Investigation into the implantation of wrong prostheses during joint replacement surgery

Independent report by the Healthcare Safety Investigation Branch

June 2018

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About HSIB

The Healthcare Safety Investigation Branch (HSIB) began operating on 1 April 2017. HSIB offers an independent service for England, guiding and supporting NHS organisations on investigations and also conducting safety investigations.

HSIB aims to improve patient safety through effective and independent investigations that do not apportion blame or liability. This is delivered through:

- **Learning for improvement** – by using findings to deliver practical solutions, address causes and contributory factors and provide support to increase the capability within local NHS systems
- **Diffusing learning** – through effective communications and engagement with the wider health and social care system

HSIB’s investigations are conducted by a team of professional investigators from a range of safety critical backgrounds. This includes the NHS, aviation, transport and the military. HSIB also draws on additional expertise when required, including human factors advisers.

HSIB investigates up to 30 safety incidents each year to provide meaningful safety recommendations and share learning across the whole of the healthcare system for the benefit of everyone who is cared for by it and works in it.

**HSIB investigators**

HSIB investigators have:

- access to any organisation we’re investigating as per standard contract
- immediate access to the proceedings of any local investigation related to our work – for example, internal complaints investigations or CQC investigations
- free access to any other relevant information as required for the investigation
- freedom to interview those considered relevant to our investigation
- the ability to preserve evidence, within appropriate Data Protection guidelines, including records and equipment (faulty equipment may be needed for analysis by the Medicine and Healthcare Products Regulatory Agency)

HSIB investigations do not replace local investigations and are focused on looking at the wider opportunities to learn from exploring where harm may or has happened.

HSIB works with patients and their families and carers, healthcare staff, trusts, hospitals and other healthcare providers across England.
How HSIB decides what to investigate

HSIB welcomes information about patient safety issues for potential investigation from individuals, groups or organisations. The decision to investigate could relate to a single event, a series of events or a problem uncovered during investigation.

HSIB investigations will not replace local investigation of patient safety incidents. HSIB’s purpose is to identify national learning from such events and consider the wider systems and processes. It considers the following criteria when deciding whether to start an investigation:

**Outcome impact**

Assessing the impact or potential impact on people is a crucial part of the process. HSIB considers the physical and/or emotional harm suffered by anyone involved. The impact on services and whether the safety issues have reduced the ability to deliver safe and reliable care is also assessed. HSIB considers whether an incident has caused a loss of confidence in the healthcare system.

**Systemic risk**

HSIB reviews the system-wide risk associated with the safety issues. How common or widespread is the problem? Does it span different areas of healthcare and/or multiple locations?

**Learning potential**

HSIB exists to support improvements in patient safety. Its purpose is to show how investigations can produce new information about safety and to identify meaningful, influential and effective recommendations designed to benefit everyone working in or being cared for by the healthcare system.

HSIB investigators use a range of approaches to focus on identifying risk and the cause(s) of incidents.
Investigation approach

HSIB never attributes blame or liability. Its focus is solely to identify opportunities to learn and to improve patient safety. HSIB does not investigate on behalf of families, staff, organisations or regulators. It may investigate similar incidents in different locations, or incidents that have occurred across different organisations.

HSIB is funded by the Department of Health and hosted by NHS Improvement. HSIB is independent from regulatory bodies, including the Care Quality Commission. Its aim is to bring a new perspective.

HSIB will identify safety actions taken and make safety recommendations and safety observations to organisations or bodies that can influence and support change.

**Safety Actions** are actions taken during the course of the investigation as a response to the issue under investigation.

**Safety Recommendations** are directed to an individual or organisation for action. The recommendation(s) are based on information from the investigation and/or other eligible sources, including safety studies. Recommendations are made with the intention of preventing similar events.

**Safety Observations** are directed to a specific individual or organisation for consideration. Observations are made when there is a lack of information on which to make a definitive safety recommendation but HSIB believes its findings warrant attention.

A note of acknowledgement

HSIB would like to thank Mr. John Hampton, the patient whose experience is central to this report. Mr. Hampton was generous with his time and was open with the investigation about how the error had – and continues to – affect him. He shared his thoughts about what happened and his empathy for the staff involved.

Mr Hampton is referred to by name throughout this report in accordance with his wishes.
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Executive Summary

The reference incident

Mr John Hampton, a 62-year-old man, was admitted to hospital for a planned total hip replacement.

Following routine pre-operative checks he was taken to theatre and his operation began. A theatre nurse collected from the stock room the first two prostheses needed to create Mr Hampton’s new hip joint. The theatre team checked they were the correct ones before opening the packaging. The surgeon then implanted the prostheses.

About 15 minutes later, the third and fourth prostheses were collected and checked by the theatre team as before. This check did not identify that these prostheses were made by different manufacturers and not compatible to be implanted together. The packaging was opened and both prostheses were implanted.

Unaware of this error, the operation was completed and Mr Hampton was discharged home a few days later.

Following joint replacement surgery, all hospitals are required to enter details about the patient, the prostheses and the operation into the National Joint Registry. The registry generates an automatic alert if incompatible prostheses have been implanted into a patient. So, when the details of Mr Hampton’s prostheses were entered into the registry several days after his operation, the system identified the problem and alerted staff to the error.

Mr Hampton was informed of the error and it was also reported to relevant external bodies as a serious incident. The hospital began an internal investigation to understand what had happened. Expert advice was sought to decide if Mr Hampton would need another operation to replace the incorrect component. After consideration of all relevant information, a further operation was not judged necessary. The hospital made arrangements to review Mr Hampton regularly to check for any problems that might be related to implantation of the wrong prosthesis.
The national investigation

The hospital conducted an internal investigation and informed HSIB about the incident for consideration as a national investigation. HSIB gathered additional information and assessed the incident against its investigation criteria (see section 3.2). HSIB decided to progress to a national investigation.

The investigation reviewed the prosthesis verification process to understand why it does not always prevent implantation of the wrong prosthesis. The human factors which may influence identification of the correct prosthesis were considered. The investigation identified opportunities and systemic remedies to reduce the risk of this happening again.

This investigation focuses primarily on hip replacement surgery but the findings are applicable to all orthopaedic joint replacement.

The investigation identified:

1. Human factors which may hinder the identification and verification of the correct prosthesis.

2. Variations in practice in how the prosthesis verification is carried out by theatre teams. Some teams have developed specific practices aimed to reduce the risk of implantation of the wrong prosthesis.

3. Existing standards for labels on prosthesis packaging are not sufficiently detailed to ensure the labels can be easily read in the operating environment.

4. The automated message that appears when data is entered in the National Joint Registry suggesting that the wrong prosthesis has been implanted due to incompatible manufacturers is not as compelling as the alert that occurs when data is entered indicating the wrong size or side has been implanted.

5. A barcode scanning system could strengthen prosthesis verification.
HSIB makes the following Safety Recommendations:

1. **Recommendation 2018/001**: NHS Improvement amends the national Prosthesis Verification Standard to incorporate the specific aspects of verification practice developed to mitigate error identified in this investigation.

2. **Recommendation 2018/002**: The British Standards Institute amends existing standards for prosthesis labels to include details of design that make them easier to read in operating theatres. The American Society for Testing and Materials’ ‘Standard Guide for Presentation of End User Information for Musculoskeletal Implants’ is a useful reference.

3. **Recommendation 2018/003**: The National Joint Registry changes the response when data is entered into the registry suggesting the wrong prosthesis has been implanted due to incompatible manufacturers, so that it is consistent with the response when data indicates the wrong size or side has been implanted.

4. **Recommendation 2018/004**: The Department of Health and Social Care expands the remit of the working group consisting of Derby Teaching Hospitals NHS Foundation Trust’s Scan4Safety Programme, the National Joint Registry, and the Medicines and Healthcare products Regulatory Agency to include alerts to identify wrong prostheses prior to implantation.

5. **Recommendation 2018/005**: The Department of Health and Social Care commissions the development and implementation of an interim basic scanning system to identify wrong prostheses prior to implantation.

HSIB makes the following Safety Observation:

1. The national serious incident reporting system does not require inclusion of data regarding human factors such as environmental conditions, and individual and team factors. It would be beneficial for future developments to the system to collect such data.
1. Background

1.1. Never Events

1.1.1 ‘Prosthesis’ is defined in this report as a medical device intended to replace an absent or impaired structure in the body. The most common prostheses replace hip and knee joints and eye lenses. ‘Implant’ is defined as a medical device which is in addition to existing structures, such as a pacemaker.

1.1.2 In 2011, placement of an implant/prosthesis different from that intended to be used was deemed a ‘Never Event’. Never Events are defined as ‘Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers’. All serious incidents should be reported on the national reporting database known as the Strategic Executive Information System (StEIS).

1.1.3 In relation to surgical Never Events in general, the mandated use of the World Health Organization’s Surgical Safety Checklist, introduced in 2009 in England and Wales, was initially thought to be the strong systemic protective barrier that would prevent such events. However, as demonstrated through serious incident reporting, they continued to happen in subsequent years across hospitals nationally. After the publication of the Never Events Policy and Framework in 2011, the NHS Commissioning Board set up a task force to look at surgical Never Events and what was needed to prevent them. The task force published its report in 2014 and made several recommendations, including the standardisation of generic operating department procedures. Responding to the task force report, NHS England published the National Safety Standards for Invasive Procedures (NatSSIPs) in 2015. One of its standards relates to prosthesis verification and details the expected checks to be carried out by a theatre team (see section 4.1 Figure 5). They include checking the type, design, style or material, size, side (laterality), manufacturer, expiry date, sterility and compatibility of multiple components. A patient

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2 There are three types of surgical Never Events: Retained foreign object post procedure (the most common being swabs), Wrong site surgery, and Wrong implant/prosthesis.
4 Department of Health (2012) Protecting patients from harm.
safety alert was issued in 2015\(^6\) to support the introduction of NatSSIPs. The alert made clear the expectation for organisations to develop and implement their own local standards based on the minimum safety requirements defined in the national standards.

11.4 The number and type of Never Events reported on StEIS are published each month by NHS Improvement and are publicly accessible\(^7\). Despite the work of the task force and the standards that resulted, since 2011, when wrong implant/prosthesis became a Never Event, there has been no decline in the rate of incidents reported: on average 52 are reported each year. The latest provisional figures available at time of writing show 65 wrong implant/prosthesis incidents reported in the year to 31 March 2018.

11.5 This national investigation was initiated following an incident concerning implantation of the wrong prosthesis during a hip replacement. This procedure is one of the most common surgical procedures performed worldwide.\(^8\) Orthopaedic joint replacement surgery involves combinations of components and processes for selecting and verifying correct prostheses that are fundamentally different to other prosthesis surgery procedures, such as eye lens replacement. The vast majority of reported Never Events involving orthopaedic prostheses relate to hip and knees\(^9\) (which are by far the most common joint replacement operations). These averaged 21 per year between 1 April 2012 and 31 March 2018 and show no sign of declining. The latest provisional figures available at time of writing show 26 in the year to 31 March 2018.

12. National Joint Registry

12.1 The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man collects information on joint replacement surgery in the NHS and the independent healthcare sector.

12.2 The National Joint Registry was set up in 2002 and began collecting data in 2003. Its work is overseen by a multidisciplinary steering committee, which includes members representing orthopaedic surgeons, implant manufacturers, regulators and patients. One of the National Joint Registry’s goals is to monitor the relative outcomes achieved by brand of prosthesis, hospital and surgeon. To achieve this, the registry has several sub-committees such as the Surgeon Performance Committee, Implant Performance Committee, Implant Scrutiny Committee and Data Quality Committee. Data submissions to

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\(^7\) [https://improvement.nhs.uk/resources/never-events-data/](https://improvement.nhs.uk/resources/never-events-data/)


\(^9\) There are a small number of wrong fixation plate incidents (4% of reported wrong orthopaedic prosthesis incidents)

[www.hsib.org.uk](http://www.hsib.org.uk)
the National Joint Registry are mandated in England through the NHS Standard Contract for hospitals and regulated by the Care Quality Commission.

