BETSY LEHMAN CENTER for Patient Safety

PATIENT SAFETY IN CATARACT SURGERY: A RESPONSE TO ADVERSE EVENTS IN MASSACHUSETTS

Summary report of the Betsy Lehman Center's expert panel finding

Following an increase in reports of adverse events involving cataract surgery in Massachusetts, the Betsy Lehman Center collaborated with the MA Society of Eye Physicians and Surgeons, the MA Society of Anesthesiologists, and the Department of Public Health to issue an advisory in May 2015. The Center then convened an expert panel of ophthalmologists, anesthesiologists, nurse managers and patient representatives to more closely examine the risks surfaced by these incidents and to develop recommendations for mitigating them.

Why focus on cataract surgery?

Cataract surgery is the most common operation in the U.S. and among the safest procedures in medicine. Almost four million cataract surgeries were performed in 2015 nationally—more than 60,000 in Massachusetts alone—and these numbers are expected to grow. Serious, permanent complications from the procedure are rare. Yet, like most surgery, cataract removal involves complex processes prone to occasional systems failures that can harm patients. While the risk to any individual patient is low, the large volume of procedures means that even a miniscule error rate can add up to many patients harmed.

Serious Reportable Events in Massachusetts

During 2014 and 2015, six hospitals and six ambulatory surgery centers in Massachusetts reported 16 Serious Reportable Events (SREs) related to cataract surgery to the Department of Public Health. These "never events" involved preventable errors that harmed patients. Five of the events caused permanent loss of vision due to globe perforation. Others required patients to postpone the procedure or undergo corrective surgery.

The most frequent type of SRE associated with cataract surgery was implantation of the wrong intraocular lens. There were also multiple mistakes in the administration of anesthesia. Other errors included surgeries performed on the wrong eye and, in one case, on the wrong patient. In addition to SREs, Massachusetts cataract surgery providers have filed reports with the state about complications related to eye blocks, including retrobulbar hemorrhage and serious systemic reactions.

The response

Over seven months, the Betsy Lehman Center's expert panel and staff reviewed a unique collection of national and local data, and conducted key informant interviews, confidential conversations with facilities that had reported SREs, and surveys of Massachusetts cataract surgeons and facilities regarding eye anesthesia practices.

The panel's finding and recommendations were released in May 2016, and are summarized here. The full report, along with supplemental materials including tools to help with implementation of the recommendations and detailed results from the eye anesthesia survey can be found on the Betsy Lehman Center's website: www.betsylehmancenterma.gov

KEY CONTRIBUTORS TO THE ERRORS INCLUDE:

- Lack of standardization within facilities—from lens orders to surgical site markings
- More than one lens in the operating room
- Incomplete or inadequate time out; or significantly separated in time from the procedure
- Poorly designed, handwritten lens order forms
- Issues related to safety culture
- Fast-paced, high-pressure environment

> *"How could this have happened [here]?...we are all right on top of it…we are very, very careful."*
>
> *- Operating room nurse at a hospital-affiliated surgery center*

* *The quotations included in this summary are drawn from voluntary, confidential conversations that the Betsy Lehman Center conducted with several of the facilities that reported SREs.*

READ THE FULL REPORT: www.betsylehmancenterma.gov/initiatives/cataract-surgery.php

The panel's recommendations in brief

1. **Institute a formal lens management policy**

   Facilities should institute a formal policy that defines uniform processes for ordering, storing, selecting, and verifying intraocular lenses.

   - Set clear standards for lens orders and avoid hand-written forms
   - Store lenses outside the OR and assess inventory management systems
   - Adopt a clear process for when, how, and by whom lenses are pulled from storage
   - Use a team systems approach to lens verification with clear procedures for verifying the lens at multiple points

2. **Adopt a uniform, facility-wide policy for marking the operative eye**

   Adhering to universal protocols, the surgical site should be unambiguously marked using a "sufficiently permanent" mechanism and clear marking scheme that is standardized across the facility. The patient should identify the site before anesthesia is administered.

3. **Perform a separate time-out prior to administering nerve blocks**

   Anesthesia providers should perform a distinct anesthesia time-out immediately prior to administering nerve blocks outside the operating room. Specified information (including patient identity, operative eye, and procedure) should be actively verified against sources such as the patient wristband, chart, consent, and surgical plan.

