Patient Safety Tip of the Week

May 17, 2016

Patient Safety Issues in Cataract Surgery

Just as a push to perform cataract surgery in the office setting has appeared, a study from Massachusetts has revealed preventable patient safety errors continue to occur in cataract surgery. Don't get us wrong – cataract surgery is one of the safest procedures of all and the rates of adverse events are very small indeed. But the Massachusetts experience would certainly would suggest the need to have the same degree of oversight and reporting of adverse events in office practice that we have in hospitals and ambulatory surgery centers (ASC's).

The Betsy Lehman Center for Patient Safety and Medical Error Reduction just published its analysis of adverse events occurring during cataract surgery in Massachusetts between 2011 and 2015 (Betsy Lehman Center 2016). The study was done in conjunction with the Massachusetts Department of Public Health, the Massachusetts Society of Eye Physicians and Surgeons, the Massachusetts Society of Anesthesiologists, and the Massachusetts Board of Registration in Medicine. Representatives from various hospital and patient safety organizations also served either on the steering committee or as reviewers.

While the numbers of adverse events were small (28 serious events over the 5 year period), the continued occurrence of wrong lens, wrong patient, and wrong eye procedures is bothersome. In addition, loss of vision from nerve blocks was also noted.

Implantation of the Wrong Intraocular Lens (IOL)

Implantation of the wrong intraocular lens (IOL) represented over half the cases in the Betsy Lehman Center report and occurred 15 times in the 5 year period. That is a problem near and dear to our heart. Twenty years ago we reviewed a scenario where two consecutive patients received implantation of incorrect intraocular lenses after another patient had been inserted into the surgical schedule because he complained he had been told he'd be the first case of the day. After our review of the cases and identification of numerous factors that contributed we commented "I can't believe this has never occurred before", only to be confronted with sheepish grins indicating this had not been the first time such had occurred. Shortly thereafter we were at a meeting of the clinical committee advising the New York State Department of Health on its incident reporting system. During the lunch break, we asked if any of the other hospitals represented had experienced similar incidents. The hands of at least a third of the hospital representatives

went up! As a result of those cases, we developed one of the very first comprehensive "timeout" polices in the US, one that later served as a model for similar policies across New York and the country (see our Patient Safety Tip of the Week "Weighing in on Double-Booked Surgery").

John Simon and his colleagues at Albany Medical College subsequently published an analysis of New York state cases as part of their retrospective review of 106 cases of surgical "confusions" in several venues (Simon 2007a, Simon 2007b, Simon 2007c). These include 42 cases from the Ophthalmic Mutual Insurance Co. and 64 cases from the New York Patient Occurrence and Reporting Tracking System (NYPORTS). 67 cases involved wrong lens implants, 15 cases wrong-eye operations, 14 cases wrong-eye block, 8 wrong patient or procedure, and 2 wrong corneal transplant. Based on these findings, they estimated an incidence of 6.9 such errors per 100,000 ophthalmologic surgeries.

Implantation of the wrong intraocular lens was the most common occurrence in both databases. Errors in both the preoperative period and operative period were found to lead to the incorrect implantation. In the preoperative period, contributory causes identified included faulty calibration of the A-scan equipment, transposition of records from the ophthalmologist's office, transcription errors, switched patient identification stickers, and transposition of IOL power calculations while faxing records on two patients at the same time.

Intraoperative errors in almost all cases involved failure to identify the lens specifications properly before implantation. Multiple contributory factors were identified, including changes in the OR schedule, changed staff assignments, staff changes during the procedure, poor lighting, multitasking and other distractions, and misreading the label on the implant box. In one case the surgeon had dropped multiple patient charts and they were out of order when reassembled.

Fortunately, analysis of the cases of implantation of the wrong IOL by Simon's group and other studies (Kelly 2011) (Rongé 2006) have helped identify many of the factors contributing to these events so that preventive measures are now recognized.