1.2.3 Any provider carrying out hip, knee, ankle, elbow or shoulder surgery is required to submit to the National Joint Registry information about all eligible primary (first-time joint replacement) and revision (repeat) procedures. Hospitals submit information to the National Joint Registry retrospectively (post-surgery). The information includes patient demographics, relevant details of the surgery and the prostheses used. Data submission has improved over time (in a retrospective audit of data submissions for 2014/15, the National Joint Registry reported that a mean of 95% of eligible hip and knee replacements had been submitted) but the National Joint Registry is still working to ensure all hospitals submit all relevant data.

1.2.4 The National Joint Registry is the world’s largest joint registry¹⁰ with more than two million entries¹¹. It has links with registries and similar organisations in other countries, including the European Federation of National Associations of Orthopaedics and Traumatology and the International Society of Arthroplasty Registers.

1.2.5 In 2008, the management of the National Joint Registry was transferred from the Department of Health to the Healthcare Quality Improvement Partnership (HQIP), a consortium comprising of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. The National Joint Registry management team is based at HQIP. The National Joint Registry has two contracts for delivery of specialist services. One is with Northgate Public Services, which is responsible for data collection and data management; the other is with the University of Bristol, which is responsible for statistical analysis of the National Joint Registry data and support research.

1.2.6 Since June 2017, following software development, an automated ‘message alert’ appears if data entered after surgery indicates a possible Never Event. The alert provides an opportunity for the person entering the data to check if they have made a typing error or if an actual wrong prosthesis incident has occurred. When an alert is triggered, an automated message is sent to one of the National Joint Registry regional co-ordinators who follows up with the hospital directly.

¹¹ Personal communication with chair of the National Joint Registry Data Quality Committee, 6 December 2017.

www.hsib.org.uk
1.3. Historical data regarding prevalence

1.3.1 National Joint Registry data from 2003 to June 2017 was reviewed to ascertain the rate of wrong prosthesis incidents. The review found a significant number of potential wrong prosthesis incidents for knee and hip prostheses but, when verified with the hospital involved, most turned out to be data entry errors not surgical errors. About half of the potential incidents identified are still in the process of being verified. Of those that have been verified, implantation of the wrong prosthesis occurred in 3.5 per 10,000 cases (0.035%) of hip replacements and 3.8 per 10,000 cases (0.038%) of knee replacements.

1.4. Hip joint replacement and prostheses used

1.4.1 Several prosthetic components are used during hip replacement surgery to create an artificial joint (similarly for knees).

![Components used in a total hip replacement](https://orthoinfo.aaos.org/en/treatment/total-hip-replacement/)

Figure 1: Components used in a total hip replacement

1.4.2 The four prosthetic components most frequently used are:

- Femoral stem - which attaches to the femoral head and supports the new hip joint. This is usually metal.
- Femoral head - which fits directly into the new socket and is attached to the femoral stem. Femoral heads come in different diameters (sizes) and offsets (how much they stick out). They are metal or ceramic.

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12 Image from https://orthoinfo.aaos.org/en/treatment/total-hip-replacement/
• Acetabular component – the bowl-shaped piece that creates the new socket. This is made of high quality plastic (which is cemented directly into the socket) or metal (which can be fitted without cement, in which case it needs a liner).

• Liner - which fits into the shell of an uncemented acetabular component and allows the femoral head to glide easily and more naturally in the socket. It is made of high-quality plastic or ceramic.

1.4.3 The first stage of hip replacement involves pulling the head of the femur (the bone that extends from the hip to the knee) out of its socket (acetabulum) in the pelvic bone. Damaged bone and cartilage is removed from the socket and it is then resurfaced with an artificial cup, the acetabular component. Depending on the type of cup used, a liner may be required and is fastened into the cup.

1.4.4 The second stage of the procedure involves removing the ball-shaped head of the femur. The top end of the shaft of the femur is then reamed out so an artificial piece, a femoral stem, can be implanted into it. The stem is then fitted with a new ball (femoral head). The combination of stem and head makes up the femoral component. Once attached, the ball-shaped head will be plugged into the newly formed socket.

1.4.5 Hip replacements fit into two broad categories – cemented and uncemented. This is based on how the implants become fixed or integrated into the bone and overall into the patient’s body. The implants used in each category are broadly similar but have specific design features.

1.4.6 Most manufacturers state in their instructions for use that their components should not be used with those of other manufacturers. However, data from the National Joint Registry demonstrates that this practice is common; it shows that many surgeons in the UK have matched a femoral component from one manufacturer with an acetabular component from another. A study, based on the National Joint Registry that looked at the prevalence and comparative outcomes, showed this is not associated with increased revision rates unless femoral heads and femoral stems from different manufacturers are used together.\(^1\)

1.4.7 Hip replacement has become increasingly complex over time because of the wide range of prostheses available, variants in design and possible combinations. The number of products available continues to grow each year.\(^2\) This means knowledge of prostheses has become increasingly specialised. Indicative of the complexity of orthopaedic surgery.

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\(^2\) Interview with chair of National Joint Registry Data Quality Committee, 6 December 2017.
representatives from some manufacturers may be routinely present in theatres to support and advise surgeons on the use of specific products and prostheses.

1.4.8 There are four main manufacturers – and many smaller suppliers – who supply hip components in England. For hip replacement operations, there are several hundred products for surgeons to choose from and multiple potential combinations of these products.15

1.4.9 Prior to surgery, the surgeon decides which make (manufacturer) and model of prostheses to use so that theatre staff can prepare the appropriate trays of equipment.

1.4.10 During surgery, when the hip joint is exposed, the surgeon makes the final decision about the size of prostheses using trial prostheses to determine the best fit. The actual prostheses to be implanted are then requested.

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15 Interview with chair of Implant Scrutiny Committee & President of the British Hip Society. See also products listed on Orthopaedic Data Evaluation Panel website http://www.odep.org.uk/products.aspx?typeid=1
Figure 2: Theatre preparations for a hip replacement. Trays containing sets of equipment (including trial prosthesis) are opened, checked and prepared ready for use.
1.5. Regulation of prostheses

1.5.1 Countries in which medical devices such as prostheses are sold have organisations responsible for confirming devices comply with European regulation. Known as notified bodies, these organisations issue certification when compliance is achieved. Oversight and audit of notified bodies is maintained by a ‘competent authority’. The Medicines and Healthcare products Regulatory Agency[^16] (MHRA) is the competent authority responsible for the oversight and audit of the five notified bodies in the UK. The MHRA co-ordinates with other competent authorities in Europe and internationally. The British Standards Institute is responsible for standardisation of implants for surgery in the UK and has links with the MHRA.

1.5.2 Hip and knee joint replacements account for approximately 90% of reconstructive orthopaedic surgery. There are an estimated 80,000 prosthesis and implant combinations that can be used during joint surgery[^17]. The label on prosthesis packaging has all the details the theatre team need to confirm during prosthesis verification. Prosthesis packaging also has a barcode which contains this information and uniquely identifies the device.

[^16]: MHRA is an Executive Agency of the Department of Health.
[^17]: Telephone conference with chairman of Beyond Compliance and the Orthopaedic Data Evaluation Panel & Head of Health Solution Strategies at Northgate Public Services, 6 Feb 2018.
2. The reference incident

2.1. The day of surgery

2.1.1 Mr John Hampton, an active 62-year-old man, was referred to his local hospital trust for a total hip replacement due to osteoarthritis. He was admitted to hospital on Wednesday 27 September 2017. He was the first patient on the morning operating list.

2.1.2 After the morning team briefing, when the operating list was discussed, the consultant surgeon spoke with a colleague about the operation he was about to perform and his choice of prostheses. He had planned to use uncemented prostheses made by JRI Orthopaedics Ltd (JRI) in accordance with the hospital’s policy for patients of Mr Hampton’s age. However, as a result of this conversation, and considering the patient’s anatomy (the shape of his femur and angle of the neck and shaft), the consultant decided instead to use a cemented femoral stem and head by a different manufacturer, Zimmer Biomet (Zimmer). He informed the theatre team and the relevant instrument sets were collected, opened and prepared for use.

2.1.3 Mr Hampton arrived in the anaesthetic room at 09:20 and was given spinal anaesthetic and sedation. He was taken into the operating theatre at 09:38. The theatre team included the consultant surgeon, his assistant, a scrub practitioner and two circulating nurses. All members of the theatre team were senior, experienced in the surgery being performed and used to working together.

2.1.4 At 10:14 the surgeon requested the first two prostheses, a JRI cup and liner, which were collected from the stock room by one of the circulating nurses.

2.1.5 The circulating nurse brought the two prostheses into the operating theatre and the scrub practitioner and surgeon checked they were correct (see section 4.1). The barcodes on the packaging were also scanned, adding the details of the prostheses to Mr Hampton’s electronic patient record. The packaging was then opened and the prostheses implanted. This circulating nurse then went for a break.

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19 The Investigator was advised that the hospital had rationalised the number of orthopaedic components used for hip (and knee) surgery guided by evidence regarding clinical outcomes. Primarily the choice of prosthesis was determined by a patient’s age and whether they were active or sedentary. That said, the surgeon could deviate if the patient’s anatomy or some other factor indicated a different choice may lead to a better outcome or be more appropriate for that particular patient.

19 Scrub practitioners assist the surgeon and are responsible for sterile equipment and swab/needle/instrument reconciliation.

20 Circulating nurses collect equipment, participate in swab and instrument counts, make sure relevant documentation is completed and help in any other way required.
Figure 3: The electronic prostheses storage system, including the keypad where the type of operation is entered (E). Fingerprint recognition allows an audit of the time and person removing the prosthesis. Prostheses are kept in different cupboards according to manufacturer.

2.1.6 At 10:29, the remaining circulating nurse went to collect the third and fourth prostheses, intended to be a Zimmer femoral stem and head. A Zimmer femoral stem was selected from the cupboard where this manufacturer’s components are kept but the JRI cupboard was then opened and a JRI femoral head selected.

Figure 4: Packaging of Zimmer femoral stem (F) and head (H) intended for implantation and the JRI femoral head that was collected (G)
2.1.7 These prostheses are not licensed to be used together. As before, when the prostheses were brought into the operating theatre, checks were carried out with the theatre team. This checking process did not identify the third and fourth components were by different manufacturers and the packaging was opened. Out of their packaging, the intended prosthesis and the prosthesis collected look the same. Consequently, the Zimmer femoral stem and JRf femoral head were implanted. As with the previous prostheses, the barcodes were scanned, adding the prosthetic details to the electronic patient records. At 11:16 the operation finished with the theatre team believing everything had gone to plan. Mr Hampton was transferred to the recovery room\textsuperscript{21} at 11:21 and returned to the ward at 12:15.

2.2. Post surgery

2.2.1 Mr Hampton was discharged from hospital to his home on 1 October 2017.

2.2.2 On 3 October the details of Mr Hampton’s surgery and the prostheses used were entered on the National Joint Registry. The system identified and alerted staff to the possible prosthesis error. This was confirmed by reference to Mr Hampton’s electronic patient record.

2.2.3 The consultant surgeon informed Mr Hampton and apologised for the error. Expert advice was sought to see if Mr Hampton would need another operation to replace the incompatible JRf femoral head. Having considered the differences in technical specifications between the intended and implanted prostheses\textsuperscript{22}, a further operation was judged unnecessary. It was agreed that Mr Hampton would be monitored for any physical problems resulting from his hip prostheses.

