BETSY LEHMAN CENTER

for Patient Safety and Medical Error Reduction

Advancing Patient Safety in Cataract Surgery

A BETSY LEHMAN CENTER EXPERT PANEL REPORT

May 2016

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

The Center is named for Betsy Lehman, a talented Boston Globe health reporter and mother of two young girls who died in 1994 as the result of a preventable medical error when she was being treated for breast cancer. Her shocking and tragic death became a catalyst for change in approaches to patient safety both in Massachusetts and nationally.

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Preface

When the Massachusetts Department of Public Health alerted the Betsy Lehman Center to an increase in reports of Serious Reportable Events (SREs) associated with cataract surgery in early 2015, we saw an opportunity to address an issue that had emerged during the Center's recent work to assess the current patient safety landscape in Massachusetts. Providers told us they were frustrated that there were not more opportunities for shared learning of actionable information from the adverse events and other patient safety data they collectively report to state and federal agencies.

It is well understood that a key obstacle to reducing the incidence of preventable harm to patients across medicine is the lack of good metrics. As they say, you can't fix what you don't measure. The recent cluster of cataract surgery adverse events allowed us to explore how that limited data set might be leveraged to "signal" the existence of risks to patient safety across a medical specialty. We also wanted to test new mechanisms for the dissemination of timely alerts and recommendations about notable patient safety risks and trends directly to providers who practice in those fields here in Massachusetts.

Our decision to focus on cataract surgery does not reflect a judgment that this particular procedure represents the most critical patient safety risk facing Massachusetts today. On the contrary, recent studies show that medication and diagnostic errors in all clinical settings are among the leading causes of preventable patient harm and death nationally.

As noted in the expert panel report that follows, cataract removal is the most frequently performed surgery in the United States and improves quality of life for most patients. Because many individual cataract surgeons will never be personally involved in a serious harm event, they may not recognize the risk. Yet the large numbers of cataract surgeries mean that even tiny rates of preventable error will result in large numbers of patients harmed unnecessarily.

The cataract surgery errors reported as SREs in Massachusetts represent so-called "never events" that were entirely preventable. By looking beneath the surface to understand the systems and actions that allowed harm to occur in these cases, there is potential to have an enormous impact by driving the number of adverse events in cataract surgery to zero.

It is impossible to overstate the importance of having willing partners among the state's professional associations, particularly the Massachusetts Society of Eye Physicians and Surgeons and the Massachusetts Society of Anesthesiologists. In addition to the expertise they contributed, their collaboration has opened up communication channels with front line physicians enabling us to gather information and disseminate this work in ways that otherwise would not be possible. We are grateful for their willingness to take a leadership role in spreading the word that patient safety gains are made when practitioners continually look at their own work and ask, 'How can I make this even safer for my patients?'

And there is more to come. As a next step, we are developing a practical set of tools that providers can use to improve the safety of their cataract surgery practices. We also will be evaluating this initiative to understand how it can be repurposed to support meaningful, measurable change in other areas of health care—with the ultimate goal of eliminating preventable patient harm in Massachusetts.

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Executive Summary

Cataract surgery is among the safest procedures in medicine. Serious, permanent complications are rare, and most patients report a significant increase in their quality of life following surgery.

This combination of low risk and high benefit—and the fact that about half of all Americans develop cataracts that affect their vision by the age of 75—have helped make cataract surgery the single most common operation in the U.S. Almost four million cataract surgeries were performed in 2015 nationally—more than 60,000 in Massachusetts alone—and these numbers are expected to grow in future years as the population ages.

Yet, like most surgery, cataract removal involves complex processes prone to occasional systems failures that can result in serious harm to 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.

In early 2015, the Massachusetts Department of Public Health alerted the Betsy Lehman Center to an uptick in reports of Serious Reportable Events (SREs) associated with cataract surgery. These "never events" involved preventable errors that should not have resulted in harm to patients. The Center's review of the data for the previous five years revealed that the most frequent type of SRE associated with cataract surgery was implantation of the **wrong intraocular lens**—that is, a lens not intended for the patient. There were also multiple **mistakes in the administration of anesthesia**, in some cases resulting in permanent loss of vision. Other errors included surgeries performed on the **wrong eye** and, in one case, on the **wrong patient**.

What can be learned from these events? Over the course of seven months, an expert panel of respected ophthalmologists, anesthesiologists, nurse managers, and patient representatives convened by the Betsy Lehman Center examined the issues. The panel relied on a unique collection of national and local data—including confidential conversations with several of the facilities that reported the SREs, surveys of Massachusetts cataract surgeons and facilities, key informant interviews, guidelines from professional organizations, and queries of other databases including malpractice insurance claims data—to develop findings and recommendations.

