The selection and insertion of vascular grafts in haemodialysis patients

Independent report by the Healthcare Safety Investigation Branch NI-003683

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A note of acknowledgement

We would like to thank David, the husband of Teri whose experience is documented in this report. We would also like to thank the healthcare staff involved in Teri’s care, for their openness with the investigation and willingness to support improvements in this area of care.

Additionally, we want to acknowledge the other NHS staff involved who gave their time to provide information and expertise which contributed towards this report, and the stakeholder organisations and professional bodies that have supported the investigation.

About Teri

Teri was a loving mother, grandmother and wife, and had a warm and easy way of relating to everyone she met. She had a passion for photography and photographed weddings and portraits for her clients. Teri’s role as a professional make-up artist earlier in life gave her an eye for detail and an artistic flair that she used to create beautiful images.

About this report

This report is intended for healthcare organisations, policymakers and the public to help improve patient safety in relation to the selection and insertion of vascular grafts. For readers less familiar with this area of healthcare, medical terms are explained in section 1.
Our investigations

Our investigators and analysts have diverse experience of healthcare and other safety-critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes:

National investigations

Concerns about patient safety in any area of NHS-funded healthcare in England can be referred to us by any person, group or organisation. We review these concerns against our investigation criteria to decide whether to conduct a national investigation. National investigation reports are published on our website and include safety recommendations for specific organisations. These organisations are requested to respond to our safety recommendations within 90 days, and we publish their responses on our website.

Maternity investigations

We investigate incidents in NHS maternity services that meet criteria set out within one of the following national maternity healthcare programmes:

- Royal College of Obstetricians and Gynaecologists’ ‘Each Baby Counts’ report
- MBRRACE-UK ‘Saving Lives, Improving Mothers’ Care’ report.

Incidents are referred to us by the NHS trust where the incident took place, and, where an incident meets the criteria, our investigation replaces the trust’s own local investigation. Our investigation report is shared with the family and trust, and the trust is responsible for carrying out any safety recommendations made in the report.

In addition, we identify and examine recurring themes that arise from trust-level investigations in order to make safety recommendations to local and national organisations for system-level improvements in maternity services.

For full information on our national and maternity investigations please visit our website.
Executive summary

Background

This investigation aims to improve patient safety by supporting healthcare staff in a surgical setting to select and insert the appropriate type of implant (vascular graft) for haemodialysis treatment.

Dialysis is a procedure to remove waste products and excess fluid from the blood when a person's kidneys stop working properly. Almost 30,000 people in the UK receive regular dialysis. The most common type of dialysis is haemodialysis, during which a patient’s blood goes through a tube into a machine to be filtered, and is then passed back into the patient’s body. To carry out haemodialysis, access is required to the bloodstream; one option for this is a vascular graft. This is a synthetic implant used to connect an artery and vein, to create a larger and stronger opening through which the blood can travel.

There are numerous types of vascular grafts produced by different manufacturers. Vascular grafts are available in different diameters and lengths, and may be either tapered or non-tapered in shape. Some vascular grafts are for delayed use, needing around 2 weeks between insertion and first use, and others are for rapid access and can be used approximately 72 hours after insertion.

This investigation used a real patient safety incident, referred to as ‘the reference event’, to examine aspects of the selection and insertion of vascular grafts, including measures to ensure the correct type is inserted. The reference event involved Teri, who had to undergo an additional procedure after the incorrect type of vascular graft was inserted for haemodialysis treatment.

The investigation’s findings, safety recommendations and safety observations aim to prevent the selection and insertion of incorrect vascular grafts from happening in the future and to improve care for patients across the NHS.

The reference event

Teri had chronic kidney disease (a long-term condition resulting in a gradual loss of kidney function) and needed regular haemodialysis.

Teri had previously received haemodialysis via a connection between an artery and a vein. However, this connection was failing due to narrowing of the blood vessels and she needed to have a vascular graft implanted so that her treatment could continue.
Teri was referred to her local hospital for insertion of a ‘rapid access’ type of vascular graft, to enable her haemodialysis treatment to be carried out as planned. Before Teri’s operation, a consultant vascular surgeon and members of the operating theatre team went to the store cupboard to look at the types of vascular grafts stocked. The consultant vascular surgeon was not sure which size would be needed, so two different sized vascular grafts were selected. However, it was not recognised at the time that they were different types of vascular graft, with one being the intended rapid access type and the other a delayed use graft.

Following surgery, the consultant vascular surgeon immediately realised that a delayed use vascular graft had been inserted instead of a rapid access graft. This was identified by the sticker from the graft’s packaging which had been placed on Teri’s medical records, and confirmed by checking the empty box that the graft had been taken from.

Because the wrong type of vascular graft was inserted, Teri needed to have another surgical procedure and an overnight stay in hospital, which may not have otherwise been needed. The further procedure was required to enable Teri to have haemodialysis during the interim period (approximately 2 weeks) before the delayed use graft could be used.

The national investigation

This incident was referred to HSIB by the Trust where the reference event occurred. This was following a serious incident investigation by the Trust; a referral to the manufacturer of the vascular graft concerning the packaging; and a notification to the Medicines and Healthcare products Regulatory Agency, due to other incidents involving similar packaging at the Trust.

HSIB’s Chief Investigator authorised a national investigation, which explored the factors that affect the ability of staff to safely select and insert vascular grafts for haemodialysis treatment. The national investigation focused on:

- The identification of factors within the healthcare system as a whole that influence patient safety risks associated with the selection and insertion of vascular grafts in an operating theatre environment.

- Exploration, using a systems approach, of the design of labelling and packaging used for the different types of vascular grafts for patients on haemodialysis treatment.

- Exploration of the impact on operating theatre teams of staff redeployment and repurposing of working environments in response to the COVID-19 pandemic.
Findings

• The packaging of rapid access and delayed use vascular grafts may be very similar, resulting in an increased risk of staff selecting and inserting the wrong type of graft.

• The wording used on packaging and labels to describe vascular grafts does not reflect the terminology used by clinicians in the operating theatre.

• There is Medicines and Healthcare products Regulatory Agency (MHRA) guidance for the labelling and packaging of medicines, but not for medical devices such as vascular grafts.

• There was a lack of standardisation and therefore variation in how checklists and ‘team briefs’ (procedures that aim to ensure patient safety) were completed/conducted and recorded in different operating theatres.

• The incorporation of national safety standards alone may not be successful without an embedded safety culture being in place.

• Barcode scanning technology (Scan4Safety) can be used to mitigate the risk of an incorrect medical device being selected/inserted. Due to the reduced central management of the Scan4Safety programme, trusts have been developing applications and using adaptations of the scanning technology, resulting in inconsistent use and variable effectiveness.

HSIB makes the following safety recommendations

Safety recommendation R/2023/236:
HSIB recommends that NHS England reviews system requirements for barcode scanning technology, in order to support local organisations to reduce the risk of incorrect selection and insertion of prostheses/implants.

Safety recommendation R/2023/237:
HSIB recommends that the British Standards Institution updates the applicable standard/s, and raises with the International Organization for Standardization, to state that medical device labelling and packaging should detail the specific use of an item. This should be developed with user input to drive consistency in the terminology used on medical device labelling/packaging.
Safety recommendation R/2023/238:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency ensures the assurance processes for designated approved bodies (to check medical device manufacturers conform to packaging standards) are amended to consider context of use and usability guidelines, to reduce the risk of selecting and inserting the incorrect device.

Safety recommendation R/2023/239:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency publishes guidance on the labelling and packaging of medical devices, to promote best practice and reduce selection of the incorrect item.

HSIB makes the following safety observations

Safety observation O/2023/226:
It may be beneficial if the term ‘user’ in the context of medical devices was defined in international and national standards to incorporate all staff who interact with the device, including those who select the device, check it before use and use it.

Safety observation O/2023/227:
It may be beneficial for healthcare organisations to deliver multi-disciplinary team training on the key principles of the revised ‘National safety standards for invasive procedures’ to support the implementation and embedding of these standards.

Safety observation O/2023/228:
It may be beneficial for trusts to assign experienced operating theatre clinicians to lead on the implementation of the ‘National safety standards for invasive procedures’, to address the cultural issues hindering implementation.
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1 Background and context

This investigation aims to improve patient safety by supporting healthcare staff in a surgical setting to select and insert the appropriate type of implant (vascular graft) for haemodialysis treatment.

HSIB identified a patient safety risk in this area of healthcare following the referral of an incident by a trust. The incident, which is referred to in this report as the reference event, involved the selection and insertion of the wrong type of vascular graft.

This section of the report explains haemodialysis and the methods, including vascular grafts, that are used to access a patient’s bloodstream to enable them to receive haemodialysis. It also explains the regulation of medical devices such as vascular grafts, and the roles of the surgical team members who were involved in the reference event.

1.1 Kidney disease

1.1.1 Chronic kidney disease (CKD) is a long-term condition that results in abnormal kidney function. Normally, the kidneys filter a person’s blood, removing harmful waste products and excess fluid which are passed out of the body as urine. If a person’s kidneys are not functioning properly, the blood will not be filtered (NHS, 2022).

1.1.2 It is estimated that around 6% of people in England (3 million) have CKD (National Institute for Health and Care Research, 2022). The type of treatment a person with CKD is given depends on how severe their condition is (NHS, 2022).

1.2 Dialysis treatment

1.2.1 Dialysis is a treatment for people with CKD. It filters out the unwanted substances and fluids from their blood (NHS, 2022).

1.2.2 Dialysis treatment can be provided in the form of haemodialysis or peritoneal dialysis:

- Peritoneal dialysis uses the inside lining of the person’s abdomen to filter their blood. It can be carried out by the patient at home and involves a thin tube (catheter) inserted into the stomach.

- Haemodialysis is the most common type of dialysis. During haemodialysis, a tube is attached to a needle into the patient’s arm. Blood passes along the tube and into an external machine. The machine filters the blood,
which is then passed through another tube back into the patient’s arm. At dialysis centres, a patient will usually have haemodialysis three times a week, with each session lasting around 4 hours (NHS, 2022).