2.3. Impact on Mr Hampton

2.3.1 Mr Hampton was contacted by the investigation to hear his views about the error and to understand its impact on him. Mr Hampton was informed about the national investigation process. Whilst Mr Hampton had not experienced any physical problems as a result of the wrong prosthesis, knowledge of the error had caused him considerable distress and anxiety.

\textsuperscript{21} Area where surgical patients are kept during the immediate postoperative period for care and recovery from anaesthesia.

\textsuperscript{22} Specifically, the investigation was advised that consideration was given to the difference in taper angle between the neck taper of the femoral stem, and the taper inside the head where they both engage. They were advised that most manufacturers aim for less than 0.1 as a tolerance limit. In relation to Mr Hampton, the difference in angles between the head and stem that was wanted and the one implanted was 0.08 degrees so within most manufacturers tolerance limits.
2.3.2 Mr Hampton described the first weeks after the error came to light, when expert advice was being obtained and he did not know if he would need another operation. He remembered this being a particularly difficult and upsetting time. He explained that he had “not been [him]self”, which his wife and children had noticed. Mr Hampton said his anxiety and worry regarding possible further surgery had been compounded by knowing his employers would only provide sick pay for a limited period of time. Should he have required further surgery, it would have meant his time off work would have extended beyond that period.

2.3.3 Although surgery was not deemed necessary, Mr Hampton described the lingering anxiety caused by knowing that an incorrect hip component is inside him.

2.3.4 Discussing the incident itself, Mr Hampton said he couldn’t understand how it happened and wanted the investigation to answer this. Despite the distress this error caused – and the worry he continues to have – Mr Hampton expressed concern regarding the welfare of the staff involved.

2.4. Clinical outcomes at the hospital where the reference incident occurred

2.4.1 This hospital has ‘better than expected’ clinical outcomes (based on revision rates) for both hip and knee replacement surgery. This indicates the occurrence of a surgical Never Event does not, of itself, indicate a cause for concern about the quality and safety of care in a hospital’s operating theatres. This echoes the findings of Moppett and Moppett (2016) who found no association between surgical Never Events and other indicators assessing safety and quality of care.

23 National Joint Registry (2017) 14th Annual Report
3. Involvement of HSIB

3.1. Referral of reference incident

3.1.1 The chief nurse at the hospital contacted the Healthcare Safety Investigation Branch (HSiB) on 7 October 2017 regarding the error and the possibility of HSiB conducting a national investigation. Further information was obtained, and the incident and the national context were presented at HSiB’s scrutiny panel on 24 October 2017. A scoping investigation was initiated to determine the learning potential of a national investigation.

3.2. Decision to investigate

3.2.1 Following an initial scoping investigation, the chief investigator authorised a full investigation as the incident met HSiB’s criteria:

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

Implantation of the wrong prosthesis can cause patients psychological harm, as well as sometimes requiring them to have another operation to rectify the error. Patients requiring joint replacement are often older and may be frail, which adds additional risk to those already attached to surgery. Such surgical errors may undermine patient confidence and trust in healthcare services and in the safety of surgery. Wrong prosthesis incidents also have a significant impact on staff. As well as the potential physical and psychological harm, such errors incur a financial burden and can seriously damage a hospital’s reputation.

b) **Systemic Risk** – How widespread and how common a safety issue is this across the healthcare system?

Data gathered from StEIS show that despite published guidance aimed at preventing these events the frequency of reported incidents has not reduced. These incidents occur across hospitals nationally. On average, 21 wrong hip and knee prosthesis incidents are reported every year – about two a month – indicating a national, systemic issue.
c) Learning Potential – What is the potential for an HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system?

A review of incidents reported to StEIS over six months\textsuperscript{25} found that ‘checking process not followed’ was listed as a root cause in all of them. This suggests that the complexities associated with the prosthesis verification process prevent it from being a strong and effective barrier to such events. It was agreed the investigation should review the process to better understand why it does not always prevent the implantation of wrong prostheses. The investigation would also identify strategies and opportunities to reduce the risk of further incidents occurring.

3.2.2 This investigation focused on hip replacement surgery but its findings apply to all orthopaedic prosthesis surgery.

3.3. Investigation process and methodology

3.3.1 This investigation used a range of methodologies including:

1) Review of patient theatre records, hospital policy, procedure, prosthesis storage and prosthesis verification at the hospital where the reference incident occurred.

2) Observations of orthopaedic operations at the hospital where the reference incident occurred and in six theatres at three other locations (a private hospital, an elective orthopaedic centre and an elective orthopaedic unit in Denmark). Two observers positioned themselves at different locations in the theatres. They made independent observations, notes and sketches of equipment layout and usage. Data was compared and reviewed later.

3) Semi-structured interviews with surgeons, nurses, and support staff at the locations visited.

4) Review of wrong prosthesis incidents reported on StEIS to ascertain the annual number of incidents and to look at a sample of completed investigation findings and recommendations.

5) Literature review.

6) Interviews and personal communications with national organisations and subject matter experts, both clinical and non-clinical, about wrong prosthesis events and possible improvements to reduce recurrence.

7) Communication with several international specialists regarding wrong prosthesis incidents.

\textsuperscript{25} The review from 1 January–30 June 2016 looked at information submitted following completion of a Serious Incident investigation. 28 wrong prosthesis incidents were recorded, of which 18 had submitted information regarding investigation findings including the root cause(s).
3.3.2 The ‘strong, systemic, protective barrier’ against prosthesis errors that is discussed in *NHS Improvement’s Revised Never Events policy and framework (2018)* relies on human checks. The investigation therefore sought the expertise of a human factors advisor.

3.3.3 The International Ergonomics Association\(^\text{26}\) define human factors as: ‘the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimise human well-being and overall system performance’. Its central stance is to recognise that humans have physical and cognitive limitations.

### 3.4. Limitations of observations

3.4.1 The primary limitation of observations is sample size. When compared to the number of trusts and private facilities providing this type of orthopaedic procedure, the number of observations was very small. However, findings were supplemented by insights from clinical subject matter experts with significant clinical experience of hip and knee replacement surgery. The findings were also supplemented by a literature review of relevant academic papers.

3.4.2 Ethnography (observations of people in their work environment) and contextual studies rely on the observers’ skill in noting the actions and activities of those being observed. The procedures observed were complex with up to nine operating staff working around the patient, and some areas were screened off from view. The limited number of operations observed may have meant not all activities were fully captured.

3.4.3 Any observations of people at work by other people introduced as ‘conducting research’ or from ‘an external body’ with apparent authority (whether real or perceived) will affect the way people behave.

\(^\text{26}\) [https://www.iea.cc/whats/index.html](https://www.iea.cc/whats/index.html)
4. Findings and analysis at the hospital where the reference incident occurred

4.1. Prosthesis verification

4.1.1 The National Safety Standards for Invasive Procedures (NatSSIPs), published in 2015, detail the prosthesis verification the theatre team are expected to follow before implanting a prosthesis (see Figure 5 below). This includes checking the type, design, style or material, size, side (laterality), manufacturer, expiry date, sterility and compatibility of multiple components.

4.10.2 DURING THE PROCEDURE

i. Before removal of the prosthesis from its packaging, the operator should confirm the following prosthesis characteristics with the procedural team:
   - Type, design, style or material.
   - Size.
   - Laterality.
   - Manufacturer.
   - Expiry date.
   - Sterility.
   - Dioptre for lens implants.
   - Compatibility of multi-component prostheses.
   - Any other required characteristics.

ii. Once the correct prosthesis has been selected, any prostheses not to be used for that patient should be clearly separated from the correct prosthesis to minimise the risk of confusion between prostheses at the time of implantation.

4.10.3 AFTER THE PROCEDURE

i. A record of the implants used must be made in the patient’s notes and appropriate details should be shared with the patient after the procedure. When a manufacturer’s label is available, this should be placed in the notes. When it is not, the following should be recorded:
   - Manufacturer.
   - Style.
   - Size.
   - Manufacturer’s unique identifier for the prosthesis, e.g. the serial number.

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

iii. The organisation must have a process in place for recording which prostheses are used for which patients.

iv. The organisation must ensure that appropriate and agreed stock levels of prostheses are maintained.

v. Instances of failed prosthesis verification, wrong prosthesis insertion and “near misses” should be reported, recorded and openly discussed at the debriefing, and fed into local governance processes to act as the basis for learning and the development of new or altered procedures to promote patient safety.

vi. Audit of prosthesis verification data must be performed.

vii. When manufacturers’ labelling, packaging or implant defects contribute to failure of prosthesis verification, a process must be in place through which both the manufacturers and the MHRA (Devices) are informed.

Figure 5: Extract from the National Safety Standards for Invasive Procedures (2015)
STANDARD OPERATING PROCEDURE FOR SELECTION AND CHECKING OF ORTHOPAEDIC IMPLANTS

PRIOR TO TEAM BRIEF THE STAFF CHECK RELEVANT PROSTHESIS AVAILABLE (I.E. HIP OR KNEE)

AT TEAM BRIEF THE TYPE OF PROSTHESIS IS DISCUSSED IN MORE DETAIL

ANAESTHETIC AND SURGERY BEGINS

WHEN READY SURGEON IDENTIFIES CORRECT SIZE OF PROSTHESIS AND THIS IS BROUGHT INTO THEATRE

THE SURGEON, SCRUB NURSE AND CIRCULATING STAFF CHECK AND VERBALLY CONFIRM THE PROSTHESIS. IDENTIFYING: INTEGRITY OF THE BOX, CORRECT OPERATING SIDE, SIZE, EXPIRY DATE, MANUFACTURER AND COMPATIBILITY OF COMPONENT

THE SURGEON THEN IDENTIFIES WHICH OF THOSE PROSTHESSES WILL BE OPENED FIRST

PROSTHESIS ID LABELS ARE SCANNED INTO V6 CARE PLAN, PLACED INTO THE THEATRE REGISTER AND ONTO THE GREEN CARE PLAN

PLEASE NOTE: ONLY THE RELEVANT PROSTHESIS IS BROUGHT INTO THEATRE ONCE THE DEFINITIVE SIZE IS DETERMINED. ANY PROSTHESIS NOT USED WILL BE REMOVED FROM THEATRE PRIOR TO THE NEXT PATIENT.

STANDARD OPERATING PROCEDURE FOR SELECTION AND CHECKING OF ORTHOPAEDIC IMPLANTS - VERSION 2

Figure 6: Local Standard Operating Procedure in place at the time of the reference incident
4.1.2 However, the national standard for prosthesis verification does not detail how the checking process is to be carried out. It does not, for instance, stipulate who should read out the details of the prosthesis on the packaging label. Should this be the member of theatre staff who collected it, the scrub practitioner or the surgeon? If not the surgeon, how does the surgeon demonstrate confirmation this is the prosthesis wanted? Is a nod of the head sufficient or is a ‘yes’ or ‘no’ required? Does the surgeon need to read the packaging label too?

4.1.3 The patient safety lead for Never Events and surgery at NHS Improvement explained that the national standard aims to “provide a framework of the minimum safety requirements within which local innovation is allowed”. Rather than imposing the specifics of how organisations should carry out the prosthesis check, the intention is for healthcare organisations to develop their own standard, including the details of how and by whom the check is completed.

4.1.4 The hospital where the reference incident occurred had a local standard operating procedure that mostly reflected national guidance (see Figure 6 above). As with the national standard, this did not include the detail of how the prosthesis verification check was expected to occur.