The Betsy Lehman Center report cites that many of the reported events stemmed from:

- Breakdowns in communication
- Failure to conduct an effective time-out
- Lack of standardization within facilities - from lens order forms to surgical site markings
- Issues related to safety culture

They also identified the following key factors contributing to incorrect IOL implantation:

1. More than one lens in the operating room
2. Reliance on paper, rather than electronic, lens order forms, and associated handwriting legibility and transcription errors
3. Non-standardized lens order forms, some of which are poorly designed
4. Inadequate or improperly followed lens verification policies

5. Short-notice changes to surgical schedule, such as cancellations or add-ons
6. Same-day lens changes due to intra-operative complications or real-time measurement technology
7. Problematic design of lens packaging (e.g., similar labels and product codes, small print)

We like to emphasize the **problem created by late changes in the surgical schedule**. In our original case 20 years ago a patient complained that his surgeon had told him he was going to be the first case of the morning. So staff rearranged the schedule, inserting his case before several others on the schedule. The surgeon had several patient charts and multiple IOL's arranged in order in the OR at the time, further complicating the situation. That led to our original "timeout" policy which set forth not only patient verification procedures but also **banned the presence in the OR of either charts or IOL's or imaging studies on more than one patient at a time**. Almost every analysis of implantation of incorrect IOL's also mentions change in the surgical schedule as a contributing factor in some cases. It's a good practice now to let all parties know when a case is taken out of order (either an add-on case, a cancellation, or other change in the order of the scheduled surgical list). While Universal Protocol should always lead to verification of correct patient, procedure, laterality, etc. the "mental image" of the surgical schedule may still lead to parties mistaking patients or items even after a properly done timeout.

And they make the following key recommendations to prevent wrong lens, wrong eye, wrong patient errors:

- Institute a formal lens management policy that defines uniform processes for ordering, storing, selecting, and verifying intraocular lenses.
- Adopt a uniform, facility-wide policy for marking the operative eye, and perform a separate time-out prior to a nerve block
- Use multiple patient identifiers and engage patients using active verification
- Perform robust time-outs before every key step in the procedure

The report stresses that **the method for lens orders should be standardized**. They note that **handwritten orders for lenses are vulnerable to errors** and instead recommend offices submit either **typed requests** for lenses **or** fill out formal forms, **preferably electronic forms**. Note that a study on wrong IOL implantations in the UK (Kelly 2011) also identified abbreviations as contributing to the problem. They warned that the **dangerous abbreviations** 'D' for diopter and '+' for plus and '-' for minus may result in confusion. The UK study also gave examples of handwritten transcription errors such as mixing up '11' and '17', '14' and '19', '10.5' and '19.5', '20' and '2D', etc. The Betsy Lehman Center study provided an example of a handwritten IOL order in which '+17.50' and '+12.50" were confused. **Bottom line: don't accept handwritten IOL orders!**

Biometry errors were also noted in the UK study (Kelly 2011). These included use of incorrect biometry formulas, misfiling biometry reports in the wrong patient record, mixing IOL powers for right and left eyes, and failure to remove contact lenses when doing biometric measurements. The UK authors recommend:

- Use only most up-to-date, accurate biometry equipment and by appropriately trained staff
- Only relying on source documents for biometry
- Avoid handwritten IOL orders
- Avoid the abbreviations 'D" for diopter and '+' or '-' for plus and minus
- Don't rely on white boards for IOL powers

Another problem may arise when patients have the **same or similar last names** (Rongé 2006). While we would hope all facilities are religiously practicing 2-factor verification for all patients, we still recommend that the surgeon, anesthesiologist, and the OR staff review the surgical schedule for the day and identify in advance any instances where patients have the same or similar last names so that special precautions may be taken