4. **Identify patients using multiple unique identifiers and active identification**

   Use at least two patient identifiers at each stage of the procedure and use active identification methods ("what is your name?"), rather than passive approaches ("are you Jane Jones?").

5. **Use the least invasive form of anesthesia appropriate to the case**

   Surgeons and anesthesiologists should use the anesthesia technique that is least invasive and carries the lowest degree of risk, taking into account the patient's profile and preferences, the procedure planned and any anticipated complications, and other circumstances of the case such as the participation of residents. For non-complicated cases, consider topical anesthesia as a first choice.

6. **Stay current on evidence-based practices for minimizing the risk of harm from anesthesia**

   All cataract surgeons and anesthesiologists, whether or not they have experienced a serious incident, should periodically reassess their clinical practices and adopt evidence-based strategies for reducing the risk of patient harm associated with anesthesia.

7. **Engage patients in decisions about anesthesia and sedation**

   Physicians should talk with patients about the tradeoffs between different anesthesia techniques as part of the informed consent process before the day of surgery. The discussion should address not only relative clinical risks, but also information about patient experience in terms of discomfort, level of consciousness, visual effects, and complications.

"We started realizing everybody in the country has a problem with [implantation of wrong intraocular lenses] whether they want to admit it or not…We had a few right in a row and we started really looking at them. How many do we have that we don't know about? And then we started asking other organizations, 'How many do you have?' ('Oh we don't have any, we are perfect and we've got none')… If we are picking it up, other places just aren't looking."

- Hospital administrator

* * *

"We have approximately [20] cataract surgeons here who do the same thing differently."

- Nurse at an ambulatory surgery center

8. **Strengthen "onboarding" of new, contracted, and *locum tenens* anesthesia staff**
    - Define clear internal criteria for credentialing, use standardized questions developed with input from staff at all levels, and promote due diligence by engaging at least one physician to evaluate the information received.
    - Formalize orientations for clinicians who are new to a practice including elements such as team introductions, facility workflow, and time-out and marking procedures.
9. **Observe the initial eye blocks of any anesthesia provider who is new to the facility**

    Providers who perform eye blocks independently should have adequate and documented training, both didactic and clinical, in safe technique, managing complications, and identifying high risk eyes and patients. For anesthesiologists who are new to a facility, an experienced physician should directly observe their initial eye blocks, regardless of their level of past experience in other settings.
10. **Perform robust time-outs with at least two care team members before every key step in the procedure**

    Time-outs should actively engage everyone present at the time– including the patient when possible. Time-outs should always involve at least two care team members with different credentials and roles who use active verification to confirm the same information elements and in the same way, every time–regardless of the physician performing the block or surgery. Every team member should feel empowered to call a "hard stop" if they suspect something may be wrong.

> *"Culture is a hard thing to change and it doesn't change overnight. It's a very slow process but you need the right leadership to be able to do that and without the right leadership we are never going to move."*
>
> *- Operating room nurse at a hospital-affiliated surgery center*

Everyone has a role to play

Any member of the team can take action. Here are some ways:

Surgeons	Anesthesiologists	Nurses and other clinical staff	Nonclinical staff	Facility leaders and administrators
• Foster a workplace culture that prioritizes patient safety, recognizing that others look to your leadership to set the tone • Observe your facility's standardized protocols–even if you prefer different approaches • Advocate for new policies if you believe safer practices exist • Participate in your facility's credentialing of new anesthesia staff by helping to evaluate providers' qualifications	• Insist on adequate orientation when starting to practice in an unfamiliar facility • Be aware of the risks associated with nerve blocks and the strategies for mitigating them • Assess how well your facility's time-out and other processes work to catch systems failures, such as wrong eye blocks, and propose improvements	• Speak up when you have concerns, and encourage your team members to do the same • Ask to participate in your facility's patient safety program planning • Be a leader in implementing and improving standardized processes at your facility	• Understand that you play an important role in preventing harm–from sending clear lens orders to correctly identifying patients at check-in • Speak up whenever you believe that a patient safety risk has not been recognized by others on the care team • Volunteer to participate in your office or facility's patient safety program planning discussions	• Insist on standardization within your facility (for example, uniform lens orders and surgical site marking) • Evaluate how well policies are being followed using observational audits, EHR analytics, or other sources • Commit to conducting transparent and meaningful root cause analyses after an adverse event occurs

See the full report for more action steps.

