INVESTIGATION INTO THE INSERTION OF AN INCORRECT INTRAOCULAR LENS
I2017/012

Independent report by the Healthcare Safety Investigation Branch

November 2018 Edition
At HSIB we welcome feedback on our investigation reports. The best way to share your views and comments is to email us at enquiries@hsib.org.uk. When we receive your feedback, we will share it with the most appropriate person to provide a response and you can expect to be contacted within five working days.

The decision to conduct a national investigation is based on specific criteria. More detail about these criteria can be found on page 19 of this report under section 3.2 Decision to investigate or on our website www.hsib.org.uk.

All information provided to HSIB is collated and may provide insight into other events and inform other investigations.

Thank you for taking the time to read this investigation report and we look forward to receiving your feedback and comments.
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, transport and the military.

HSIB also draws on additional expertise when required, including human factors advisors.

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 benefits of everyone who is cared for by it and works in it.

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

Safety issues for potential investigations can be shared by individuals, groups or organisations. The decision to start an investigation could relate to a single event, a series of events or an issue discovered through current, ongoing investigations.

A HSIB investigation does not replace the local investigation of a patient safety incident. Instead, the aim is to identify national learning from these events to consider the wider systems and processes involved.

The following three criteria are used to determine whether the HSIB will commence an investigation:

OUTCOME IMPACT
Assessing the impact, or potential impact, on people is a crucial part of the process. It helps identify the most serious issues as these usually involve significant impact physical and emotional harm.

The impact on services, and whether the safety issues have, for example reduced the ability to deliver safe and reliable care is also considered.

The HSIB also considers whether an incident has caused a loss of confidence in the healthcare system.

SYSTEMIC RISK
The systemic risk associated with the safety issues is reviewed. How common or widespread is the problem? Does it occur in different areas of healthcare and/or multiple sites?

LEARNING POTENTIAL
HSIB will consider whether its investigation will bring added benefit to the safety issue in terms of meaningful, influential and effective Safety Recommendations.

INVESTIGATION APPROACH
HSIB investigations do not attribute blame or liability; their purpose is to provide lessons for future safety and identify wider opportunities for systemic learning.
Although funded by the Department of Health and hosted by NHSI, HSIB is operationally independent. We’re also independent from regulatory bodies like the Care Quality Commission (CQC).

A HSIB investigation is not intended to replace a local investigation carried out by the healthcare organisation in which the incident happened. The HSIB focus is on learning and identifying themes and patterns. Investigations may consider similar incidents in different locations, or incidents across different organisations.

The HSIB’s independent status ensures that its investigations are not conducted on behalf of the families, staff, organisations or regulators. Safety Recommendations will be made to the organisation that the HSIB considers is best placed to address the identified risks both within and outside the NHS.

Following investigation, Safety Recommendations, Safety Observations or Safety Action taken may be identified.

Safety Recommendations will be directed to a specific individual or organisation for action. They will be based on information derived from the investigation or other sources such as safety studies, made with the intention of preventing future, similar events.

Safety Observations may be made for wider learning within the NHS or may be directed to a specific individual or organisation for consideration. They will be made when there is insufficient or incomplete information on which to make a definite recommendation for action but where findings are deemed to warrant attention.

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

A NOTE OF ACKNOWLEDGMENT
HSIB would like to thank the patient, whose experience is central to this report. The patient and her family have chosen to remain anonymous and HSIB have made every effort to respect their wishes.
EXECUTIVE SUMMARY

The reference safety event
An 86-year-old woman attended hospital to undergo a planned operation to remove a cataract from her left eye and to insert an artificial (intraocular) lens (IOL).

The patient attended a pre-assessment clinic where measurements of both eyes were taken (ocular biometry). The consultant ophthalmologist and the patient agreed that the target refractive outcome (uncorrected vision) following surgery would be -0.25D and this was documented on the consent form. Following surgery the patient would expect to have good distance vision with little or no need for distance glasses. The results of the biometry were transferred to an ophthalmology electronic patient record system (OEPR) used by the organisation.

On the day of surgery, the patient was assessed by the operating surgeon who was a locum consultant ophthalmologist. The surgery took place in a general operating theatre rather than one that was used exclusively for ophthalmology surgery. There was a delay to the start of the operating list caused by lack of space for pre-operative assessment, missing records and missing equipment.

Prior to surgery the consultant ophthalmologist consulted the OEPR record to select the lens required to achieve the agreed vision in the left eye, but he inadvertently used the information for the right (incorrect) eye.

Because the consultant ophthalmologist selected the lens from the range for the incorrect eye on the software, the data fields did not auto-populate as they usually would with information about the selected lens. The software did not provide any warning to alert him of the error. He assumed that this was a technical issue and used an override facility to enter the selection manually.

During a routine check immediately before starting the operation, the assisting nurse identified a discrepancy between the lens strength shown on the consent form (0D) and that shown on the OEPR screen (-0.25D). However, the surgeon decided that the discrepancy was within tolerable limits and the operation proceeded.

After the operation, the nurse remained concerned about the discrepancy and sought advice from another consultant ophthalmologist working in an adjacent operating theatre. However, the second consultant agreed with the operating surgeon’s assessment that there would be no significant effect on the patient’s vision.

The event was reported to the local incident reporting system in line with the Trust’s procedures. The patient was subsequently informed and an apology given. There is a plan to have the same procedure at a later stage on the other (right) eye.

The National Investigation
HSiB was contacted in October 2017 and made aware of a recurrent issue concerning the insertion of incorrect IOL despite the existence of national guidelines and local procedures to prevent this. HSiB identified the reference event and with the support of the Trust commenced a scoping investigation. The findings were considered against the HSiB investigation criteria, and a decision was made to progress to a national investigation. The national investigation gathered evidence relating to the reference event and examined the process for selection, retrieval and verification of IOLs across a number of organisations. The investigation team accessed relevant research and patient safety literature, discussed the case with relevant experts, consulted with professional bodies and industry experts, considered the human factors relating to implantation of incorrect IOL and explored the risks and benefits of technology used in this area of ophthalmology.

Findings and analysis
Cataract removal and implantation of an artificial lens is the most common surgical procedure undertaken by the NHS.

Investigation and analysis of the reference event found:
1 Selection of an incorrect IOL did not affect the patient’s vision enough to require further surgery in this case.

2 The working environment, facilities and processes for cataract surgery were not optimal, although the Trust had made some improvements following a previous inspection. The investigation also noted that there were different work procedures at the different sites within the Trust where surgery was carried out.

3 There was pressure on the Trust to meet operational performance targets in the face of a large backlog of patients waiting for surgery. There was also pressure felt by members of the operating theatre team to start on time, increase utilisation and efficiency. The combination of pressures led to low staff morale.
The design of the OEPR software interface used in theatre meant it was prone to usability issues, even for those who were familiar with its operation.

The wider investigation found:
5 Available national data on implantation of an incorrect IOL is likely to be incomplete and does not provide enough information to understand the incidence, consequences and causal factors.

6 Errors leading to implantation of an incorrect IOL may occur at a number of points in the patient pathway: during biometry, during selection of the IOL and when confirming the retrieved IOL.

7 There is significant variation of processes between organisations at each stage of the patient pathway for cataract surgery, especially those procedures used for selection of the IOL.

8 There is variation between organisations in the way that existing guidance and the World Health Organization Surgical Safety Checklist (WHOSSC) are applied and used, including whether a version of the WHOSSC specifically adapted for cataract surgery is used.

9 The WHOSSC ‘time out’ check is not adequate by itself to prevent implantation of an incorrect IOL.

10 There are differences in the presentation and content of data between the paper biometry printouts and OEPR systems.

11 The design of the information display of OEPRs, and other aspects of usability, is not optimal for use in operating theatres. When an OEPR is used in operating theatres, it is integrated into each organisation’s processes in different ways.

12 The OEPRs seen by the investigation had not undergone human factors engineering and usability assessments. There are no standards for OEPR design or different ‘Use Cases’, particularly in regard to safety.

13 Some trusts use scanning technology to track and reconcile equipment, prostheses and implants, and procedures for each patient. This could be extended to implantation of IOLs and provide an alert when there is a patient/product mismatch.

**HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATIONS**

1 **Recommendation 2018/014:** The Medicines and Healthcare products Regulatory Agency should strongly recommend the manufacturers of ophthalmology electronic patient record systems (including systems for making and storing ocular biometry measurements), where they fall under the remit of the Medical Device Regulations, undertake an assessment against the MHRA Human Factors and Usability Engineering guidance and this should form part of the documents assessed by a Notified Body as part of any declaration or assessment of conformity with the requirements of the Medical Device Regulations.

2 **Recommendation 2018/015:** The Department of Health and Social Care commissions a set of standards for the NHS that utilises appropriate technologies to provide digital alerts when incorrect intraocular lens are selected.

3 **Recommendation 2018/016:** The Royal College of Ophthalmologists establish an expert working group to evaluate the variance of practice for cataract surgery, and subsequently establish standardised and workable processes to minimise the risk that a patient will receive an incorrect intraocular lens.

**HSIB MAKES THE FOLLOWING SAFETY OBSERVATION**

Safety Observation
The National Ophthalmology Audit could be a useful vehicle for capturing the relevant information for the insertion of an incorrect artificial intraocular lens. The resulting data, when analysed, may improve understanding of why these events continue to occur and provide supporting evidence for further safety measures to prevent them.
CONTENTS

1  Background 9
2  The Reference Event 15
3  Involvement of the Healthcare Safety Investigation Branch 19
4  Analysis of findings at the hospital where the event occurred 21
5  Findings and analysis from the wider investigation 26
6  Summary of Findings and Recommendations 37
7  References 39
8  Appendix 41
1 BACKGROUND

1.1 Cataracts

1.1.1 A cataract is when the lens becomes cloudy or opaque, which prevents a clear image being focused onto the retina. Symptoms may include faded colours, blurry vision, halos around light, trouble with bright lights, and trouble seeing at night.

1.1.2 The image is largely focused by the cornea, a clear layer at the front of the eye, and further by the lens. The lens is soft and its shape can be changed by small muscles. This allows the eye to adjust its focus between distant and near objects. This adjustment is called accommodation. As people age, they gradually lose the ability to accommodate, which means many older people need to use reading glasses. Figure 1 shows the anatomy of the eye.

1.1.3 Cataracts are common with ageing, resulting from changes in the structure and composition of the lens. Cataracts may also occur in younger people from causes such as injury to the eye, medication, and birth defects.