4.1.5 The staff involved with Mr Hampton’s operation reflected on the prosthesis verification during his surgery. It should be noted that these interviews took place six weeks after the incident. Memory recall at this timeframe may be affected by many factors and so have limited accuracy.27 However, recollections are helpful in providing insight into usual or expected practice.28 The team members involved in prosthesis verification during Mr Hampton’s surgery were the consultant surgeon, the scrub practitioner and the two circulating nurses who collected the prostheses.

4.1.6 The circulating nurse who collected the incompatible femoral stem and head described writing down details of the prostheses requested on a board which was kept in theatres for this purpose. She said she did not write down the manufacturer because this was not common practice. The nurse could not understand why she had gone to different cupboards that contained prostheses from different manufacturers. She recalled bringing the femoral stem and head into the operating theatre. She described showing both prostheses, holding one box on top of the other, to the consultant surgeon and scrub

27 Ebbinghaus H (1885) Über das Gedächtnis, which was later translated into English as “Memory. A Contribution to Experimental Psychology” (1913) New York, Teachers
practitioner to check. She remembered everybody pausing and the consultant reading out loud the details on the box, including the size and expiry date but not the manufacturer. The nurse said everyone checked the details but no one noticed the different manufacturers and different boxes (see Figure 4). The nurse explained that she knew of the standard operating procedure for prosthesis verification but commented that ‘nobody [knew] it properly’.

4.2. Individual and team factors

4.2.1 The circulating nurse recalled feeling tired on the day of Mr Hampton’s surgery, having returned the night before from a two-day course. She explained she had slept badly because it was her first time staying away from her children and partner. The investigation reviewed the work rota of the circulating nurse, which showed she had worked shifts totalling 59 hours in the previous seven days. This was well in excess of her contracted working week of 37.5 hours.

4.2.2 Fatigue is recognised to negatively affect performance\(^\text{29}\). Prosthesis verification is an activity the operational team engages in (rather than just one person). However, the human factors advisor said a checking process may be compromised if the ability, skills and vigilance of any one individual are impaired. In this incident, the tired member of staff was one of those responsible for collecting prostheses, so had a critical role. This nurse and other staff also spoke of the general time pressure in theatres – pressure to complete all planned cases on the operating list and to complete them on time.

4.2.3 A review of completed investigation findings from the national serious incident database (StEIS) regarding wrong prosthesis incidents from 1 January – 30 June 2017 did not identify fatigue or time pressure as contributory in previous events. However, StEIS does not require the inclusion of such individual and organisational factors. Given that the quality of local investigations by trusts is known to often be limited in focus\(^\text{30}\), the apparent absence of such contributory factors may not reflect the reality.

4.2.4 The circulating nurse spoke about relationships and teamwork in the operating theatres. She described the theatre team as “like a family”. Several of the staff interviewed speculated whether the familiarity and trust between the operating team had led them to

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be complacent about checking. A staff member at one of the observation sites also mentioned the risk of over-familiarity, describing the result being “...you don’t really check”. This risk was acknowledged by the Never Event taskforce in their report (2014) in relation to team functioning. The report noted that confident, comfortable teams may become ‘less vigilant’31, a point also made in academic literature32. However, the lack of familiarity of staff working with each other was raised more frequently with the investigation as a greater risk for error. This was echoed by clinical subject matter experts and is reflected in research comparing error rates between familiar and unfamiliar teams33.

4.2.5 At the time of writing, the national serious incident database is under review. This may, therefore, be an appropriate time to consider the inclusion of human factors (such as environmental, organisational, individual and team factors) as part of data collection to aid understanding of the aetiology of error.

HSIB therefore makes the following safety observation:

**Safety Observation for NHS Improvement**

The national serious incident reporting system does not require inclusion of data regarding human factors such as environmental conditions, and individual and team factors. It would be beneficial for future developments to the system to collect such data.

4.2.6 The consultant surgeon pointed out the favourable conditions surrounding Mr Hampton’s procedure. Mr Hampton was first on the operating list, the consultant had not been on call the night before (so was not tired), he was working with a “fantastic” senior assistant and a “good team”, with whom he was familiar. Like the other team members involved with the prosthesis verification, the consultant was surprised and distressed by the event. He could not recall the details of the prosthesis verification during the operation as there was nothing out of the ordinary about it. He could not remember whether the circulating nurse wrote prostheses details on the board and took it with her to collect the prostheses or if the prostheses boxes were shown together. The consultant was, however, very clear that he always pauses, reads and checks the prosthesis packaging label, so he was certain he would have done that. Like other team members involved with the prosthesis verification, the consultant explained the focus of attention was not on the manufacturer but on

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other details such as the size, material, and side (when relevant to the surgery). He recalled past experience of being brought the wrong sized component but had never been brought the wrong manufacturer. This was not, therefore, an error experience had taught him to be alert to. He commented on how different the packaging of the JRI femoral head was from the Zimmer femoral head (see Figure 4). He was surprised the difference was not noticed if the boxes had been shown together.

4.2.7 The circulating nurse who collected the first set of prostheses (acetabular cup and liner) was on a break when the incompatible prostheses were collected. He could not recall if he wrote the details of the cup and liner requested on the board before collecting them from the stock room. He described holding the prostheses boxes together, as “always happens”, for checking by the scrub practitioner and surgeon. The nurse noted that the focus of the prosthesis verification was on the size, other component details and expiry date – not the manufacturer. The nurse could not recall if the manufacturer was usually included in the check or not, explaining it could have been said “automatically” but it was not the focus.

4.2.8 Due to the length of time between the event and staff interviews, and there being no other evidence about the prosthesis verification that took place, it cannot be known precisely what checks were undertaken, or at what point the process failed. The initial error of collecting the incompatible femoral head and stem appears to have been caused by a lapse in memory or a slip in attention. It is notable that both manufacturers had been discussed for Mr Hampton. JRI was the consultant’s initial choice of manufacturer but he decided on a Zimmer femoral stem and head after talking with his colleague. Memory lapses or slips in attention are well recognised as the types of error skilled, experienced staff make34 as opposed to errors arising from lack of knowledge or understanding.

4.3. Variation in practice

4.3.1 During interviews with the staff involved – and with other members of the wider theatre team – it was clear the prosthesis verification process was not carried out in a standardised way. Sometimes a circulating nurse read out the details on the prosthesis packaging label to the scrub practitioner and surgeon, who then read the label themselves. Sometimes a circulating nurse would show the packaging to the scrub practitioner, who would read the label details and the surgeon would confirm agreement without reading the

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label. Other variations in practice were also observed. The variations seemed dependent on the staff involved.

4.3.2 Staff interviewed consistently reported that prosthesis verification did not always include a check of the manufacturer, as required in the national and local standard. They explained that the focus was on confirming the right size or right variant of component, of which there are multiple options. Significantly, staff noted that the manufacturer is agreed before surgery and rarely changes during the operation. Furthermore, staff interviewed had not experienced prostheses of incompatible manufacturers being brought into the operating theatre but could recall instances of the wrong size or variant being collected. Such errors were almost always identified during subsequent checks. The rationale for not focusing on the manufacturer during the final prosthesis check is, therefore, consistent with the staff’s experience of the risk of error.

4.4. Local developments to mitigate risk of error

4.4.1 The investigation observed practices that staff had developed to minimise the risk of implanting the wrong prosthesis; for example, by holding together (during prosthesis verification) the boxes of prostheses that need to be compatible. Thus, femoral head and stem boxes were observed being held together because they need to be made by the same manufacturer. The boxes of an implanted cup and liner were held with the box of a femoral head about to be implanted to confirm the sizes were correct. Several staff interviewed speculated whether, in this incident, the femoral head box was opened without showing it to the scrub practitioner and surgeon. Another possibility raised was that the femoral stem and head boxes had been shown separately as they believed the visual difference between the boxes would have alerted staff to the error had they been shown together. The boxes may appear to be very different but research shows that when attention is focused on specific elements (here, the size, material and other variants of the component) seemingly obvious differences may be missed35. The consultant surgeon involved in the incident summed up this situation when he said of the differing JRI and Zimmer boxes they were “not in my conscious mind”.

4.4.2 The investigation learned of another practice introduced to reduce error after a similar incident in July 2017. This was the introduction of the requirement to write on a board the

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35 This is a well-recognised psychological phenomenon, referred to as inattentive blindness, or perceptual blindness. Repeated experiments have demonstrated people’s inability to detect unexpected objects (irrespective of being brightly coloured) if their attention is elsewhere. In essence, without attention there is no conscious perception. See for example, Mack A. & Rock I (1998) Inattentional Blindness. Cambridge, MA: MIT Press.

Also relevant to this incident and other wrong prosthesis incidents is a psychological trait known as selective attention. This was first recognised by Broadbent in 1958 (Broadbent D. E. Perception and Communication. Pergamon, London). The effect of this phenomenon is that we see only what we expect to see.
details of prostheses requested to take with them to the stock room. This was to prevent staff forgetting details between leaving the theatre and collecting prostheses. On returning to the operating theatre, the board should be shown to the scrub practitioner and surgeon alongside the prostheses boxes to confirm they match (see Figure 7).

4.4.3 Staff said this practice was useful because they were often distracted by interactions with other colleagues after leaving the theatre. Despite this, staff reported that the board was not always used or not used consistently; for example, some staff wrote on the board but then did not take it with them to the stock room. The investigation heard staff had previously written details of requested prostheses on their hand or on a piece of paper to prevent forgetting details. Use of the board therefore formalised the workarounds staff had adopted.

Figure 7: Simulation of the prosthesis board with details of prosthesis requested, alongside collected prostheses being shown to the operating team.
4.5. Actions resulting from the local investigation

4.5.1 The Trust’s internal investigation into Mr Hampton’s wrong prosthesis resulted in several safety actions being introduced to reduce the risk of recurrence. The key actions were:

**Safety Action 1**

Amendment of the hospital’s prosthesis verification standard operating procedure to include that, where two prosthetic components fit together, they are checked at the same time and, if one component is not needed immediately, it is rechecked at the time of use. The same member of staff should ideally collect all prostheses.

**Safety Action 2**

Manufacturer details for each prosthetic component to be included on the prosthesis board. All details to be checked with the surgeon prior to taking the board to the stock room for prosthesis collection.

**Safety Action 3**

A prosthetic check ‘stop point’ should take place when the circulating nurse, scrub practitioner and surgeon stop and read aloud, together, the details of the prosthesis to be opened and these are checked against the prosthesis board.

**Safety Action 4**

Development of an additional prosthesis checking form that includes all factors to be checked for each prosthesis. Details of staff involved to be recorded for accountability. Compliance with the form to be audited.

4.5.2 The internal Trust investigation also made several recommendations. Some reiterated current expected practice such as the manufacturer and compatibility of components to be included in the checking. Others related to behaviours during the checking process (‘it should be carried out carefully and be unbiased, with no assumption of a previous check being correct’). Exploring the possibility of a barcode scanning system was also mentioned.

4.5.3 The investigation observed a hip operation in the hospital where the reference incident occurred. This observation took place approximately six weeks after the interviews with staff and approximately three months after the incident. The prosthesis board was observed being used. However, the additional implant checking form was observed being completed after the prosthesis was implanted so would not have helped to prevent error. The investigation’s human factors advisor questioned whether another level of checking was the solution. He noted that such a check is subject to the same limitations as the existing checks – specifically, that staff will, inevitably, have slips in attention and memory lapses.
STANDARD OPERATING PROCEDURE FOR SELECTION AND CHECKING OF ORTHOPAEDIC IMPLANTS

Prior to team brief the staff check relevant prosthesis available (i.e. hip or knee)

At team brief the type of prosthesis is discussed in more detail

Anaesthetic and surgery begins

When ready surgeon identifies correct size of prosthese and this is brought into theatre

The surgeon, scrub nurse and circulating staff check and verbally confirm the prosthesis. There must be concentration on the implant check only. Identifying: integrity of the box, correct operating side, size, expiry date, manufacturer and compatibility of component

NB. In the event of more than one prosthesis per patient, the same circulator must collect and check all prosthesis

The surgeon then identifies which of those prostheses will be opened first

Prosthesis ID labels are scanned into V6 Care Plan, placed into the theatre register and onto the green care plan

please note: only the relevant prosthesis is brought into theatre once the definitive size is determined. Any prosthesis not used will be removed from theatre prior to the next patient.