To advance safe and reliable cataract surgery in Massachusetts…

- Foster a safety culture in which preventing patient harm is the top priority
- Engage physicians and staff at all levels to develop and implement a patient safety program
- Standardize and adhere to protocols and processes, including effective time-outs
- Reassess anesthesia practices
- Conduct a meaningful informed consent process that engages patients in lens and anesthesia choices
- Recognize that even the best-engineered systems require continuous improvement to address persistent and emerging risks

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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

The anesthesia-related incidents prompted deliberation over the choice of anesthesia technique and credentialing and orientation of new anesthesia staff.

KEY RECOMMENDATIONS

In addition to the more general principles for advancing safe and reliable cataract surgery noted above, the panel developed the following 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

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

The call to action is for all who participate in the delivery of cataract surgery to put themselves in the shoes of their peers who once thought, "It will never happen to me." The panel's recommendations encourage providers to promote a culture of safety and to implement patient safety programs and evidence-based best practices to prevent events like the ones reported in Massachusetts from happening again.

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

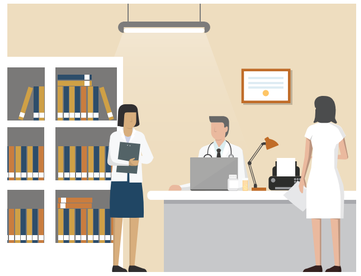
MISTAKES CAN HAPPEN AT ANY POINT →

1 — DOCTOR'S OFFICE

EXAM ROOM

- Biometry results mis-filed or mis-entered
  ➤ **WRONG LENS**
- Inadequate informed consent on anesthesia and lens choice
  ➤ **UNANTICIPATED OUTCOMES**

OFFICE



- Lens order unclear or mis-transcribed
- Lens order sent last-minute to surgical facility
  ➤ **WRONG LENS**

2 — SURGICAL FACILITY

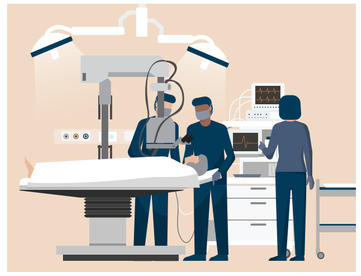
RECEPTION

- Patient misidentified
  ➤ **WRONG PATIENT SURGERY**

PRE-OP HOLDING AREA

- 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**

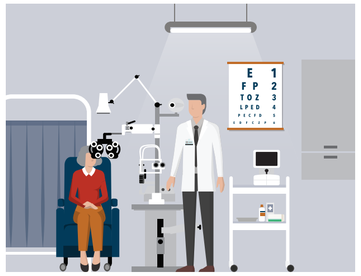
OPERATING ROOM



- Multiple lenses in OR
  ➤ **WRONG LENS**
- Inadequate time-out
- Patient misidentified
  ➤ **WRONG PATIENT SURGERY**
- Inconsistent or obstructed site markings
  ➤ **WRONG EYE SURGERY**

3 — OFFICE

EXAM ROOM



- Discovery of errors and complications

EVERYONE PLAYS A ROLE IN PREVENTING HARM →

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

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

DOCTOR'S OFFICE

- Engage patient in shared decision-making on anesthesia and lens options

DOCTOR'S OFFICE

- Use surgical facility's standard lens order form
- Avoid handwritten orders
- Send lens orders >24 hours before surgery

SURGICAL FACILITY

- Use at least 2 patient identifiers here and at each stage
- Use *active* patient confirmation ("What's your name," *not* "Are you Jane Jones?")

SURGICAL FACILITY

- Perform 2+ person time-out right before administering anesthesia
- Credential, orient, and observe new anesthesiologists before they perform eye blocks independently

SURGICAL FACILITY

- Perform time-outs to identify patient and to verify eye and lens
- Standardize surgical marking
- Store lenses outside the OR

OFFICE

- 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

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Advancing Patient Safety in Cataract Surgery

Cataract surgery is among the safest procedures in medicine. Serious, permanent complications are rare, and the vast majority of patients report a dramatic increase in their quality of life.[1]

This combination of low risk and high benefit—and the fact that about half of all Americans develop cataracts that affect their vision by the age of 75—have helped make cataract surgery the single most common operation in the U.S.[2,3] Almost four million cataract surgeries were performed in 2015 nationally[4]—more than 60,000 in Massachusetts alone[5]—and these numbers are expected to grow in future years as the population ages.[6]

Yet, like most surgery, cataract removal involves complex processes prone to occasional systems failures that can result in serious harm to 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.

In 2015, the Massachusetts Department of Public Health took note of an uptick in hospital and ambulatory surgery center reports of Serious Reportable Events (SREs) associated with cataract surgery during the previous year. These SREs are also known as "never events"—preventable errors that should not have resulted in patient harm. The Betsy Lehman Center's review of the data for the previous five years revealed that the most frequent type of SRE associated with cataract surgery was implantation of the wrong intraocular lens—that is, a lens not intended for the patient. There were also multiple errors in the administration of local anesthesia, in some cases resulting in permanent loss of vision. Other errors included surgeries performed on the wrong eye and, in one case, on the wrong patient.