1.1.4 Cataracts can be treated surgically by replacing the natural lens with an artificial implant, known as an intraocular lens (IOL). This procedure will usually restore full vision, but not the ability to adjust focus between near and distant objects.

1.2 Cataract surgery

1.2.1 When a patient attends a pre-assessment clinic and is considered suitable for cataract surgery, there will be a discussion regarding their expected visual result in terms of the planned or likely remaining refractive error (deviation from perfect optical focus, residual distance glasses prescription) following surgery. This is referred to by ophthalmologists as the target or expected refractive outcome. Refractive power is expressed in dioptres (D).

1.2.2 The power of the IOL to be used is selected to achieve the patient’s desired refractive outcome post surgery; this outcome is agreed by the patient and the ophthalmologist.

1.2.3 For the purposes of this report, selection will be used to refer to the process of choosing which brand, type and power of IOL to be implanted. Retrieval is used to describe the collection of the selected lens from the lens bank or store.

1.2.4 To identify the desired power of IOL for the anticipated outcome, measurements of both eyes are taken using a dedicated machine. This process is called biometry. The measurements are stored by the machine and can also be transferred to an electronic patient record (EPR) or printed out.

1.2.5 IOL power calculation is affected by many factors, including; the length and curvature of the eye, the brand and type of IOL and the target refraction.
1.2.6 To allow the ophthalmologist to select an appropriate type of lens for each patient, the biometry results will normally include required powers for a range of IOL types and manufacturers, which can be pre-programmed into the machine according to local or individual preference.

1.2.7 There are several formulae that can be used for the calculation; the selected formula will depend on the individual’s circumstances, for example their axial length or whether they have had eye surgery in the past.

1.2.8 Lens power calculation to achieve a desired refractive outcome is not able to give an exact prediction for each patient. The National Ophthalmology Audit (2017) found a range of refractive outcomes around the target and demonstrated that predictability lies within a range of +/-1 dioptre. Predicting lens power depends on a number of poorly understood factors about the eye, the healing after surgery (such as small variations in the precise location of the IOL within the eye and corneal changes as a result of the incision) and may vary between different patients and different ophthalmologists (Sheard, 2014).

1.2.9 These inputs can be made to the biometry machine and printed out but can also be transferred electronically to a specialist ophthalmology electronic patient record (OEPR). There are two specialist OEPRs in use in the UK (referred to as OEPR1 and OEPR2). Both can transfer data from the biometry machine, receive the inputs described above and perform the necessary calculations. Where Trusts use a generic electronic patient record, the biometry results can also be added to the patient record, usually by scanning the printout as an image. The generic electronic patient record cannot directly interact with the system (see Figure 2).

1.2.10 The biometry results will be available in paper and/or electronic form and will be checked by the operating ophthalmologist prior to surgery. If an OEPR is being used, the ophthalmologist can select the lens at any time.

**IOL SELECTION**

1.2.11 The calculation based on the selected target refractive outcome will offer a range of IOL powers and predicted refractive outcomes. As
Intraocular lenses are available with a range of powers in half dioptre increments, it is not always possible to achieve the exact target refractive outcome. The ophthalmologist will select an IOL power to produce a result closest to the target, but usually erring towards a slightly minus (myopic, or short-sighted) refractive outcome. Table 1 shows the predicted refractive outcome for a range of IOL powers.

**Table 1**  
*An example of IOL powers and refractive outcomes offered by the biometry printout*

<table>
<thead>
<tr>
<th>IOL Power (D)</th>
<th>Predicted Refractive Outcome (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.0</td>
<td>-1.23</td>
</tr>
<tr>
<td>16.5</td>
<td>-0.83</td>
</tr>
<tr>
<td>16.0</td>
<td>-0.44</td>
</tr>
<tr>
<td>15.5</td>
<td>-0.05</td>
</tr>
<tr>
<td>15.0</td>
<td>0.34</td>
</tr>
<tr>
<td>14.5</td>
<td>0.72</td>
</tr>
<tr>
<td>14.0</td>
<td>1.10</td>
</tr>
</tbody>
</table>

1.2.12 In the example above, the desired refractive outcome is zero. Because this option is not available, the ophthalmologist will choose the 15.5D IOL, producing an expected refractive outcome of -0.05D.

1.2.13 The effect of this is that the patient will be slightly short-sighted but will be able to see objects in the distance without the need for glasses or with minimal correction. They will be able to see objects nearby without glasses.

### Managing the Demand for Cataract Surgery

1.2.14 There is a high demand for cataract surgery. Between 1 April 2016 and 31 March 2017 there were 396,317 lens replacement operations in England (NHS Digital, 2017).

1.2.15 Until recently, patients were assessed by a consultant or one of their team and subsequently admitted for surgery by the same consultant team. Some Trusts attempting to increase operational efficiency are placing patients on the next available operating list, where the operation may be done by a different consultant. This effectively pools operating lists for cataract surgery. Even if the patient is admitted under the same consultant’s team, they may have been seen in clinic by a trainee or associate doctor, who may or may not operate on the patient.

1.2.16 It is the operating ophthalmologist who is ultimately responsible for the selection of the IOL.

### Preparation for Surgery

1.2.17 When patients arrive for their surgery, their personal details are confirmed, and they are given an identification wristband.

1.2.18 The operating ophthalmologist assesses the patient pre-operatively to confirm they still want to proceed with the surgery, explains the procedure and obtains or re-confirms their consent. The ophthalmologist reviews the medical record (paper or electronic) and usually re-examine the patient’s eyes, to confirm the initial findings. The medical record should include the biometry results and IOL selection, if this has been made. If IOL selection has not occurred before to the day of surgery, the ophthalmologist uses this opportunity to determine the most appropriate lens for the patient. If IOL selection has already taken place, the operating ophthalmologist will review and confirm the selection. If the range of powers, IOL type/brands, or formula used does not meet their requirements a recalculation may be required.

1.2.19 The theatre team may vary but usually includes an anaesthetic assistant or operating department practitioner (ODP), scrub nurse, circulating nurse and healthcare assistant. There may also be an anaesthetist present.

1.2.20 Prior to starting an operating list, the team conduct a team brief during which they introduce themselves and discuss each patient and highlight any additional requirements, equipment or anticipated problems.

1.2.21 The World Health Organization Surgical Safety Checklist (WHOSSC) is used at three key stages during the procedure. This checklist was published by the World Health Organization in 2008 and introduced as a requirement by the NHS in 2009. Trusts are encouraged to adapt the checklist for
local use and some use a version produced specifically for cataract surgery. Some examples are available on the Royal College of Ophthalmologists (RCOphth) website. More information about the WHOSSC is given at Appendix 1.

1.2.22 Trust procedures are also required to be compliant with the National Safety Standards for Invasive Procedures (NatSSIPs) (NHS England, 2015). These provide a set of outline standards for invasive procedures carried out at any site in a Trust; Trusts are required to adapt them for local use as Local Safety Standards for Invasive Procedures (LocSSIPs).

1.2.23 The intention of the NatSSIPs is to improve patient safety by ensuring that organisations develop documented standardised local processes for invasive procedures (including cataract surgery) that are aligned to a common national standard.

1.2.24 The NatSSIPs report noted “There has been wide variation in adoption of the [WHO] checklist between Trusts, often reflecting the organisational safety culture and, in particular, the clinical leadership in the operating theatre” (NHS England, 2015).

1.2.25 Patients having cataract surgery normally walk into the anaesthetic room or theatre or arrive in a wheelchair. They can be anaesthetised in a specially adapted ‘eye chair’ (which acts as a wheelchair but can be fully reclined and used during the procedure), on a trolley from which they are subsequently transferred to the operating table, or on the operating table.

1.2.26 The WHOSSC is used for all procedures in theatre. The ‘sign in’ is completed with the aim of ensuring the correct patient is in the theatre, with the correct eye marked for anaesthesia and surgery. This normally occurs when the patient is first brought into theatre or into the anaesthetic room. The ‘sign in’ is usually completed by two staff members, who may include the nurse, healthcare assistant and ophthalmologist. Meanwhile the scrub nurse is making preparations. The IOL to be used is usually confirmed at this stage and retrieved by a member of the theatre team (see section 1.3.28).

1.2.27 Most cataract surgery procedures will be carried out under a local anaesthetic, administered by the operator, anaesthetist or ODP. Topical local anaesthesia (local anaesthetic eye drops) or a blunt cannula ‘block’ are the most often used.

RETRIEVAL OF THE IOL AND TIME OUT CHECK

1.2.28 A member of the team retrieves the agreed intraocular lens from the lens bank. There should only ever be one intraocular lens in theatre at any time.

1.2.29 When the patient is prepared, and immediately before surgery, the theatre team conduct the WHOSSC ‘time out’ check. This allows a final check of patient identity, known allergies, patient consent, side for surgery and the lens being inserted. There is also an opportunity to check any patient-specific requirements.

1.2.30 For cataract surgery, the ‘time out’ check includes confirmation of the consent and requires confirmation of correct IOL. The team confirms that the information on the lens box matches the required lens, wherever this information is presented. This will include:

- lens type/brand
- power (measured in half dioptre increments)
- batch number and expiry date
- source biometry

1.2.31 Once the ‘time out’ check has taken place surgery commences.

COMPLETION OF SURGERY

1.2.32 When the procedure is complete, the team finalise the WHOSSC ‘sign out’ check, confirming the procedure, the swab and instrument count is complete, and identifying any issues arising during the procedure and any special instructions for post-operative care.

1.2.33 The patient is transferred out of theatre and, if recovery is as expected, they are given follow-up instructions and relevant medications, and allowed to go home after one to two hours.

1.2.34 At the end of the operating list, the team undertakes a team debrief, during which team members discuss the list and highlight what went well and what could be improved for next time.
1.4 Biometry results presentation

1.4.1 Biometry testing and the display of results always includes both eyes, which allows the ophthalmologist to:

- detect any obvious discrepancy which may result from a biometry error
- consider and plan for the patient’s overall vision capabilities, the function of the other eye and the likelihood of second eye surgery, when determining the desired refractive outcome.

1.4.2 The same biometry records can also be used later if the second eye is operated on. Current RCOphth guidance does not specify how long biometry remains valid; this is generally accepted as three years (Lai & Ursell, 2017) unless there is a specific change in the status of the eye.

1.4.3 When health records include diagrams of the patient’s body or a part of the body, the convention is to depict the patient as viewed by the observer. So, in the case of the eyes, viewed from in front of the patient, the left eye will be on the right of the diagram. Biometry information is presented in the same way. Figure 3 and Figure 4 show examples of biometry data as presented on a paper printout and on the screen of OEPRI. The layout of the fields will vary depending on the supplier and local preferences, however the left eye information will always be presented on the right side of the page.