Standard operating procedure for selection and checking of orthopaedic implants - Version 3

Figure 8: Amended prosthesis verification standard
Figure 9: Additional implant checking form, which includes the checks to be undertaken and requires details of staff involved for accountability.
4.6. Entry of data into the National Joint Registry

4.6.1 The reference incident was identified when Mr Hampton’s surgical data was entered on the National Joint Registry. As discussed in section 1.2, when data is entered indicating the wrong side or size has been implanted, a ‘Component Validation Error’ alert appears (see Figure 9). If the situation occurs (as in this incident) where the femoral head and femoral stem are incompatible because they are made by different manufacturers, a ‘Component Combination Validation Comments’ message appears (see Figure 11) but it is not as visually commanding as the alert. The message does not make clear to the person entering the data that a possible Never Event has occurred and that the consultant must be informed immediately. Neither does it result in an automated message to a National Joint Registry coordinator to follow up.

![Image of NJR Number: 2821581](image)

Figure 10: ‘Component Validation Error’ alert that appears when details have been entered into the registry that indicate incompatible components have been implanted due to size or side. In this example, a femoral head size that is incompatible with liner/cup size.
Figure 11: ‘Component Combination Validation Comments’ message that appears when details have been entered into the registry that indicate incompatible components have been implanted due to a manufacturer mismatch. In this example, the same component details were entered as those used in Mr Hampton’s surgery to simulate the message that would have appeared.

4.6.2 The Programme Director for the National Joint Registry (who is also head of health solution strategies at Northgate Public Services) agreed it may be beneficial to amend the incompatible manufacturer message to make it consistent with the size or side error alert. HSIB therefore makes the following safety recommendation:

**Safety Recommendation to National Joint Registry**

**Recommendation 2018/003:** It is recommended the National Joint Registry change the response when data is entered into the registry suggesting the wrong prosthesis has been implanted due to incompatible manufacturers, so that it is consistent with the response when data indicates the wrong size or side has been implanted.

4.6.3 As mixing and matching of some acetabular cups and femoral components from different manufacturers does not cause any clinical problems (see section 1.4) it would seem appropriate to filter these out from the alert.
5. Findings and analysis from the wider investigation

5.1. Error points

5.1.1 The investigation identified the following possible errors that may occur between the surgeon requesting a prosthesis and the wrong one being presented to him or her:

- The surgeon gives the team member the wrong details
- The team member collecting the prosthesis does not hear the details properly
- The team member does not remember the details or writes them down incorrectly
- The team member selects the wrong prosthesis box because
  - the box is not in the position expected and/or
  - they misread the text on the box label and/or
  - they are distracted between instruction and collection

5.1.2 The following errors may be made in the prosthesis verification process:

- The operating team members checking the box label misread or mishear the details
- The surgeon mistakenly trusts team members have correctly read the box label so does not independently check or fully check the label
- The surgeon cannot discern the text on the box label and so relies on others to have correctly done so
- The surgeon checks the boxes but sees only what he or she expects to see

5.2. Prosthesis verification process

a) Diversity of practice

5.2.1 Staff observed at work in operating theatres as part of this investigation were told that ‘general theatre practice’ was being observed, rather than any specific aspect. The observations in England with the human factors advisor revealed diversity in prosthesis verification practice. Variation was observed in how prosthesis verification was carried out both between operating theatres within the same organisation and between organisations. Practice varied according to team members present. Sometimes not all team members present at the start of the procedure were present at the end of the procedure. Sometimes team members were present at the beginning and the end, but not throughout the whole procedure.
5.2.2 The observers witnessed:

- the scrub practitioner reading aloud the details on the prosthesis box label and the surgeon joining in
- the surgeon reading aloud the details on the box label
- the manufacturer representative acting as the circulating nurse and collecting and reading out the details on the prosthesis box label
- the manufacturer representative reading to the scrub practitioner and the scrub practitioner checking the details without the surgeon being involved apart from confirming by saying ‘aha’ to the scrub practitioner
- the manufacturer representative telling the surgeon the size of the implant and material and the surgeon saying ‘yes’

5.2.3 In common with the hospital where the reference incident occurred, the manufacturer was not routinely included at the time of prosthesis verification. The focus of attention was on the size and other variants of the prosthesis and its expiry date. During the operations the investigation observed, the manufacturer’s name and model of prostheses was stated at the outset of the operation and did not change. Staff confirmed it was rare for the manufacturer to change once the operation was under way. The chair of the National Joint Registry Data Quality Committee said: “I’ve never heard anyone read out the manufacturer.” Staff at observation sites and other clinical subject matter experts interviewed consistently reflected this view. The National Joint Registry chair of the Implant Scrutiny Committee also said he “couldn’t recall it” ever being mentioned, reflecting the focus on size, expiry and correct material and design of component. This aspect of national guidance is not, therefore, aligned with actual practice.

5.2.4 Observed practice revealed other deviations from organisations’ local standards. One organisation’s standard said the details of the prosthesis should be ‘written on the whiteboard’ and ‘company representatives should not be responsible for checking or opening prosthesis’. Neither of these requirements was consistently followed. The investigation observed a representative providing support and guidance to a theatre team. The surgeon sought advice from the representative throughout the operation and the representative collected and opened prostheses and was involved in their verification, effectively acting as one of the theatre team. The investigation noted that in some countries, such as the United States, a company representative attends most orthopaedic operations, collecting and/or checking the implants before opening. Their presence reflects the value of their expert knowledge of components.\(^{36}\)

\(^{36}\) Personal communication with Senior Director, Orthopaedics & Trauma, Maine Medical Partners, 19 January 2018.
b) Independent developments in practice to mitigate risk of error

5.2.5 The investigation noted that safety procedures developed by the theatre team where the reference incident occurred had also been independently developed by teams at other hospitals. The investigation observed, for example: boxes of prostheses that need to be compatible being shown together; boxes of prostheses already implanted being retained and shown at the same time as those about to be implanted.

5.2.6 The president of the British Hip Society, commenting on the value of the latter practice, pointed out that there is a gap of 10–30 minutes between the cup and liner being implanted and the femoral stem and head being implanted. He explained that this is ample time to forget the detail of what has been put in, especially if the surgeon has chosen a prosthesis different from normal practice. He noted that incompatibility of head and liner size is a frequent cause of wrong hip prosthesis incidents.

5.2.7 The investigation also observed theatre staff writing down details of prostheses requested. Sometimes this was on a scrap of paper, their hand or a board in theatres. Given the fallibility of human memory – and the potential for distraction if staff need to leave theatres to collect stock – an aid to memory seems helpful. The safety action of a prosthesis board introduced at the hospital where the reference incident occurred may, therefore, seem beneficial. However, the human factors advisor pointed out this practice is not risk-free because it creates another opportunity for error, i.e. the risk of writing down incorrect information. A further potential risk may be created if the board is not wiped clean between operations in the anticipation that some details are relevant to the next operation. The human factors advisor noted that mitigating these risks would require clarifying the accuracy of the information written down, introducing an additional step in the process.

5.2.8 Another practice the investigation observed was the surgeon reading aloud the details on the prosthesis label rather than having them read to him or her, thus creating an independent check. The vice chair of the National Joint Registry Surgeon Performance Committee said he had adopted this practice having become increasingly aware of wrong prosthesis incidents as a result of his work with the National Joint Registry. He said it was important that the surgeon, the person ultimately responsible for the surgery, read out loud the details on the label. He explained: “What’s on the box may not be what’s in your head”. Reading out the details creates a pause to process the information. The president of the British Hip Society agreed, saying the operation was the surgeon’s responsibility and so “…it has to be the surgeon to read it [details on the packaging label] out loud”, and not the circulating or scrub practitioner reading to the surgeon. The president of the British Orthopaedic Association made the same point, noting that reading the label aloud can help address any preconceptions about the prosthesis collected for use.
5.2.9 The importance of the independence of two (or more) person checks is reflected in academic literature (see section 5.2.4) and was endorsed by the investigation’s human factors advisor.

c) Standardisation of prosthesis verification

5.2.10 The human factors advisor considered the variation observed in the prosthesis verification and whether it should be standardised as to precisely who does what and in what order. He thought not. He noted the many reasons why clinical staff may not comply with tightly prescribed standards of practice.37 He believed it more appropriate to share those observed aspects of practice endorsed by clinical subject matter experts for operating teams to incorporate within their local checking process. Specifically:

- The surgeon reading out loud the details on the prosthesis label without them being read out loud in advance by anyone else.
- Boxes of prostheses that need to be compatible being shown together during prosthesis verification.
- Details of prostheses requested being written down when stock is stored outside the operating theatre. Details written being confirmed with the surgeon at the time of writing and when the prostheses are shown for verification.

HSIB therefore makes the following safety recommendation:

Safety Recommendation to NHS Improvement

Recommendation 2018/001: It is recommended that NHS Improvement amends the national Prosthesis Verification Standard to incorporate the specific aspects of verification practice developed to mitigate error identified in this investigation.

d) Limitations of human checks

5.2.11 Recommendations from previous wrong prosthesis investigations were also considered with the human factors advisor. The investigation reviewed completed wrong prosthesis investigations on StEIS between 1 January - 30 June 2017 together with other studies of learning from surgical Never Events.38 These reviews showed that recommendations primarily consisted of reminders to staff to be vigilant when checking and/or the creation of an additional check (as was proposed by the local hospital in response to the reference incident). The human factors advisor noted that another level of checking, involving one

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person checking with another the contents of a label, is unlikely to be effective because it does not address the underlying human factors that cause error. Team checking processes already in place have not reduced the number of wrong prosthesis incidents, suggesting that more of the same is not the solution. One member of theatre staff said: “I don’t think we can have more checks”. Another summed up the effect of repeated checks of the same details as tending to “…switch off the brain…giving false reassurance”. Another member of staff agreed: “It doesn’t make you any safer…[it] makes you complacent”.

5.2.12 The investigation considered published literature concerning the efficacy of double (or triple) staff checks in improving safety. Although most of the literature focuses on medication errors, much of the learning can be generalised to the theatre scenario. The research highlights that repeat checking is far from infallible in preventing error\textsuperscript{39}. As one author points out: ‘Double-checking requires that one fallible person monitors the work of another imperfect person.’\textsuperscript{40} This makes it prone to psychological phenomena such as bias and ‘auto processing’, where the act of checking is given little active thought. Double-checking was found to be most effective when the checks were independent, i.e. when the person checking must form their own judgement without cues from the person who did the initial check\textsuperscript{41}. The literature, therefore, supports the practice of surgeons always reading aloud, for themselves, the details on the prosthesis label (rather than having the details read to them) as this is an independent check.

5.2.13 Whilst changes in the prosthesis verification process may reduce the risk of error, the effect is likely to be limited because it still involves individuals checking each other’s checks. As the president of the British Hip Society said: “Protocols can be followed and you can still get it wrong, you can just be blinded; you can read everything but not process the information, it happens”. He described the Hip Society’s annual meeting with 200-300 people where he asked anyone who had implanted a wrong prosthesis or knew of a recent case where it happened or almost happened to put up their hand, “…nearly every hand went up”.

