



Process Assessment is Key to Prevention of Certain Ophthalmology Events

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ABSTRACT

An estimated 24 million Americans have cataracts, making cataract removal and intraocular lens insertion one of the most common surgeries performed in the United States. Cataract surgery is safe, and serious injuries rarely occur. So when an increase in reports of Serious Events related to cataract procedures occurred in one year in Massachusetts, the Betsy Lehman Center for Patient Safety responded. The Center collaborated with a number of state and professional agencies, formed an expert panel, and consulted with the Pennsylvania Patient Safety Authority. The Authority found that from July 1, 2004, through June 30, 2015, Pennsylvania acute care facilities reported 4,307 events related to cataract procedures and 23 wrong-site anesthesia eye injections. Since July 2004, reporting of intraocular lens procedure-related events, which includes near misses and good catches, has steadily increased while the number of incorrect intraocular lens implant events has decreased. The Authority estimates the incidence of cataract-related surgical confusions in Pennsylvania at 61.8 per 1 million procedures for the July 1, 2004, through June 30, 2015, period. In response to a rising trend of intraocular lens-related reports, increased vigilance towards prevention is necessary. Active participation by engaged staff in executing the Universal Protocol—including engaging the patient—and use of an ophthalmology-specific perioperative checklist remain the recommended best practices to prevent wrong eye identification, incorrect lens implantation, and wrong-site anesthesia eye injections. (Pa Patient Saf Advis 2016 Sep;13[3]:92-99.)

INTRODUCTION

In 2015, representatives of the Betsy Lehman Center (The Center) for Patient Safety, a non-regulatory Massachusetts state agency, contacted the Pennsylvania Patient Safety Authority about cataract-surgery events in Massachusetts hospitals and ambulatory surgical facilities. The Center staff were interested in comparing Massachusetts' trends with those in Pennsylvania. Of interest were the implantation of intraocular lenses (IOL) not intended for the patient and wrong-site anesthesia eye injections; an increase in these types of errors had been reported to Massachusetts regulators the previous year.

Implantations of IOLs not intended for the patient and wrong-site anesthesia eye injection events continue to be reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS). More than 4,300 events related to cataract procedures were reported between July 2004 and June 2015. Although the overall number of IOL-related reports has been increasing since 2004, the number of incorrect lens implants has been decreasing and wrong-site eye injections have declined since 2004.

There is sparse research for comparison; however, in a study of 106 “surgical confusions”^{*} in ophthalmology in New York state over a 23-year period, the most common confusions cited were wrong lens implant (63%) and injection of anesthesia into the incorrect eye (13%).¹ The study further analyzed claims data for a five-year period (2001–2005) and suggested an incidence of 69 surgical confusions per 1 million eye operations.¹

Because of Pennsylvania's adverse event database and broader scope of reporting requirements, a comparison of trends of these types of events could prove useful to The Center for interpreting the Massachusetts' serious reportable events (SREs)[†] data.² The inquiry prompted the Authority to perform an analysis related to implantation of IOLs not intended for the patient and wrong-site anesthesia injections in Pennsylvania.

METHODS

Analysts queried PA-PSRS for intraocular cataract-related events and events meeting the criteria for wrong-site surgery[‡] in acute care facilities (i.e., acute care hospitals, ambulatory surgical facilities) for the period July 1, 2004, through June 30, 2015. This time frame is consistent with the Authority's previously published wrong-site surgery analyses and aligns with the time frame of procedure data available from the Pennsylvania Health Care Cost Containment Council (PHC4).

Analysts individually reviewed the event report narratives and searched the cataract-related event details for the terms, “cataract,” “lens,” “IOL,” “wrong,” “incorrect,” “tear,” “pressure,” and “IOP.”

^{*} Surgical confusions were defined as: wrong implant, wrong-eye block, wrong patient or procedure, wrong eye, or wrong transplant.

[†] Massachusetts mandates the reporting of Serious Reportable Events as defined by the National Quality Forum: http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx

[‡] The definition used for the Authority's wrong-site surgery program follows the National Quality Forum's definition as outlined in the Serious Reportable Events In Healthcare—2011 Update: A Consensus Report.