1.4.4 The presentation of results by an OEPR is similar to but not exactly the same as a biometry printout which could affect how the team check and use the information. Figure 4 shows a schematic of the ‘biometry’ screen display provided by OEPRI. For each lens brand/type, it gives a range of IOL powers predicted to give an outcome closest to the target refractive outcome.

1.4.5 When the ophthalmologist makes the intraocular lens selection using OEPRI, they will use the software to select the required lens brand/type/power combination shown on the computer screen. This in turn populates the relevant fields in the ‘operation’ screen.

FIG 3 SCHEMATIC SHOWING BIOMETRY MACHINE PRINTOUT PRESENTATION

For each eye, it presents the results of the eye measurements, the formula used for calculating the IOL power and for each of four lens brands/types, a range of lens powers and predicted refractive outcomes around the target (the power closest to the target refractive outcome is highlighted in bold).
1.4.6 If using the paper printout, the chosen lens brand/type/power combination on the biometry printout should be highlighted. In some cases, the chosen lens power will be written somewhere else in the medical records. The ophthalmologist should always check back to the source biometry data (the printout) if they are recording values to allow for handwriting errors.
2 THE REFERENCE EVENT

2.1.1 Mrs A was an 86-year-old woman with cataracts in both eyes who attended hospital for cataract removal and insertion of an intraocular lens (IOL) in her left eye.

2.1.2 She had previously attended a pre-assessment clinic at which two biometry technicians carried out measurements of both eyes. The consultant ophthalmologist (OA) and Mrs A agreed the target refractive outcome for the patient’s left eye would be -0.25D, and for the right eye it would be zero. This meant that following surgery, Mrs A would have good distance vision with little or no need for distance glasses. She would still require glasses for reading. Mrs A was listed for left cataract removal and insertion of an IOL. As was the practice in this Trust, OA took consent from Mrs A and wrote the target refractive outcome for the left eye on the consent form.

2.1.3 Mrs A arrived in the day surgery ward at 07:30hrs. A nurse booked her in and confirmed her identity, applied a wristband and took her observations. The nurse explained to Mrs A and her daughter that the consultant ophthalmologist who would be operating (O1) would see her before surgery, that she was the first patient on the operating list and that the expectation was that she should be able to go home by 11:00hrs.

2.1.4 O1 was a locum consultant ophthalmologist who had been employed by the Trust.

2.1.5 The Trust has three operating theatres which are used for ophthalmology: this included a dedicated ophthalmology theatre in the main theatre department (location 1) and two additional general operating theatres available for use by the ophthalmology department in a different part of the hospital (location 2). One of these theatres is used more frequently than the other. On this day, all three theatres were being used.

2.1.6 O1’s cataract surgery list was operating in the least frequently used theatre in location 2. Theatre staff told the investigation they would prefer to work in the dedicated ophthalmology theatre as they have easier access to equipment and managerial support. This was the third occasion on which O1 had worked at location 2.

2.1.7 The operating ophthalmologist usually sees each patient prior to surgery to confirm their consent to proceed with the operation, assess the patient’s eyes and select the IOL power and brand/type. The hospital has one room and one slit-lamp (used for eye examination) to assess patients pre-operatively but, on this day, there were three eye lists scheduled, with three consultant ophthalmologists required access to the pre-assessment room. The ophthalmologists agreed that ophthalmologist 3 (O3) would go first, followed by ophthalmologist 2 (O2) (who didn’t need the slit-lamp), then O1 would go last.

2.1.8 While O1 was carrying out pre-operative assessments, the theatre team were setting up the theatre for the day. This involved collecting and checking the equipment required for the list. At 08:00hrs the team did not have an Operating Department Practitioner (ODP) for anaesthetics. A member of staff was re-allocated from another theatre and the full complement of staff was present at 08:10hrs.

2.1.9 Although the day surgery team had liaised with the medical records department prior to the day of surgery, Mrs A’s medical records were not available in the day surgery unit until after 09:00hrs.

2.1.10 O1 spent 30 minutes waiting to access a room and the slit lamp, to enable the assessment of his patients.

2.1.11 O1 saw Mrs A, confirmed her consent to surgery, assessed her eyes using the slit lamp and confirmed the target refractive outcome. He did not select the lens as a computer was not available in the room.

2.1.12 O1 assessed the second patient. The third patient was cancelled as there was no consent taken. The medical records for the fourth patient were not available. O1 decided to start the list.
2.1.13 By 09:00hrs, O1 should have assessed all the patients on his list, conducted the team brief and commenced the first operation. Because of the delay in accessing a room to undertake assessments, O1 arrived in the theatre later than planned at 09:25hrs and so the team brief started 40 minutes late. Team members introduced themselves and O1 noted the team was different from the one he had worked with during his last two sessions in the same site.

2.1.14 During the brief, O1 informed the team that the list would be reduced to two patients. They discussed the equipment that would be required for transferring and operating as no eye chair was available. The Trust was using an OEPR and O1 identified there was no computer mouse available for the theatre computer. This meant the patient’s surgical records could not be completed. A member of the theatre team borrowed a mouse from the adjacent theatre while a replacement was sought. Meanwhile, another member of the theatre team left to locate an operating chair.

2.1.15 Because of the delays, Mrs A’s operation started at 09:30hrs instead of 09:00hrs. The ODP brought Mrs A into the anaesthetic room and O1 and the ODP completed the WHOSSC ‘sign in’. The anaesthetist administered local anaesthetic into the patient’s left eye while O1 was in theatre completing the patient’s medical record on the OEPR. O1 had used the OEPR previously in this Trust and other Trusts.

FIG 5 DIAGRAM OF BIOMETRY SCREEN AND OPERATION SCREEN IN THEATRE

This section should populate values based on the selection in the screen above. These boxes are used to confirm the IOL in theatre matches the selection.
2.1.16 O1 reviewed the results from Mrs A’s biometry in the OEPR and selected the intended IOL from the range available on the ‘biometry’ page of the OEPR. However, O1 selected an IOL from the range available based on the biometry values recorded for the (incorrect) right eye. (see Figure 5).

2.1.17 O1 attempted to save this selection in the OEPR four times, but the system would not permit him to do this, as left eye surgery had been selected on the ‘operation’ screen of the OEPR. O1 assumed the inability to save the selection he made was a technical issue, rather than a safety feature to prevent incorrect selection. The software did not show an IOL power in the operation section of the screen because a lens for the left side eye had not been selected. O1 manually typed in the IOL power for the right eye value and proceeded with the operation.

2.1.18 During the WHOSSC ‘time out’ check, the target refractive outcome documented on the consent form was -0.25D and O1 read out zero from the OEPR. The assisting nurse questioned the discrepancy as the target refractive outcomes did not match. In O1’s clinical judgement, he felt the difference would not make any significant difference to the patient’s visual outcome and decided to proceed. At this point O1 was not aware he had selected an IOL power using data from the incorrect eye.

2.1.19 The scrub nurse told the investigation she had felt uncomfortable proceeding as the target refractions did not match. The scrub nurse questioned O1 a second time but felt that she did not have sufficient knowledge of the lens selection processes to justify further questioning.

2.1.20 The scrub nurse went on to complete the ‘time out’ check, but the IOL box had not been brought into the theatre as local policy required. Usually, the operating ophthalmologist would retrieve the required IOL themselves. However, O1 was under the impression a member of the theatre team would undertake this task as this had been the practice when he previously worked at a different site in the same Trust. The healthcare assistant then retrieved the requested lens from the lens bank.

2.1.21 At this point, O1 had decided to insert a 21D lens, had manually recorded this value on the computer software, and the healthcare assistant had brought this lens into theatre. The theatre team and O1 completed the WHO ‘time out’ check, confirming the IOL matched the intended lens. Surgery then commenced.

2.1.22 Immediately prior to insertion of the lens, the circulating nurse and scrub nurse confirmed the IOL power and expiry date shown on the box. The circulating nurse then opened the IOL package and placed the lens on the trolley. The scrub nurse handed the IOL to O1 for insertion and the procedure was completed. Mrs A was transferred back to the day surgery unit to recover.

2.1.23 The second patient on the list was already in the anaesthetic room, undergoing checks and anaesthesia in preparation for surgery. O1 was documenting the follow up arrangements for Mrs A. The scrub nurse still felt unsure about the lens that O1 had selected for Mrs A and went into the adjacent theatre to seek advice from O2.

2.1.24 O2 agreed with O1’s assessment that a difference of -0.25D would have no significant effect on Mrs A’s visual outcome. However, he did acknowledge that, as per local policy, the target refractive outcomes on the consent form and OEPR should match. O2 agreed to speak to O1 to demonstrate how to resolve the issue.

2.1.25 O2 entered the theatre and asked O1 to demonstrate what he had done. When O1 tried to show O2, he realised he had been selecting the IOL from the right eye values rather than the left. O1 went to check on Mrs A in the day surgery ward and confirmed that the correct (left) eye had been operated on but recognised that he had selected the incorrect IOL.

2.1.26 As the second patient on the list was now ready for surgery, O1 proceeded with the second operation. The incident was reported to local and national reporting systems.

2.1.27 Mrs A’s daughter later reported that she suspected that something wasn’t right after O1 came to check which eye was operated on.
2.1.28 The patient safety manager phoned Mrs A’s daughter the following day and asked if they would be able to come back in on the next working day. Mrs A’s daughter was concerned and asked why they needed to come back in. The patient safety manager explained the incorrect IOL had been inserted and they wanted to apologise and explain the next steps. Mrs A’s daughter felt returning to the hospital would cause her mother more distress and therefore accepted the phone call was sufficient. The patient safety manager explained the investigation process and agreed a plan with Mrs A’s daughter regarding follow up.

2.1.29 Although the IOL inserted was not the intended one, Mrs A did not require further surgery as the difference in power was both negative and small and the visual outcome was satisfactory. At the time of the investigation, the Trust was working to identify measures to allow Mrs A to undergo further surgery on her second eye.
3 INVOLVEMENT OF THE HEALTHCARE SAFETY INVESTIGATION BRANCH

3.1 Notification of the event

3.1.1 HSIB was contacted in October 2017 to highlight the recurrent issue of implantation of the incorrect intraocular lens (IOL). Despite the existence of national guidelines and local work procedures designed to improve the process of selection and confirmation of the correct IOL, these events were still occurring nationally.