1.3 Preparing for haemodialysis treatment

1.3.1 Access to the bloodstream is needed so that blood can be taken from the patient, passed through the haemodialysis machine and back into the patient’s body continuously throughout their treatment. This ‘access’ can take three different forms (see figure 1):

- An arteriovenous (AV) fistula. This is created by connecting a vein to a nearby artery in the patient’s arm to allow the blood vessel to enlarge and become thicker.

- An AV graft. This is a graft of synthetic tissue which can be used to connect an artery and vein, usually in the arm. This is the preferred option if the patient’s veins are too narrow for an AV fistula. The procedure to insert an AV graft takes place in an operating theatre with the patient under local anaesthetic.

- A haemodialysis central venous catheter. This is used for patients where an AV fistula or AV graft is not technically possible, or dialysis treatment is needed urgently. The catheter (tube) is usually inserted into the jugular (neck) vein.
Figure 1 Arteriovenous (vascular) fistula, vascular graft and central venous catheter

A arteriovenous fistula
B arteriovenous graft

From dialysis machine

Synthetic bridge graft

To dialysis machine
C central venous catheter

From dialysis machine

Catheter

To dialysis machine

Right atrium
1.4 Types of arteriovenous grafts

1.4.1 AV grafts vary in characteristics such as length, width and shape – for example they can be tapered or non-tapered. They can be for delayed use (which means they cannot be used for haemodialysis for approximately 2 weeks after they are inserted) or rapid access/early cannulation (which means they can be used within 72 hours of insertion).

1.4.2 For readability, in this report arteriovenous (AV) grafts are referred to as vascular grafts or grafts.

1.5 Never Events

1.5.1 A vascular graft is a type of implant (prosthesis). The insertion of an incorrect implant is classified as a ‘Never Event’ (NHS Improvement, 2018). Never Events are ‘patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers’ (NHS Improvement, 2018).

1.6 Medical device regulation and standards

1.6.1 To comply with the EU’s Medical Device Directives (EU Council Directive 93/42/EEC, 1993) and the UK regulations (Medical Device Regulations 2002 (SI2002 No 618, as amended), manufacturers must undertake a ‘conformity assessment’ before devices can be used. This covers the whole process of providing a safe product (such as production or labelling). The device is then certified by an ‘approved body’ in the UK and a ‘notified body’ in the EU (Medicines and Healthcare products Regulatory Agency, 2020a).

1.6.2 There are a number of approved bodies in the UK and, until 30 June 2023, the Medicines and Healthcare products Regulatory Agency will also continue to accept assessments carried out by named notified bodies within Europe (Medicines and Healthcare products Regulatory Agency, 2020a).

1.6.3 Legislation is being put in place to extend the acceptance of CE marked devices on the Great Britain market beyond June 2023. CE marked devices currently make up the majority of those on the UK market and they are assessed by EU Notified Bodies over which the MHRA has no authority (Medicines and Healthcare products Regulatory Agency, 2023).

1.6.4 The International Organization for Standardization (ISO) and the British Standards Institution (BSI) provide standards for manufacturers to work to. These standards enable manufacturers to demonstrate to the approved bodies their compliance with the regulations. However, adoption of the
standards is voluntary. The standards relating to medical device packaging are ISO 15223-1:2021 (International Organization for Standardization, 2021), and ISO 15223-2:2010 (International Organization for Standardization, 2010).

1.7 Operating theatre multidisciplinary team composition

1.7.1 The operating theatre multidisciplinary team members involved in the reference event are referred to by their job titles in this report. Their roles and responsibilities are outlined in table 1.

<table>
<thead>
<tr>
<th>Multidisciplinary team member</th>
<th>Roles and responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant vascular surgeon</td>
<td>• A consultant surgeon has overall responsibility for the management of patient care.</td>
</tr>
<tr>
<td></td>
<td>• They usually specialise and may become highly skilled in one or two specific areas of surgery, in this case vascular surgery (specialising in conditions relating to the blood vessels) (Royal College of Surgeons of England, 2022).</td>
</tr>
<tr>
<td>Anaesthetist</td>
<td>• An anaesthetist is a specialist doctor responsible for providing anaesthesia and pain management to patients before, after and during surgical procedures (Royal College of Anaesthetists, 2023).</td>
</tr>
<tr>
<td>Anaesthetic practitioner</td>
<td>• An anaesthetic practitioner provides professional assistance and support to the anaesthetist. They may be a registered nurse with an approved anaesthetic qualification or a registered operating department practitioner (ODP).</td>
</tr>
<tr>
<td></td>
<td>• They are the link between the surgical team and other parts of the operating theatre and hospital (NHS England, 2023a).</td>
</tr>
</tbody>
</table>
| Scrub practitioner | • A scrub practitioner is either a registered nurse or a registered ODP. They assist surgeons during operations by handing and receiving swabs, needles and instruments in the sterile area around the operating theatre.

• Before surgery starts, they check that the equipment and instruments needed for the operation are complete.

• During the operation, they carry out a series of counts of instruments, swabs, needles, and equipment, to ensure that all are accounted for (RCNi, Nursing Jobs 2022).

| Circulating practitioner | • A circulating practitioner could be a registered nurse, registered ODP or a HCA (they were a registered nurse in the reference event).

• They perform safety checks with the patient and the rest of the team on arrival in the operating theatre.

• They assist the ‘scrubbed’ (wearing personal protective equipment) team members and open anything they require such as needles, swabs, extra instruments, and implants.

• They are also responsible for documentation during surgery.

• They count the instruments, sets and accountable items with the scrub practitioner (RCNi, Nursing Jobs 2022).

| Healthcare assistant (HCA) | • The role of an HCA in the operating theatre includes patient support, staff support (helping to set up and clear after each operation) and general duties. |
2 The reference event

This investigation used the following patient safety incident, referred to as ‘the reference event’, to examine the issue of incorrect graft selection and insertion.

2.1 Teri’s story

2.1.1 Teri needed dialysis treatment for chronic kidney disease (CKD). She had other pre-existing conditions including diabetes, limited mobility and poor vision. She had also been treated for colon cancer and a stroke. She lived with her husband who was her primary carer.

2.1.2 Before the reference event, Teri had been receiving haemodialysis via an arteriovenous fistula in her arm (see 1.3.1). However, the fistula was failing because of narrowing blood vessels and an alternative plan for treatment was needed.

2.1.3 Teri was seen in an outpatient clinic by a consultant vascular surgeon, who carried out an ultrasound doppler (a test using sound waves). This was to determine which of Teri’s veins and arteries could be used for haemodialysis.

2.1.4 After the appointment, the consultant vascular surgeon discussed the next steps for Teri’s treatment at a vascular multidisciplinary team meeting. To enable her to continue having haemodialysis, it was agreed to insert the rapid access type of vascular graft (see 1.4.1) and remove the failing arteriovenous fistula.

2.1.5 On the day of the vascular graft insertion, Teri was admitted to the day case suite at 07:15 hours. Here the consultant vascular surgeon and consultant anaesthetist (hereafter referred to as anaesthetist), discussed the planned procedure with Teri. The vascular surgeon then returned to the vascular operating theatre to start preparations for the operations scheduled for that day (the operating list), while Teri was on the ward being prepared for surgery. The preparations included a team brief.

2.1.6 At approximately 08:00 hours a discussion took place between the consultant vascular surgeon and scrub practitioners 1 and 2, regarding which vascular graft to use in the operation. It had been documented previously in the consultant vascular surgeon’s notes that Teri required the rapid access type of vascular graft.
2.1.7 The consultant vascular surgeon, assisted by scrub practitioners 1 and 2, went to the store cupboard in the vascular operating theatre. They were not sure which size of vascular graft would be needed, so a tapered vascular graft measuring 4 mm to 6 mm, and a 6 mm non-tapered type were selected. The consultant vascular surgeon believed both grafts to be the rapid access type. However, one was a 6 mm rapid access graft and the other a 4 mm to 6 mm tapered delayed use graft.

2.1.8 At approximately 09:22 hours, before Teri’s arrival in the vascular operating theatre, a team brief was held to discuss all the patients on the operating list for that day. The team brief took place in the anaesthetic room, with the consultant vascular surgeon, anaesthetist, scrub practitioners 1 and 2, and healthcare assistants (HCAs) 1 and 2. It was led by the consultant vascular surgeon, who acknowledged that two grafts had been placed on the trolley in the operating theatre.

2.1.9 Teri arrived in the vascular operating theatre at 09:41 hours and following preparations, the operation started at 10:54 hours. Teri remained awake throughout the procedure, talking to HCA 2.

2.1.10 The circulating nurse, who had been covering breaks for the team and supporting scrub practitioner 2, left for a lunch break at midday. This was before the implant check to confirm the details of the vascular graft before it was inserted.

2.1.11 When it was time to insert the graft, the consultant vascular surgeon asked for the smaller 4 mm to 6 mm vascular graft (a graft that tapers from 4 mm at one end to 6 mm at the other). Scrub practitioner 2 showed the vascular graft box to the consultant vascular surgeon and then to scrub practitioner 1, for them to check the details before opening the outer packaging.

2.1.12 During these final checks of the vascular graft before insertion, HCA 1 was outside the ‘scrub area’ in the vascular operating theatre (see figure 2). This is the sterile area where everyone must be in sterile gowns, sterile gloves and face coverings. Inside the scrub area were the consultant vascular surgeon and scrub practitioners 1 and 2.
Figure 2 Layout of the vascular operating theatre

A - Theatre table
B - Arm board
C - Scrub practitioner’s trolley
D and E - Trolleys containing equipment trays
F - Anaesthetic equipment
PC - Computer
Blue icon - Consultant anaesthetist
Orange icon - Operating department practitioner
Yellow icon - Healthcare assistant 2
Teal icon - Scrub practitioners 1 and 2
Green icon - Consultant vascular surgeon
2.1.13 Scrub practitioner 1 and HCA 1 left the vascular operating theatre at approximately 13:00 hours to prepare for an afternoon operating list in another location. The consultant vascular surgeon, scrub practitioner 2, the anaesthetist, HCA 2 and the ODP remained in the operating theatre. Teri’s procedure was completed at 14:04 hours and she was taken to the recovery/day surgery ward.