Analysts requested a custom report from PHC4* using Current Procedure Terminology (CPT), Healthcare Common Procedure Code System (HCPCS), supplementary classification of factors influencing health status and contact with health services (V-codes), and the International Statistical Classification of Diseases and Related Health Problems (ICD-9) procedure codes for outpatient and inpatient eye and cataract procedures from July 2004 through June 2015. These data were analyzed and used to estimate rates and incidences for Pennsylvania.

To estimate incidences of surgical confusions in Pennsylvania commensurate with New York state claims data of Simon et al., a subset of PA-PSRS and PHC4 data was analyzed for the five-year period of 2010 to 2014. This time frame was selected because July 2004 was the first full month in which events were reported through PA-PSRS, it reflected the most recent five full years of PA-PSRS and PHC4 data available at the time of this study, and the coding adjustments were fully implemented (see Limitations).

* The Pennsylvania Health Care Cost Containment Council (PHC4) is an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of health care, and increasing access to health care for all citizens regardless of ability to pay. PHC4 has provided data to the Authority in an effort to further PHC4's mission of educating the public and containing health care costs in Pennsylvania. PHC4, its agents, and staff have made no representation, guarantee, or warranty, express or implied, that the data - financial, patient, payor, and physician specific information - provided to this entity, are error-free, or that the use of the data will avoid differences of opinion or interpretation. This analysis was not prepared by PHC4. This analysis was done by the Pennsylvania Patient Safety Authority. PHC4, its agents and staff, bear no responsibility or liability for the results of the analysis, which are solely the opinion of this entity.

RESULTS AND ANALYSIS

Incorrect Intraocular Lens Implants

The query resulted in 4,962 events; 4,307 met the criteria for analysis related to cataract procedures.

Of the 4,307 events

- 77 (1.8%) were associated with incorrect IOL implants (i.e., not intended for the patient)
- 32 (0.7%) were associated with elective lens exchanges
- 7 (0.2%) were associated with an expired lens being implanted
- 1 (0.02%) was surgery performed on the wrong eye

Although the number of IOL-related reports has increased since 2004, the number of incorrect lens implants has decreased (Figures 1 and 2). An analysis of wrong-site eye injection events revealed that the annual number reported has also declined since 2004. The causes of these events were not described in the

event detail in sufficient quantity to make extrapolations possible.

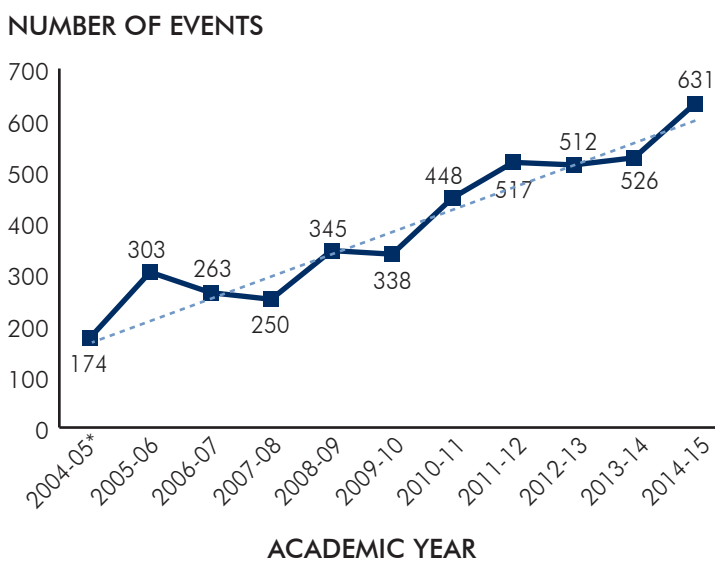
Examples of reported incorrect IOL implants include the following:[†]

During the postoperative visit, the surgeon noted that the wrong IOL power was inserted into the correct eye. When the causes were reviewed, it was discovered that the surgeon wrote the correct diopter lens on the patient's medical record; however, the incorrect lens was selected by the circulator. Additionally, the final verification had not been completed prior to start of procedure.