5.2.14 All prostheses and implants have a barcode on their packaging which contains all the information needed for prosthesis verification. An increasing number of hospitals scan the barcodes in theatres as part of their electronic patient records and/or their stock control. It therefore seems appropriate to consider barcode scanning as a way to reduce wrong


prosthesis incidents. A scanning system could supplement the current checking process, providing a more robust barrier to error. Such a system would need to alert staff to incompatible components before implantation. This would require bespoke software to be developed (see section 6.1).

5.3. Environmental impediments

a) Noise

5.3.1 The human factors advisor considered the environment in which the prostheses are requested and the verification process is performed. He noted theatre staff are subject to a high cognitive and physical workload and must perform multiple tasks throughout the operation in a noisy environment.

5.3.2 Orthopaedic theatres are usually equipped with laminar airflow ventilation (LAF) which is intended to reduce airborne bacteria and lower post-operative infection. Key staff involved with the prosthesis verification, such as the scrub practitioner and surgeon, stand under a canopy in the LAF area (see Figure 2). The background sound of this ventilation is constant and significant.

5.3.3 Recent research has questioned the value of such ventilation. Bischoff et al (2017) state in their systematic review and meta-analysis: ‘The available evidence shows no benefit for laminar airflow compared with conventional ventilation’. Similarly, Gastmeier et al (2012) conclude in their review: ‘It would be a waste of resources to establish new operating rooms with LAF, and questionable as to whether LAF systems in existing operating rooms should be replaced’. Further research to establish conclusively if LAF is justified may be of benefit.

5.3.4 In addition to the LAF, in some theatres the surgeon and scrub practitioner wear a hood with an in-built visor (see Figure 2) to protect both the patient and surgeon from infection. The hood has a battery-operated air-flow device that makes a sound like air-conditioning, adding further noise. One consultant said of the device ‘...you can’t hear clearly’.

5.3.5 The investigation saw some surgeons wearing hoods and visors, others wearing a mask with integral visor and others just wearing a mask. Two clinical subject matter experts

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www.hsib.org.uk
expressed doubt about the benefit of a hood and integral visor in reducing infection risk. Further research to determine the value of these hoods is needed.

5.3.6 Noise comes from other sources too – conversations between staff, electric or air-powered surgical equipment, hammers, suction apparatus, anaesthetic monitors, and alarms – all of which may impede hearing. Furthermore, there is often music playing in theatres. The investigation measured the noise in theatres during observations and found it to be 64-72 decibels (dB), about as loud as a vacuum cleaner.

5.3.7 The deleterious effects of noise, the distracting effects of social conversations and noise from equipment are well documented in the literature. Katz (2014) states that exposure to noise can hamper psychomotor, intellectual, attention and memory functions. He points out: ‘This impairment is especially apparent when an individual is exposed to “irrelevant speech” while engaged in mental activities that rely heavily on working memory, such as during multitasking.’

The detrimental effect of noise was also demonstrated in a study by Murthy et al (1995) in which deterioration of mental efficiency and short-term memory was observed among anaesthetists exposed to a recording of typical operating-room noises.

5.3.8 A useful review was undertaken by The Joint Commission (2017). It notes that although the US Environmental Protection Agency’s (EPA) recommended level for continuous background noise in hospitals is 45dB, this can still interfere with concentration. The review’s authors point out that when considering surgical operations, orthopaedic procedures are amongst those with the highest sustained continuous background noise, with intermittent peak levels often exceeding 100dB.

5.3.9 The literature reveals a complex picture of how music affects human performance. It can increase the performance of those undertaking repetitive factory production line tasks, provided it is simple and without singing. For problem-solving or highly cognitive, complex tasks, the literature suggests it may be advisable to avoid lyric-based music because it is likely to interfere with the task. The music played during the observations in theatres was either popular lyric-based music or live radio. Staff in one theatre were observed initiating conversation in response to a radio news bulletin.

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46 The Joint Commission, Division of Health Care Improvement (2017) Minimizing noise and distractions in the OR and procedural units. Quick Safety 35.
5.3.10 Weldon et al (2015) provide a useful review of the issues related to music in operating theatres. They cite sources indicating that music is played in 53-72% of surgical operations. They found noise in UK operating theatres typically exceeded WHO recommendations of 30dB. They note music was seldom recognised as a potential safety hazard. However, analysis of its effect on communication found that repeated requests (e.g. for a surgical instrument) were five times more likely to occur in places playing music than in those not playing music. The authors recognise that music may have benefits too, such as creating an improved sense of wellbeing.

5.3.11 In conclusion, there are multiple sources of noise in orthopaedic operating theatres. Whilst some may have positive effects, they all have the potential to impair communication and information processing. This adds further weight to the value of surgeons reading aloud, for themselves, the details on the prosthesis label.

b) Impediments to vision

5.3.12 In addition to the sub-optimal conditions for hearing, the ability to read information may be impeded by multiple factors. These are described by Haene et al (2009) and include:

- the effect of looking from bright light under the operating lamps to a less bright area (as the eye takes time to adapt to different light levels)
- glare from operating theatre lamps and light reflection from a plastic visor into the surgeon’s eyes
- the distortion of light passing through curved plastic visors and the distortion of visual information, such as through a fold line down the middle of the cellophane outer sleeve of packaging
- spatter of visors by body fluid droplets during surgery
- the effect of eyewear (glasses and contact lenses), particularly when they are calibrated for eye-to-hand working distance

5.3.13 In the operations observed in England, the staff member holding the prostheses boxes did not enter the laminar airflow area at the time of prosthesis verification. Some scrub practitioners and surgeons had only limited movement because of the operative tasks

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49 ibid. p.2764.
they were engaged in. Canopies marking the LAF area (see Figure 2) are about 3m x 3m\textsuperscript{51}. The distance at which boxes were viewed by the surgeon and scrub practitioner varied but was typically 1-3m\textsuperscript{52}.

5.3.14 As stated in section 5.3.1, there has been some questioning of the value of laminar air flow in reducing surgical infection. It is also unclear how disturbing the LAF for a few seconds impacts on the risk of infection. The investigation observed the LAF being disturbed in theatres in Denmark, where the circulating nurse entered the LAF to show prostheses boxes up close to the surgeon (see section 5.7). Further research and definitive guidance are required on this issue.

5.4. Complexity of equipment

5.4.1 Even a straightforward hip or knee replacement demands a large amount of surgical equipment, prostheses and related instruments. The number of prostheses and components is greater for complex revision surgery. Figure 2 shows the sets opened for two straightforward hip replacements. Up to 27 sets may be opened for a complex revision of a hip joint.\textsuperscript{53} The investigators saw the stock area and the range of brands available, which theatre staff must know about to retrieve the required prostheses. The greater the range of prostheses and variants in design and combinations available, the more specialist and complex the knowledge required and the greater the risk.

5.4.2 The National Joint Registry collates information about the performance of implants over time to provide an evidence base to guide choice of prostheses (see section 1.2). The review of orthopaedic surgery published in 2015.\textsuperscript{54} highlighted variation and opportunities to improve effectiveness and cost efficiency. Based on this review – and information from the National Joint Registry – many Trusts have rationalised their stock of prostheses and implants.\textsuperscript{55} These Trusts have agreed to use only particular manufacturers and brands for various patient groups (based on age and/or level of activity). The hospital where the reference incident occurred had rationalised its stock in 2011.

\textsuperscript{52}Of note, these issues have been highlighted in other case studies. See, for example, Jones A. (2012) Orthopaedic implants: a cautionary tale. Journal of Perioperative Practice Procurement Guide15.
\textsuperscript{53}Personal communication with vice chair of the National Joint Registry Surgeon Performance Committee and chair of Data Quality Committee, 21 February 2018.
\textsuperscript{55}The Programme Report to the National Quality Board meeting on 22/11/17 stated that 75% of Trusts had rationalised their stock.
5.4.3 Clinical staff at the observation sites and clinical subject matter experts commented on how a greater range of stock increases the risk of error. The chair of the National Joint Registry Data Quality Committee noted the “massive advantages to staff” of a limited range of stock that staff can become familiar with. A theatre nurse who spoke to the investigation at one of the observation sites agreed. She said it was “mentally easier” since the range of stock had been rationalised. Other hospitals contacted by the investigation about wrong prosthesis incidents echoed the value of rationalising stock as a way to reduce risk.

Figure 12: Orthopaedic stock rooms in two organisations, including colour-coded storage shelves for different manufacturers (I).

Figure 13: Lists showing ranges of individual components for one manufacturer (J) and range for one component for one manufacturer (K).

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56 President, British Orthopaedic Association; Chair, National Joint Registry Implant Scrutiny Committee & President, British Hip Society.
57 Personal communications with Health Foundation Quality Improvement Fellow & Improvement Advisor, past Medical Director Weston Area Health Trust, 19 January 2018, and with Health Foundation/IHI Quality Improvement Fellow & Consultant at Glasgow Royal Infirmary, 25 January 2018.
5.4.4 The observation sites had different stock storage systems. However, they all (including the site of the reference incident) separated stock by manufacturer and component type to help reduce the risk of selecting the wrong component. The chair of the National Joint Registry Data Quality committee said such separation of stock occurred in other hospitals too. He noted how stock arrangement can help to reduce error, giving as an example the storing of left and right knee components in separate areas.

5.5. Packaging and labelling

a) Label design

5.5.1 As stated in Section 5.3, the prostheses boxes presented for verification may be up to three metres from the scrub practitioner and surgeon. Therefore, the design of labels and the visibility of key information (size, side, expiry date) are of critical importance. The human factors advisor thought the labelling of some manufacturers might contribute to error. Some labels include clusters of information in small print. Although the information that needs to be checked is always included on the box label, on some labels vital information, such as the component size, takes up only a small part of the label area and so does not stand out. If the numbers are similar, such as 32 and 36, or 26 and 28, it may difficult to distinguish between them in the operating theatre environment, especially at a distance. One of the most common errors identified from National Joint Registry data was mistaking 26mm for 28mm and vice versa in relation to femoral head size.\(^58\)

5.5.2 Clinical staff at observation visits and the clinical subject matter experts\(^59\) raised concerns about the impact on patient safety of packaging labels. The possible relationship between labelling and wrong prosthesis incidents has been presented in orthopaedic conferences\(^60\). The president of the British Hip Society explained that he and others on the National Joint Registry Steering Committee had shared their concerns with manufacturers and with the Association of British Healthcare Industries\(^61\). The president of the British Hip Society and the vice chair of the National Joint Registry Surgeon Performance Committee spoke of the need for a labelling standard to include specific requirements for items such as font size and type. The president of the British Hip Society said labels were usually on the ends of boxes as that is the visible part when they are stacked on storage shelves. This leaves the large space on the top of the box empty. This could be exploited for verification purposes. The human factors advisor agreed with

\(^{58}\) Interview with Programme Director for the National Joint Registry and Head of Health Solution Strategies at Northgate Public Services; Interview with President of British Hip Society.

\(^{59}\) President of the British Orthopaedic Association; president of the British Hip Society; vice chair of Surgeon Performance Committee.

\(^{60}\) For example, the presentation by the President of the Hip Society in 2017 on ‘Patient Safety: How to AvoidNever Events’.

\(^{61}\) A trade association for manufacturers which has links with the British Orthopaedic Association and the National Joint Registry.
the need for a labelling standard which included details regarding the size and layout of information. He believed there should also be a requirement for testing in the operating environment with the intended end users (clinical staff).

Figure 14: Labelling of knee prostheses by one manufacturer. Note the reflection of overhead lighting typically found in the theatre environment.

Figure 15: Labelling of knee prostheses by a different manufacturer demonstrating an alternative layout of information. Note, again, reflection of overhead lighting typically found in the theatre environment.
b) Labelling concerns reflected in literature

5.5.3 Published articles detail issues about the legibility of orthopaedic labels (including font size, layout of text and cluttering of information). Jones (2012) described three wrong prosthesis incidents involving 28mm femoral heads being implanted in place of 26mm heads62. As in the reference incident, the checking procedure had failed to identify the error.