These incidents took place in a wide range of settings, from hospitals to ambulatory surgery centers, large and small, academic and non-academic, spanning the state from Cape Cod to Western Massachusetts. One commonality was a sincere belief by the care team—physicians, nurses, and administrative staff—that they were not at risk for the types of errors that occurred or for the harm that resulted not only to patients, but to themselves and in some cases to the facility's reputation.

> *"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*

Confidential provider conversations

The Betsy Lehman Center conducted voluntary confidential conversations with several of the facilities that reported adverse events to the state. These sessions included face-to-face interviews with 32 surgeons, nurses, technicians, and administrators from three facilities—an ambulatory eye surgery center, a hospital-owned outpatient multi-specialty surgery center, and a teaching hospital—plus a phone interview with a risk management director from a fourth facility. The conversations yielded compelling qualitative information that was influential in the panel's deliberations. ***The quotations that appear throughout this report are drawn from these sessions.***

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A basic tenet of medicine dating back to Hippocrates has been to do no harm to patients. Thus, the cluster of cataract surgery SREs presents a unique set of challenges and opportunities. First, to leverage this "signal" data to promote safety culture and the implementation of patient safety programs in a medical field that is widely considered safe despite the fact that some patients continue to experience preventable harm. Second, to determine how best to motivate health care professionals to accept the need for process improvements in a high volume, low risk specialty where many of them may never be individually responsible for a serious harm event.

I. A "call to action" to improve patient safety in cataract surgery in Massachusetts

In response to the 2014 cluster of cataract-associated SREs, the Massachusetts Department of Public Health, the Massachusetts Society of Eye Physicians and Surgeons, and the Massachusetts Society of Anesthesiologists joined the Betsy Lehman Center in a collaborative effort to issue an advisory for the purpose of increasing awareness of these potential patient safety threats among ophthalmologists, anesthesiologists, and staff at the facilities where cataract surgeries are performed. In the fall of 2015, the Center convened an expert panel to identify and disseminate actionable strategies for reducing the risk of future harm. The panel included leading frontline providers in Massachusetts: ophthalmologists, anesthesiologists, cataract surgery nurses, and facility administrators from diverse settings. Its members also included two patient advisors who contributed important perspectives as medical consumers.

The goal of the panel's work was to learn as much as possible from available data and literature, increase awareness of common safety risks, and trigger the implementation of evidence-based best practices at all Massachusetts cataract surgery facilities. Providers often implement process improvements after experiencing a significant adverse event. The call to action is for all who participate in the delivery of cataract surgery to put themselves in the shoes of their peers who once thought, "It will never happen to me." This initiative encourages surgeons, anesthesiologists, nurses, technicians, and administrators to scrutinize their current practices and implement steps to prevent events like the ones reported in Massachusetts from happening again.

Why focus on patient safety in cataract surgery?

- Increasingly **large numbers of cataract surgeries** performed each year mean that even low rates of adverse events will impact large numbers of people.
- Although severe permanent harm to patients is rare, the **rate of preventable error** in eye surgery is at least twice as high as most other surgical specialties due to risks associated with left-right side confusion and the use of implants. [7-9]
- Proven "best practices" already exist to mitigate virtually all of the risks of patient harm in cataract surgery, so **major advances in patient safety are within reach**.

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The expert panel's work…and what informed it

The expert panel worked under the auspices of the Betsy Lehman Center, and was charged with developing evidence-based recommendations for improving patient safety in cataract surgery in Massachusetts. The panel held five in-person meetings over a seven-month period. Additional subgroup and member-to-member communications took place in between meetings. The panel's deliberations were informed by a thorough literature review and other essential research and analysis conducted by Center staff, partner organizations, and expert panel members, including:

- Analysis of data from mandatory adverse event reporting systems in Massachusetts operated by the **Department of Public Health** and the **Quality and Patient Safety Division** at the **Board of Registration in Medicine**
- Surveys of Massachusetts cataract surgery providers regarding anesthesia practices:
  - Cataract surgeons, in collaboration with **Massachusetts Society of Eye Physicians and Surgeons**
  - Ambulatory Surgery Centers, in collaboration with the **Massachusetts Association of Ambulatory Surgery Centers**
  - Hospitals, in collaboration with **Massachusetts Hospital Association**
- Key informant interviews:
  - 12 Massachusetts cataract surgeons
  - 12 national experts in ophthalmology, anesthesiology, patient safety, and patient advocacy
- Analysis of payer claims by Massachusetts providers to detect practice patterns and errors and complications related to cataract surgery:
  - Massachusetts All Payer Claims Database (APCD), in partnership with the **Health Policy Commission**
  - Medicare claims data, in partnership with the **Department of Health Policy and Management at the Harvard T.H. Chan School of Public Health**
- Queries by the **Pennsylvania Patient Safety Authority** of its adverse event databases for errors and "near misses" associated with eye surgery during 2004 – 2015
- Analysis of malpractice claims data related to cataract surgery:
  - Anesthesia Closed Claim Project of the **Anesthesia Quality Institute**
  - **CRICO** Comparative Benchmarking System
- Analysis of data from national voluntary reporting systems and surveys:
  - **National Anesthesia Clinical Outcomes Registry (NACOR)**
  - **ASC Quality Collaboration**
  - **Anesthesia Incident Reporting System (AIRS)**
  - Annual national survey of **American Society of Cataract and Refractive Surgeons (ASCRS)** members

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II. Cataract surgery in Massachusetts today

A. The practice of cataract surgery in Massachusetts

Analyses of Medicare, MassHealth (Medicaid), and commercial billing claims data indicate that approximately 62,000 cataract surgeries took place in Massachusetts in 2015 – likely an underestimate given that this figure does not include procedures performed in the state's Veterans Health Administration facilities. Approximately 75% of procedures were performed on Medicare patients, most of whom are age 65 and over. Nearly 65% were performed in ambulatory surgery centers (ASCs).[10,11]

B. Errors in cataract surgery

i. What is the risk?

During 2014 and 2015, six hospitals and six ASCs in Massachusetts reported a total of 16 SREs related to cataract surgeries to the Department of Public Health (DPH). Over this same period, the Quality and Patient Safety Division at the Board of Registration in Medicine (QPSD at BORIM) received confidential reports of six additional cataract surgery incidents that met its definition of a reportable "major incident" but were not reported as SREs; QPSD at BORIM de-identified and summarized the information from the confidential reports for the Betsy Lehman Center. The Center also reviewed SRE data from 2011-2013, which contain reports of an additional 12 cataract surgery events. The SRE data are summarized in Table 1.

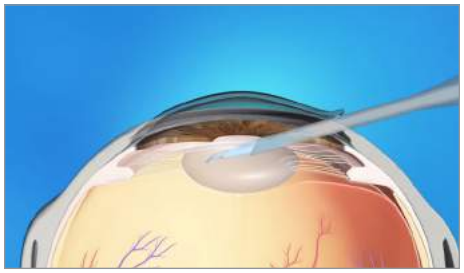
Table 1. Cataract surgery "never events" reported as SREs to the Massachusetts Department of Public Health in 2011-15

Event type	Number 2011-15 (2014-15)
Wrong lens implanted	15 (7)
Surgery on wrong patient	1 (1)
Surgery on wrong eye	1 (0)
Wrong eye anesthetized	5 (3)
Nerve block causing loss of vision	5 (5)
Other	1 (0)
TOTAL	**28 (16)**

About cataract surgery

A cataract is a clouding of the lens. During surgery, the ophthalmologist replaces the natural eye lens with an artificial one. In most cases, patients receive local anesthesia, either through a nerve block (injection of local anesthetic into the space surrounding the nerves that provide sensation to the eye), or with topical numbing eye drops. Cataract surgery is almost always performed on an outpatient basis. Patients usually make a quick recovery, with little pain and improved vision within a day.

Figure 1. Lens implantation



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Also included in both the DPH and QPSD at BORIM data are several reports of retained foreign objects, infections, and other preventable adverse events. For example, three of the non-SRE cases involved suspected Toxic Anterior Segment Syndrome (TASS), often associated with deficiencies in instrument sterilization. It is worth noting that although there were no recent Massachusetts reports of medication error in cataract surgery, improper eye blocks involving the wrong type or concentration of anesthetic have been reported elsewhere.[12]

While data from these state-mandated reporting systems offer a window into the types of preventable harm events that are occurring in Massachusetts, they do not answer the question of how often these events take place. Data on incidence are limited for several reasons. It is well-established that adverse events are under-reported throughout medical practice, not primarily from intentional noncompliance but because providers often fail to detect the adverse events that are happening within their own practices.[13] And because state reporting systems are mainly designed to capture only the most serious incidents, many events involving preventable harm are not reportable at all. On that note, it is not clear whether the surge in SREs reported in 2014-15 reflects an increase in errors or simply better detection and reporting.

In addition to state mandated reporting systems, several national organizations maintain databases of voluntary reports of adverse events in which cataract surgery data can be found. Given that reporting to these systems is entirely optional, and that many facilities do not report data to them at all, they too are of limited value for establishing a more precise adverse event rate for cataract surgery—but much more informative as to the types of errors and serious complications that are happening nationwide. These data resources—including the ASC Quality Collaboration[14] and the Anesthesia Quality Institute's National Anesthesia Clinical Outcomes Registry[15]—strongly suggest that the types of adverse events that facilities have reported in Massachusetts are no different than those occurring throughout the country.