The patient was scheduled to have a cataract removal of the left eye with an IOL implant of diopter 12.0. Instead the patient received a 23.5 diopter. The error was discovered when the nurse was preparing the

[†] The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

Figure 1. Number of Intraocular Lens Procedure-Related Events Reported by Academic Year* through PA-PSRS (N = 4,307)

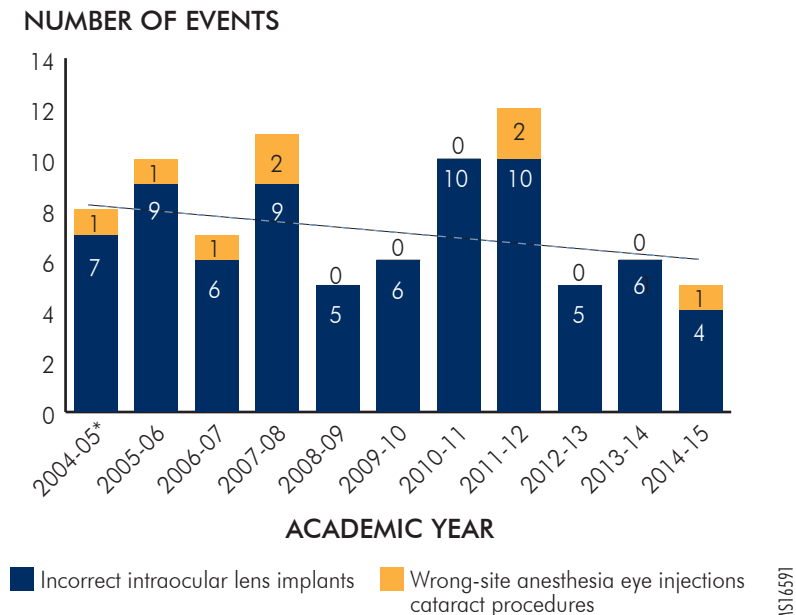


* July 2004 was the first full month in which events were reported through PA-PSRS.

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Figure 2. Incorrect Intraocular Lens Implants (N = 77) and Wrong-Site Anesthesia Eye Injections involving Cataract Procedures (n = 8) Reported through PA-PSRS by Academic Year*



OR suite for the next surgery. The patient was returned to the operating room for insertion of the correct lens.

Detection

Of the 77 incorrect IOL implant events:

- 53 (68.8%) mentioned when the error was detected
 - 34 (64.2%) of the events were discovered on the day of surgery
 - 19 (35.8%) of the events were discovered after the day of surgery (e.g., post-operative visit in the physician’s office)
- 48 (62.3%) reports indicated that the patient returned to the operating room or had an additional procedure performed

Lens Characteristics

Analysts reviewed the 77 events involving incorrect IOL implants. Forty-four (57.1%) of the 77 reports mentioned the

lens strength, type, size, or other as being incorrect (these data are not mutually exclusive). Of the 44:

- 33 (75.0%) reports mentioned the lens power
- 9 (20.5%) reports mentioned two or more lens-related items
- 8 (18.2%) reports mentioned the lens type
- 5 (11.4%) reports mentioned the lens size
- 1 (2.3%) report mentioned lens displacement or other effect and was classified as *Other*

Harm

Analysts reviewed the 77 events by harm score.* Figure 3 shows the percentage of IOL implantation events not intended for the patient by harm score. Thirty-four (44.2%) were reported as an unsafe condition (A-D) or no harm event, and 43 (55.8%) events were reported as

contributing to or resulting in temporary harm (E-F) and required either treatment or intervention or initial or prolonged hospitalization.

Facility

The majority of events, 51 (66.2%), were reported by ambulatory surgical facilities, where most lens-implant procedures are performed.