Furthermore, the Betsy Lehman Center study suggests that lenses should be **stored** in a separate space outside the operating room. **Only the lens or lenses for the current patient should be present in the OR**. In cases we had seen in the past, an anachronistic practice in which ophthalmologists would get their IOL's from vendors on consignment and literally bring a whole bag of IOL's into the OR was a major factor in these adverse events. They also recommend designating a limited number of individuals **who may retrieve the IOL's** from storage and place them with the patient chart. In addition, **verification** of the IOL should be done by several individuals (e.g., lens room staff, the nurse who retrieves the lens, and the surgeon) independently and as a team check to make sure that the lens is correct at multiple points such as when the lens is pulled from the storage closet, when the operating room is prepared for the patient, and immediately before lens enters the sterile field. It is important that several source documents be used during the verification process. These would include the patient chart, the original calculation sheet, the surgeon's IOL order form, and the surgical print-out. From these sources the eye size, the lens model and lens power should be verified against the lens packaging. Like any other timeout or verification process, this is not a passive event. Rather each person should verbally verify the required information and anyone should be able to stop the case if there is any doubt or discrepancy identified. The process should also require documentation of the verification.

We'd also like to again stress the **importance of having all source documents available** before you start a case. In our June 5, 2007 Patient Safety Tip of the Week "Patient Safety in Ambulatoy Surgery" we lamented that the quality of the medical records is often not as good in ambulatory settings. The "facility" medical record is often scant and the physician often brings in his/her office notes that are "unofficial" as far as the facility is concerned. Often critical information is in the physician office record and never appears in the facility medical record. It is therefore incumbent upon the facility and entire team to ensure the adequacy of the medical record and all documentation prior to the procedure.

Ironically, one contributing factor identified in the UK study (Kelly 2011) was the use of white boards in the OR to list the power of the IOL. Sometimes IOL on the white board

was not erased and updated when a new patient entered the OR. This was particularly a problem when the order of patients was changed.

And, of course, all the procedures, protocols, and checklists in the world will fail if all staff do not adhere to them. Failure to devote full attention of all staff during timeouts or other verifications, failure to use active rather than passive responses during such verifications, and cultures that do not allow any member of the OR team to stop a procedure are all problems we see over and over again in review of adverse events.

Time pressures are also a concern. Surgeons doing cataract surgery may have many cases scheduled in a single morning. Liz Kowaczyk, the Boston Globe's excellent health correspondent writing on the Betsy Lehman report (Kowalczyk 2016), interviewed an anonymous nurse who described the surgeon coming in and saying "I have to be out of here by noon so let's get going." Bet none of your surgeons ever say that! Right!

Organizations should utilize some of the resources available for patient safety in both hospitals and the ambulatory surgery setting. The American Academy of Ophthalmology has issued good guidance statements on avoiding wrong-site surgery and avoiding incorrect intraocular lens placement (AAO 2011) with good examples of how checklists might be utilized, including The Wrong-Site Wrong-IOL Checklist in its Appendix 3. Also, in our June 8, 2010 Patient Safety Tip of the Week "Surgical Safety Checklist for Cataract Surgery" we discussed the UK National Patient Safety Agency (NPSA) Surgical Safety Checklist: for Cataract Surgery ONLY, based upon the WHO Surgical Safety Checklist.

The proliferation of so many new IOL options, such as multifocal and aspheric optics, has perhaps increased the odds of making mistakes (Rongé 2006). One of the discussants in that article, Dr. David Chang, called on lens manufacturers to help surgeons and ASC personnel avoid confusion by using different colors on their IOL boxes. The Betsy Lehman Center report also mentioned design of lens **packaging** (eg. similar labels and product codes, small print) as being problematic.

We refer you to that article from EyeNet (Rongé 2006) for descriptions of how several ambulatory centers have developed protocols for matching patients with the correct IOL's.