5.5.4 The article highlighted impediments to vision in the operating environment. Text on the packaging can be obscured by the seal on the outer protective wrapping, covering details of the implant size. The distance a circulating nurse holds a prosthesis box from a scrub practitioner and surgeon can make it hard to discern information on the label. The glare of operating lights bouncing off cellophane wrappers can be exacerbated and further reflected by eye protection.

5.5.5 Haene et al (2009) raised the same legibility issues63. Their research aimed to produce guidelines for orthopaedic implants to increase the legibility of labels and thus improve safety. Their work included the effect on visibility of factors such as the spacing of text, text/background colour combinations and the importance of decluttering information. The authors concluded that the minimum standard for text height on implant labels should be 4mm. Haene et al’s audit of 57 implant labels from five main manufacturers led them to conclude that the labels were generally ‘of insufficient standard to ensure patient safety in theatres’. They found half of implant labels had text below their minimum standard text height. Furthermore, clinical subject matter experts and the human factors advisor believed that the text size should be much bigger than 4mm. Haene et al described other factors in the operating theatre that ‘would collectively degrade visual acuity’, for example, it was common to find the seam of the cellophane wrapper directly over the label’s text, obscuring information.

5.5.6 Other writers64 have raised the issue of implant labelling and the value of requiring manufacturers to comply with a labelling standard. The American Society for Testing and Materials (a not-for-profit international standards organisation) produced a ‘Standard Guide for Presentation of End User Information for Musculoskeletal Implants’65, which addresses many of the labelling concerns. However, the society says that the ‘use and

implementation of this guide is optional and at the sole discretion of the implant’s manufacturer.

c) Labelling regulation

5.5.7 There is an international standard for medical devices which includes a general statement about implant labelling. This states: ‘Information supplied by the manufacturer and intended for direct visual recognition shall be legible when viewed under illumination of 215 lx (bright light) using normal vision, corrected if necessary, at a distance that takes into account the form and size of the individual implant.’

5.5.8 The European Medical Device Regulation (2017/745) was published in May 2017 and will be implemented by May 2020. This states: ‘The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.’ Information being ‘easily legible’ or ‘clearly comprehensible’ are not defined and no guidance is offered on how manufacturers might demonstrate achievement of these requirements. Similarly, the extant European regulation, the Medical Device Directive (93/42/EEC) says the label must include, ‘...the details strictly necessary to identify the device and the contents of the packaging especially for the users’ but does not say how this should be tested.

5.5.9 Representatives from the Medicines and Healthcare products Regulatory Agency (MHRA) told the investigation they were aware of the concerns of orthopaedic surgeons about visibility and readability of labels in the operating environment. They spoke of the difficulties of influencing manufacturers governed by European legislation. The MHRA explained that they would need to prove that there was a Europe-wide safety issue. The UK market is relatively small compared to the European market. The MHRA has experience of consultants raising concerns (a representative sits on the National Joint Registry Executive Steering Committee) but they said these are rarely reported to them in writing, making it difficult to evidence the problem. MHRA representatives said that labelling may contribute to error, but it would be difficult to prove causation between labelling and a wrong prosthesis being implanted.

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66 BS EN ISO 14630:2012 Non-active surgical implants – General requirements. The requirement relating to labelling is given in section 11.1 Information supplied by the manufacturer.
68 Ibid. p24 – Article 10(11) General obligations of manufacturers.
70 The representatives were: Group Manager; Devices Information and Operations Group; Senior Clinical Adviser; Devices; Head of Biosciences and Implants, Clinical Director of Medical Devices; Devices Clinical Team Coordinator and Analyst.
5.5.10 The investigation was informed by the MHRA that they had no direct input into standards, being purely a regulatory body. However, they may have influence on standards by presenting evidence of patient safety concerns to manufacturers through, for example, expert advisory group reports. The MHRA agreed to discuss labelling concerns with the other European authorities that they link with and who have a similar remit to MHRA. The MHRA have proposed to the British Standards Institute that the international standard for medical devices be amended to state: ‘Information supplied by the manufacturer...shall be legible...at a distance of 1 m’. This is under consideration and, if accepted, will be put to the International Organization for Standardization.

5.5.11 This proposal would not necessarily address all the factors that affect legibility, such as text size, font colour, background and spacing of information (see section 5.5.1 and 5.5.2). In 2017, the MHRA published human factors guidance for manufacturers of medical devices ‘and notified bodies responsible for assuring the quality of those devices’71. This guidance details how the design of devices and packaging should consider the person using the device, the environment within which it is to be used and the device-user interface. In relation to prostheses, the interface includes the label as this is key to correct identification of the device.

5.5.12 The MHRA Guidance notes: ‘All EU medical device manufacturers are obliged ....to have a systematic procedure in place to review the experience gained from their devices in the post-market phase and... to apply any necessary corrective action’72. This is referred to as ‘post-market surveillance’. The European Medical Device Regulation (2017) gives examples of how the data should be used, including: ‘to update the design and manufacturing information, the instructions for use and the labelling’73.

5.5.13 The MHRA guidance notes that as part of these obligations EU medical device manufacturers are obliged to inform relevant authorities of adverse incidents and corrective actions concerning their products. They also note the guidance says: ‘Feedback from competent authorities needs to be considered as part of post-market surveillance’74. The MHRA document notes all relevant data sources should be actively reviewed. Examples are given, such as articles in journals and ‘user studies and observational studies of users to identify lower level issues that may not have been

72 Ibid. p24.
73 Ibid. Section 1, Article 78, 3 (b).
74 Ibid. p24. The relevant European guidance is found in European Commission MEDDEV 2.12-1 rev 8 January 13 – Guidelines on a Medical Devices Vigilance System.
implicated in patient harm but that nevertheless negatively affect user experience and efficiency.\textsuperscript{75}

5.5.14 This section has discussed prosthesis packaging and labelling, the regulations that govern it, and concerns about legibility of labels in the operating theatre. The American Society for Testing and Materials has produced a standard guide for musculoskeletal implants, which addresses many of the concerns.

HSIB therefore makes the following safety recommendation:

\begin{quote}
Safety Recommendation to the British Standards Institute

Recommendation 2018/002: It is recommended the British Standards Institute amend existing standards for prosthesis labels to include details of design that make them easier to read in operating theatres. The American Society for Testing and Materials’ ‘Standard Guide for Presentation of End User Information for Musculoskeletal Implants’ is a useful reference.
\end{quote}

5.6. Cognitive biases

5.6.1 A cognitive bias is an influence that can affect the judgement of human beings without the person or group of people affected being aware of it. In other words, it can occur unconsciously.\textsuperscript{76} The human factors advisor noted the role cognitive bias can play in error.

5.6.2 Research has shown human observations are biased towards confirming the observer’s conscious and unconscious expectations and view of the world. In essence, we are inclined to see what we expect to see, ignoring contradictory information until it becomes overwhelming. This is known as confirmation bias. In the reference incident, the scrub practitioner and surgeon were expecting the femoral head brought into theatres, and possibly shown to them, to be the one the surgeon had requested [Zimmer]. They had no experience of a previous similar error, so no reason to doubt this would happen.

5.6.3 Search satisfaction bias is also common in medicine. It refers to the tendency to stop looking for information as soon as the individual believes they have found the answer. In the reference incident, if the prosthesis box was shown to him, the surgeon may have seen the information he and others usually focus on such as size, material, and expiry, and not seen or processed any other information, such as the manufacturer or packaging design.

5.6.4 The human factors advisor also explained the cognitive bias of goal-orientated motivated reasoning, which is often associated with time-pressured scenarios. Researchers have found if someone is motivated to achieve a goal then, like confirmation bias, only facts that support it are considered. Facts that do not support the individual’s assumptions are reasoned away.\textsuperscript{77}

5.6.5 Mushtaq et al\textsuperscript{80} (2018) analysed 145 surgical safety incidents and found the most common (30.1\%) contributors to error were cognitive rather than technical, procedural or communicative. Similarly, Thiels et al\textsuperscript{80} (2015) considered surgical Never Events and the role of cognitive biases. The authors used a validated Human Factors Analysis and Classification System (HFACS) to analyse and code human factor elements contributing to 69 surgical and invasive procedural\textsuperscript{80} Never Events\textsuperscript{81}. Cognitive factors were found to contribute significantly to these errors with ‘channelled attention on a single issue’, overconfidence, inadequate vigilance and distractions being the most important. Confirmation bias was the most commonly coded perceptual error, reflecting the influence of this cognitive element.

5.6.6 Thiels et al advocate systems-based strategies that mitigate cognitive and perceptual errors. They give as an example the introduction of a barcode system in the authors’ healthcare organisation\textsuperscript{82}. This reduced the incidence of retained surgical sponges by 93\%. However, the authors highlight findings from their analysis that suggest that an individual’s or team’s cognitive capacity leading up to an incident may be outpaced by cognitive demand; for instance, through increased patient or procedure-related complexity. Thiels et al therefore conclude that systems interventions are only part of the solution. They suggest that measures to decrease cognitive workload or ways to share it between team members are also important.

5.6.7 Staff at the observation sites repeatedly commented on time pressure including pressure both to complete the planned operating list and to complete it on time. The national task

\textsuperscript{77} This bias has been described as ‘a form of implicit emotion regulation in which the brain converges on judgements that minimize negative and maximize positive affect states associated with threat or attainment of motives’. Weston D., Blagov P. S., Harenksi K. et al (2006) Neural Bases of Motivated Reasoning. Journal of Cognitive Neuroscience 18:11 1947-56.


\textsuperscript{80} 40 of the events occurred in the operating theatres, 29 occurred in a procedural area such as endoscopy or interventional radiology.

\textsuperscript{81} Of note, the authors analysed four types of surgical Never Event: Wrong site; Wrong implant; wrong procedure and Retained Foreign Objects.

force review of Never Events [2014] also highlighted time pressure as a source of error in the literature about preventable surgical adverse events.\(^{83}\)

5.6.8 The human factors advisor noted actual time pressure is not as important as the individual’s perception of time pressure. He commented on the ‘speed-accuracy’ or ‘thoroughness-efficiency’ principle that Hollnagel\(^{84}\) and others have written about. This is a trade-off between efficiency or effectiveness on one hand and thoroughness on the other. Demands for productivity tend to reduce thoroughness while demands for safety tend to reduce efficiency. This means staff are constantly juggling the risks and benefits of safety actions against increased efficiency.

5.7. Observations from Denmark site visit

5.7.1 The investigation visited a specialist orthopaedic unit in Denmark. The site was chosen because it uses a barcode scanning system to supplement the human prosthesis verification process during surgery. The investigation observed and discussed the scanning system (see section 6.1) and noted several differences from English theatre practice.

5.7.2 The most obvious difference was that the Danish theatres were quieter, mainly because they did not play music. The noise measured 47 dB compared to 64-72 dB at the English sites. This is closer to the recommended safe level of 45 dB discussed in section 5.3. The Danish surgeons were surprised music was played in theatres. One said “we don’t use it. You must concentrate”. Like the theatres visited in England, staff had worked together for many years and appeared relaxed and friendly with each other. However, their conversations during surgery directly related to the procedure, making this a quiet time of single focus. The team wore masks with integral visors rather than hoods with integrated airflow systems.

5.7.3 The quiet environment was enhanced by a lack of disturbance. Once surgery began, no one entered or left the theatre unless it was critical to patient care. Stock had been rationalised and was kept in cupboards in each theatre, with any ad hoc requests made by phone to a theatre coordinator who delivered anything required via an interconnecting cupboard linked to a common area between theatres.