The bottom line is that reporting deficiencies and other data limitations make it impossible to precisely define the magnitude of preventable harm in cataract surgery. But two points are clear. First, even using conservative estimates, the high number of cataract surgeries means that unacceptably large numbers of patients are being harmed. Second, these risks of harm are not unique to the facilities that demonstrated vigilance in detecting and responsibility in reporting adverse events to the state. Indeed, there is good reason to believe that the errors they reported could have happened at many other facilities where cataract surgery is performed.

> *"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*

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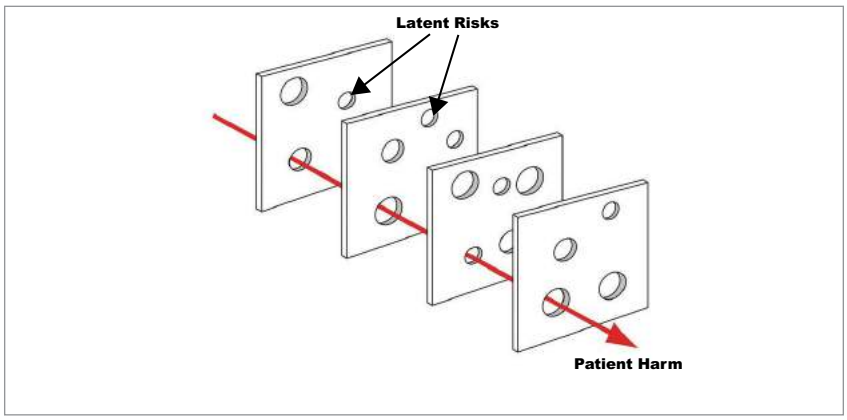
ii. How do cataract surgeons perceive the risk?

In a dozen key informant interviews, Massachusetts cataract surgeons say they worry more about complications from cataract procedures than they do about "never event" types of errors. In particular, surgeons cited infections, retinal detachment, patients' medical conditions that might lead to cardiac events, and allergic reactions as more likely to "keep them up at night" than errors such as wrong side surgeries or implanting the wrong intraocular lens. Three of 12 surgeons also said they worry about patients' satisfaction with their surgical outcomes. Errors were cited as secondary concerns, and only six surgeons mentioned concerns about errors at all.

> *"It's a little like a whack-a-mole. When you think you have it all under control, then something else comes up. It almost seems like there's an infinite number of ways to make mistakes."*
>
> *- Ophthalmologist at a hospital*

Figure 2. Reason's Swiss cheese model of systems failure



"The Swiss cheese model of accident causation" by Davidmack (March, 2014) is licensed under CC BY-SA 3.0 and was modified by the Betsy Lehman Center (2016). Original source for illustration: Reason, J. (2000) "Human error: models and management." British Medical Journal 320 (7237): 768-770.

These views are understandable. Medical complications are more common than preventable harm events. And the high volume/low risk nature of cataract surgery makes it particularly susceptible to errors from "latent" risks—systemic hazards that lie beneath the surface and lead to a false sense of security that is reinforced when surgeons and the rest of the care team do the same thing over and over again without apparent incident.

These attitudes point to the broader need for increased awareness of the latent risks associated with cataract surgery. Because human error is a fact of life, high reliability systems must be put in place to prevent the known mistakes and to "catch" the unpredicted ones that are inevitable before patients are harmed. The iconic illustration of this point is James Reason's 'Swiss cheese model' which demonstrates the holes in every system—and the need to take steps to plug these holes to prevent them from aligning and causing patient harm.

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C. The meaning of "harm" in cataract surgery

In discussions with stakeholders and in several of the SRE reports to DPH, a common theme was that "the patient was not harmed" by errors such as a wrong lens implant. The apparent suggestion is that the patient suffered no harm if he or she ends up with good vision after a subsequent corrective surgery.

Figure 3: Incident narrative from a Massachusetts SRE report

Patient was consented for right eye cataract surgery. The patient was admitted prepped for surgery and eye drops were put in the right eye. The patient was se the left eye was inadvertently blocked. No harm was done to the patient. The p

SRE Attestation

Excerpt of a Serious Reportable Event report submitted via the Massachusetts Health Care Facility Reporting System (HCFRS). Printed with permission from the Massachusetts Department of Public Health (2016).

So what constitutes harm in the context of an adverse event in cataract surgery?

There should be no question that patients who experience any unexpected outcome as the result of an error during their surgery have indeed been harmed, regardless of the ultimate result. Harm in these instances may include the considerable stress and inconvenience of a repeat or delayed surgery. It may also entail emotional distress and distrust, particularly if provider communications about the error are not timely, clear, and conducted with sensitivity and respect. A patient who has undergone a procedure on the wrong eye—or a surgery intended for a different patient—could be deeply unsettled by that realization. And if the patient has suffered long-lasting or irreversible harm such as loss of vision, the harm may, of course, be devastating.