Wrong-Site Anesthesia Eye Injections

The PA-PSRS query resulted in 23 event reports that met the criteria for a wrong-site event. Nineteen (82.6%) were associated with wrong-side anesthesia injections (i.e., wrong eye identified) and 4 (17.4%) were associated with unintended anesthesia injections of the correct eye; for example, the following errors were found:

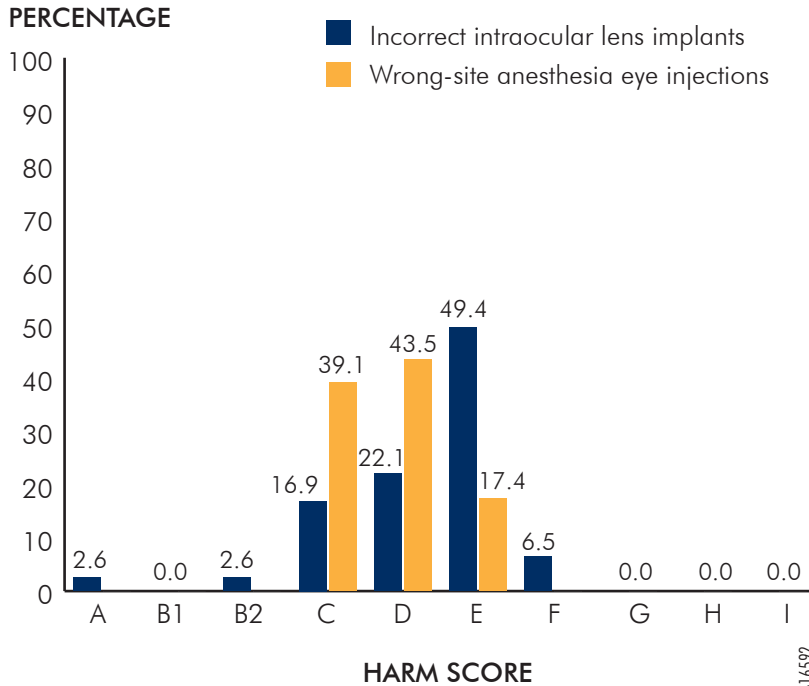
- Re-injection of an anesthetic instead of an antibiotic
- Injection of the wrong concentration and mixture of an anesthetic
- Injection of the wrong anesthetic
- Injection of the anesthetic prior to marking the pupil

Discipline and Type of Anesthesia Injection

Analysts reviewed the event detail of the reported events to determine which disciplines performed the injection and what types of anesthesia injection were involved. The majority, 17 (73.9%) of the 23, were performed by a surgeon, and 6 (26.1%) were performed by an anesthesiologist.

* The Authority’s event-reporting system uses an adaptation of the National Coordinating Council for Medication Error Reporting and Prevention harm index and the Veterans’ Administration National Center for Patient Safety severity assessment code system to distinguish between harm and no-harm events. The Pennsylvania Patient Safety Authority Harm Score Taxonomy is available exclusively online at [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/mar;12\(1\)/PublishingImages/taxonomy.pdf](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/mar;12(1)/PublishingImages/taxonomy.pdf)

Figure 3. Incorrect Intraocular Lens Implant Events (N = 77) and Wrong-Site Anesthesia Injections (n = 23) by Harm Score Reported through PA-PSRS, July 1, 2004, through June 30, 2015



Of the 17 injections performed by a surgeon:

- 14 (82.4%) were wrong-side anesthesia blocks, of which 4 specifically mentioned the location
 - Two were retrobulbar injections
 - One was a posterior auricular injection
 - One was a peribulbar injection
- Three (17.6%) were unintended-eye injections administered in the correct eye, of which one specifically mentioned the location
 - One was an inferotemporal quadrant injection behind the limbus

Of the six injections performed by an anesthesiologist:

- Five (83.3%) were wrong-side anesthesia blocks of which four specifically mentioned the location
 - Two were retrobulbar injections
 - One was a periorcular injection
 - One was a peribulbar injection
- One (16.7%) was an injection of the anesthetic before the pupil was marked for the specific lens implant (i.e., against standard procedure for this facility)

Examples of reported wrong-side anesthesia injections include the following:

A patient was scheduled to have a cataract removal. The surgeon performed a block to the incorrect eye after verifying the incorrect eye with the patient. The error was discovered

prior to the cataract removal, and the correct eye was then anesthetized and operated on.