5.7.4 Equipment and layout were standard in each theatre. For example, the clock for timing the cement used with some prostheses was the same in each theatre and in the same

place. At the observation sites in England, mobile phones, watches or wall clocks (both digital and analogue) were used for timing. At the Denmark site, the desk layout was the same in each theatre and there was an absence of clutter. A large screen (about 0.9 metres × 0.6 metres) on the wall of each theatre displayed patient x-rays. Senior staff told us that there had been a programme of work over a number of years to simplify and streamline all aspects of theatre practice. One theatre manager explained they had scrutinised the rationale for everything, from equipment to “old habits...We asked of everything, why are we doing this? What is the benefit?”

![Image](image.png)

**Figure 16:** Desk layout observed in each theatre, including the scanner (L) and cement timer (M).

5.7.5 During the prosthesis verification process, the investigation observed circulating nurses hold the prosthesis boxes within one metre of the surgeon, entering the LAF area if needed. The surgeon stopped and read aloud the details on the box. The investigation was advised that Denmark does not have a national standard for prosthesis verification but the details checked were similar to those observed in England. Notably, surgeons reported no concerns when asked about any difficulty reading the labels. Factors such as the proximity of reading the prosthesis labels and cessation of all other activity by the surgeon for this task may have contributed to the absence of concern.

5.7.6 Following the human check, the prosthesis were scanned before opening (see details in section 6.1). After the operation, and before skin closure, the surgeon left the LAF area to check the scanned items on the computer screen. As discussed above (see section 5.3.2), it is unclear whether disturbing the LAF affects the risk of infection.
Figure 17: Circulating nurse silently holding prostheses boxes to show the surgeon, who stops all other activity to read aloud the details on the box.

Figure 18: Surgeon leaving the laminar flow area to check scanned items. Includes stock cupboards (N) and the X-ray screen (O)
6. Opportunities for technological intervention

6.1. Barcode scanning

6.1.1 The investigation discussed the potential benefits of barcode scanning with the following subject matter experts:

- President of the British Orthopaedic Association
- Chair of National Joint Registry Surgeon Performance Committee & Implant Scrutiny Committee
- Chair of Orthopaedic Data Evaluation Panel (ODEP)85 and Beyond Compliance Advisory Group86
- Consultant surgeons during observation site visits
- National Joint Registry Management Team (HQIP)
- MHRA

6.1.2 The potential to develop such a system was also discussed with the Head of Health Solution Strategies at Northgate Public Services. Northgate Public Services developed the current automatic alert when incompatible prostheses data are entered into the National Joint Registry after surgery. Development of a scanning system was also discussed by surgeons at the National Joint Registry Implant Performance committee87 and the National Joint Registry Steering committee88. These subject matter experts have extensive experience and knowledge of how wrong prosthesis incidents occur. These individuals and groups agreed about the potential benefits of a barcode scanning system for use during surgery to reduce the risk of implanting the wrong prosthesis.

6.1.3 The investigation was informed by Northgate Public Services of different degrees of sophistication possible in the development of a scanning system. The most basic level and quickest to implement would be a web-based application, linked to the component registry in the National Joint Registry. This application would generate an immediate alert by sound, colour or haptic effect if the prostheses were incompatible in any way.

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85 The Orthopaedic Data Evaluation Panel (ODEP) was set up in 2002. Through the submission of data (against agreed standards) at set timeframes, a rating is assigned to prostheses providing a benchmark of performance. The Panel began with hip replacements and now includes knee and shoulder replacements: http://www.odep.org.uk/Home.aspx

86 The Beyond Compliance Advisory Group are an independent panel of experts who work with implant manufacturers to assess the relative risk of any new product, and the rate at which it should be introduced to the market. The service collects data about patients who receive these implants and about their recovery following surgery. This data is made available to clinicians using the implant, to the manufacturer, and to independent assessors from the Beyond Compliance Advisory Group, to provide real-time monitoring of the implant’s performance: http://www.beyondcompliance.org.uk/Home.aspx

87 Committee meeting, 23 February 2018

88 National Joint Registry Steering Committee, 23 April 2018
6.14 This software could be developed to incorporate the functionality to have the information contained in the barcode projected onto a screen, or read out by an electronic voice, mitigating the problems reading packaging labels.

6.15 A more sophisticated scanning application would automatically transfer the information into the National Joint Registry, saving time and duplication of entering the data later and eliminating the risk of transcription error. If such a scanning system was universal, another benefit would be 100% real-time completeness of National Joint Registry data.

6.16 An even more advanced development would include an interface for information scanned to transfer automatically to, and integrate with, a hospital’s electronic patient records and stock control system.

6.17 Ast et al (2014) described a barcode scanning system where an image of the label is displayed on a monitor in a standardised way and confirms the compatibility of scanned components, as well as the size, type/material, description and expiry date. They report use of this system decreased wasted implants from 5.7% to 0.8% of total knee arthroplasty cases.

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Figure 19: Barcode scanning in progress.

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6.1.8 The orthopaedic unit in Denmark has used barcode scanning since 2017. The system links to electronic patient records and Denmark’s national joint registry. Scanning takes place during surgery, after the human check and before implantation. The investigation asked one of the consultants whether there had been a reduction in wrong prosthesis incidents since the introduction of scanning. This consultant did not know the rate of wrong prosthesis incidents before or after the scanning system so could not say. However, he recalled an incident when human checks failed to spot incompatibility between a femoral stem and head. Barcode scanning identified the mistake and implantation of the wrong prosthesis was prevented.

6.1.9 The Danish alert consists of merely a screen message that only the person scanning, usually the circulating nurse, sees. The human factors advisor cited research recommending a stronger alert, such as that created by sound or haptic effect.

6.2. National Scan4Safety Programme

6.2.1 The investigation explored the potential connectivity between scanning software that could be linked to the National Joint Registry and the national Scan4Safety programme. This programme, launched in 2015 and piloted in six NHS Trusts, uses barcode scanning to track patients, staff, equipment and their locations. This makes it possible to track a patient’s journey through a hospital, and know what equipment is used where and by which staff.

6.2.2 Barcode scanning offers other benefits. Scanning all products used in surgery can improve stock management by removing human inventory errors and automatically flagging expiry dates. The data captured ensures transparency in cost and shows any variation in cost between clinical staff performing the same procedures. Using barcodes on products means if any fault is identified requiring products to be recalled, the patients they have been used on can be quickly traced.

6.2.3 The investigation discussed with the Department of Health and Social Care lead for Scan4Safety possible future developments of the technology, such as alerts at the point of care i.e. that alert staff to potential errors before they are made. He was positive about the benefits of such alerts but said the defined priorities for the next phase of roll out does not include these. However, a working group consisting of one of the pilot Scan4Safety sites, Derby Teaching Hospitals NHS Foundation Trust, the National Joint Registry and MHRA has recently been established to review how data collected through Scan4Safety could automatically populate the National Joint Registry. The national

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90 https://www.scan4safety.nhs.uk/
91 Personal communication with Scan4Safety Programme Manager at Derby Teaching Hospitals NHS Foundation Trust, 8 February 2018
Scan4Safety lead and programme lead at Derby Teaching Hospitals NHS Foundation Trust believed the working group’s remit could be usefully expanded to explore alerts for wrong prostheses at the point of care if funding could be made available. This would serve as a test of feasibility and usability for the most sophisticated level of scanning system. Information from this scanning system could populate the National Joint Registry, populate electronic patient records, link to stock control, as well as help to prevent implantation of wrong prostheses. Findings could inform the national Scan4Safety programme.

HSIB therefore makes the following safety recommendation:

**Recommendation 2018/004: Recommendation to the Department of Health and Social Care**

It is recommended the Department of Health and Social Care expands the remit of the working group consisting of Derby Teaching Hospitals NHS Foundation Trust’s Scan4Safety Programme, the National Joint Registry, and the Medicines Healthcare products Regulatory Agency to include alerts to identify wrong prostheses prior to implantation.

6.2.4 The investigation is mindful that national implementation of a scanning system of this level of sophistication will take time to implement. In the interim, a basic scanning system, as described in section 6.1, could be relatively quickly developed and introduced.

HSIB therefore makes the following safety recommendation:

**Safety Recommendation to the Department of Health and Social Care**

**Recommendation 2018/005:** It is recommended the Department of Health and Social Care commissions the development and implementation of an interim basic scanning system to identify wrong prostheses prior to implantation.

### 6.3. Limitations of a barcode scanning intervention

6.3.1 Barcode scanning may reduce the risk of implantation of the wrong prosthesis but the human factors advisor noted the potential problems:

1) Additional equipment in the operating theatre may not be welcome.
2) Scanning is quick but it is still another check staff would have to complete, adding time to surgery.
3) Hand-held mobile data equipment can fail. Batteries can run flat or devices may lose connectivity.
4) Evidence from the review of wrong prostheses incidents on StEIS and other reviews of surgical Never Events\(^2\) shows that procedures are not always complied with.

5) Staff can be reluctant to use new technology so human factors which influence use would need to be considered\(^3\).

6) Staff may become over-reliant on the equipment. No technology is 100% reliable.

6.3.2 The human factors advisor said it was essential that any system was tested in an operating environment with input from the clinical staff who would be using the system. The scan should augment, not replace, the existing human checks which are usually effective.


7. Summary of HSIB Findings, Safety Recommendations and Safety Observations

7.1. Findings

The investigation identified:

1. Human factors which may hinder the identification and verification of the correct prosthesis.

2. Variations in practice in how prosthesis verification is carried out by theatre teams. Some teams have developed specific practices aimed to reduce the risk of implantation of the wrong prosthesis.

3. Existing standards for labels on prosthesis packaging are not sufficiently detailed to ensure the labels can be easily read in the operating environment.

4. The automated message that appears when data is entered in the National Joint Registry suggesting the wrong prosthesis has been implanted due to incompatible manufacturers, is not as compelling as the alert that occurs when data is entered indicating the wrong size or side has been implanted.

5. A barcode scanning system could strengthen prosthesis verification.
7.2. Safety Recommendations

HSIB makes the following Safety Recommendations:

1. **Recommendation 2018/001**: NHS Improvement amends the national Prosthesis Verification Standard to incorporate the specific aspects of verification practice developed to mitigate error identified in this investigation.

2. **Recommendation 2018/002**: The British Standards Institute amends existing standards for prosthesis labels to include details of design that make them easier to read in operating theatres. The American Society for Testing and Materials’ ‘Standard Guide for Presentation of End User Information for Musculoskeletal Implants’ is a useful reference.

3. **Recommendation 2018/003**: The National Joint Registry changes the response when data is entered into the registry suggesting the wrong prosthesis has been implanted due to incompatible manufacturers, so that it is consistent with the response when data indicates the wrong size or side has been implanted.

4. **Recommendation 2018/004**: The Department of Health and Social Care expands the remit of the working group consisting of Derby Teaching Hospitals NHS Foundation Trust’s Scan4Safety Programme, the National Joint Registry, and the Medicines Healthcare products Regulatory Agency to include alerts to identify wrong prostheses prior to implantation.

5. **Recommendation 2018/005**: The Department of Health and Social Care commissions the development and implementation of an interim basic scanning system to identify wrong prostheses prior to implantation.

7.3. Safety Observations

HSIB makes the following Safety Observation:

1. The national serious incident reporting system does not require inclusion of data regarding human factors such as environmental conditions, and individual and team factors. It would be beneficial for future developments to the system to collect such data.
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 submitting a safety awareness form.

Contact Us

@hSafetyIIB is our Twitter handle. We use our feed to direct followers to publications, news and events. Unfortunately we won’t be able to answer queries via Twitter but please do contact us via email using enquiries@hsib.org.uk.

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