Patients and their families are not the only ones who suffer in the wake of a serious harm event. The doctors, nurses, and staff are likely to be affected as well. This strong theme ran through the Betsy Lehman Center's conversations with staff at facilities that had experienced an adverse event: because no one goes into health care to hurt patients, when something goes wrong, it is deeply disturbing to the entire care team.

"For the patient, that's not right. You have to go back and get another procedure. It's a big deal."

- Circulating nurse at a hospital-affiliated surgery center

* * *

"I think every one of us understands how precious your vision is. For any patient to even have the chance of not having an excellent outcome…it all hits us very personally."

- Nurse administrator at an ambulatory surgery center

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III. Findings and recommendations

From both the Massachusetts adverse event data and the literature, the panel identified four predominant risks associated with preventable harm in cataract surgery:

1. Implantation of an intraocular lens not intended for the patient
2. Surgery on the wrong patient (or wrong procedure on the patient)
3. Surgery or anesthesia on the wrong eye
4. Other injuries related to anesthesia

For each of these four categories, the panel developed findings as to the key causes or contributors, as well as specific recommendations for reducing the risk of harm. Many of the adverse events can be traced to the same contributing factors, most notably the lack of an effective time-out: a multistep process to prevent wrong patient/wrong procedure/wrong site surgery that includes active verification of information by all members of the surgical team, is initiated by a designated team member, and prevents the start of a planned procedure if any team member expresses concerns. The panel therefore offers crosscutting recommendations calling for more robust time-outs at all stages in a cataract surgery to catch errors before patients are harmed.

Guiding principles

The following principles underlie the panel's recommendations, which are:

- **Evidence-based**, grounded in robust, published evidence to the extent possible; but recognizing that qualitative expert opinion, the collective experiences of the panel's members, and reasonable judgment can be brought to bear to recommend sensible steps for ensuring safer care for cataract patients
- **Reflective of established clinical and safety guidelines**, so that they reinforce and build from—rather than reinvent—existing protocols
- **Patient-centered**, promoting the delivery of care that is "respectful of and responsive to individual patient preferences, needs, and values"[16]
- **Broadly targeted** to the wide range of staff who play a role in the process—surgeons, anesthesiologists, nurses, technicians, administrators, office staff, and front desk staff—with the understanding that real impact will be achieved only if everyone contributes to the safety of complex health care systems

"It's horrifying, and it scars you forever. I can tell you where it was, what time it was, who I was with [when I was informed of the error]."

- Operating room nurse at a hospital

* * *

"We're a great place! We do things as a team. We do things to the letter… I want to just erase that blemish, you know…it kind of just sullies our whole name. We all have a level of pride that we do our job and we do our job well."

- Nurse administrator at an ambulatory surgery center

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- **Actionable,** accompanied by model protocols and tools when possible to facilitate their adoption
- **Grounded in the core principles of patient safety,** which recognize the fundamental importance of patient safety culture and applies safety science methods to achieve high reliability systems with the ultimate goal of eliminating harm

Most of the panel's recommendations are not new, and neither are the persistent risks that they address. On the contrary, the recommendations are drawn from evidence-based best practices previously published by other leading authorities such the Joint Commission, the American Academy of Ophthalmology, the Pennsylvania Patient Safety Authority, and the Veterans Health Administration. As is true across medical practice in Massachusetts and elsewhere, **the adoption of best practices to avoid harm in cataract surgery has lagged behind the knowledge of what can be done—and what is being done successfully in some practice settings.**

The specific recommendations that follow should not be read as a mandate for all providers to adopt the same approach or to apply every best practice strategy referenced. **Instead, the "call to action" is for the leadership, clinicians, and staff at each facility to be aware of the risks identified in this report and to engage in an internal process to take stock of their current safety programs in order to:**

1. **Assess** how well their systems are designed to detect and prevent the types of errors that have been reported in Massachusetts
2. **Implement** evidence-based strategies best suited to their particular facility to fill any gaps
3. **Standardize**—and adhere to—certain critical processes in order to achieve safe and reliable care
4. **Continuously reassess** their systems, knowing that despite best efforts and successes, threats to safety can re-emerge after they have been "solved"

It is not possible to overstate the importance of safety culture in developing safe and reliable systems to prevent patient harm. Although everyone has a role to play, safety culture will not take root in the absence of strong leadership and support from the top.[17, 18]

Safety culture is paramount

Human error won't go away. Because most medical errors are caused by 'bad systems, not bad people,' systems must be built to be highly reliable: to prevent injury in settings where mistakes can be expected due to complexity and ever-present hidden risks.

Yet even the best-engineered systems will fail unless an organization has a strong culture of safety.

Such organizations are committed to eliminating preventable patient harm by:

- Establishing patient safety as the top priority
- Fostering a sense of teamwork and encouraging all staff to speak up when they see a problem
- Promoting a "just culture" in which everyone is accountable for adhering to policies, but individuals who make or report mistakes are not punished
- Learning from mistakes and implementing corrective action plans

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WRONG LENS, WRONG EYE, WRONG PATIENT: FINDINGS AND RECOMMENDATIONS

RISK 1 Implantation of the wrong lens

Implantation of an intraocular lens (IOL) not intended for the patient represents more than half of all cataract-related SREs reported in Massachusetts since 2011. Other national and international data sources[19] and most of the published literature on errors in cataract surgery are consistent, making wrong IOLs the most common error in cataract surgery. A patient who receives an implant of the wrong power, type, or size usually must return for corrective surgery to replace that lens with the correct one.

Getting the right lens to the right patient involves a complex multistep process that begins with biometry in the physician's office, continues through the transmission of a lens order from the office to the surgical facility and retrieval of the lens by facility staff, and ends when the surgeon implants the lens in the operating room. Mistakes can happen at multiple points along the way and for many different reasons, as outlined below.

KEY CONTRIBUTING FACTORS

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 schedules, 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 had so many different order sheets is the problem. We had a calculation sheet coming from this office and another one coming from a different office. They all look different. They've been faxed and photocopied multiple times."*
>
> *- Ophthalmologist at a hospital*

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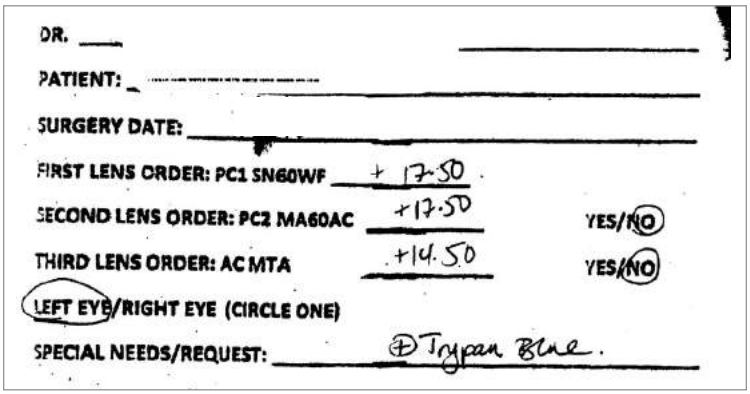
RECOMMENDATION Institute a formal lens management policy

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

1. **Lens orders.** Set clear standards for lens orders. *Hand-written lens order forms from medical offices are a known hazard.* One solution is for facilities to insist that offices submit typed or electronic forms. As demonstrated in Figure 4, handwriting will always be subject to misinterpretation.

Figure 4. Does this order form call for a +12.50 or a +17.50 lens?


OR. ____

PATIENT: ____

SURGERY DATE: ____

FIRST LENS ORDER: PC1 SN60WF + 17.50

SECOND LENS ORDER: PC2 MA60AC +17.50 YES/NO

THIRD LENS ORDER: AC MTA +14.50 YES/NO

LEFT EYE/RIGHT EYE (CIRCLE ONE)

SPECIAL NEEDS/REQUEST: + Trypan Blue.

In this 2015 SRE, a patient went home with a +12.50 lens instead of the +17.50 lens that the surgeon had ordered.
Reprinted with permission from the Massachusetts Department of Public Health (2016).

2. **Storage.** Store lenses in a separate space *outside* the operating room. Only the lens or lenses for the current patient should be present in the OR. Assess inventory management systems for avoiding confusion between diopters and lens types, and restructure as necessary.

3. **Lens retrieval.** Adopt a clear process for when, how, and by whom lenses are pulled from the storage space. While there is no one-size-fits-all solution, one approach to consider is designating a few select staff as the only individuals permitted to select lenses and place them with the patient chart. Pulling lenses the day before surgery offers more time to respond to discrepancies or missing information.

4. **Lens verification.** Implement a team-systems approach to lens verification with clear procedures under which multiple people (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. At a minimum, these points include: when the lens is pulled from the storage closet; when the operating room is prepared for the patient; and during surgery, immediately before lens enters the sterile field. For

> *"We were all confident that what was on that paper was the lens we had, because it was pretty clearly written. It doesn't look scribbly. We were shocked [the surgeon] ordered the wrong lens. We've seen pretty bad handwriting."*
>
> *- Circulating nurse at a hospital-affiliated surgery center*

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each point, specify which source documents (e.g., patient chart, original calculation sheet, surgeon's IOL order form, surgical print-out) should be present, which information (e.g., eye size, lens model, lens power) should be verified against the lens packaging, and which staff should verbally participate in and document the verification.