When the patient was asked which eye he was having his cataract surgery on, he was unsure. The medical record was checked and confirmed the left eye was to be operated on. The patient suddenly became restless and began retching. It took several minutes for the patient to settle down. During this time, the non-operative eye was mistakenly marked, and the anesthesia block was given to the incorrect eye. This mistake was identified once the patient arrived in the OR. The correct eye was then anesthetized.

Surgical Procedure

Analysts reviewed the event detail of the 23 wrong-site injections to determine the surgical procedure involved. A slight majority (n = 12, 52.2%) mentioned the surgical procedure performed and of those:

- 66.7% (n = 8) were cataracts
- 16.7% (n = 2) were vitrectomies
- 8.3% (n = 1) was an ectropion correction
- 8.3% (n = 1) was an endophthalmitis

See Figure 2 for the number of wrong-site injections of anesthesia involving cataract procedures.

Patient Harm

Analysts reviewed the 23 events by the reported harm score. Figure 3 shows the percentage of wrong-site eye injection events by harm score. The majority, 19 (82.6%), were reported as an unsafe condition or no harm event.

Facility Type

The majority of events, 12 (52.2%), were reported by hospitals.

DISCUSSION

National and State Statistics

By current estimates 20 million to 24 million Americans have cataracts.^{3,4}



The National Eye Institute projects that cataracts will affect more than 38 million Americans by 2030 and more than 50 million by 2050.⁴ Annually in the United States and Pennsylvania, an average of 3 million and 149,000 cataract procedures are performed, respectively.^{4,5} In a 2006 study on wrong-site surgeries, Seiden and Barach analyzed reports from four databases spanning one year and determined that “cataract procedures were the second most common wrong-site incidents.”⁶

Healthgrades reports that cataract removal is the number one procedure performed in the United States.⁷ Cataract surgery is safe, serious injury is rare, and most patients report an improved quality of life after the procedure.^{8,9}

In Pennsylvania for the study period July 1, 2004, through June 30, 2015, for which PHC4 procedure data are available, the incidence of surgical confusions is 61.8 per 1 million cataract procedures (see Table for types of events).

It is difficult to make comparisons or benchmarks because of the lack of standardized definitions and dearth of research and statistics about intraoperative cataract procedure events. Simon et al. used the number of eye procedures, not cataract procedures, and suggested an incidence of 69 surgical confusions per 1 million eye operations in New York state.¹ In comparison, the Authority estimates 41.0 per 1 million eye procedures and

47.6 per 1 million *cataract* procedures for a comparable five-year period (2010 through 2014). Cataract procedures make up 86.1% of all eye procedures for this comparative time period.⁵

As noted, the reporting of IOL procedure-related events, including good catches such as preoperative identification of incorrect eye or lens power documentation, has steadily increased since reporting began in 2004. The overall increase in reporting may be related to a corresponding increase in eye and cataract procedures in Pennsylvania.⁵ However, the trend of incorrect IOL implant events and wrong-site anesthesia eye injections has gradually decreased.

It is encouraging to note that Pennsylvania hospitals and ambulatory surgical facilities are reporting cataract-related Incidents. This reporting trend suggests that facility staff are learning from Incidents, the Authority’s equivalent of good catches and near misses, which is a characteristic of high reliability organizations.

In the Authority’s most recent published update on wrong-site eye surgery, 174 events were related to anesthesia blocks.¹⁰ Of those events, 23 (13.2%) were wrong-site anesthesia eye injections. The Authority estimates an incidence of wrong-site anesthesia injections is 14.1 per 1 million cataract procedures in Pennsylvania for the period July 1, 2004, through June 30, 2015.

