Still Not Seeing Clearly—A Second Look at Intraocular Lens Implant Events

In the March 2005 issue of the *Patient Safety Advisory*, an article reviewed the Serious Events and Incidents reported through PA-PSRS regarding eye surgery. Two distinct patterns were identified at that time: (1) wrong-side surgery and (2) incorrect intraocular lens (IOL) implants. This follow-up article looks at the frequency of incorrect IOL placement events since the inception of PA-PSRS to discuss the identified process issues that may have contributed to the surgical error and the risk reduction strategies that are being implemented to reduce the incidence of further events.

Since PA-PSRS began in June 2004 through December 2007, 48 cases involving implantation of the wrong IOL have been reported. The number of these events has remained on average about 10% of all lens-related events per year. In 32 of these events, patients required a second procedure to implant the correct IOL. Four of the patients did not require surgical intervention, and reports of the remaining 12 cases did not include this information (see Figure).

Lessons Learned

Cataract surgery patients, in most instances, are scheduled back-to-back. The patients are quite similar. If staff skip steps in the verification of the IOL, surgical errors can result.^{2,3}

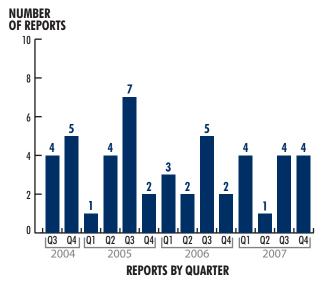
The doctor pulled the patient's office chart and the lens he would be using for the case. The doctor checked the lens with the office chart. A 23.0 diopter lens was inserted. Postoperatively, the doctor realized he had pulled the wrong patient's chart. The patient was to receive an 18.0 diopter lens. Additional surgery was necessary to remove the incorrect lens and implant the correct one.

Two patients were scheduled for cataract surgery. It was decided to do the second patient first. The time-out was proper, and the proper patient, site, and surgery were done. However, the lens implant for the first patient scheduled was implanted in the second patient.

In the reports, the facilities identified several issues that led to implanting the wrong IOL. The event data shows that the verification process is central in the majority of the reports. Issues identified included the following:

- 1. The physician or his or her office staff gave information from the wrong patient's office chart regarding the lens to be used.
- 2. The surgeon/resident/other team members were inattentive during the time-out.
- The surgeon's office record was not available in the operating room (OR) to review during the time-out.
- 4. The nurse picked up the wrong lens.

Figure. PA-PSRS Wrong Intraocular Lens Implant Reports by Quarter



- 5. OR staff members used information from the wrong patient's medical record.
- 6. More than one lens was available in the OR.
- 7. The sequence of the scheduled patients was changed without corresponding changes to their respective verification processes.

Changes Going Forward

Events that result in implanting the wrong IOL can be reduced by following strict policies of checking and double-checking that the correct IOL is being used.4 The Joint Commission requires that the time-out performed immediately before starting the procedure will include confirmation that the correct implant is ready for use.⁵ The American Association of Ophthalmologists (AAO) has made suggestions to reduce instances of wrong IOL implants consistent with the guidance provided by the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person SurgeryTM. These suggestions focus on the importance for the surgeon and OR personnel to develop good and consistent communication processes surrounding the verification of the IOL before implantation. AAO's suggestions were reprinted in the aforementioned March 2005 Advisory article (http://www.psa.state.pa.us/psa/lib/psa/advisories/ v2n1march2005/vol_2-1-march-05-article_f-eye_ surgery.pdf).

After implanting the wrong IOL, one Pennsylvania facility took specific steps to reduce the risk of this error recurring. The facility conducted a root-cause analysis that showed that the staff had multiple inconsistent processes for verifying the IOL before

implantation. The facility standardized on a single process with which all staff was to comply. The facility has found that implementing and following a consistent process has been effective in reducing the risk of implanting the wrong IOL. The implemented process is as follows:

- The surgeon sends the office chart, which includes the A-scan, to the OR before the surgery.
- During the preoperative visit on the day of surgery, the circulating nurse verifies that the A-scan is in the record and is the correct scan for patient undergoing the procedure.
- Immediately before the surgery, the surgeon visits the patient, reviews the A-scan, selects the lens, and hands the lens to the circulating nurse. Preselection of the lens has been eliminated because a change in schedule may lead to the wrong lens being set up for the wrong patient.
- Once in the room, the time-out is performed with the entire OR team. The patient, procedure, site, and lens are verified by the surgeon and the scrub nurse. The staff has the patient's office chart, surgical medical record, lens, and lens box available to review during the time-out.
- The circulating nurse and surgeon double-check the IOL power together before beginning the surgery.