And what do you do if you make a mistake like implantation of an incorrect IOL? We refer you to our columns on **disclosure and apology** listed below. Sometimes a patient would have required use of corrective lenses anyway after cataract surgery and they will simply require a different corrective prescription than they would have otherwise. But they still need to be told of the error(s) made, with an appropriate and sincere apology. Multiple studies have now validated the "disclosure and apology" approach as being not only the right thing to do but also reducing liability costs in the long run.

Wrong-Eye Anesthesia or Surgery

Surgery or anesthesia on the wrong eye was the second most common event in the Betsy Lehman Center report. Most events were anesthetizing the wrong eye, highlighting the **importance of performing a separate timeout prior to nerve blocks**. Key contributing factors apply to both anesthesia and surgery:

1. "Laterality" (left side-right side) confusion, compounded when patients have surgeries planned on both eyes within weeks
2. Inconsistent, idiosyncratic, or unclear schemes for marking the surgical site
3. Surgical drapes covering the site mark on the operative side
4. Inadvertent removal of site mark on operative side during skin prep
5. Time lapse between when the time-out is performed and when the procedure takes place
6. Lack of a separate time-out prior to injection, in the case of nerve blocks
7. Fast paced, high pressured environment
8. Inadequate communication

The importance of **involving the patient in verification of the correct eye** should be stressed. Again, an active rather than passive response from the patient should be sought (have the patient tell you which eye is to be operated on rather than asking "It's this eye, isn't it?"). But we'll add our own caveat: given the demographics of the patient population undergoing cataract surgery there will be a substantial prevalence of cognitive dysfunction. We've all seen cases of wrong-site surgery where the patient indicated the wrong side. So it is critical that **all source documents be consulted** as part of the verification process either for the anesthesia or the surgery.

Surgical **site marking** is important and must be standardized across your facilities. Key features of such marking include that the mark should be unambiguous and should be "sufficiently permanent" to last through the procedure and be placed in an area that will still be visible after the patient is prepped and draped. There are examples where, for example, a "sticky colored dot" affixed to the skin over the eye intended for surgery becomes dislodged during the prep and draping.

Nerve Blocks Leading to Loss of Vision

The Betsy Lehman Center report included five cases of serious harm to patients, several of whom suffered permanent loss of vision, which occurred in a single day as a result of eye blocks administered by a contracted anesthesiologist during his second day at the facility and noted several reports elsewhere of other complications related to retrobulbar and peribulbar blocks.

The report recommends that:

- The risks and benefits of forms of anesthesia be considered in each individual case
- The least invasive form of anesthesia be considered for each case

- The patient should be engaged in the discussion about choice of anesthesia techniques
- Sufficient evidence of the ability of physicians to perform such blocks be considered during the credentialing and privileging process

Wrong Patient Surgery

Though there was only one reported case of wrong patient surgery in the Betsy Lehman Center report, the report has a discussion on ways to prevent wrong patient surgery. We refer you to our numerous columns on wrong-site, wrong-patient surgery listed at the end of today's column.

The report goes on to detail recommendations for healthcare organizations and their leadership, ophthalmologists, surgeons, anesthesiologists, nurses and patients. It also emphasizes the important role that non-clinicians (eg. office staff) have in ensuring patient safety. The report is very well referenced and you'll find it very valuable.

There are several other adverse events not included in the Betsy Lehman Center Report:

Methylene Blue Accidents

Another adverse event seen in cataract surgery is the **inadvertent injection of methylene blue (dye) instead of trypan blue** which results in catastrophic loss of vision (see our prior columns of May 20, 2014 "Ophthalmology: Blue Dye Mixup" and September 2014 "Another Blue Dye Eye Mixup"). That is a problem calling for a system fix as described in those columns.

Intraoperative Floppy Iris Syndrome (IFIS)

In our June 8, 2010 Patient Safety Tip of the Week "Surgical Safety Checklist for Cataract Surgery" we noted that the UK National Patient Safety Agency (NPSA) Surgical Safety Checklist: for Cataract Surgery ONLY, included a question about whether the patient was on tamsulosin or other alpha blocker. That is because of the risk of the "intraoperative floppy iris syndrome (IFIS)" and other complications (Bell et al 2009).