Interstate Agency Cooperation

The Center was established to coordinate and strengthen patient safety efforts in Massachusetts through data analysis, consumer engagement, communications, and sharing of best practices.¹¹

In 2014, 11 serious reportable events (SREs) related to cataract surgeries had been reported to the Massachusetts Department of Public Health. In a review of data from the previous five years, The Center discovered that “the most frequent type of SRE associated with cataract surgery was implantation of the incorrect IOL.”⁸ “The panel determined that system failures appeared to be involved in incidents that resulted in either implantation of IOLs not intended for the patient or wrong-site injections of anesthesia.”¹² The Center, working closely with the Massachusetts Department of Public Health, the Massachusetts Society of Eye Physicians and Surgeons, and the Massachusetts Society of Anesthesiologists, issued an advisory to hospitals and ambulatory surgery facilities informing them of what was being reported, why they were being informed, what next steps were being taken, and what the facilities could do to prevent patient harm.¹² Additionally, The Center assembled an expert panel of anesthesiologists, ophthalmologists, nurse administrators, and patient advisors to analyze the contributing factors to these events and to identify strategies to reduce risk.¹²

Similar to what was done in Massachusetts, in Pennsylvania, the Authority identified reports of wrong-site anesthesia eye injections and a wrong-site eye surgery events. In Pennsylvania the harm scores associated with these events indicated a range from unsafe conditions to temporary patient harm.

Risk Reduction Strategies

Checklist Advocated

Relying on memory alone to confirm surgical details can increase the likelihood of errors.^{13,14} In a study by Pikkell et al.,

Table. Incidence of Cataract-Related Surgical Confusion Events as Reported through the Pennsylvania Patient Safety Reporting System in the state, July 1, 2004, through June 30, 2015 (N = 101)

TYPE OF EVENT	NUMBER	INCIDENCE PER 1 MILLION CATARACT PROCEDURES
Incorrect intraocular lens implant	77	47.2
Wrong-site anesthesia injection	23	14.1
Wrong eye surgery	1	0.6

Note: 1,633,039 = Number of cataract procedures performed in Pennsylvania, July 1, 2004, through June 30, 2015, provided by custom report from the Pennsylvania Health Care Cost Containment Council. 2016 Jun.

cataract surgeons attempted to identify the correct operative side without using a preoperative verification process. “Before entering the operating room (OR) surgeons were asked to identify the correct operative side by using only the patient’s name and then upon entering the OR, the surgeons were asked to identify the correct operative side by looking at the patient’s face standing near the patient but not close enough to see the dilated pupil. The surgeons incorrectly identified the operative side in 27% of the cases using name only and in 17% of the cases looking at the patients’ faces.”¹⁵

The use of a surgical checklist enhances the likelihood of identifying safety hazards.^{16,17,18} Simon asserts that the use of the Universal Protocol would have prevented wrong-lens implants, wrong-eye surgeries, and wrong-eye anesthesia blocks in 85% of the cases studied in New York state.¹ The American Academy of Ophthalmology (AAO) convened a wrong site task force and in 2014 revised its recommendations for preventing wrong-site ophthalmology surgery and updated its Ophthalmic Surgical Safety Checklist.^{19,20} AAO specifies steps to follow prior to the day of surgery (e.g., the order for surgery and communication with surgery staff) and on the day of surgery (e.g., consent process, hard stop empowerment, marking the operative eye in the preoperative area, and the time-out).¹⁹ AAO also issued a list of special considerations for the various types of eye surgeries that depend on preoperative calculations; for IOL surgery, recommendations include performing an independent double check of IOL powers and documenting “patient’s name, eye, and IOL power on a white board or taped to the operating microscope.”¹⁹

The Authority’s resources for preventing wrong-site surgery are available at <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx>. These resources include preoperative checklists such as the Surgeon’s Office Checklist to

Prevent Wrong-Site Surgery²¹ and the Self-Assessment Checklist for Program Elements Associated with Preventing Wrong-Site Surgery.²² Previous Authority publications on this topic have provided best practices to decrease the likelihood of implanting the incorrect lens or performing wrong-site surgery.^{23,24} In response to concerns that staff are just “going through the motions” of the Universal Protocol, the Authority created and distributed a poster, titled *Patients and Surgical Teams Work Together to Avoid Wrong-Site Surgery* that engages the patient in the confirmation process (http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Documents/poster_avoid%20wss.pdf).¹⁰

Expert Panel Strategies

The Center’s expert panel key recommendations to prevent wrong-lens, wrong-eye, and wrong-patient errors and injuries related to ocular anesthesia appear below.^{25*} Please refer to the panel’s full report for details.