2.1.14 While completing the notes after the operation, the consultant vascular surgeon saw the stickers that had been taken from the vascular graft packaging by HCA 1 and placed in the notes. This indicated that a delayed use type of graft had been used. The consultant vascular surgeon immediately reviewed the discarded packaging to confirm the type of vascular graft that had been implanted. They then contacted the operating theatre matron to explain what had happened.

2.1.15 The consultant vascular surgeon spoke to Teri about what had happened and explained that she would need to have a haemodialysis catheter (see 1.3.1) inserted, to enable dialysis to continue while waiting to use the delayed use vascular graft. This was done at 18:06 hours without complication and Teri was discharged home the next day.

2.1.16 Approximately 2 weeks after the delayed use vascular graft was inserted, it could be used for dialysis. Teri recovered well from the procedure to insert the vascular graft and the subsequent haemodialysis catheter.

2.1.17 Since the reference event, Teri has sadly passed away from an unrelated cause.
3 Analysis and findings – the reference event

This section outlines the findings of the investigation’s analysis of the reference event, using the Systems Engineering Initiative for Patient Safety (SEIPS) (Holden et al, 2013). More information about the analysis methods used is available in the appendix.

The investigation aimed to understand the factors within the healthcare system that contributed to the selection and insertion of the incorrect vascular graft. The investigation considered:

- operating theatre procedures to mitigate the risk of incorrect prosthesis selection and insertion
- the vascular operating theatre team members’ knowledge, experience, and currency (how recent their experience was)
- the learning culture in vascular operating theatres.

3.1 Operating theatre procedures to mitigate the risk of incorrect prosthesis selection and insertion

Storage and selection of the different types of vascular grafts

3.1.1 The investigation was informed that the type of vascular graft used will depend on the needs of the patient, the trust’s preferred supplier and the preference of each surgeon. At the Trust where the reference event took place, this information was documented in A4 folders for the vascular operating team to refer to before working with different surgeons. For newly appointed surgeons this was particularly important as the operating theatre team would need to ensure the medical devices/equipment required were ordered/in stock.

3.1.2 There was a limited stock of vascular grafts within the Trust as they were expensive and used infrequently. If needed, a surgeon could order additional vascular grafts before planned surgical procedures.

3.1.3 The investigation was told that at the time of the reference event, the delayed and rapid access types of vascular grafts were not separated in the vascular operating theatre store cupboard.

3.1.4 In Teri’s case, the vascular operating theatre team was unaware of the consultant vascular surgeon’s preferences and the surgeon was unfamiliar with the types of vascular grafts stocked. This was because they were performing the procedure for the first time since being appointed to the Trust.
The consultant vascular surgeon wanted to see the types of vascular grafts available before the day’s operating list started, which is why they went to the store cupboard with the scrub practitioners before the team brief.

3.1.5 Once at the store cupboard, it became apparent to the consultant vascular surgeon that the vascular grafts stocked by the Trust were made by a different manufacturer than those they had used at their previous trust. The consultant vascular surgeon recalled saying, “show me your [name of manufacturer] rapid access grafts, I want to use a [name of manufacturer] rapid access graft for the procedure today”. They referred to the vascular graft in various ways, by brand name, manufacturer, and its specific properties.

3.1.6 Scrub practitioner 1 told the consultant vascular surgeon that there were two sizes of vascular grafts and held the two boxes up, one on top of the other (see figure 3). Because the consultant vascular surgeon was not sure which size they needed, they asked for both types to be brought into the operating theatre, so a decision could be made during surgery. The consultant vascular surgeon told the investigation that they assumed the requested vascular grafts were different sizes of the rapid access type. At the time of the reference event, the tapered 4 mm to 6 mm size of vascular graft was only available at the Trust as a delayed use type.
Figure 3 Vascular grafts as presented to the consultant vascular surgeon at the store cupboard
3.1.7 At the time of the reference event the consultant vascular surgeon was unaware that there were only subtle differences between the packaging of the rapid access and delayed use types, which were made by the same manufacturer (see figure 3). The investigation noted that, other than the brand name, they were almost identical. There was no further information about the properties of each type of vascular graft on the packaging/labelling, which placed the onus on the user to remember which brand name related to which type of vascular graft. The vascular operating theatre team considered that only the consultant vascular surgeon would have been able to identify whether the vascular graft was a delayed or a rapid access type from the brand name only.

3.1.8 Because the consultant vascular surgeon believed both vascular grafts were the same type, they focused on the size of the graft during the pre-insertion checks rather than the type. The consultant vascular surgeon said:

“When we did the brief, we said we’ll be using a graft, and we’ve put the two possible sizes on the side, and we’ll choose which one at the time of operation. By then in my head I had already got two [rapid access grafts], and the possibility of one of them not being [a rapid access graft] had not crossed my mind. Then when it came to the surgery and we did the procedure and I saw what size, I then chose the 4 to 6 [mm] on the fact it was the size I wanted for her little vessels because it was a bit smaller.”

3.1.9 The investigation was told by vascular operating theatre staff that the terminology used to describe the different types of vascular graft varies and may not be recognised by all members of the team. For example, in the reference event the intended vascular graft was referred to sometimes by brand name, or by type (‘rapid access’) but the latter term was not included on the packaging.

3.1.10 The two types of vascular graft brought into the operating theatre had different brand names. They also differed in size and whether they were tapered or not. The different brand names correlated with the properties of the vascular grafts – that is, whether they were the rapid access type or delayed use – but not whether they were tapered or of differing sizes.

3.1.11 The terminology used, the labelling and the similar packaging led to misunderstanding and mis-selection during the vascular graft selection process. This occurred at the store cupboard and in the operating theatre. In relation to the former, a lack of familiarity with the types of vascular grafts stocked by the trust appeared to be contributory to the safety event occurring.
Timing of the team brief and vascular operating theatre scheduling (documentation of communication tasks)

3.1.12 It was normal practice for the vascular operating theatre team to meet before the operating list started to carry out a ‘pre-start brief’. The Trust told the investigation that the process for undertaking a team brief would be for the team to stand in a circle in the anaesthetic room or operating theatre. They would introduce themselves (name, job title, role if relevant), and talk through all the patients on the operating list for that day/session. The discussion would normally include details of patients’ past medical history, the procedure to be performed, the instruments, and any additional items needed, including implants/prostheses. The team brief would also provide an opportunity for the anaesthetist and wider team to discuss any additional requirements or concerns they may have.

3.1.13 The team brief was usually carried out before 08:30 hours, before the arrival of the first patient on the operating list. On the day of the reference event, Teri was the first patient on the operating list and the team brief was carried out before she arrived at the vascular operating theatre, in line with the Trust’s usual procedure. However, the team brief took place later than usual; it was documented as starting at 09:22 hours. This resulted in the late running of the operating list for the rest of the day, which impacted on the consistency of the team during the procedure and the attendance at the ‘debrief’ at the end of the operating list (see 3.3.8).

3.1.14 During the team brief, the consultant vascular surgeon discussed the selected vascular grafts with the team. The consultant vascular surgeon said: “I’ll be using a [brand name] rapid access graft. We’ve already got them out and put them on the side.” Scrub practitioner 1 could not recall writing down anything about the vascular grafts on their copy of the operating list, as “it had already been decided which was to be used.”

3.1.15 The selection of the vascular grafts before the team brief was not in line with the Trust’s prosthesis verification policy, which stated that ‘the requirement for any prosthesis during a theatre list should be discussed at the pre-start brief’. The availability of the required item would then be checked after the brief, and the item selected from the storeroom. This variance with policy was due to the consultant vascular surgeon’s unfamiliarity with the types of vascular grafts stocked by the trust (see 3.1.3).
Consistency of the vascular operating theatre team

3.1.16 Not all of the staff were present for the entirety of Teri’s surgery. Different staff rotated in and out of the vascular operating theatre due to the late running of the operating list (see section 3.3), staff breaks and afternoon operating list commitments. It was normal practice to stagger breaks so that there were always staff available for cases throughout the day.

3.1.17 The investigation found that not all the team members present at the team brief were in the vascular operating theatre at the time of the vascular graft insertion. As outlined in 2.1.13, scrub practitioner 1 and health care assistant (HCA) 1 left the operating theatre at 13:00 hours. This was to enable them to prepare for an afternoon operating list elsewhere.

3.1.18 The consultant vascular surgeon told the investigation: “I don’t always get the same people for the whole day, so you introduce yourself to one set of people, and then at some point other people come and some people go and you don’t necessarily get introduced to the people that have come.” The surgeon would not always be aware who was in the operating theatre and their levels of knowledge, experience or role. In the case of the reference event, it also meant that there were fewer staff available who had been at the initial team brief who could have identified that the vascular graft was not the intended one.

Documentation of the type of vascular graft to be used

3.1.19 At the time of the reference event, a ‘WHO [World Health Organization] checklist’ (World Health Organization, 2023) was completed in the vascular operating theatre for each patient. The checklist was carried out using a laminated sheet, which was wiped clean before being used again for the next patient. It encompassed a ‘sign in’ (before induction of anaesthesia), ‘time out’ (prior to skin incision) and ‘sign out’ (before the patient leaves the operating theatre). The checklist was worked through at these pre-determined points during the surgical procedure.

3.1.20 While there was no permanent record of the WHO checklist for each patient, the information temporarily captured on the laminated sheet was transferred to an electronic ‘VTE [venous thromboembolism]/WHO verification tool’ (see figure 4). This was completed in Teri’s case. The investigation noted that there was no space on the ‘VTE/WHO verification tool’ to record the type of vascular graft to be used. It could not be determined whether this was recorded elsewhere, for instance on the scheduled theatre list.
Figure 4 WHO verification tool used by the Trust

![WHO Verification Tool](image-url)

**VTE/WHO Verification Tool**

- **Your Name & Designation**: (Must be a registered practitioner)
- **WHO Checklist**
  - Pre-start Brief
  - Sign In (Before induction)
  - Time Out (Before skin incision) - VTE assessment must be complete on paper and verified above as part thereof
  - Check Out (Before leaving theatre)
  - Post-list Debrief
- **Anaesthetics**: Were there any anaesthetic issues for the patient?

**Submit**
3.1.21 Similarly, the investigation observed that the electronic records used in the operating theatre did not include the type of vascular graft to be used, although there was a prompt, ‘Have essential equipment / implants / monitoring … been checked?’. Staff recognised this was an opportunity to identify any safety issues.