3.2 Decision to investigate

3.2.1 Following initial enquiries and an evaluation of the safety issue(s) against HSIB criteria, the Chief Investigator authorised a full investigation.

3.2.2 The safety issues were evaluated against the following criteria:

**Outcome Impact** - What was, or is, the impact of the patient safety risk on people and services across the healthcare system?

3.2.3 Cataracts are more prevalent in older people and many patients have cataracts in both eyes. An operation for each eye will normally require surgery on two separate occasions. Insertion of an incorrect IOL may result in a requirement for exchange surgery to replace the IOL, exposing the patient to further surgical risk.

**Systemic Risk** - How widespread and how common is this patient safety risk across the healthcare system?

3.2.4 Insertion of an incorrect IOL was the most commonly reported Never Event in England between April 2016 and March 2017 (see section 5.2.1 for more information about Never Events). Despite the introduction of measures to improve safety, including computer software, this event continues to occur. The World Association of Eye Hospitals has selected insertion of an incorrect IOL as its 2018 issue to resolve.

**Learning Potential** - What is the potential for an HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system?

3.2.5 Initial information gathered by HSIB identified the patient safety risk at a national systemic level. The investigation aims to understand why measures currently in place do not always prevent the insertion of an incorrect lens.

3.3 Investigation process and methods

3.3.1 A variety of investigative methods were used, which included:

- Interviews with all staff involved in the reference event, including those who were part of the supporting processes.
- A review of patient medical records, hospital policies, procedures, external review reports, previous serious incident reports, audit data, training materials and practice regarding cataract surgery and IOL selection at the hospital where the reference incident occurred.
- Observations of practice in seven operating theatres across three trusts and a detailed conversation with staff from one further organisation.
- Interviews with staff at each location visited.
- A review of nationally reported Serious Incidents involving insertion of an incorrect IOL, and a snapshot review of completed investigation findings and recommendations following these events.
- A literature review and comparison of findings with current data in the National Reporting and Learning System (NRLS) database.
- Interviews and personal communications with leaders of relevant national organisations and subject matter experts.
Meetings with commercial organisations to understand the design and development of electronic software for use in cataract surgery.

3.3.2 The evidence and associated safety issues were analysed using human factors based methodologies.

LIMITATIONS OF OBSERVATIONS

3.3.3 There are many Trusts and private facilities offering cataract surgery; the investigation was only able to observe activities at a small number of these. However, findings were supplemented by insights from clinical subject matter experts with experience of cataract surgery and a review of the relevant literature and incident data.

LIMITATIONS OF EVIDENCE FROM INTERVIEWS

3.3.4 Witness memory is useful for understanding an individual's perception of events and exploring other contextual factors. It can be prone to unintentional error whereby details of events are forgotten, altered or falsely added into memory as time passes (British Psychological Society Research Board Working Group, 2008). Such errors are a natural consequence of the way in which people organise and interpret information.

ANALYTICAL TOOLS

3.3.5 Analysis of this event was informed by the Australian Transport Safety Bureau (ATSB) model (Australian Transport Safety Bureau, 2008). The model is a derivative of the concept of organisational accidents, introduced by James Reason. This describes a hierarchy of organisational and local conditions that harbour latent risks, and unsafe acts which combine with these conditions and lead to accidents. It encompasses Reason's ‘Swiss cheese’ model of systemic defences or barriers at each level, which may be incomplete and fail when the ‘holes’ in the barriers line up (Reason, 1997).

3.3.6 These models capture the key concept which is that many of the causal factors leading to a failure at the ‘sharp end’ – in this case, insertion of an incorrect IOL – may lie well away from where the error occurred, within the organisation or the wider system.

3.3.7 A diagrammatic representation of the ATSB model is shown in Figure 6.

FIG 6 AUSTRALIAN TRANSPORT SAFETY BUREAU INVESTIGATION MODEL
4 ANALYSIS OF FINDINGS AT THE HOSPITAL WHERE THE EVENT OCCURRED

4.1 Individual actions

4.1.1 A number of individual actions were identified which increased and mitigated safety risk:

• The team performed a number of actions to ensure they had the staff and equipment required, including the re-allocation of an Operating Department Practitioner (ODP) from another theatre, retrieving a computer mouse and an operating chair, and changing the list order so that medical records would be available.

• The team carried out a team brief and correctly completed the ‘time out’ check.

• O1 incorrectly selected the IOL using data from the wrong eye, disregarding the abnormal behaviour of the OEPR (attributing it to a technical malfunction), and manually entered the IOL on the ‘operation’ screen.

• The scrub nurse twice questioned the discrepancy between the target refractive outcome on the consent form and what was presented by the OEPR.

• O1 decided the difference identified would not have any significant effect on the patient’s visual outcome. Although this was justified in hindsight, there was no further enquiry at the time into why the discrepancy might have occurred.

• The scrub nurse subsequently raised her concerns with O2, whose response led to the error being identified.

• Once the error was recognised the team and the Trust took the necessary steps to make sure the patient was safe, and the outcome was satisfactory. The Trust informed the patient, and an apology was issued. The incident was reported and a local investigated initiated.

4.2 Local conditions

4.2.1 The Trust has one room for pre-operative assessment with a slit lamp and computer. This would be adequate under conditions with one ophthalmology list running, but was inadequate with three consecutive operating lists.

4.2.2 Missing or delayed medical records compounded delays for Mrs A and for other patients.

4.2.3 O1 noted, the medical records for all his patients did not arrive until around 09:00hrs, and there was no computer in the location, so the IOL selection could not be made for the two patients who were assessed. O1 was expected in theatre at 08:45hrs to undertake the team brief but, as a result of the delay caused by missing records and insufficient facilities, he arrived in theatre at 09:25hrs.

4.2.4 During the team brief, it became apparent the computer mouse was missing and that there was no eye chair for the patient to sit/lie on during the operation. The theatre team focused on borrowing these items from other areas of the hospital.

4.2.5 Although the theatre at location 2 had undergone risk assessment for suitability, staff reported they found it more difficult to work in because of its locality and its smaller working environment. They preferred not to work there and found it difficult to move around the theatre without knocking into equipment or each other.

4.3 Organisational influences

4.3.1 The Trust is made up of two acute hospitals, which feature in the top 20% of counties for an ageing population (Office for National Statistics, 2016). The Trust management team commented to the investigation on the challenges of recruiting staff.

4.3.2 Previously, the Trust had a series of ‘Never Events’ in ophthalmology. The Royal College of Ophthalmologists were invited in to review their service. The investigation observed that some recommendations were acted upon, but some had not been embedded into practice. For example, the College
recommended the team should refer to the source biometry printout during the ‘time out’, but this was not documented in the Trust guidelines or observed in practice. The College also recommended the information on the source biometry printout (rather than the OEPR screen) be used for making the decision on IOL selection and checking.

4.3.3 Following Never Events in other specialties the Trust provided human factors training for staff in all theatres.

STAFF ATTITUDE AND MORALE

4.3.4 Theatre staff told the investigation they prefer to be familiar with their working location and the people they are working with. Difficulties with recruitment have led to an increased use of agency staff and locum doctors.

4.3.5 Some of the staff reported low morale within the theatre team due to staff leaving, reliance on locum and agency staff, pressure to start on time and meet efficiency targets, and changes in management. They also reported feeling undervalued at times. This was reflected in both theatre staff and consultant interviews.

4.3.6 There was pressure to start lists on time, both to make sure lists didn’t run over and patients weren’t cancelled. There was also pressure from Trust managers to improve utilisation so more patients could be treated.

4.3.7 At the time of the event, the ophthalmology service was closed to new referrals due to a backlog in patients awaiting surgery.

4.3.8 Low morale is an emotional reaction to the stressors described (Salas and Driskell, 1996) and can negatively affect an individual’s readiness to perform their tasks. The stressors described could serve as a distraction resulting in the narrowing of attention, information being filtered out and/or reducing the capacity in working memory available to perform a task (Klein, 1996).

4.4 Risk controls - standardisation of practice

STANDARDISATION AGAINST AVAILABLE GUIDANCE

4.4.1 The National Institute for Health and Care Excellence (NICE) guideline for cataract surgery NG77, *Cataracts in adults: management* (NICE, 2017), has been adopted by RCoPhth as its key guidance. The investigation identified parts of the NICE guidance where the Trust was non-compliant. This included use of the WHO checklist for cataract surgery and the timing of selection of the IOL.

4.4.2 The Trust had two standard operating procedures (SOPs) for cataract surgery, one for each site. Neither of the SOPs specified whether the general surgical version or the cataract version of the WHO SSC should be used. Neither covered the period prior to arrival in theatre or the IOL selection processes.

4.4.3 The Trust also provided the investigation with three further documents:

• A local National Safety Standards for Invasive Procedures (NatSSIPs) policy which reproduces the lens check process included in the national document.

• SOPs for undertaking biometry and manually entering data into the OEPR. This does not mention IOL selection.

• Booking guidelines, which state a patient cannot be listed for surgery without consent, biometry and agreed documented target refractive outcome.

4.4.4 The UK Ophthalmology Alliance (UKOA) is a specialty interest group with 48 members from organisations across the UK providing ophthalmology services. The UKOA aims to provide a forum to share, develop and agree best practice from clinical care through to commissioning and financing.

4.4.5 In addition to NICE guidance NG77, the UKOA has developed, in conjunction with the RCoPhth, a quality standard entitled *Correct IOL implantation in cataract surgery – quality standard 2018* (UK Ophthalmology Alliance, 2018).

4.4.6 The UKOA document above standardises elements of the process. It has been endorsed by the RCoPhth and published on the College website. The UKOA standard
states IOL selection should take place prior to the surgeon entering theatre. NICE guidance makes no reference to when or where the lens selection occurs.

4.4.7 Both the NICE and UKOA documents focus on checks to confirm the information on the lens box in theatre matches the selection made, rather than if the correct IOL has been accurately selected.

VARIATION IN PRACTICE BETWEEN SITES

4.4.8 As described above, the Trust had SOPs for cataract surgery but the SOPs were different for the two sites. The investigation also observed ophthalmology practice varied between individual ophthalmologists as well as at each site.

4.4.9 The theatre staff worked at one site only, yet the ophthalmologists worked across both sites and used both SOPs.

4.4.10 The observed aspects of practice that varied between the sites is shown in Table 2 below.

TABLE 2
EXAMPLE DIFFERENCES BETWEEN PROCESSES AT EACH LOCATION

<table>
<thead>
<tr>
<th>SITE ONE</th>
<th>SITE TWO (EVENT LOCATION)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataract version of WHO checklist</td>
<td>General WHO surgical checklist</td>
</tr>
<tr>
<td>Any member of team retrieves lens from lens bank</td>
<td>Ophthalmologist retrieves lens from lens bank</td>
</tr>
<tr>
<td>Only ‘operation’ screen open in theatre</td>
<td>Biometry and ‘operation’ screen open in theatre</td>
</tr>
</tbody>
</table>

4.4.11 O1 had worked predominantly at site one. This was his third session at site two. O1 told the investigation that the day of the event was the first time he had been informed by the theatre team that it was policy for him to retrieve the lens from the lens bank. O1 wasn’t sure if this was a new organisational policy or a policy for this specific team as he hadn’t worked with them before and hadn’t been told this during his two previous sessions at site two. O1 told the team this wasn’t his experience when he worked previously at the hospital, but the team explained this had always been the policy.

4.4.12 There were different options available for equipment used to bring patients to theatre, including use of an eye chair, a bed with or without the addition of a trolley. In this case the anaesthetist preferred to use a trolley. This option made it difficult to manoeuvre the patient and transfer them to the operating bed in a theatre which had limited space.

SELECTION OF IOL

4.4.13 NICE guidance makes no reference to when or where the lens selection occurs.

4.4.14 The UKOA quality standard states that “IOL selection should take place during the assessment clinic or in the pre-operative ward-round”.

4.4.15 One of the authors of the quality standard told the investigation the rationale for making the IOL selection decision prior to theatre was that this offered a quieter, less stressful environment than theatre.

4.4.16 Neither of the Trust’s SOPs specified the stage at which the IOL should be selected.

4.4.17 In this case, and another observed theatre list with a different consultant ophthalmologist at the Trust, the practice was to select the lens upon entering theatre after seeing patients pre-operatively and before the start of the team brief.

4.4.18 O1 was unable to select the IOL during pre-operative assessment as there was no computer available; he couldn’t select the IOL in theatre before the team brief because he could not use the computer as there was no mouse. This resulted in the selection being made immediately prior to surgery.

4.4.19 The selection of IOL is ultimately the responsibility of the operating
ophthalmologist. In Trusts operating pooled lists the selection decision cannot be made at the pre-assessment clinic because the operating ophthalmologist may not be the person undertaking the assessment. In this Trust the lists are finalised for both the patients and operating ophthalmologist one week before surgery which could provide an opportunity to review patient notes in the week prior to the scheduled surgery. However, this becomes more difficult with locum ophthalmologists who are not allocated administration time.

**ROLE OF THE OEPR IN IOL SELECTION**

4.4.20 The data on the OEPR biometry screen is similar to the information printed from the biometry machine. There are some differences in presentation and availability of some of the data. This will also vary depending on the OEPR that is being used, creating potential for misinterpretation of the data.

4.4.21 The OEPR used in the reference case allowed the surgeon to enter the side of operation on the ‘operation’ screen and to select from the range of suggested IOLs on the ‘biometry’ page. Under normal use, once the lens was selected the relevant section on the ‘operation’ screen would have been automatically populated. On this occasion no auto-population occurred as the selected lens corresponded to the incorrect eye; the software did not provide any warning to the user.

4.4.22 The OEPR does provide the ability to input data manually on the ‘operation’ screen. The functionality to input power and target refraction manually is required in some cases, for example when a patient has undergone laser refractive surgery and further adjustments are needed.

4.4.23 The OEPR has alerts to notify the user if an unusual selection or action is made, for example if the user selects an intraocular lens using a formula not recommended. An alert would inform the user the formula is not recommended. When this occurs the user is only able to click ‘OK’ to acknowledge the alert and take action.

4.4.24 The software manufacturer told the investigation that a fine balance exists between clinical safety and avoiding “alert fatigue” (Cvach, 2012). This informs decisions as to when to appropriately use alerts in clinical software.

4.4.25 Alert fatigue is the term used to describe desensitisation to alerts which may occur when the user is bombarded by frequent audible or visual alerts. This can result in clinicians disabling alarms, not paying sufficient attention to and/or missing important alerts (Cvach, 2012).

**RETRIEVAL AND CHECKING OF IOL AND ADEQUACY OF CHECKS**

4.4.26 In the reference event, there was a discrepancy between the target refractive outcome values shown by the OEPR, and what was written on the consent form (at the pre-assessment clinic); the consent form stated -0.25D and the OEPR screen showing 0D. This is within the range of target refractive outcomes which a surgeon might choose to achieve so it was not immediately obvious to O1 that there may have been an error.

4.4.27 Checking practices are intended to ensure the selected IOL is inserted into the patient’s eye rather than to ensure the correct IOL has been selected. The WHOSSC ‘time out’ provides an opportunity to check the lens box matches the selection in terms of both brand/type of lens and power. The checking process is not designed to confirm whether the lens selection is correct or whether the selection has been made from the correct data.

**THE ROLE OF THE WHO SURGICAL SAFETY CHECKLIST**

4.4.28 The investigation was informed by staff that there was routine use of the WHOSSC and the Trust provided observational audit data to support this. Site two, where the event occurred, used the standard WHOSSC. Site one used the version adapted for cataract surgery, which has a time out section customised for checking the planned refractive outcome and IOL.

4.4.29 The WHOSSC form is completed for each patient and filed in their medical records. This gives no indication of the quality of each stage of the checklist process. The investigation observed practice in an ophthalmology theatre and noted that
not all members of the team were actively participating in the checks and the form was completed retrospectively.

4.4.30 NICE guidance NG77 requires “at least two members of the team, including the surgeon, have previously checked the appropriateness, accuracy and consistency of all: formulas, calculations and intraocular lens constants” (NICE, 2017). This is to ensure the selection is made from appropriate data.

TEAMWORK AND UNDERSTANDING OF ROLES

4.4.31 Theatre start times are regularly reported across the department to support efforts to improve efficiency. As previously mentioned above, there are factors outside the control of the theatre team that impact their ability to start on time. In the reference event, the delay in assessing patients pre-operatively made the surgeon arrive late to theatre; the theatre team were unaware of the surgeon’s circumstances.

4.4.32 Other issues impacting on the day include three concurrent ophthalmology lists, the team had not worked together before, nor had they previously worked with this surgeon or had recent ophthalmology theatre experience.

4.4.33 There was no clear understanding between the surgeon and the theatre team about the process for collecting the IOL prior to surgery, as this varied across sites and between theatres.

4.4.34 The investigation observed in the absence of standardised working practices for cataract surgery, staff utilised past experience. This situation was compounded by this being a new team in a different environment. The team was also, faced with low morale and a variety of pressures.

4.4.35 The theatre staff didn’t recognise the implications of a missing computer mouse until O1 identified it. Waiting for a computer mouse to arrive created further frustrations.

TRAINING IN OPHTHALMOLOGY FOR THEATRE STAFF

4.4.36 In this Trust, all theatre staff are required to work an on-call rota, requiring all staff to be competent across all specialities. Team leaders work in one theatre and approximately 80% of their time will be in the primary speciality for which that theatre is used. All other staff work in theatres on a rotational basis every three to four months. Within two years, they should have rotated through all areas.

4.4.37 The only theatre nurse that was an ophthalmology nurse was on annual leave on the day of the event. No other staff member had received formal training in ophthalmology. A national programme for training theatre staff in ophthalmology does not exist.

4.4.38 Staff are trained to ask questions and challenge the surgeon if there are discrepancies. Staff do not have the clinical knowledge to explain or understand the discrepancies or rationale from the surgeon.

4.4.39 In this case, the scrub nurse believed something wasn’t right but wasn’t able to identify what it was. She did question O1 and created an opportunity for the team to review the task and IOL selection. O1 believed the difference would not impact the surgical outcome.
5 FINDINGS AND ANALYSIS FROM THE WIDER INVESTIGATION

5.1 Observational studies and error mapping

To understand the environment, technology, process and potential opportunities for error during cataract surgery, the investigation observed cataract lists both at the Trust where the event occurred and at two other Trusts, across several locations. The investigation held discussions with staff at a further trust, who described their processes in detail, although their practice was not observed.

5.1.1 In the Trust where the event occurred, observations were carried out at both sites. However, because of the irregular use of the theatre where the event took place, the investigation was not able to observe cataract surgery in this location.

5.1.2 Based on this observational work and a review of NICE guidance NG77, a map of the stages of the patient journey was developed.

5.1.3 Using the evidence obtained, 27 types of potential error were identified and mapped to the stage where they might occur. Where multiple errors could occur at the same stage, this was taken to indicate an increased risk.

5.2 Review of reported incidents

NEVER EVENTS

5.2.1 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” (NHS Improvement, 2018a). Prior to 1 April 2018 an incorrect IOL selection that was otherwise correctly implanted was classified as a Never Event. Since that date, the definition only encompasses cases where the selected IOL was not the one implanted – i.e. it does not cover an incorrect selection.

5.2.2 In the year ending 31 March 2017, there were 53 Never Events reported in which the wrong implant or prosthesis was used. The greatest number was in the category of implantation of wrong IOL (21 incidents), followed by wrong knee prosthesis (20 incidents) and wrong hip implant (5 incidents) (NHS Improvement, 2018b).

STEIS AND NRLS DATA

5.2.3 The investigation reviewed data from the Strategic Executive Information System (SteIS) and National Reporting and Learning System (NRLS) over a 34-month period, for incidents occurring between 1 March 2015 and 31 December 2017 relating to insertion of an incorrect IOL.

<table>
<thead>
<tr>
<th>STAGE OF ERROR</th>
<th>NUMBER OF INCIDENTS (STEIS)</th>
<th>% OF TOTAL</th>
<th>NUMBER OF INCIDENTS (NRLS)</th>
<th>% OF TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biometry</td>
<td>11</td>
<td>15%</td>
<td>48</td>
<td>28%</td>
</tr>
<tr>
<td>Target refraction</td>
<td>1</td>
<td>1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selection</td>
<td>18</td>
<td>24%</td>
<td>46</td>
<td>27%</td>
</tr>
<tr>
<td>Retrieval</td>
<td>10</td>
<td>14%</td>
<td>11</td>
<td>6%</td>
</tr>
<tr>
<td>WHO time out</td>
<td>22</td>
<td>30%</td>
<td>48</td>
<td>28%</td>
</tr>
<tr>
<td>Change in surgical plan</td>
<td>5</td>
<td>7%</td>
<td>8</td>
<td>5%</td>
</tr>
<tr>
<td>Manufacturing</td>
<td></td>
<td></td>
<td>1</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Unknown</td>
<td>7</td>
<td>9%</td>
<td>11</td>
<td>6%</td>
</tr>
<tr>
<td>Total</td>
<td>74</td>
<td>100%</td>
<td>173</td>
<td>100%</td>
</tr>
</tbody>
</table>
5.2.4 SteIS identified 74 reported incidents relating to insertion of an incorrect IOL. 61 were reported as Never Events. Table 3 and Figure 7 show the number of incidents by the stage of error.