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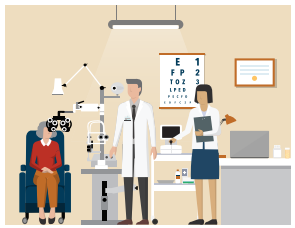
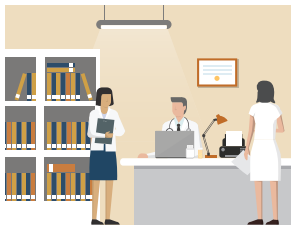
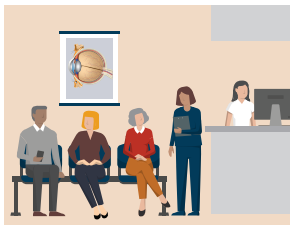
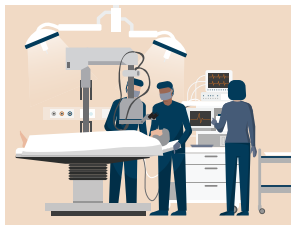
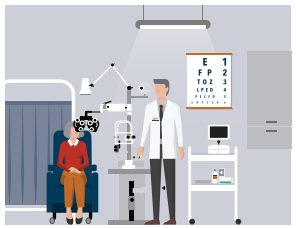
The Betsy Lehman Center is a state agency that uses communications, research and data to catalyze the efforts of providers, policymakers, and consumers working toward safer health care in Massachusetts.

WHAT'S YOUR PLAN TO ENSURE SAFE AND RELIABLE CATARACT SURGERY?

MISTAKES CAN HAPPEN AT ANY POINT →

EVERYONE PLAYS A ROLE IN PREVENTING HARM →

ARE YOU USING THESE STRATEGIES TO KEEP YOUR PATIENTS SAFE? →

1		2			3
DOCTOR'S OFFICE		SURGICAL FACILITY			OFFICE
EXAM ROOM	OFFICE	RECEPTION	PRE-OP HOLDING AREA	OPERATING ROOM	EXAM ROOM
					
• Biometry results mis-filed or mis-entered ↳ **WRONG LENS** • Inadequate informed consent on anesthesia and lens choice ↳ **UNANTICIPATED OUTCOMES**	• Lens order unclear or mis-transcribed • Lens order sent last-minute to surgical facility ↳ **WRONG LENS**	• Patient misidentified ↳ **WRONG PATIENT SURGERY**	• Inadequate time-out before eye marking and anesthesia • Delay between time-out and anesthesia ↳ **WRONG EYE ANESTHETIZED** • Insufficient credentialing and orientation of new and contracted anesthesiologists ↳ **IMPROPER EYE BLOCKS**	• Multiple lenses in OR ↳ **WRONG LENS** • Inadequate time-out • Patient misidentified ↳ **WRONG PATIENT SURGERY** • Inconsistent or obstructed site markings ↳ **WRONG EYE SURGERY**	• Discovery of errors and complications

Time-pressured environment | Poor communication | Punitive response to mistakes

• Engage patient in shared decision-making on anesthesia and lens options	• Use surgical facility's standard lens order form • Avoid handwritten orders • Send lens orders >24 hours before surgery	• Use at least 2 patient identifiers here and at each stage • Use *active* patient confirmation ("What's your name," *not* "Are you Jane Jones?")	• Perform 2+ person time-out right before administering anesthesia • Credential, orient, and observe new anesthesiologists before they perform eye blocks independently	• Perform time-outs to identify patient and to verify eye and lens • Standardize surgical marking • Store lenses outside the OR	• Disclose errors to patient • Notify surgical facility and participate in root cause analysis • Develop and implement corrective action plan to prevent future errors

Standardize internal processes | Adhere to safety protocols | Audit safety practices | Commit to continuous improvement | Foster a culture of safety

BETSY LEHMAN CENTER
for Patient Safety and Medical Error Reduction

www.BetsyLehmanCenterMA.gov