3.1.22 The investigation found that in Teri’s case, the checking procedure carried out before the packaging was opened and the vascular graft inserted (see 2.1.11) did not include details about the type of graft. The Trust’s standard operating procedure (SOP) stated: ‘At the ‘Time Out’ the surgeon will verbally verify the required prosthesis (in conjunction with notes/imaging etc.) including size and laterality.’

3.1.23 The investigation heard that the learning from a previous, similar Never Event (see 1.5) that took place in the Trust’s orthopaedic operating theatres had not been shared more widely. An action from this incident was to use a whiteboard as a visual check to match the intended implant against the selected implant.

3.1.24 Since the reference event, the Trust has amended its SOP to include the requirement for operating theatre staff to take a small whiteboard to the storeroom when selecting implants/prostheses, to verify the details during selection. However, it was evident that the staff would need a level of knowledge to enable the identification of the correct grafts from the store cupboard.

3.1.25 The Trust has also introduced the recording of implants/prostheses on the operating theatre whiteboard, to be checked by the scrub practitioner and surgeon. The Trust considers these changes have had a positive effect on safety, as no further Never Events have been reported by the vascular operating theatre team.

Observation of the ‘stop’ moment before the insertion of a graft

3.1.26 The record completed by the operating department practitioner (ODP) indicated that the ‘WHO Time Out’ had been completed by the ‘Scrub Team’. However, this did not include a ‘stop’ moment to enable the exact details of the vascular graft to be checked with the consultant vascular surgeon. Since the reference event, an ‘additional stop moment’ has been introduced to check the implant/prosthesis just before it is inserted. At this point, all activity in the operating theatre stops while the whole team (not just the scrub team), check the details and confirm they are happy to proceed.
3.1.27 The investigation found that the way implants/prostheses were presented and checked by the operating theatre team varied. During Teri’s procedure, when scrub practitioner 2 showed the box containing the vascular graft to the consultant vascular surgeon and then scrub practitioner 1, scrub practitioner 2’s focus was not on the type of graft. They said: “The surgeon looks at it and says yes, and then the scrub nurse looks at it and says yes.” The consultant vascular surgeon said the box was held up briefly and they said: “I checked the size and the expiry date, but in my head they were already definitely [brand name] grafts.” Scrub practitioner 2 did not read aloud the type of graft, size or expiry date, as this was not their normal practice.

3.1.28 In line with the ‘National safety standards for invasive procedures’ (NatSSIPs) (NHS England, 2015), the local policy in place at the Trust at the time of the reference event included the following instruction:

‘Before the prosthesis is removed from its packaging the circulator should hold up the item for the surgeon and scrub practitioner to confirm:

- Type, design, style or material
- Size
- Laterality [which side of the body it is for]
- Manufacturer
- Expiry Date
- Sterility
- Compatibility of multi-component prostheses
- Any other required characteristics.’

3.1.29 The Trust’s policy did not stipulate how to confirm the prosthesis was the correct one, or what to check against and with whom. However, the Trust policy has now been amended to say: ‘Before the prosthesis is removed from its packaging the circulator should hold up the item for the surgeon and scrub practitioner, and the surgeon should read aloud to confirm …’

3.1.30 Evidence from HSIB’s investigation highlights that the following factors had a negative impact on the selection of the vascular graft and the checks of the graft before it was inserted:
• the storage
• understanding of stock held
• similar looking packaging (see figure 3)
• a disconnect between terminology used by staff and the wording used by manufacturers on the packaging.

3.2 Knowledge, experience, and recency of experience (currency) of the team

Knowledge and experience of the vascular operating theatre team members

3.2.1 The consultant vascular surgeon had been appointed to the Trust 7 months before the reference event. This was their first consultant post. Before this they had gained experience during registrar training in several hospitals, using the same type of rapid access graft used in Teri’s case, and also other brands. Teri’s case was their first vascular graft insertion since being appointed to the Trust.

3.2.2 The consultant vascular surgeon was unfamiliar with the team members they were working with on the day of the reference event and their level of experience/expertise. The anaesthetist was not a regular member of the vascular team, while the ODP and scrub practitioner 2 were both recently qualified and had no prior experience of vascular procedures. HCA 2 had been with the Trust for less than a year at the time of the incident and worked with different specialities, including vascular, as part of their training.

3.2.3 Scrub practitioner 1 had many years of experience in the vascular team. However, they had moved to the day surgery team approximately a year before the incident and so did not have recent experience in vascular operating theatres. They had also not worked with the consultant vascular surgeon before.

3.2.4 The circulating nurse had had many years’ experience in vascular surgery as a senior nurse before retiring. They subsequently returned to the Trust in a more junior nursing role and had not worked in vascular surgery for approximately 6 years.
3.2.5 HCA 1 had been with the Trust for 15 years and described the vascular team as “home”. However, they were not involved in the checking of the vascular graft before insertion and did not witness the checks or the insertion. HCA 1 was first aware that the incorrect graft had been implanted when they saw the consultant vascular surgeon after the procedure.

Skill mix and currency of the vascular operating theatre team members

3.2.6 The Trust’s clinical lead for vascular and emergency surgery theatres said that the importance of ‘skill mix’ was said to be generally understood by operating theatre staff and if they did not feel that there was an appropriate mix of experience within the team, they could ask for additional support.

3.2.7 On the day of Teri’s operation, the staffing of the vascular operating theatre team was in line with the Association for Perioperative Practice (2022) guidance. The presence of two scrub practitioners, a circulating nurse and two HCAs meant there was adequate cover for staff breaks and for team members who had to leave to fulfil other work commitments before Teri’s surgery was completed.

3.2.8 While the staffing levels on the day of Teri’s operation were in line with guidance, some members of staff were new to the vascular team, recently qualified or did not have recent experience in vascular surgery. Additionally, vascular graft insertion was not a procedure that was carried out frequently, with staff describing it as a “sporadic procedure” and “infrequent”. The Trust’s investigation report states that the staff in the vascular operating theatre on the day of Teri’s procedure were ‘not all … experienced in vascular surgery and familiar with the devices [vascular grafts]’. These factors resulted in a skill mix that was considered by the Trust to be ‘insufficient to support a newly appointed surgeon’.

3.2.9 The consultant vascular surgeon told the investigation that their ‘usual’ team, with whom they had worked regularly since joining the Trust, was not available on the day of Teri’s surgery. They told the investigation that this was not as reassuring as working with members of staff with whom you had built a relationship: “You get some members of staff that you work very comfortably with and you see them and you’re like, ‘Oh, thank goodness’.” The consultant vascular surgeon also said: “… right from the beginning I’ve had a mostly regular team, but that day my mostly regular team was not there.” They explained that familiarity with the team is important: “It’s really important. It’s really important because you feel – everything happens much more smoothly if you all know each other’s strengths, weaknesses, likes, dislikes, how things are going to run.”
3.2.10 The investigation was told by the Trust’s clinical lead for vascular and emergency surgery operating theatres that the aim was to have standard and consistent teams. However, at times inadequate staffing levels resulted in this being an unreliable safety control, hence the requirement for good and thorough team briefings as discussed in section 3.1.

3.2.11 During the first wave of COVID-19, before the reference event took place, a number of the team members, notably the ODP, scrub practitioner 2, the circulating practitioner and the HCAs, had been redeployed to the intensive care units and COVID-19 wards. This had an impact on the currency of these team members (that is, how recent their vascular operating theatre experience was). In addition, scrub practitioner 1 had not worked in vascular operating theatres for approximately 12 months. One member of staff stated they had never seen this procedure before and have only seen another two vascular graft insertions in the 18 months between the incident and the start of the reference event investigation.

3.2.12 The investigation found that there was a mismatch between skill mix and currency of the vascular operating theatre team members. This was in relation to experience in vascular surgery generally, and in some cases, recent experience in the specialty. The outcome was a team who were generally unfamiliar to the consultant and with each other, which did not appear to be fully appreciated at the time of the event.

3.2.13 Following on from this, actions to support the mitigation of future risk were outlined in the Trust’s serious incident report. These included helping surgeons to organise operating lists according to staff mix and ensuring newly appointed surgeons were adequately supported for specialised cases by providing an appropriately experienced team.

3.3 Learning culture in vascular operating theatres

Operating theatre scheduling and the late running of the operating list

3.3.1 Teri was the first patient on the elective (planned rather than emergency) operating list. Two patients were on the list for surgery after Teri, both scheduled for the creation of arteriovenous fistulas. These were all described as more complex procedures by the Trust’s clinical lead for vascular and emergency surgery.

3.3.2 The morning vascular operating theatre start time was scheduled each day for 08:30 hours. However, there was a delay of 1 hour and 11 minutes in transferring Teri from the day case suite to the operating theatre. This was
because she needed to go to medical physics for precise mapping of her veins, to identify the best place to insert the vascular graft. This had to be done on the day of surgery so that the marking was clear and did not rub off.

3.3.3 Teri’s procedure was completed at 13:53 hours, and the third (and final) procedure of the day at 17:55 hours. Therefore, the delayed start time resulted in the late running of the operating list all day. The delay also meant that scrub practitioner 1 had to de-scrub and leave the vascular operating theatre before Teri’s procedure was completed, affecting the consistency of team members.

3.3.4 The matron for operating theatres told the investigation that learning from operating theatre scheduling issues was ongoing and initiatives to start operating lists on time needed engagement from the wider hospital, not just the operating theatres. This was highlighted by one of the vascular operating theatre team members, who told the investigation, “there’s this kind of vortex between the patient being sent for and the patient being present in [the operating] theatre”.

3.3.5 There is national guidance for trusts, entitled ‘The productive operating theatre’ (NHS England, 2020), to support operating theatre teams to work more effectively together. One of the aims of the guidance is to improve the effective use of operating theatre time so they can be managed more productively and efficiently. Scheduling is part of this, and was highlighted by the matron, who told the investigation about the importance of the operating list starting at 08:30 hours and of using the hour beforehand to adequately check equipment and prepare for the day’s operating lists.

Team debrief and subsequent learning

3.3.6 The vascular operating theatre team typically held a team debrief at the end of each day. The debriefs included discussion of what went well, what did not go well, and what could be done better.

3.3.7 The vascular operating theatre staff involved in the selection, checking and insertion of Teri’s vascular graft described that they had been upset about the events that occurred but had continued with the rest of the day’s operations. It was recorded in the operating theatre computer system that the team debrief took place at 18:10 hours, after the last patient had left the operating theatre.

3.3.8 The late start of the operating list on the day of the event, and the subsequent late running of the list for the rest of the day, affected staff attendance at the debrief. The only team members present were the consultant vascular surgeon, scrub practitioner 2 and the circulating nurse.
3.3.9 During the debrief, staff recalled that the main reason given for the incorrect graft insertion was the similar colour and design of the packaging used for the rapid access and delayed use grafts. Those present at the debrief said they all agreed there should be a system for labelling and storing the different types of graft to prevent something similar happening again. The investigation heard that aside from the issues relating to the storage, labelling and packaging of the vascular grafts, nothing else was discussed at the debrief. There was also no subsequent debrief for the whole vascular operating theatre team involved in Teri’s case. This was reported to have led to ongoing negative feelings within the team and an emotional impact for some of the staff.

3.3.10 Following the event, brief detail of what happened, and the subsequent actions taken were added to a ‘Never Event actions’ notice board, close to the vascular operating theatre. This was still in place at the time of the investigation’s visit. Staff told the investigation that this served as a constant reminder of what had happened, and had negative connotations for them, which was not the intended outcome.

3.4 **Summary of issues identified from the reference event**

3.4.1 The investigation found that at the time of Teri’s surgery, there was limited evidence of system-focused interventions (see figure A1) to mitigate the risk of incorrect vascular graft selection and insertion. The interventions that were in place were predominately ‘less effective’ and people-focused (see figure A1).

3.4.2 Key findings from the reference event analysis included a delayed use vascular graft being implanted in error because of similar packaging and unclear labelling. Additionally, checklists/checking processes were not effective in preventing the reference event.

3.4.3 Following on from this, there are issues which are applicable to other healthcare settings:

- the labelling of vascular grafts does not provide detail about the types and properties of the grafts in terminology that is understood by the wider team
- rapid access and delayed use grafts have similar packaging
- the implementation of operating theatre procedures is variable
- the skills mix/roles and duties of the operating theatre team is inconsistent.
4 Analysis and findings – the wider investigation

This section of the report sets out the investigation's findings from its analysis of the factors that affect clinicians’ ability to select and insert a correct implant/prosthesis, in the context of the wider healthcare system. This part of the investigation focused on:

- the identification of the factors within the healthcare system that influence patient safety risks associated with the selection and insertion of vascular grafts in an operating theatre environment

- the exploration, using a systems approach, of the design of the labels and packaging used for the different types of vascular grafts for patients on haemodialysis treatment.

The wider investigation explored measures to reduce the safety risk (mitigations) using categories from the Hierarchy of Intervention Effectiveness (Institute for Safe Medication Practices, 1999). This is a model that ranks the effectiveness of mitigations from ‘most effective’ to ‘least effective’ (see figure A1).

The categories relevant to this safety issue are (from more effective to less effective):

- automation and computerisation

- simplification and standardisation

- reminders, checklists and double-checks.
4.1 Automation and computerisation

Exploration of the use of scanning technology for the selection of vascular grafts

4.1.1 Evidence from the investigation indicates there appears to have been an emphasis on ‘people-focused’ solutions (see section 4.3 and figure A1), to implement and embed practices to reduce the risk of incorrect implant/prosthesis insertion. This is despite efforts to create ‘system-focused’ solutions (see sections 4.1, 4.2 and figure A1), to ‘design out’ the safety risk, or at least to adopt a blended approach incorporating training alongside the ‘more effective’ solutions.

4.1.2 Technology-based safety measures are considered to be more effective than those that rely on the actions of people (Institute for Safe Medication Practices, 1999). Therefore, the investigation explored the use of scanning technology to mitigate the safety risk of mis-selection errors. It specifically looked at the use of ‘Scan4Safety’, which is a system that aims to ensure the ‘right patient, right product, right place, right process’ (Department of Health and Social Care, 2021).

4.1.3 NHS England advised the investigation that Scan4Safety uses the barcodes on medical device packaging to track items through the hospital system. The use of barcodes was initially used by hospitals as part of a stock management system, to monitor the availability of stock and order accordingly. It became clear that such a system could also enhance safety in by enabling staff to monitor, track and check items at the point of care, using ‘GS1’ standards for tracking purposes (Department of Health and Social Care, 2021).

4.1.4 An initial 2-year trial of Scan4Safety began in 2016 at six ‘demonstrator’ sites. The trial was funded by the Department of Health and Social Care (DHSC). At some of the Scan4Safety trial sites, patients had a unique barcode on their wristband, which captured the NHS number (along with other patient demographics). This barcode could be used to confirm the correct implant had been selected at point of care (see figure 5), by scanning the product before use and then electronically assigning it to the patient.

4.1.5 The investigation was told by one of the demonstrator sites that it was possible for a medical alert to be issued if the scanning of a prosthesis/implant differed from the patient’s wristband barcode. They further advised that, to enable this type of alert, trusts would be required to configure their systems.
4.1.6 During the trial period, the DHSC reported patient safety benefits, reduced costs and efficiency savings (GS1 UK, 2020). The DHSC specifically measured the number of Never Events and the reduction in numbers resulting from the use of the technology. HSIB has previously made safety recommendations to national healthcare organisations relating to the potential of Scan4Safety (Healthcare Safety Investigation Branch, 2018a) and how it may help reduce the reliance on checking processes by clinical staff.

**Figure 5 Barcode on patient’s wristband being scanned before a procedure (GS1, 2020)**

Image courtesy of Scan4Safety.
4.1.7 The investigation carried out observation visits at two of the Scan4Safety demonstrator sites, and brief case studies were compiled (see figures 6 and 7).

Figure 6 Observation visit at Scan4Safety trial site (Trust 1)

**Background:** Trust 1 was one of the six demonstrator sites.

**Local experience and learning:**

- Scanning technology was initially introduced as a finance/inventory tool but the Trust could see its potential for improving patient safety, so its use was widened.

- The Trust recognised that Scan4Safety needed to interface with other systems to monitor stock levels and enable items to be tracked.

- The central stores team initially scanned the equipment when delivered and logged expiry dates for example, to provide an additional safety measure.

- The point-of-care scanning system was rolled out across eight operating theatres with up to 12 specialities.

- Initially, the Trust omitted to provide information to the staff on the potential benefits of Scan4Safety and the reasons why it was being trialled, which had an impact on staff’s engagement with the trial.

- The Trust described a number of local adaptations to continue data capture, and considered this task would be better if driven nationally.

**National learning:**

1. The Trust’s experience is that it has been on its own journey rather than the initiative being driven centrally, which has resulted in ‘silo working’.

2. The Trust described being less supported at a national level than they had been previously, creating issues in terms of implementation.

3. There was an opportunity to collect (and use) a lot of data. However, while collecting data at a Trust level, there has been no data capture and analysis at a national level.
Background: Before Scan4Safety was implemented, the Trust had a stock management system which was used in some operating theatre areas. The Trust worked with the supplier of this system to enable the number assigned to each patient to be visible and their NHS number displayed, so products could be attributed to patients.

Local experience and learning:

- Flags were added to the stock management system so that implantable products could be easily identified.
- Specialist inventory managers and teams were introduced to operating theatre areas.
- Products that were ordered frequently were added to the inventory.
- Electronic replenishment of stock was enabled.
- Products could be scanned at the point of care on a handheld device in the operating theatre leading to a greater understanding of the products.
- Products are now linked to the patient, so there is a record of implants.
- The introduction of dedicated teams to look after inventory is integral to the running of operating theatres. The Trust holds less than 21 days of stock in these areas and confidence comes from the work of the inventory team in each area.
- Storage areas managed by inventory teams are well maintained and products in similar packaging are separated and clearly labelled.
- The recall time for implanted items had been reduced, meaning an error would be detected in a timelier fashion.
- The region has a collaborative board which meets on a quarterly basis to share good practice.
- In terms of next steps, the Trust is planning to interface the operating theatre management system with the stock management system. This will enable the selection of products by procurement specialists in advance and automatically capture the surgeon’s identity for a specific case. Interfacing with the patient’s electronic patient record (EPR) is also planned to enable the recording of implantable items directly into the records.
National learning:

1. The Trust’s experience is that a lack of governance has led to a dilution of what Scan4Safety can do in practice.

2. The Trust considered that the lack of a central Scan4Safety team resulted in Trusts using the system in isolation.

3. The Trust considered that data should be recorded centrally. This would be of benefit to the patient and would allow data to be analysed.

4. The Trust thought that a national catalogue of products would be useful and for the patient’s unique identification number linked to the NHS Application.

Following the 2-year trial period

4.1.8 After the trials of Scan4Safety at the demonstrator sites, the programme continued, but with reduced momentum. The programme is currently managed by NHS England, which told the investigation that approximately 20% of trusts across the country have scanning capability. NHS England also said that trusts that had been more successful in implementing Scan4Safety were using both the procurement and inventory management functions alongside the point-of-care scanning capability. This approach results in a focus on patient pathways, which is recognised as an important factor from a patient safety perspective.

4.1.9 The investigation was told by NHS England that several of the trusts with scanning capability were no longer using the software. Of the trusts that were still using the technology, some were using it as intended and others only parts of it. For example, some trusts were only using the stock management system and not tracking the use of medical devices with the patient. The investigation heard that these local adaptations of Scan4Safety had created inconsistencies.

4.1.10 Further to the consequences of not having enough funding to drive the national Scan4Safety programme, more funding has been secured. GS1 (GS1 UK, 2023) outlined that ‘NHSE [NHS England] will be exploring ways of making electronic registry data submission easier and accelerating the adoption of barcode scanning through the Scan4Safety programme and automation technologies’.
HSIB makes the following safety recommendation

**Safety recommendation R/2023/236:**

HSIB recommends that NHS England reviews system requirements for barcode scanning technology, in order to support local organisations to reduce the risk of incorrect selection and insertion of prostheses/implants.

### 4.2 Simplification and standardisation

**Issues relating to the labelling and packaging of vascular grafts**

4.2.1 The investigation reviewed data covering a 4-year period extracted from the Strategic Executive Information System (StEIS) (see figures A3 and A4). StEIS is a national database used to report and monitor the progress of serious incident investigations across the NHS. The review, which looked at the data for Never Events classified as involving ‘wrong implant/prosthesis’, revealed key themes and findings relevant to this investigation.

4.2.2 One theme was ‘labelling/packaging’ (noted in 26 incidents), and the investigation found that several adaptations to mitigate the risks created by similar packaging had been put in place. Operating theatre storage areas were being modified in some trusts, for example by separating different sizes of implants/prostheses that have similar packaging. Some trusts explicitly mentioned contacting the manufacturer directly about the packaging.

4.2.3 In relation to the labelling of implants/prostheses to help staff select the correct items, colour coding or handwritten labels were being used to identify implants more easily. Figure 8 shows one example of implant labels used on device packaging that reflect the terminology understood by the operating theatre team – that is, a ‘stepped’ type of vascular graft is referred to as ‘tapered’ and a ‘straight’ type is referred to as ‘non-tapered’. A further theme identified from the data was the need for readable information on packaging, specifically the use of a larger font size on labels.
Figure 8 Handwritten labelling to clarify type of graft
4.2.4 Analysis of the data on packaging and labelling issues indicates that this is a risk that applies across healthcare, wherever staff select medication or devices at the point of care. The HSIB investigation into ‘Implantation of wrong prostheses during joint replacement surgery’ (Healthcare Safety Investigation Branch, 2018a) contains information and a safety recommendation regarding the packaging/labelling of medical devices, which is relevant to this investigation.

**Review and interpretation of medical device regulation and standards relating to labelling and packaging of vascular grafts**

4.2.5 The British Standards Institution (BSI) told the investigation that the Medical Devices Regulations 2002 do not detail the symbols or specific information to be included on packaging or labelling. These are covered under the various medical device standards. Devices can be assessed against a number of different medical device standards (Department of Health and Social Care, 2022). These include the International Organization for Standardization (ISO), European standards (EN) or BSI standards. The standards cover a wide variety of factors that need to be considered for medical devices including labelling and packaging.

4.2.6 Labelling symbols are specifically covered in ISO 15223-1:2021, ‘Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements’ (International Organization for Standardization, 2021). The application of standards is not mandatory in the UK, but they can be used to demonstrate compliance with the medical device regulations in the technical documentation.

4.2.7 The Medicines and Healthcare products Regulatory Agency (MHRA) told the investigation that before a medical device enters the UK market, an approved body will have completed an assessment to ensure it conforms with the current regulations (see section 1.6). The different approved bodies may vary in their scope regarding which products they can provide conformity assessments for. The MHRA advised that it regularly audits the approved bodies to ensure that the correct evidence has been provided by the manufacturer and assessed appropriately.

4.2.8 The MHRA told the investigation that medical devices in use in the UK must have either of two marks to show they meet the relevant requirements: a CE mark or a UKCA mark. The requirement for this is laid down in the Medical Devices Regulations 2002 and the European (EU) Directive 93/42/EEC. To obtain a CE or UKCA mark, both the Medical Device Regulations 2002 and the EU Directive 93/42/EEC require that the labelling and packaging of medical devices should be designed in such a way that users can identify the contents:
13. Information supplied by the manufacturer

13.1. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users.

This information comprises the details on the label and the data in the instructions for use.

13.3. The label must bear the following particulars:

(b) the details strictly necessary for the user to identify the device and the contents of the packaging;

4.2.9 The MHRA told the investigation that there is no requirement for Approved Bodies to assess the lowest risk (Class I non-measuring or non-sterile devices) or custom-made devices before they enter the market. For medium risk devices (Class IIa and IIb non-implantable) the Approved Body will sample the technical documentation for the devices on the certificate over the certification period.

The application of engineering usability to implants

4.2.10 During observation visits and when speaking to national bodies, including the MHRA, the investigation found several instances of similar labelling and packaging of different medical devices. It was apparent that the similarity increased the risk of staff selecting the incorrect graft either before a procedure or when checking the device during the procedure (see figure 3).

4.2.11 The MHRA advised the investigation that it had reviewed its registrations database and compiled a list of vascular grafts used for haemodialysis access in the UK. It found that there were two rapid access types of vascular grafts, made by two different manufacturers. The investigation found that these two manufacturers used similar looking packaging for the rapid access types of vascular grafts and the delayed use type (see figure 9).
Figure 9 Examples of labelling and packaging of different types of vascular grafts
4.2.12 Staff in acute trusts and a subject matter advisor (a consultant vascular surgeon) told the investigation that similar looking packaging makes selecting and checking the right medical device more difficult. In relation to labelling, different words were used by different manufacturers to describe similar properties, such as ‘stepped’ and ‘tapered’, potentially causing confusion. Relevant to this investigation, the labelling of the device used in the reference event did not say whether the vascular graft was a rapid access type or delayed use type.

4.2.13 The BSI has agreed to raise the issue of unclear/confusing medical device labelling and packaging with the ISO, although the timeframe for implementation will be dependent on the ISO standard revision process.

**HSIB makes the following safety recommendation**

_Safety recommendation R/2023/237:_

HSIB recommends that the British Standards Institution updates the applicable standard/s, and raises with the International Organization for Standardization, to state that medical device labelling and packaging should detail the specific use of an item. This should be developed with user input to drive consistency in the terminology used on medical device labelling/packaging.

4.2.14 The investigation was told that there are many users of the medical device who may be involved in the selection and checking processes, and all of these users should be considered when labelling and packaging items. Users include non-medical members of the operating theatre team, namely scrub practitioners, circulating practitioners and operating department practitioners. Previous HSIB investigations have highlighted issues relating to the labelling and packaging of medical devices, specifically that it needs to be accessible to all users involved in selecting and checking processes (Healthcare Safety Investigation Branch, 2018a; 2018b).

4.2.15 Neither the Medical Devices Regulations 2002 nor the EU Directive EU 93/42/EEC define who the user is, or what the expected equipment ‘use environment, training and knowledge’ requirements are. The MHRA document ‘Guidance on applying human factors and usability engineering to medical devices including drug-device combination products in Great Britain’ (Medicines and Healthcare products Regulatory Agency, 2021) provides guidance on user testing of medical devices. The MHRA told the investigation that it considered:

- ‘users’ to be the surgeon and the staff involved in both the selection and the second checking of the vascular graft
‘user insights’ would include experience, knowledge and currency (recency of experience)

‘use environment’ would include the store cupboard where the grafts were selected and the operating theatre where they were implanted.

4.2.16 The term ‘user’ in the context of medical devices has been defined in the International Medical Device Regulators Forum (2019) guidance document as ‘The person, professional or lay, who uses a medical device. The patient may be that user.’ The guidance document does not specify that the user may incorporate all staff who interact with the device, including those who select the device, and those who check it before use (in addition to those that use it).

HSIB makes the following safety observation

Safety observation O/2023/226:
It may be beneficial if the term ‘user’ in the context of medical devices was defined in international and national standards to incorporate all staff who interact with the device, including those who select the device, check it before use and use it.

4.2.17 The ‘Principles of labelling for medical devices and IVD medical devices’ (International Medical Device Regulators Forum, 2019) state that ‘the primary purpose of labelling is to identify the medical device or IVD [in vitro diagnostics] medical device and its manufacturer, and provide essential information about its safety, performance, and appropriate use to the user or other relevant persons’. It also states that ‘The medical device or IVD medical device should be identified through the use of a brand or trade name that allows differentiation from other products from the same or similar type’.

4.2.18 During observation visits, the investigation found that use of a brand or trade name means that users have to rely on remembering the properties of the device based on the brand name rather than being able to see the details on the packaging/labelling. Hospital staff and the subject matter advisor told the investigation that it would be clearer to explicitly state the type of graft on the packaging/labelling, rather than relying on staff recognising the type by the brand name or interpreting the details on the packaging/labelling.
4.2.19 The BSI advised the investigation that they were working with the ISO on the symbols used on labelling and packaging to identify the purpose of medical devices.

**HSIB makes the following safety recommendation**

**Safety recommendation R/2023/238:**

HSIB recommends that the Medicines and Healthcare products Regulatory Agency ensures the assurance processes for designated approved bodies (to check medical device manufacturers conform to packaging standards) are amended to consider context of use and usability guidelines, to reduce the risk of selecting and inserting the incorrect device.

4.2.20 The ‘Best practice guidance labelling and packaging of medicines’ (Medicines and Healthcare products Regulatory Agency, 2020b) advises that medicines are packaged and labelled in a way that mitigates the chances of the wrong item being selected. The MHRA told the investigation that there is currently no similar guidance for medical devices.

**HSIB makes the following safety recommendation**

**Safety recommendation R/2023/239:**

HSIB recommends that the Medicines and Healthcare products Regulatory Agency publishes guidance on the labelling and packaging of medical devices, to promote best practice and reduce selection of the incorrect item.

4.3 Reminders, checklists, and double checks

**Analysis of the data relating to checking procedures and checklists**

4.3.1 During its review of ‘wrong implant/prosthesis’ Never Events data over a 4-year period (see table A3), the investigation found that 34% of these incidents were categorised as ‘wrong type’ – that is, incidents in which the wrong type of implant/prosthesis was used – of which 44% were reported under the theme of ‘checking processes/procedures’ (see figure 10 and table A4). Additionally, the data review highlighted that staff were not performing checks of implants/prostheses and ‘human error’ was noted to be the cause in 10% of cases (see figure 10 and table A4). Therefore, there is potentially an overlap with this theme too.

4.3.2 The term ‘human error’ in this context does not aid the understanding of the factors across the healthcare system that contribute to patient safety incidents. This is supported by Shorrock (2019) who stated: ‘As an explanation in a complex system, the concept [of human error] is widely misused and abused, especially to infer causation.’
Figure 10 Themes of ‘wrong implant/prosthesis’ Never Events from StEIS (between 1 April 2018 and 31 March 2022)
4.3.3 Learning from the aviation industry suggests that although checklists can be used to enhance safety, they are not error proof. The ‘Flightcrew human factors handbook’ (Civil Aviation Authority, 2016) states: ‘Checklists are vulnerable to the way human skills work. The repeatable nature of checklist tasks means that the brain can turn checklist tasks into skills in the same way as any other tasks.’

4.3.4 The use of checklists has become a standard feature in the operating theatre environment. The World Health Organization (WHO) Safety Checklist (World Health Organization, 2023) was introduced in 2008 and comprises a sequence of steps that need to be carried out at various stages of surgery, with a tick box to denote completion.

4.3.5 At the time of the reference event, the ‘National safety standards for invasive procedures’ (NatSSIPs) (NHS England, 2015) were in place. These standards did not specify how checks should be performed and although they outlined what should be checked with ‘the team’, they did not appear to consider the team may only involve one or two people in an operating theatre.

4.3.6 A review of the StEIS incident reports themed under ‘checking processes/procedures’ revealed several findings relevant to this investigation. It was evident that some trusts had added a safety step to their surgical safety checklists for implants/prostheses and linked to this, a pause moment prior to the insertion of implants/prostheses. The data also indicated that certain trusts advocated the practice of reading implant/prosthesis information aloud followed by a verbal confirmation by a colleague.

4.3.7 The ‘Flightcrew human factors handbook’ refers to the importance of reading checklists aloud to overcome distractions and prevent other tasks taking priority. Further work within the aviation industry has identified that it is necessary for everyone to understand the importance of checklists and that they are carried out in particular ways to fulfil their purpose. Checklists work most effectively when designed and implemented in the context of teams. This ensures that everyone has a role to fulfil and is a contributor to both the checklist’s development and its roll-out (Higgins and Boorman, 2016).

4.3.8 In military aviation, the generally accepted process for carrying out a checklist procedure involves one person reading aloud while a second person performs the checks and confirms the item is complete. In a previous HSIB investigation, checklists were looked at in detail and therefore are not explored further here (Healthcare Safety Investigation Branch, 2022b).
4.3.9 The Centre for Perioperative Care (2023) has published a revised version of NatSSIPs (NatSSIPs 2), which is designed to reduce misunderstandings or errors and to improve team cohesion. NatSSIPs 2, written by clinicians from multiple professions and specialties, re-launches the safer surgery checklist. The standards explicitly state that ‘Checklists are not, and never have been a solution in themselves and are dependent on the system and culture in which they are used’. The standards mandate key ‘stop’ moments throughout a surgical procedure, during which patient-specific details are clarified. This is to improve both patient safety and team working (Centre for Perioperative Care, 2023).

4.3.10 The Centre for Perioperative Care (2023) draws on experience from the use of the earlier version of the standards and the results of an implementation survey conducted by NHS Improvement in 2017. The survey report stated that ‘the existence and implementation of NatSSIPs and associated local standards (LocSSIPs) has been inconsistent and challenging’. The survey found that the main organisational-level barriers to embedding the important safety guidance included:

- time pressures and lack of protected staff time
- lack of opportunities for multidisciplinary training
- not seeing NatSSIPs as a priority.

4.3.11 Further revisions to NatSSIPs 2 also address some of the other issues relevant to this investigation. NatSSIPs 2 states that any changes to the staffing of the team during the day should be recorded and trigger a second briefing, where appropriate. The team brief should also provide an opportunity to discuss staff familiarity with procedures (Centre for Perioperative Care, 2023).

4.3.12 NatSSIPs 2 specify that checks must be carried out throughout the process of inserting an implant. This includes confirmation of the type of implant required and recording the detail on paper or a whiteboard so it can be checked during selection and insertion.

4.3.13 ‘The NatSSIPs Eight’ flowchart (Patient Safety Learning, 2023) (see figure 11) combines the NatSSIPs 2 sequential standards with the WHO Surgical Safety Checklist to provide a visual reminder tool for health and care staff. It includes a new step (step 5), ‘Implant verification (EPR [electronic patient record]/scan-for-safety), which is completed during the invasive procedure.
4.3.14 The expectation regarding the checks at the implant insertion stage (the ‘implant time out’) is that the whole team will focus and be silent. During this specific check, ‘the runner [circulating nurse] obtains the implant and shows it to the operator, who ‘reads aloud’ the implant details:

- Type
- Laterality (when applicable)
- Size
- Expiry date
- Sterility’ (Centre for Perioperative Care, 2023).
NatSSIPs 2
SEQUENTIAL STEPS
The NatSSIPs Eight

WHO Surgical Safety Checklist PLUS
Invasive Never Events in red

1. Consent and Procedural Verification
2. Team Brief
3. Sign In
4. Time Out
5. Implant Verification (EPR / Scan-for-safety)
6. Reconciliation (counting) of items including needles, swabs & instruments
7. Sign Out
8. Debrief / Handover

Wrong Site
Wrong Implant
Retained Foreign Object

Author: Nigel Roberts, Head Theatre Practitioner (Head of Nursing) at Birmingham Women’s and Children’s NHS Foundation Trust, 2023. Supported by Patient Safety Learning and Dr Annie Hunningher.

Version 1 – March 2023
4.3.15 A review of StEIS Never Event data for ‘checking processes/procedures’ highlighted the importance of embedding the NatSSIPs and ‘Local safety standards for invasive procedures’ (LocSSIPs) into operating theatre departments.

4.3.16 NatSSIPs 2 incorporates ‘human factors’ training as a key part of improving patient safety in the operating theatre. As outlined by the Centre for Perioperative Care (2023), ‘key principles in NatSSIPs 2 include: the need to consider human factors with systems thinking, culture, psychological safety and teamwork to underpin NatSSIPs 2 implementation’. Following from this, it is apparent that a multidisciplinary approach to the implementation and embedding of NatSSIPs 2 is required, with human factors training central to the delivery.

**HSIB makes the following safety observation**

**Safety observation O/2023/227:**
It may be beneficial for healthcare organisations to deliver multi-disciplinary team training on the key principles of the revised ‘National safety standards for invasive procedures’ to support the implementation and embedding of these standards.

**Embedding patient safety into the organisational culture**

4.3.17 NHS England told the investigation that the new additions and updates to NatSSIPs 2 are intended to promote best practice within operating theatres. This includes the impact of organisational culture on patient safety. The standards make it clear that organisations must allow adequate time for embedding patient safety into the organisational culture, rather than just rolling out to frontline staff. Embedding NatSSIPs 2 is integral to ensuring a culture of patient safety.

4.3.18 The investigation observed operating theatre procedures in three different trusts. Differences in the way surgical safety checklists were completed, and in the organisational culture of the teams were noted. These differences included the time and priority given to a team brief; the ability of all staff to feel comfortable to speak up and ask questions; the operating theatre environment in terms of noise/other interruptions during the procedures; and the priority placed on a team debrief.

4.3.19 A review of StEIS Never Event data supported these observations. The investigation found that one of the themes highlighted as needing review/exploration was the culture of working relationships between the operating theatre team and medical staff.
4.3.20 As NatSSIPs 2 notes, the success of various interventions (such as checklists) depends very much on the culture of the organisation and the importance placed on such tasks. Shouhed et al (2012) state that ‘To improve working environments for the entire team and sustain positive systemic changes, one must fully understand the violations [unauthorised deviation from a standardised procedure] and why individuals and organisations drift away from safety’.

4.3.21 The Chair of the NatSSIPs committee told the investigation that as integrated care boards (ICBs) commission services, they should have a role in ensuring NatSSIPs are embedded into the culture of healthcare organisations. At an organisational level, the Chair considered that the operational leadership in a trust for NatSSIPs should be carried out by experienced operating theatre clinicians. Underpinning this should be a multi-disciplinary team who are committed to the implementation.

**HSIB makes the following safety observation**

**Safety observation O/2023/228:**
It may be beneficial for trusts to assign experienced operating theatre clinicians to lead on the implementation of the ‘National safety standards for invasive procedures’, to address the cultural issues hindering implementation.
5 Summary of findings, safety recommendations and safety observations

5.1 Findings

- The packaging of rapid access and delayed use vascular grafts may be very similar, resulting in an increased risk of staff selecting and inserting the wrong type of graft.

- The wording used on packaging and labels to describe vascular grafts does not reflect the terminology used by clinicians in the operating theatre.

- There is Medicines and Healthcare products Regulatory Agency (MHRA) guidance for the labelling and packaging of medicines, but not for medical devices such as vascular grafts.

- There was a lack of standardisation and therefore variation in how checklists and team briefs (procedures that aim to ensure patient safety) were completed/conducted and recorded in different operating theatres.

- The incorporation of national safety standards alone may not be successful without an embedded safety culture being in place.

- Barcode scanning technology (Scan4Safety) can be used to mitigate the risk of an incorrect medical device being selected/inserted. Due to the reduced central management of the Scan4Safety programme, trusts have been developing applications and using adaptations of the scanning technology, resulting in inconsistent use and variable effectiveness.

HSIB makes the following safety recommendations

**Safety recommendation R/2023/236:**
HSIB recommends that NHS England reviews system requirements for barcode scanning technology, in order to support local organisations to reduce the risk of incorrect selection and insertion of prostheses/implants.

**Safety recommendation R/2023/237:**
HSIB recommends that the British Standards Institution updates the applicable standard/s, and raises with the International Organization for Standardization, to state that medical device labelling and packaging should detail the specific use of an item. This should be developed with user input to drive consistency in the terminology used on medical device labelling/packaging.
Safety recommendation R/2023/238:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency ensures the assurance processes for designated approved bodies (to check medical device manufacturers conform to packaging standards) are amended to consider context of use and usability guidelines, to reduce the risk of selecting and inserting the incorrect device.

Safety recommendation R/2023/239:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency publishes guidance on the labelling and packaging of medical devices, to promote best practice and reduce selection of the incorrect item.

HSIB makes the following safety observations

Safety observation O/2023/226:
It may be beneficial if the term ‘user’ in the context of medical devices was defined in international and national standards to incorporate all staff who interact with the device, including those who select the device, check it before use and use it.

Safety observation O/2023/227:
It may be beneficial for healthcare organisations to deliver multi-disciplinary team training on the key principles of the revised ‘National safety standards for invasive procedures’ to support the implementation and embedding of these standards.

Safety observation O/2023/228:
It may be beneficial for trusts to assign experienced operating theatre clinicians to lead on the implementation of the ‘National safety standards for invasive procedures’, to address the cultural issues hindering implementation.
6 References

Association for Perioperative Practice (2022) Staffing for patients in the perioperative setting, 4th edition.


