacturer's label is available, this should be placed in the notes.

When it is not, for example with electronic patient records, the following should be recorded:

- Manufacturer
- Style
- Size
- Manufacturer's unique identifier for the implant, or the serial number
- Expiry date

Compliance with local, national and international implant registries is encouraged, and in certain cases may be a mandatory legal requirement.

Monitoring Tool

This should include realistic goals, timeframes and measurable outcomes.

How will monitoring be carried out?

Who will monitor compliance with the guideline?

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.
	Compliance with key consent and site marking standards	Regular reporting via Theatre dashboard	At TACCSS governance meetings	Theatre staff	Governance lead Band 7 and Band 8 Theatre staff	6 times per year

References

National Safety Standards for Invasive Procedures 2 (NatSSIPs) January 2023. Centre for Perioperative Care. https://cpoc.org.uk/sites/cpoc/files/documents/2022-12/CPOC_NatSSIPs2_Implant_2023.pdf

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Orthopaedic Consultant Surgeons: Mr Docker, Mr Bell, Mr O'Dwyer
Theatre Manager: Matthew Trotman
Theatre Manager – Kim Simpson

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Surgical Quality Governance Lead – Louise Shaw Jones

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	NA	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
5.	**If so can the impact be avoided?**	NA	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	NA	
7.	**Can we reduce the impact by taking different action?**	NA	

If you have identified a potential discriminatory impact of this key document, please refer it to Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Human Resources.

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval