Insertion of an incorrect intraocular lens

27 February 2018

This interim bulletin contains facts which have been determined up to the time of issue. It is published to inform the NHS and the public of the general circumstances of events and incidents and should be regarded as tentative and subject to alteration and correction if additional evidence becomes available.
Notification of event and decision to investigate

The Healthcare Safety Investigation Branch (HSIB) was made aware of a safety issue relating to the insertion of an incorrect intraocular lens implant during cataract surgery.

Insertion of an incorrect intraocular lens into the eye is considered a 'Never Event' under the NHS England Never Events Framework (2015). Never Events are defined as incidents that are 'wholly preventable, where 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 England, 2015).

'Cataracts are a common eye problem where the lens in the eye becomes cloudy. They cause blurry, misty vision and sight loss.' (NICE, 2017). Cataract surgery involves removal of the cloudy lens and replacement with an artificial lens. Prior to surgery, measurements of the eye are taken and then a lens strength is selected, based on the measurements and the patient’s previous history.

The HSIB’s initial investigation found that despite national guidance and safety recommendations being implemented, the current system of selecting and checking intraocular lenses is not robust enough to prevent these events occurring.

The Chief Investigator authorised a full investigation as it met the following criteria:

Outcome Impact – What impact has a safety issue had, or is having, on people and services across the healthcare system?

Cataracts are more prevalent in older people and often they will have cataracts in both eyes. When this occurs, patients have a separate operation on each eye to correct this. Insertion of an incorrect lens can result in a patient requiring exchange surgery, which exposes them to further risk. Exchange surgery is an operation where the incorrect lens is removed and replaced with the correct lens. Patients may also experience psychological harm; the requirement for exchange surgery can increase anxiety and stress.
Systemic Risk - How widespread and how common a safety issue is this across the healthcare system?

Insertion of an incorrect intraocular lens was the most commonly reported Never Event in England between April 2016 and March 2017. Despite the introduction of various systems to improve efficiency and safety, including computer software, these events continue to occur.

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

The investigation will review the safety measures currently in place, seeking to understand why they do not always prevent the insertion of an incorrect lens. It will seek to identify strategies and opportunities to reduce the frequency of this event.

History of the event

An 86-year-old woman attended hospital to undergo a planned surgical procedure intended to remove a cataract from her left eye and to insert an intraocular lens of the correct strength.

The patient attended pre-operative assessment where measurements of both eyes were taken. The ophthalmologist (eye doctor) and the patient agreed that the target refraction would be -0.25. This means that following surgery the patient should have good distance vision with little or no need for distance glasses.

On the day of surgery, a new theatre team were working together and there were four patients on their list. However, the medical notes were not available for one patient and the consent form was not completed for another; therefore the list was reduced to two patients. Surgery was delayed by 30 minutes, due to scheduling and equipment not being available.

During the pre-operative checking process, the surgeon selected a lens he thought appropriate to achieve the agreed target vision. To undertake this task, the surgeon used a computer based system.
In this case, the surgeon misread the computer screen and used the values from the right-side eye to calculate the lens power for the left-side eye and did not recognise that the wrong value had been selected before starting the procedure.

During the checking process, a discrepancy between the documented target refraction and the target refraction for the lens selected was identified by a member of the theatre team. The discrepancy was deemed within tolerable limits and the operation proceeded.

After the operation was complete, a member of the theatre team was still unsure about the significance of the discrepancy and sought advice from a colleague who was working in an adjacent operating theatre. Subsequently, it was identified that the lens to meet the target refraction for the right-side eye was inserted into the patient’s left-side eye.

It was decided that the patient’s left-side intraocular lens would not be exchanged and will be corrected with an adjustment in their prescription glasses. At the time of writing, plans are in place for surgery on her right-side eye.

**National context**

Cataract surgery is the most common operation undertaken in England; between 1 April 2016 and 31 March 2017 there were 396,317 cataract and lens replacement surgeries (NHS Digital, 2017). Many organisations have undertaken steps to reduce the likelihood of the incorrect intraocular lens being inserted through the introduction of computer based systems, the addition of further safety checks and enhanced training for ophthalmic and theatre teams.

The WHO Surgical Safety Checklist (World Health Alliance for Patient Safety, 2008), mandated for all patients in the NHS undergoing a surgical procedure in 2010, was adapted for use in cataract surgery to recognise the complexity of the checks required to ensure the correct lens is inserted.

In 2015, NHS England published National Safety Standards for Invasive Procedures (NatSSIPs) which provided a framework for local organisations to develop Local Safety Standards for Invasive Procedures (LocSSIPs), with the intention of standardising practice for
interventional procedures across an organisation. Despite these initiatives, events continue to occur, indicating there are opportunities for further improvement.

**Identified safety issues**

During the HSIB’s initial review, the following safety issues were identified and will form the basis of the ongoing investigation.

- The process of procuring and implementing software to support clinical decision making and practice.
- How software is developed, including the interface between the software and the user.
- The effectiveness of the various processes used to check and confirm the selection and insertion of the correct lens.
- The effect of environmental factors on team resilience.

**Next steps**

The HSIB investigation will continue to explore the identified safety issues and welcomes further information that may be relevant, regardless of source. The HSIB will report any significant developments as the investigation progresses.

**References**