5.2.5 Most reported errors (44%) occurred in theatre due to an incorrect IOL being brought into theatre and this was not identified by the WHOSSC ‘time out’ check (see ‘Retrieval’ and ‘WHO time out’ segments). A few additional errors occurred as a result of a change in surgical plan, often involving an unanticipated surgical complication.

5.2.6 The next most frequent category of error was the selection of an incorrect IOL (24%).

5.2.7 These two groups of errors account for approximately two-thirds of incidents involving insertion of an incorrect IOL, and form the focus of the investigation analysis. Errors resulting from a change in surgical plan were not considered in this investigation.

5.2.8 The search of the NRLS database found 173 reported incidents relating to the insertion of an incorrect IOL. Of these, 131 (76%) resulted in no harm, 20 (12%) resulted in low harm, 19 (11%) resulted in moderate harm and three (1%) resulted in permanent harm.
5.2.9 A review of the free text information submitted for each incident on NRLS found the proportion of errors at each stage was similar to the StEIS data. There was a higher proportion of biometry errors and lower proportion of retrieval errors. Table 3 and Figure 8 show the number of incidents by the stage of error.

5.2.10 Searching the national reporting systems is challenging due to both the data fields and search criteria, which makes reporting of incidents where an incorrect IOL has been inserted difficult. The data fields used by both systems do not capture sufficient and accurate information to allow an understanding of the process which led to the error, the outcome for the patient and any remedial actions taken.

THE NATIONAL OPHTHALMOLOGY DATABASE (NOD)

5.2.11 In 2014 the RCOphth was commissioned by the Health Quality Improvement Partnership (HQIP) and funded by NHS England and the Welsh Government to manage the National Ophthalmology Database (NOD) Audit. This database is part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The NOD Audit has been funded until to August 2019.

5.2.12 The NOD Audit collects and analyses a standardised, nationally agreed cataract surgery dataset from all centres providing NHS cataract surgery in England and Wales. The NOD updates the benchmark standard of care and provides a powerful quality improvement tool (Royal College of Ophthalmologists, 2013). RCOphth expects all OEPR systems to conform to this dataset. The investigation was informed by a representative of the RCOphth that there are approximately 125 NHS organisations performing cataract surgery in England and Wales. Approximately two-thirds of these organisations submit data to NOD, and the majority of these do so via an OEPR.

5.2.13 The most recent NOD Audit reported a reduction in complications during and after cataract surgery (NOA, 2017). The clinical lead for the NOD Audit told the investigation they believed the reduction in complications may have been, in part, a result of engagement with organisations identified by their data – often because of poor quality data submitted (National Ophthalmology Audit).

5.2.14 The NOD dataset does not currently include sufficient information to allow the...
identification of insertion of an incorrect IOL, or the potential causes. If extended, this audit may be a useful vehicle for capturing the relevant information to improve understanding of why this event continues to occur and inform potential measures to prevent it.

THE INVESTIGATION MAKES THE FOLLOWING SAFETY OBSERVATION

Safety Observation
The National Ophthalmology Audit could be a useful vehicle for capturing the relevant information for the insertion of an incorrect artificial intraocular lens. The resulting data, when analysed, may improve understanding of why these events continue to occur and provide supporting evidence for further safety measures to prevent them.

5.3 Role of Information Technology

USE OF SOURCE BIOMETRY IN IOL SELECTION

5.3.1 Printouts and OEPR screens present similar, but not identical data.

5.3.2 The investigation observed three forms of practice in how this data is translated into an IOL selection:

- biometry data presented on an OEPR
- biometry data presented on an OEPR but subsequently checked against a biometry printout
- printed biometry data

5.3.3 Some organisations have an OEPR but do not use the system to make selections, relying solely on the biometry printout and paper health record.

5.3.4 Kelly and Jalil (2011) and Steeples et al. (2016) reviewed incidents reported to the National Reporting and Learning System related to wrong IOL. Both found errors at each stage including right/left eye confusion. Kelly and Jalil (2011) made a series of recommendations. One recommendation was for “consideration of the use of electronic patient records”. Steeples et al. (2016), recommended IOL selection and checking should use the source biometry documents. The studies have conflicting recommendations. The review by RCOphth of the process used in the trust involved in the reference event resulted in a similar recommendation to Steeples et al. (2016).

5.3.5 Differences in the way the information is presented and how it is used to inform lens selection creates opportunities for error. The likelihood for error may also increase with locums. Standardisation across organisations in the presentation of information is a system-focused approach to intervention (Cafazzo & St-Cyr, 2012).

USABILITY OF THE OEPR IN THE THEATRE ENVIRONMENT

5.3.6 The investigation observed issues with the usability of OEPRs in the theatre environment which led to variations in practice.

5.3.7 OEPR1 presents data in two windows: the ‘biometry’ screen containing biometry data, and the ‘operation’ screen with the selected IOL and operation information. The latter is the record of what actually took place in the operating theatre, and is used to produce the operation note and the discharge letter.

5.3.8 The investigation observed that some users open both windows, while some use the operation screen exclusively. If the IOL details have been entered manually on the operation screen in the latter case, the user cannot be certain that the selected IOL relates to the correct biometry data.

5.3.9 There are no national standards for using an OEPR in theatre, which had led to variations in practice between organisations. The Trust in the reference event included instructions for the use of the OEPR in their SOPs, but these were different at each site. The developer of OEPR1 provides an electronic manual and training materials for use of the software but told the investigation they don’t tell organisations how use of the software should be integrated into local processes or procedures. The developer saw the functionality of the software as responding to users’ needs and would change it if there was a demand or if a common standard for use had emerged.

5.3.10 Users of OEPR1 reported usability issues with the system to the investigation. These focused on readability of information, the relevance of some data, and key information not being present.
5.3.11 One organisation in which observations were carried out used OEPR2 but did not use it to review patient information or make IOL selections as they believed that the software system was not suitable for use in theatre. The OEPR was used after surgery to document the surgery, and the lens power and brand was manually entered into the relevant fields. The OEPR was only used to store information related to the patient, to produce letters for the patient and the patient’s GP, and to submit data to the National Ophthalmology Audit.

HUMAN FACTORS

5.3.12 The error in the reference event, where the ophthalmologist unintentionally looked at the data for the wrong eye, is defined as a slip. This type of error occurs particularly during highly routine actions, and results from attention breakdown resulting in the intended action not being executed as planned. When carrying out highly practised tasks or series of actions, people tend not to invest the same amount of attention. This may result in assuming a match for something that looks like the object they are searching for because it is in the same location, looks similar or does a similar job (Reason, 1990).

5.3.13 The likelihood of such a slip was increased because information for each eye was presented in an adjacent position on the screen.

5.3.14 The tendency to make this type of error is particularly increased by distraction, stress and fatigue (Reason, 1990). O1 was operating in an unfamiliar environment with a team he had not previously worked with, and was likely to have felt a time pressure because of the delays.

5.3.15 Good equipment design takes human factors into account and will conduct usability testing to understand how the user and machine function safely and effectively together. Where weaknesses are identified, the interface or software can be redesigned; this may include the use of barriers or alerts to reduce or prevent errors.

5.3.16 The OEPR used in the reference event includes alerts to warn users about some types of error. In the reference event, the eye for which O1 attempted to select an IOL was not the eye that had already been entered on the operation page. As a result, the software did not automatically populate the fields on the operation page; it did not alert the user or provide a reason. O1 was then able to enter the data in the operation page manually, essentially overriding the electronic system and altering accurate data. In this case, the barrier built into the system to prevent selection of an IOL for the wrong eye could be identified as weak, as it can be overridden without the user knowing that an error has occurred.

5.3.17 A consultant ophthalmologist who was involved in procuring the OEPR at the Trust where the reference event occurred stated he found the system difficult to use. When asked for examples he said “it’s hard to tell you because we just get used to working around it”.

SAFETY AND USABILITY ASSESSMENTS OF OEPRS

5.3.18 Medical devices must meet the requirements of the EU Medical Devices Directive (93/42/EEC), which are enforced in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA). Devices compliant with the EU Medical Devices Directive can be CE marked and sold in the EU.

5.3.19 Manufacturers must demonstrate their product is compliant by conducting a conformity assessment, which varies according to the class of device:

- Class I - generally regarded as low risk
- Class IIa - generally regarded as medium risk
- Class IIb - generally regarded as medium risk
- Class III - generally regarded as high risk (MHRA, 2013)

5.3.20 A basic OEPR is unlikely to be classed as a medical device. However, an OEPR is likely to be a medical device if it includes calculations on which treatment is based (Class I) or includes image viewing for diagnosis (Class I) or image manipulation for diagnosis (Class IIa or b). The Trust where the reference event occurred was using an OEPR that is listed by MHRA as a Class 1 device. The investigation also observed a basic OEPR.
When an OEPR is a Class I device, the manufacturer is required to evaluate and document its product before declaring conformity to the essential requirements for design and safety set out in the EU legislation. Once the manufacturer has registered the device with MHRA (or an equivalent body in the EU), the manufacturer is responsible for assuring the quality of the medical device once it is in use.

In September 2017 MHRA published ‘Guidance on applying human factors to medical devices’ which was “intended for manufacturers of all device classes and developers of medical devices and drug-device combination products, and Notified Bodies responsible for assuring the quality of those devices” (MHRA, 2017). The guidance does not need to be applied to medical devices retrospectively and existing OEPR systems do not require review or updating. Any new OEPR products or releases after this date should follow the guidance.

The MHRA told the investigation that OEPRs would be reclassified to Class IIa or IIb by 2020 under the new Medical Device Regulations. This will require a conformity assessment by a Notified Body, who are designated for the purpose by MHRA in the UK. Equivalent bodies to the MHRA in other European countries designate Notified Bodies in their countries. A manufacturer can use any Notified Body in Europe.

