Implant Verification

Insertion of an implant is a key procedural event. It is important that the correct patient receives the correct implant(s) and that this is achieved safely and efficiently.

These simple safety standards aim to minimise errors and take away some of the cognitive burden, helping teams to insert implants safely by providing standardised pre- and peri-procedural processes for checking that the correct implant is selected for use.

The implant checks should be brief/minimal in duration, to reduce the risk of a wrong implant and keep in perspective the actual level of risk. Lengthy checks may introduce new risks by over burden of checks, checking fatigue and unnecessary delay.

Planning in advance of the procedure, standardisation of processes and education of all staff are important elements in ensuring that the correct implant is chosen.

These processes aim to increase understanding of risk and to strike a balance between a rigid checklist and the avoidance of automaticity which may lead to error.

Technological / engineered solutions may be of benefit, but currently, and for the foreseeable future, there will be human involvement in selection and checking processes HSIB have completed relevant investigations to this standard with a systems perspective.[92 93]

Definition of an implant

An implant is an item intended to remain within the patient's body long term. The term prosthesis is sometimes used, but this usually implies a replacement part. The term implant is used here as it is broader and includes stents, pacemakers and similar devices.

What is not an implant?

An item which is intended to be removed, e.g. a wire to hold a fracture that will be removed in clinic in a few weeks. An item which is left in the body that was not intended to be an implant, e.g. the tip of a drill bit which breaks in a bone and a decision is made that it would be better to leave it in the body than to retrieve it.

Sometimes a device or kit is used to insert an implant, such as a stapling device in bowel surgery. An understanding of the component parts is important to avoid a retained foreign object and should be subject to count procedure (See standard 6 Reconciliation of items). If an implant is used, a full count procedure is required in any invasive setting e.g. pacemakers, knee replacement.

Types of Implant Terminology

Type specific implant - chosen for laterality, power, size e.g. knee, breast, lens, coils, stents

Custom implant - made for the patient e.g. cranioplasty

Biological implant - from a human or animal e.g. rib in rhinoplasty or valve in cardiac

Electrical implant - e.g. generator or pacemaker

Multi-part implant - compatible parts fit together

Onyx/Glue Implant - is an injectable substance that hardens into an implant

Standards dependent on timing of implant decision

In general, the choice of implant is made at one of three times, and this will affect the process for checking the implant(s) before implantation:

a) **Known implant.** When the exact implant(s) is known before the procedure. This includes custom-made or biological implants. It also includes batteries / generators for an in-situ device that need changing, a lens in eye surgery or a custom cranioplasty implant.

b) **Restricted/evolving decision/choice.** When the exact size or type of implant is decided upon during the procedure. e.g. joint prostheses.

c) **Unplanned or unexpected implant insertion.** Local practice will determine whether on table measurement or templating is required to guide which intended implant is requested, for example, endovascular stents or knee replacement.

The requested implant details should be written down in any situations where there is an appreciable time gap between request and implantation, or where implants are in a different physical location. Local units must agree on a process that meets these standards, taking into account local practices and environment.

Standards dependent on the number of implants

- If there is only one implant, the minimum information that should be checked is:
  - Type of implant/prosthesis/device
  - Laterality (when applicable)
  - Size (all relevant dimensions)
  - Expiry date
  - Sterility
- In addition, if the implant is custom-made, the name, date of birth, and a unique number (NHS number and/or hospital number) should be cross-checked with the patient's identity band. Some specialties will specify additional items.

Standards dependent on more than one implant (including screws)

- The key additional factor for the second and subsequent implants that should be checked is compatibility. Some specialties will have additional items, for example, an orthopaedic operation which involves the use of different screws may wish to add "size 40, four zero" on giving and receiving each. Compatibility will be context specific, e.g. type of material, size of implant relative to other components. The key question for the operator and those giving the implant is simply, 'Is this the correct implant to be used in this situation?' There will be occasions when the operator deliberately and appropriately chooses to use implants that are not intended to be used together. This is a justifiable clinical decision.

Standards for organisations

- When permanent stocks of implants are maintained in the organisation, a named individual should be responsible for: checking stocks, ordering, organised storage, ensuring that expiry dates are checked regularly, and that any implants that have passed their expiry dates are removed and cannot be used.
- Some organisations use scanning technology to track and reconcile equipment, prostheses and implants, and procedures for each patient. This could be extended to more implants and / or provide an alert when there is a patient/product mismatch,[92 93] in addition to providing up to date stock information.
- The organisation must have a process in place for recording which implants/prostheses are used for which patients. For most implants this documentation is a national requirement, e.g. breast and joint implants.
- The organisation should ensure that appropriate and agreed stock levels of implants/prostheses are maintained.
- Errors or near misses with correct implant insertion should be reported, recorded and openly discussed at the Debrief, and fed into local governance processes to act as the basis for learning and the development of new or altered procedures to promote patient safety.
- When manufacturers' labelling, packaging or implant defects contribute to failure of implant verification, a process should be in place through which both the manufacturers and the MHRA (Devices) are informed.[94]
  - Access MHRA reporting via this link https://yellowcard.mhra.gov.uk/

Before the procedure

- When the patient is scheduled for an invasive procedure, the waiting list or scheduled list information should be clear and detail whether or not an implant(s) is required. This is of particular relevance to custom or type specific implants.
- Implants should be kept adjacent to the procedure room. Local units should ensure that excessive numbers of unneeded implants are not in the theatre/room.
- Elective lists, within reason, should have information of which implants are required before the day of the procedures. Emergency or Trauma list information will enable implant stock checks or decisions on the day.
- A named team member, usually a senior practitioner or team lead, should be responsible for ordering the implant(s) and checking that the correct implant has been delivered and stored 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 foreseeable 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; and which are compatible with each other.
- 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. Local units must agree on a process that meets these standards, taking into account local practices and environment.
- 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.
- Any operator sight issues and the need for spectacles to assist checking should be declared and acknowledged.

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). This Implant check step is sometimes called an 'Implant Time Out' or 'surgical pause for implant'[93] and helps refocus the team in theatre. The runner obtains the implant and shows it to the operator, who 'reads aloud' the implant details:
  - Type
  - Laterality (when applicable)
  - Size
  - Expiry date
  - Sterility
- If it is a custom-made implant, the name, date of birth and another identifier (NHS number or hospital number) 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:
    i) Is this compatible with the previous implant?

ii) Any other information relevant to this specialty, e.g. size

- 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.

In summary

Implants checks are required for all specialties that insert implants

Before starting: Formally verify that expected implants are available

On requesting: Write it down if there is a time gap between request and implantation

Before implanting:

Formal verification by operator

Always confirm compatibility for multiple implants

After implantation:

Ensure details are recorded in an auditable process

Please see the 'Performance Indicators NatSSIPs'