- To prevent wrong-lens, wrong-eye, and wrong-patient errors:
 - Institute a formal lens management policy that defines uniform processes for ordering, storing, selecting, and verifying IOLs
 - 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
- To prevent injuries related to anesthesia:
 - Use the least invasive form of anesthesia appropriate to the case

- Stay current on evidence-based practices for minimizing the risk of patient harm from anesthesia
- Engage patients in decisions about anesthesia and sedation
- Strengthen “onboarding” of new and contracted anesthesia staff, including thorough credentialing, formalized orientations, and observed eye block assessments

Performance Improvement

Accrediting and licensing agencies require ongoing assessments of safety and quality processes.^{26,27} Organization and medical staff leadership may proactively conduct periodic observational surveillance of compliance with perioperative processes including the Universal Protocol. Additionally, eligible providers can report quality-of-care compliance through the Physician Quality Reporting System.²⁸

Should a wrong-site eye surgery or other adverse event or near miss occur, facility staff may benefit from studying the event and analyzing the contributing factors and root causes. Evaluating and reinforcing successful processes may also be of value.²⁹ Collecting and analyzing data over time allows facilities to follow trends and measure improvements. The Authority has a Wrong-Site Surgery Error Analysis Form that provides a format to capture “information about wrong-site surgery, near misses, and actual occurrences”³⁰ and a template for Gap Analysis and Action Plan to Prevent Wrong-Site Surgery; the template allows facilities to compare surgical observations to evidence-based principles, goals, and measurement standards.³¹ Information learned from these analyses can be used to reduce safety hazards, implement risk reduction strategies, and reward successful interventions.²⁹

LIMITATIONS

Relevant information is derived from the event type taxonomy and from free-text narratives; categorization and

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narrative detail are provided by the report submitter.

Every effort was made to ensure that applicable procedure codes were identified to present a comprehensive depiction of eye and cataract procedures in Pennsylvania, including recognition that coding adjustments occurred during the data collection period and impacted the calculation of the number of cataract procedures before the third quarter of 2007. As PHC4 explains, “Prior to Q3-2007, PHC4 outpatient data was reported with a primary procedure and additional five secondary procedure code fields; giving facilities the option of submitting ICD-9 [inpatient] codes, CPT codes (HCPCS LEVEL I) and HCPCS LEVEL II codes. Effective Q3-2007 facilities must report either HCPCS LEVEL I OR HCPCS LEVEL II codes. ICD-9 codes are no longer valid for outpatient data.”⁵ Although every effort was made to identify a

comprehensive list of eye and cataract procedures, some may have been unknowingly excluded.

CONCLUSION

Events of incorrect IOL implants and wrong-site anesthesia eye injections are still reported through the Authority, even though the incidence and level of harm are low. However, events have steadily increased, indicating the opportunity to evaluate processes to prevent the potential for these events. Individual facilities will find it beneficial to trend and analyze their own data and perioperative practices. Information learned can be used to reduce safety hazards and implement risk reduction strategies.

The Center’s expert panel identified a number of procedure-specific recommendations to reduce the likelihood of error in cataract surgery. Encouraging patient

and family engagement with active participation by staff in the implementation of the Universal Protocol and use of an ophthalmology-specific perioperative checklist remain the recommended best practices for preventing incorrect lens implantation, wrong-eye surgery, and wrong-site anesthesia eye injections.

The Authority welcomed the opportunity to share data trends and information with The Center in Massachusetts, a colleague organization with complementary patient safety goals. Willingness to contact resources, share knowledge, and cooperate with one another towards the common goal of improving cataract-related patient safety not only enhances interagency expertise but furthers patient safety work on a national level.

Acknowledgments

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NOTES

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PENNSYLVANIA PATIENT SAFETY ADVISORY

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