**Recommendation 2018/014:** The Medicines and Healthcare products Regulatory Agency should strongly recommend the manufacturers of ophthalmology electronic patient record systems (including systems for making and storing ocular biometry measurements), where they fall under the remit of the Medical Device Regulations, undertake an assessment against the MHRA Human Factors and Usability Engineering guidance and this should form part of the documents assessed by a Notified Body as part of any declaration or assessment of conformity with the requirements of the Medical Device Regulations.

The use of electronic product identification and matching systems

The NHS standard contract now requires provider organisations to be compliant with the NHS eProcurement strategy (Department of Health, 2014) which mandates the use of GS1 standards. GS1 is a not-for-profit organisation that develops and maintains global standards for business communication. In addition, NHS Terms and Conditions for the Supply of Goods and the Provision of Services requires suppliers to place their product data in a GS1 certified data pool, which is a database containing detailed information about each product.

For ophthalmology, the product data to be deposited in a GS1 certified data pool includes manufacturer, product code and description, including lens power, as well as data to support supply chain management. Once manufacturers have deposited this data in a GS1 data pool, trusts can extract the data for re-use in their local IT systems. Under the Medical Device Regulations, production data (such as batch or serial number and expiry date) must be made available on the packaging label in a form that can be read by machines (for example, a barcode) and by humans.

Implementation of the NHS eProcurement strategy has also led to the Scan4Safety programme, led by the Department of Health and Social Care. This programme is evaluating, in six NHS demonstrator Trusts, the use of GS1 and PEPPOL standards to facilitate all products used by the NHS to be recorded, trackable and traceable. Roll out of Scan4Safety beyond the six demonstrator sites to all acute trusts is under consideration by the Department of Health and Social Care.

Once fully implemented Scan4Safety will allow an organisation to track each device or implant a patient has received or the location it’s stored in. It will also optimise the supply chain. Scan4Safety requires the use of scanning technology together with GS1 compliant barcodes for each location, patient and product.

The implementation timescales for implementation of technologies to track and trace implants allows time for Electronic
Patient Record manufacturers to incorporate these standards into software to provide an alert where there is a mismatch between the patient, selection and product. Scanning the product barcode will also provide an alert if a product has exceeded its expiry date or if the batch has been recalled.

5.3.29 Organisations carrying out cataract surgery which are Scan4Safety demonstrator sites, are able to track the IOL to the patient, the date and location of surgery. These sites are not currently able to link this information with their OEPR.

FIG 9  SCAN4SAFETY RECORD FOR AN IOL

5.3.30 The investigation was able to observe the use of Scan4Safety technology for cataract surgery at one of the demonstrator sites. The record for a patient having cataract surgery included details of each item used during the operation, including the IOL. The record included an option to mark an item as opened but not used, a situation that might arise if there was a complication during surgery that required a change of lens selection.

5.3.31 Figure 9 shows the Scan4Safety record for an IOL, including the brand, power, expiry date and batch number, as well as a surgery reference which is linked to the patient.

5.3.32 Scanning technology can only assist in preventing a mismatch between the IOL selection and the box in theatre when it is able to link to an electronic system which also records the selected IOL. This might be expected to be more reliable than the current checking process in theatre which relies on staff reading and confirming the information on the lens box in theatre matches the documentation.

5.3.33 Manual processes are susceptible to error, which may originate in bias. Expectation bias occurs when there is a strong expectation or mental model of what will be seen, particularly if a task is frequently performed. Expectation strongly influences how we search for and interpret information and may cause us to perceive what we expect to see, rather than what is actually presented (Goldstein, 1999). The likelihood of this increases when information is in an adjacent location, looks similar or does a similar job (Reason, 1990). For example, staff expecting to see a label reading 25.0 may misread it and confirm a label showing 20.5 is correct, as the expected digits are all present. This also applies to auditory tasks; a member of staff might read out the lens power and the ophthalmologist hears what he or she
expects. If an IOL is incorrectly stored in the lens bank, it could be selected in error by a member of staff who expects a lens of the required power to be stored in a specific location. The use of scanning as a method of matching and confirming selections has been demonstrated to be an effective checkpoint within the supply chain. If the OEPR/technology system verified the selection of the physical asset, the investigation considered this would provide an additional barrier to prevent error occurrence.

5.3.34 The Department for Health and Social Care were able to confirm that all but one IOL manufacturer currently have GS1 standards barcode labels on their respective products.

**HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION**

**Recommendation 2018/015:** The Department of Health and Social Care commissions a set of standards for the NHS that utilises appropriate technologies to provide digital alerts when incorrect intraocular lens are selected.

### 5.4 IOL selection

#### TIMING OF IOL SELECTION

5.4.1 The investigation observed different practices for selecting the IOL. These varied from the timing of the decision, the source of the information used, and how the selection was recorded.

5.4.2 The decision could be made:

- at the pre-operative assessment or on the day of surgery prior to the operation
- using either the paper biometry printout or the OEPR
- and recorded on the paper biometry printout or into the OEPR

5.4.3 Some examples of practice observed by the investigation are shown below. It is likely there are many more variations:

- During the pre-assessment clinic, the selection is made using the OEPR by the ophthalmologist. The selection is checked by the surgeon at the pre-operative assessment on the day of surgery using the biometry results on the OEPR.

- Prior to the list, the OEPR is consulted and the lens power is written on the theatre list. During the pre-operative assessment, the selection is confirmed against the biometry printout and circled on the page.

- During the pre-operative assessment the IOL selection is circled on the biometry printout and the selected power and brand is noted on a separate lens selection sheet. This is recorded on the patient’s health record.

- In theatre, immediately before the patient is brought into the operating room, using only the OEPR.

- In theatre, after the pre-operative assessment of all patients on the list, but before the team brief, using only the OEPR.

5.4.4 NICE guidance NG77 does not specify when the selection is to be made. The UKOA Quality Standard states that “IOL selection should take place during the assessment clinic or in the preoperative ward-round” (UK Ophthalmology Alliance, 2018).

5.4.5 A review of the SOPs for cataract surgery process in two other organisations (not the Trust where the reference event occurred) found that when the IOL selection should take place was not specified.

5.4.6 The investigation team questioned seven consultant ophthalmologists about their own practice. There was a consensus that lens selection would be less prone to error if the ophthalmologist had time, away from clinic and theatre, to review each patient’s medical record a week before surgery. The consultants who were from smaller organisations and clinics said that this was a necessity to ensure that the selected IOL and additional potential lens choices (for example, in case of complications) were available in theatre at the time of surgery.

5.4.7 The investigation observed an organisation using an OEPR to make a decision regarding lens selection between pre-assessment and surgery (for example, during the week prior to surgery). The investigation compared this to its observations of a paper record system and noted the expediency of a computer-based system. It also noted that the paper record system is
further complicated when cataract surgery takes place at several sites within an organisation.

5.4.8 The investigation findings were tested with a group of 25 members of UKOA. They agreed the timing of selection was affected by the use of pooled or staggered lists, availability of patients’ medical records (complicated by multi-site working), and availability of the ophthalmologist. They suggested the decision on lens selection should be made in a quiet place with no interruptions or distractions.

THE EFFECT OF POOLED LISTS

5.4.9 Operating lists are not managed by ophthalmologists. Lists are managed by administration staff who are under pressure to maintain or increase throughput on behalf of the trust. One response to this has been to run pooled lists.

5.4.10 This means that, in order to comply with good clinical practice, lens selection cannot take place until an operating ophthalmologist is assigned to a list.

5.4.11 The investigation spoke to many ophthalmologists; there was a divide in their opinion regarding seeing each patient and conducting an assessment prior to making an intraocular lens selection, rather than just using the biometry information. The issue of pooled lists is a more general topic that is outside the scope of this report and may be covered in a future investigation.

METHOD OF SELECTION

5.4.12 To make the correct IOL selection requires 10 items of information. NICE guidance NG77 states that “on the day of surgery”, a checklist based on the WHOSSC should be used to ensure “at least two members of the team, including the surgeon, have previously checked the appropriateness, accuracy and consistency of all: formulas, calculations and IOL constants”. Four ophthalmologists were asked how they met this requirement; the consensus was that it wasn’t feasible or practicable to do so, and that theatre staff weren’t trained in biometry and lens selection.

5.4.13 Each ophthalmologist will determine the lens selection based on predicted outcomes from the biometry/OEPR and their own experience of outcomes following surgery.

5.5 The use and value of the WHO Surgical Safety Checklist and NatSSIPs

5.5.1 The use of the WHOSSC is mandated in the NHS (National Patient Safety Agency, 2009). WHO guidance on implementation of the WHOSSC states, “To ensure successful implementation, it is important to make sure the Checklist is suitable for your setting. Adaptation after local consultation is encouraged.” (WHO, 2008). WHO publishes a short guide to adapting the checklist “to better fit the needs and processes of care in specific environments and surgical disciplines”.

5.5.2 NICE guidance NG77 recommends the use of a version of the WHOSSC modified to include items specific to cataract surgery. This recognises the need to undertake additional checks to prevent implantation of the wrong IOL.

5.5.3 The RCOphth website contains an example of a checklist adapted for cataract surgery (see Appendix 1).

THE TEAM BRIEF

5.5.4 The NatSSIPs has a specific section relating to the ‘team brief’. The UKOA quality standard for correct IOL implantation in cataract surgery (UKOA, 2018) also states that a team brief should occur and that all team members should be present and introduce their name and role.

5.5.5 The investigation observed variation in the team brief across all organisations visited. Examples included:

• no team brief (as the team members were familiar with one another)
• a ‘let’s just see how we go’ approach
• discussion of individual patients during the brief, including the IOL power and brand/type for each
• team members writing the lens power and brand/type on their copy of the theatre list, which was then used as a reference document

THE SIGN IN CHECK

5.5.6 The ‘sign in’ check may take place in the anaesthetic room or in theatre. As well as the standard checks, such as confirming the patient’s identity, consent and any allergies, for cataract surgery it is necessary to confirm
that the source biometry, target refractive outcome and selected IOL relate to the correct eye and patient in theatre.

5.5.7 This may be achieved at the 'sign in', or deferred to the 'time out' check, depending on practice at the Trust. The source documentation used for this may be the biometry printout, another document or the OEPR computer screen.

THE TIME OUT CHECK

5.5.8 The 'time out' check is the final check before surgery to confirm the identity of the patient in front of the team, the type and side of operation, and any equipment or materials requirements.

5.5.9 For cataract surgery, this would include confirming the correct IOL is present and which eye is to be operated on. For this reason, the final draping of the eye is not completed until after the check.