Other healthcare facilities in Pennsylvania include the following steps in their verification process:

- 1. Only the current surgical patient's medical record will be in the OR.
- 2. Only the current patient's IOL will be in the room at the time of surgery.
- The time-out process will include the medical record from the physician's office, with lens model and diopter clearly documented.
- 4. The surgeon will select and pull the lens and place it on the patient's medical record before the procedure and announce it to the nurse when handing it into the sterile field.

Conclusion

The IOL verification process begins in the physician's office and ends with the correct lens being implanted. The information gathered from these PA-PSRS events

may assist healthcare facilities in evaluating processes and preventing adverse events. Reducing the incidence of wrong IOL implantation is a team effort. The importance of developing a verification process within a facility that is followed by the entire surgical team is crucial in reducing these surgical errors.

Notes

- Pennsylvania Patient Safety Reporting System. Focusing on eye surgery. PA PSRS Patient Saf Advis 2005 Mar; 3(1):12-4.
- Ronge LJ. Human error during cataract surgery: right patient, wrong lens. EyeNet Magazine [online]. 2006 Mar [cited 2008 Jan 17]. Available from Internet: http://www.aao.org/aao/publications/eyenet/200603/index.cfm.
- Jin GJ, Crandall AS, Jones JJ. Intraocular lens exchange due to incorrect lens power. Ophthalmology 2007 Mar; 114(3):417-24.
- Laber D. Intraocular lenses: incorrect power calculations analyzed. EyeWorld [magazine online]. 2006 Aug [cited 2008 Jan 17]. Available from Internet: http://www. eyeworld.org/article.php?sid=3310.
- Joint Commission. Implementation expectations for the universal protocol for Preventing Wrong Site, Wrong Procedure And Wrong Person Surgery™ [online]. 2003 [cited 2008 Jan 17]. Available from Internet: http://www.jointcommission.org/NR/rdonlyres/ DEC4A816-ED524C04-AF8C-FEBA74A732EA/0/ up_guidelines.pdf.
- American Academy of Ophthalmology, American Society of Ophthalmic Registered Nurses, American Association of Eye and Ear Hospitals. Patient Safety Bulletin. Minimizing wrong IOL placement [online]. 2005 [cited 2008 Apr 4]. Available from Internet: http://one.aao.org/CE/PracticeGuidelines/Patient_Content.aspx?cid=38305f4c4cb4406a-953f-fc193cf2ade3.

Reviewer Commentary:

At Wills Eye Hospital and also our ambulatory surgery center, we have the doctors fill out a preferred lens form for each patient. The form is then faxed to the facility prior to surgery. The lens is selected by the nurse in the operating room. The lens is then verified the day of surgery with the nurse and the doctor, and the doctor signs off that the correct lens has been picked and inserted.

Michael L. Kay, MD Wills Eye Hospital

PENNSYLVANIA PATIENT SAFETY ADVISORY

This article is reprinted from the Pennsylvania Patient Safety Advisory, Vol. 5, No. 3–September 2008. The Advisory is a publication of the Pennsylvania Patient Safety Authority, produced by ECRI Institute and ISMP under contract to the Authority as part of the Pennsylvania Patient Safety Reporting System (PA-PSRS). Copyright 2008 by the Pennsylvania Patient Safety Authority. This publication may be reprinted and distributed without restriction, provided it is printed or distributed in its entirety and without alteration. Individual articles may be reprinted in their entirety and without alteration provided the source is clearly attributed.

This publication is disseminated via e-mail.
To subscribe, go to https://www.papsrs.state.pa.us/
Workflow/MailingListAddition.aspx.

To see other articles or issues of the Advisory, visit our Web site at http://www.psa.state.pa.us.
Click on "Advisories" in the left-hand menu bar.

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS



The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI Institute, as contractor for the PA-PSRS program, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority's Web site at www.psa.state.pa.us.



ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures and drug technology.



The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a nonpunitive approach and systems-based solutions.