7 Appendices

Investigation Approach

Decision to investigate

The Chief Investigator authorised a national investigation based on HSIB’s patient safety risk criteria:

**Outcome impact – what was, or is, the impact of the safety issue on people and services across the healthcare system?**

A search of the literature and incident databases did not find evidence of serious harm associated with patients who had the incorrect type of vascular graft. However, having to repeat surgery increases demand on surgical resources and increases the risk of infection for patients.

**Systemic risk – how widespread and how common a safety issue is this across the healthcare system?**

HSIB used the Strategic Executive Information System (StEIS) to search for incidents involving incorrect vascular graft insertion *(see table A1).*
### Table A1 Incidents involving incorrect vascular graft insertion from 1 April 2017 to 1 January 2023

<table>
<thead>
<tr>
<th>Source:</th>
<th>StEIS, NHS England (2023b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of extraction:</td>
<td>2 March 2023</td>
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<tr>
<td>Reported incident dates:</td>
<td>01/04/2017 – 01/01/2023</td>
</tr>
<tr>
<td>Filters:</td>
<td>Incident Type: Surgical invasive OR Medical equipment/device</td>
</tr>
<tr>
<td>Search field:</td>
<td>Incident Description</td>
</tr>
<tr>
<td>Search term:</td>
<td>Graft</td>
</tr>
<tr>
<td>Notes:</td>
<td>97 reported incidents including reference event. No other relevant incidents relating to wrong graft type</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Source:</th>
<th>StEIS, NHS England (2023b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of extraction:</td>
<td>02/03/2023</td>
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<tr>
<td>Reported incident dates:</td>
<td>01/04/2017 – 01/01/2023</td>
</tr>
<tr>
<td>Filters:</td>
<td>None</td>
</tr>
<tr>
<td>Search field:</td>
<td>Incident Description</td>
</tr>
<tr>
<td>Search term:</td>
<td>Graft AND vascular</td>
</tr>
<tr>
<td>Notes:</td>
<td>61 reported incidents including reference event. No other relevant incidents relating to wrong graft type</td>
</tr>
</tbody>
</table>
HSIB then used the Never Events data (NHS England, 2023b) to search for ‘wrong implant/prosthesis’ Never Events (see table A2). Between 1 April 2017 and 4 January 2022, there were 264 ‘wrong implant/prosthesis’ Never Events reported to StEIS. Of these, the vast majority related to orthopaedic (bone/joint/muscle) or ocular (eye) surgeries. HSIB has previously published reports relating to the implantation of the wrong prosthesis during joint replacement surgery (Healthcare Safety Investigation Branch, 2018a), the insertion of an incorrect interocular lens (Healthcare Safety Investigation Branch, 2018b) and a wider thematic report into Never Events (Healthcare Safety Investigation Branch, 2022a).

Table A2 ‘Wrong implant/prosthesis’ Never Events reported from 1 April 2017 to 31 December 2022

<table>
<thead>
<tr>
<th>Source:</th>
<th>NHS England (2023b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of extraction:</td>
<td>20 February 2023</td>
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<tr>
<td>01/04/2017 – 01/01/2023</td>
<td></td>
</tr>
<tr>
<td>Reported incident dates:</td>
<td>01/04/2017 – 31/12/2022</td>
</tr>
<tr>
<td>Filters:</td>
<td>Data from 2017/18 onwards was captured and compared (it was not possible to compare data in previous years as the Never Events Policy and Framework and the Never Events list was revised in 2015). NatSSIPs were also first published in 2015</td>
</tr>
<tr>
<td>Search field:</td>
<td>Never Events</td>
</tr>
<tr>
<td>Search term:</td>
<td>‘Wrong implant/prosthesis’ Never Events</td>
</tr>
<tr>
<td>Notes:</td>
<td>2017/18 – 63 wrong implant/prosthesis</td>
</tr>
<tr>
<td></td>
<td>2018/19 – 63 wrong implant/prosthesis</td>
</tr>
<tr>
<td></td>
<td>(1 vascular graft)</td>
</tr>
<tr>
<td></td>
<td>2019/20 – 47 wrong implant/prosthesis</td>
</tr>
<tr>
<td></td>
<td>2020/21 – 30 wrong implant/prosthesis</td>
</tr>
<tr>
<td></td>
<td>(1 vascular graft)</td>
</tr>
<tr>
<td></td>
<td>2021/22 – 47 wrong implant/prosthesis</td>
</tr>
<tr>
<td></td>
<td>(2 vascular access device)</td>
</tr>
</tbody>
</table>
Data was then extracted from StEIS covering a 4-year period between 1 April 2018 and 31 March 2022. The StEIS data was initially coded in respect of whether the ‘incorrect’ element was due to size, type, or laterality (that is, the implant/prosthesis was for the wrong side of the body) (see table A3). In the case of the reference event, the category was ‘wrong type’.

Table A3 Numbers of ‘wrong implant/prosthesis’ Never Events by category from 1 April 2018 to 31 March 2022

<table>
<thead>
<tr>
<th>Category of ‘wrong implant/prosthesis’ Never Event</th>
<th>Numbers reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong side</td>
<td>42</td>
</tr>
<tr>
<td>Wrong size</td>
<td>110</td>
</tr>
<tr>
<td>Wrong type</td>
<td>77</td>
</tr>
</tbody>
</table>

The number of reported incidents and themes identified from the ‘root causes’/other information cited in the narrative were then analysed (see table A4).
### Table A4 Numbers of ‘wrong implant/prosthesis’ Never Events by theme from 1 April 2018 to 31 March 2022

<table>
<thead>
<tr>
<th>Theme of ‘wrong implant/prosthesis’</th>
<th>Numbers reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labelling and packaging</td>
<td>26</td>
</tr>
<tr>
<td>‘Human error’</td>
<td>28</td>
</tr>
<tr>
<td>Distraction</td>
<td>11</td>
</tr>
<tr>
<td>Checking processes/procedures</td>
<td>122</td>
</tr>
<tr>
<td>Time of day</td>
<td>2</td>
</tr>
<tr>
<td>Documentation</td>
<td>26</td>
</tr>
<tr>
<td>Communication</td>
<td>11</td>
</tr>
<tr>
<td>Storage</td>
<td>16</td>
</tr>
<tr>
<td>Time pressures</td>
<td>13</td>
</tr>
<tr>
<td>Computer systems</td>
<td>8</td>
</tr>
<tr>
<td>Training</td>
<td>9</td>
</tr>
<tr>
<td>Staffing</td>
<td>8</td>
</tr>
</tbody>
</table>

### Learning potential – what is the potential for an HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system?

Wrong implant/prosthesis incidents are a well-recognised but persistent safety risk. This suggests there are complexities associated with preventing these types of Never Event that need to be understood and acknowledged.
A national safety investigation can provide insight into persistent safety risks and make safety recommendations that stimulate change. In addition, they provide an opportunity to share learning from stakeholders and/or healthcare providers who have made beneficial improvements to positively influence processes and practices across organisations.

Evidence gathering and verification of findings

Evidence gathering

Sources of evidence included:

• Observation visits to three different trusts across England, to observe implant/prosthesis insertion procedures in the operating theatre.

• Visits to two of the early adopter sites for scanning technology.

• Review of literature relevant to the safety risk. Specifically, literature regarding checklists, human factors in operating theatres (including safety culture), scanning technology, regulation and standards for medical devices.

• Interviews with operating theatre clinicians.

• Interviews with operating theatre nursing staff.

Analysis of the evidence

The following methods/framework was used:

• Systems Engineering Initiative for Patient Safety (Holden et al, 2013). SEIPS is a framework for understanding structures, processes and outcomes and the relationships between them.

Model of investigation

The investigation used the Hierarchy of Intervention Effectiveness (Institute for Safe Medication Practices, 1999) risk management theory (see figure A1). The Hierarchy of Intervention Effectiveness rates the effectiveness of a range of interventions when seeking to make improvements or mitigate risks. Those interventions relating to human behaviour are towards the bottom of its scale as they are less effective. Technological interventions represent system-based solutions. These are more effective as they do not rely on individual human attention or vigilance and so are more reliable.
Figure A1 Hierarchy of Intervention Effectiveness (Institute for Safe Medication Practices, 1999)
Stakeholder engagement and consultation

The investigation engaged with stakeholders and a subject matter advisor (a consultant vascular surgeon) to gather evidence during the investigation. Engagement with stakeholders also enabled checking for factual accuracy and overall sense-checking. The stakeholders contributed to the development of the safety recommendations based on the evidence gathered.

Table A5 Stakeholder engagement during investigation

<table>
<thead>
<tr>
<th>Individuals, reference organisations and observation sites</th>
<th>National organisations</th>
</tr>
</thead>
<tbody>
<tr>
<td>The NHS Trust where the reference event took place</td>
<td>Medicines and Healthcare products Regulatory Agency</td>
</tr>
<tr>
<td>NHS foundation trust with multiple sites (Hospital 1).</td>
<td>British Standards Institution</td>
</tr>
<tr>
<td>The patient’s family</td>
<td>NHS Supply Chain</td>
</tr>
<tr>
<td>Three different trusts across England, where the investigation observed implant/prosthesis insertion procedures in the operating theatre</td>
<td>NHS England – Scan4Safety Programme</td>
</tr>
<tr>
<td>Two early adopter sites for scanning technology</td>
<td>NHS England – Patient Safety Team</td>
</tr>
<tr>
<td>Subject matter advisor</td>
<td>Royal College of Surgeons</td>
</tr>
<tr>
<td></td>
<td>Federation of Surgical Specialty Associations</td>
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</tbody>
</table>
Further information

More information about HSIB – including its team, investigations and history – is available at www.hsib.org.uk

If you would like to request an investigation then please read our guidance before contacting us.

@hsib_org is our Twitter handle. We use this feed to raise awareness of our work and to direct followers to our publications, news and events.

Contact us

If you would like a response to a query or concern please contact us via email using enquiries@hsib.org.uk

We monitor this inbox during normal office hours - Monday to Friday from 09:00 hours to 17:00 hours. We aim to respond to enquiries within five working days.

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