5.5.10 The investigation team observed that the theatre team's focus during the 'time out' check is on making sure the IOL in theatre matches the selected IOL. This requires comparison of the information on the lens box or package with the selected IOL power and brand/type. The way in which this is done varies.

5.5.11 Different practices were observed across a number of Trusts or described during the investigation:

- At the Trust where the reference event occurred, the target refractive outcome is written on the consent form by an ophthalmologist at the pre-assessment clinic. During the 'time out', the surgeon and scrub nurse check the lens power and brand stated on the lens box against the operation screen, and check that the target refraction on the consent form and on the operation screen match.

- Using the OEPR screen, the whole theatre team, including the surgeon, checks that the target refraction is between OD and -0.5D. If it is outside this range, the theatre team will challenge the surgeon about the reason for this. The team then confirms that the information on the lens box matches the lens power and brand on the operation screen.

- The IOL selection is made using the OEPR prior to the day of surgery. During the pre-operative assessment, the surgeon transcribes the IOL selection information onto the theatre list, and the IOL selection is circled on the source biometry printout. The OEPR is not used during the time out check. The surgical team check the information on the lens box in theatre corresponds to the IOL selection on the source biometry and the IOL power on the annotated theatre list.

- The surgeon leads the 'time out' check, guiding the team through each check and using the patient's paper records, which include the biometry printout, a lens selection sheet and the consent form. The check includes patient identity, side of operation, review of the biometry, formula, target refractive outcome and lens selection. The team check the selection corresponds with the documented power and lens brand on the lens selection form, and the information on the lens box matches both the source biometry and lens selection form.

5.5.12 In many cases, all available staff participated in the 'time out' check, in some Trusts only the scrub nurse and ophthalmologist were present. Another Trust required a member of the anaesthetic team, the ophthalmologist and scrub nurse to participate. The investigation observed the time out starting without the ophthalmologist present because they were still scrubbing or preparing the patient. On these occasions the ophthalmologist only joined in when available. The investigation observed conversations between other team members at the same time as the 'time out'. This potentially creates distraction and is not in keeping with the principle of the WHOSSC.

5.5.13 The NatSSIPs also include a section on prosthesis verification which includes intraocular lenses. The requirement is:

*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.’

5.5.14 Organisations can adapt the NatSSIPs as required to produce local standards (LocSSIPs).

ADEQUACY OF TIME OUT AS A BARRIER TO PREVENT INSERTION OF THE WRONG IOL

5.5.15 The IOL which is brought to theatre must be, when correctly implanted, able to provide the patient with the refractive outcome agreed at the assessment clinic. This requires accurate biometry, calculation of the required power of a suitable IOL using an appropriate formula and is selected by a trained and experienced ophthalmologist.

5.5.16 To be able to confirm all elements in this complicated process, those conducting the time out check must have access to this information and be able to match it to the correct patient and eye. The time out check can only ensure the correct lens is brought into theatre.

5.5.17 Even when the surgeon checks all elements in the selection process, other team members, even if experienced, may have limited knowledge of the nuances of biometry and lens selection and may be unable to identify an error.

USE OF A CATARACT SURGERY VERSION OF THE WHOSSC

5.5.18 NICE guidance NG77 recommends the use of the WHOSSC modified to include items specific to cataract surgery. This recognises the need to undertake additional checks to prevent implantation of the wrong IOL.

5.6 Variation in practice

5.6.1 The wider investigation found substantial variations across organisations’ practice, resources and training, use of technology, use of checklists, and compliance with guidance. Each were compounded by significant system pressures. It may be questionable if it is even possible to comply fully with existing guidance.

5.6.2 Through the investigation discussions, it was apparent many practices are directed at Trust level. The additional and specific requirements of ophthalmology are often not considered.

5.6.3 The investigation consulted with a group of UKOA members who agreed that, even accounting for variations in Trust practice and constraints, there are elements clearly applicable to all organisations, for instance;

- all should use the WHO cataract surgery safety checklist
- the surgical mark must be visible
- the time out check must be carried out before draping the patient’s face
- the theatre should be quiet other than the person conducting the checks

5.6.4 The investigation used available information to identify the types and frequency of error that have led to implantation of an incorrect IOL. In some cases, the errors were independent of other actions; in others there was a dependency, where one action affected another. For example, if an incorrect IOL is brought into theatre this might be identified through the WHOSSC ‘time out’ process. In contrast, an IOL selection using expired biometry data or data for the wrong patient might not be identified through any of the subsequent checks.

HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION

Recommendation 2018/016: The Royal College of Ophthalmologists establish an expert working group to evaluate the variance of practice for cataract surgery, and subsequently establish standardised and workable processes to minimise the risk that a patient will receive an incorrect intraocular lens.
6 SUMMARY OF FINDINGS AND RECOMMENDATIONS

6.1 Findings

6.1.1 Removal of cataract and implantation of an artificial lens is the most common surgical procedure undertaken by the NHS.

6.1.2 Investigation and analysis of the reference event found:

1 Selection of an incorrect IOL did not affect the patient’s vision enough to require further surgery in this case.

2 The working environment, facilities and processes for cataract surgery were not optimal, although the Trust had made some improvements following a previous inspection. The investigation also noted that there were different work procedures at each site.

3 There was pressure on the Trust to meet operational performance targets in the face of a large backlog of patients waiting for surgery. There was also pressure felt by members of the operating theatre team to start on time, increase utilisation and efficiency. The combination of pressures led to low staff morale.

4 The design of the OEPR software interface used in theatre meant it was prone to usability issues, even for those who were familiar with its operation.

6.1.3 The wider investigation found that:

1 Available national data on implantation of an incorrect IOL is likely to be incomplete and does not provide enough information to understand the incidence, consequences and causal factors.

2 Errors leading to implantation of an incorrect IOL may occur at a number of points in the patient pathway: during biometry, selection of the IOL and when confirming the retrieved IOL.

3 There is significant variation in organisations’ processes at each stage of the patient pathway for cataract surgery, especially those procedures used for selection of the IOL.

4 There is variation between organisations in the way that existing guidance and the World Health Organization Surgical Safety Checklist (WHOSSC) are applied and used, including whether a version of the WHOSSC specifically adapted for cataract surgery is used.

5 The WHOSSC ‘time out’ check is not adequate by itself to prevent implantation of an incorrect intraocular lens.

6 There are differences in the presentation and content of data between the paper biometry printouts and OEPR systems.

7 The design of the information display of OEPRs, and other aspects of usability, is not optimal for use in theatre. When an OEPR is used in theatre, it is integrated into each organisation’s processes in different ways.

8 The OEPRs seen by the investigation had not undergone human factors engineering and usability assessments. There are no standards for OEPR design or different ‘Use Cases’, particularly in regard to safety.

9 Some Trusts are using scanning technology for tracking and the reconciliation of equipment, prostheses and implants, and procedures for each patient. This could be extended to implantation of IOLs and provide an alert when there is a patient/product mismatch.

6.2 Safety Recommendations

HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATIONS

Recommendation 2018/014: The Medicines and Healthcare products Regulatory Agency should strongly recommend the manufacturers of ophthalmology electronic patient record systems (including systems for making and storing ocular biometry measurements), where they fall under the remit of the Medical Device Regulations, undertake an assessment against the MHRA Human Factors and Usability Engineering guidance and this should form part of the documents assessed by a Notified Body as part of any declaration or assessment of conformity with the requirements of the Medical Device Regulations.
Recommendation 2018/015: The Department of Health and Social Care commissions a set of standards for the NHS that utilises appropriate technologies to provide digital alerts when incorrect intraocular lens are selected.

Recommendation 2018/016: The Royal College of Ophthalmologists establish an expert working group to evaluate the variance of practice for cataract surgery, and subsequently establish standardised and workable processes to minimise the risk that a patient will receive an incorrect intraocular lens.

6.3 Safety Observations

THE INVESTIGATION MAKES THE FOLLOWING SAFETY OBSERVATIONS

The National Ophthalmology Audit could be a useful vehicle for capturing the relevant information for the insertion of an incorrect artificial intraocular lens. The resulting data, when analysed, may improve understanding of why these events continue to occur and provide supporting evidence for further safety measures to prevent them.
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ENDNOTES

1 PEPPOL provides a set of technical specifications that can be implemented in existing eProcurement solutions and eBusiness exchange services to make them interoperable between disparate systems across Europe.
The World Health Organisation Surgical Safety Checklist (WHOSSC) is used for all surgical operations undertaken. In 2009 the National Patient Safety Agency (NPSA) released a safety alert to all NHS organisations undertaking surgery mandating the use of the WHOSSC. Four versions of the document were available: surgery, cataract surgery, radiological interventions and maternity. Figure 10 shows the cataract surgery surgical safety checklist. The Royal College of Ophthalmologists recommend the use of the cataract surgery checklist when ophthalmologists are undertaking cataract surgery.

The five steps to safer surgery include:

1. **Team brief** – performed once by the whole theatre team at the beginning of the surgical list, each team member introduces themselves and their role, and each patient is discussed, together with any special requirements.

2. **Sign In check** – performed for each patient prior to administration of anaesthesia, usually by the anaesthetic team. Intended to ensure that the patient in the room is the correct patient to be operated on and to ensure that everyone is aware of plans regarding anaesthesia.

3. **Time Out check** – a final check performed for each patient just before the start of the procedure.

4. **Sign Out check** – performed when the procedure is completed. Includes confirmation of all swab and instrument counts and identification of post-operative requirements for the patient.

5. **Team debrief** – performed at the end of the operating list or session. An opportunity for the team to reflect on what went well and not so well, and to learn for next time.

FIG 10

**FIGURE 10 WHO SURGICAL SAFETY CHECKLIST: FOR CATARACT SURGERY**

The checklist is for Cataract Surgery ONLY

This modified checklist must not be used for other surgical procedures.
Each organisation was asked to identify an executive and clinical lead for the surgical safety checklist by 1st February 2010. Each organisation must ensure that the safety checklist is completed for every patient undergoing surgery and that a record of this is included in the patient’s medical records. Organisations are able to adapt the checklist to meet their local needs.

The implementation of the WHO surgical safety checklist was deemed to be the strong systemic protective barrier that would prevent safety incidents in surgery, such as:

- Wrong site surgery
- Operating on the wrong patient
- Retaining swabs and/or instruments inside the patient
- Inserting the wrong implant
- Anticipating complications and preparedness – for example bleeding

In relation to implantation of an incorrect IOL, the surgical safety checklist provides an opportunity for the team to confirm that the IOL in theatre matches the selected lens, as documented.
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.

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

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