Moving Cataract Surgery to the Office?

In today's introductory paragraph we noted the likely trend of moving cataract surgery away from hospitals and ambulatory surgery centers to the office setting. Such a trend is likely to follow after a recent study demonstrated the relative safety and effectiveness of such procedures done in the office setting (Ianchulev 2016). We expect that payors will

also push for that trend since the overall costs will likely be lower. But few states have robust systems in place for reporting adverse events in the office setting. Given the findings in the Betsy Lehman Center report we would be very leery of such a move unless appropriate regulatory oversight and reporting is put in place for the office setting.

Cataract surgery in general is one of the safest surgeries undertaken today. Yet the Betsy Lehman Center report emphasizes that errors and adverse events still occur and that system interventions need to be implemented to minimize the risks even in this relatively safe surgery.

Some of our previous patient safety columns involving ophthalmology issues:

June 5, 2007 "Patient Safety in Ambulatoy Surgery"
March 11, 2008 "Lessons from Ophthalmology"
June 8, 2010 "Surgical Safety Checklist for Cataract Surgery"
June 2012 "Tailored Timeouts for Ophthalmologists"
May 20, 2014 "Ophthalmology: Blue Dye Mixup"
September 2014 "Another Blue Dye Eye Mixup"

Some of our prior columns related to wrong-site surgery:

September 23, 2008 "Checklists and Wrong Site Surgery"
June 5, 2007 "Patient Safety in Ambulatory Surgery"
July 2007 "Pennsylvania PSA: Preventing Wrong-Site Surgery"
March 11, 2008 "Lessons from Ophthalmology"
July 1, 2008 "WHO's New Surgical Safety Checklist"
January 20, 2009 "The WHO Surgical Safety Checklist Delivers the Outcomes"
September 14, 2010 "Wrong-Site Craniotomy: Lessons Learned"
November 25, 2008 "Wrong-Site Neurosurgery"
January 19, 2010 "Timeouts and Safe Surgery"
June 8, 2010 "Surgical Safety Checklist for Cataract Surgery"
December 6, 2010 "More Tips to Prevent Wrong-Site Surgery"
June 6, 2011 "Timeouts Outside the OR"
August 2011 "New Wrong-Site Surgery Resources"
December 2011 "Novel Technique to Prevent Wrong Level Spine Surgery"
October 30, 2012 "Surgical Scheduling Errors"
January 1, 2013 "Don't Throw Away Those View Boxes Yet"
January 2013 "How Frequent are Surgical Never Events?"
August 27, 2013 "Lessons on Wrong-Site Surgery"
September 10, 2013 "Informed Consent and Wrong-Site Surgery"
July 2014 "Wrong-Sided Thoracenteses"

Some of our prior columns on Disclosure & Apology:

July 24, 2007 "Serious Incident Response Checklist"
June 16, 2009 "Disclosing Errors That Affect Multiple Patients"
June 22, 2010 "Disclosure and Apology: How to Do It"

September 2010	"Followup to Our Disclosure and Apology Tip of the Week"
November 2010	"IHI: Respectful Management of Serious Clinical Adverse Events"
April 2012	"Error Disclosure by Surgeons"
June 2012	"Oregon Adverse Event Disclosure Guide"
December 17, 2013	"The Second Victim"

Other very valuable resources on disclosure and apology:

- IHI's "Respectful Management of Serious Clinical Adverse Events" (Conway 2010)
- The Canadian Disclosure Guidelines (Canadian Patient Safety Institute 2008)
- The Harvard Disclosure Guidelines (Massachusetts Coalition for the Prevention of Medical Errors 2006)
- The ACPE Toolkit (American College of Physician Executives)
- Oregon Patient Safety Commission Oregon Adverse Event Disclosure Guide.

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