RISK 2 Surgery or anesthesia on the wrong eye

Surgery on the wrong eye

All surgical procedures on symmetric and paired organs and tissue carry the risk that surgery will be performed on the wrong side—in the case of cataract surgery, on the wrong eye. Loss of attention, even for an instant, is a common occurrence given the many disruptions that happen in a pre-op area or operating room, and can lead to wrong side surgery. Wrong side procedures usually require patients to undergo additional corrective surgery.

Anesthesia on the wrong eye

Wrong side anesthesia—the administration of a nerve block to the wrong eye—was the second most common error reported to the state. These errors typically require the patient to return another day for surgery. The literature also notes cases in which wrong side anesthesia led to wrong side surgery.

KEY CONTRIBUTING FACTORS

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

> *"We basically had to shove the lens in [the surgeon's] face to make her read it. And she would just say, "Yeah, yeah, yeah," and that's just how she always was."*
>
> *- Surgical technician at a hospital-affiliated surgery center*

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RECOMMENDATIONS Adopt a uniform, facility-wide policy for marking the operative eye, and perform a separate time-out prior to a nerve block

1. **Surgical marking.** Effective surgical site marking is detailed in protocols from such authorities as the American Academy of Ophthalmology[20] and the Joint Commission.[21] These protocols universally advise that:

   - The surgical site should be unambiguously marked using a consistent and "sufficiently permanent" mechanism
   - The mark should be placed on an area that will still be visible after prepping and draping
   - The patient should be actively involved in identifying the site before anesthesia is administered

   While there are currently no studies to confirm whether eye shields reduce wrong side errors, some facilities require staff to place clear plastic eye shields over the non-operative eye prior to the initial time-out, sedation, and eye block (when applicable).

   A number of resources for preventing wrong-site surgery, including self-assessment checklists and auditing tools, are available from the Pennsylvania Patient Safety Authority, which has observed a decline in reports of wrong side eye injections over the last decade.[22]

2. **Nerve block time-out.** Perform a *separate* time-out prior to administering nerve blocks outside the operating room. See the crosscutting recommendation below for more information on effective time-outs.

> *"We have approximately [20] cataract surgeons here who do the same thing differently."*
>
> *- Nurse at an ambulatory surgery center*
>
> * * *
>
> *"Often times, things would happen because there was some unusual event that occurred that morning, that day, or in the middle of surgery. And we didn't really have a system or a standardized way of dealing with that unexpected event."*
>
> *- Risk manager at a hospital*

RISK 3 Wrong-patient surgery

Both surgery on a misidentified patient and surgical procedures intended for a different patient on a correctly-identified patient are included here. Patient misidentification can happen at virtually any point in the process: when a patient is called from the waiting room; when the patient is transferred from the anesthesia holding area to the operating room; and finally in the operating room if the patient record does not match the patient in the room.

Misidentification mistakes that are not caught may result in irreversible injury to the patient, and they often require the patient to return for corrective surgery. Unnecessary procedures always subject patients to additional risk of complications and other harm.

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In a study of national malpractice claims and other data reported to the state of New York, nearly eight percent of adverse events in cataract surgery involved wrong patient/wrong procedure errors.[23] In Massachusetts, one SRE involving wrong patient cataract surgery was reported in 2015. In recognition of the persistent problem of wrong patient procedures throughout medicine, the Joint Commission has made improving the accuracy of patient identification its "Patient Safety Goal 1" for 2016.[24]

KEY CONTRIBUTING FACTORS:

1. Failure to communicate with the patient
2. Insufficient active verification of more than one patient identifier
3. Presence of more than one patient chart in pre-operative area or operating room
4. Inadequate time-out, or lapse between when time-out occurs and when procedure begins

RECOMMENDATION Use at least two ways to identify a patient… and repeat

1. **Multiple patient identifiers.** The Joint Commission recommends using at least two patient identifiers at each stage of the procedure. Effective identifiers include both the individual's name and a number such as date of birth or medical record number.
2. **Active identification.** Patients who have hearing loss, cognitive difficulties, or simple anxiety may mistakenly confirm their names or their procedures when passive identification is used ("Are you Jane Jones?"). Active identification ("What is your name?") is more effective at preventing misidentification.
3. **Patient engagement.** Talk to patients or their representatives as part of the identification protocol, explaining the need for medical and administrative staff to ask them the same questions repeatedly.

"The surgeon would come in and say, 'I have to be out of here by noon, so let's get going.' And I was like, 'One piece at a time, slow down!'"

- Operating room nurse at a hospital-affiliated surgery center

* * *

"Sometimes you would have…a policy that was good and approved and there would be a breakdown.… It wasn't because the policy wasn't right, it was that…someone would get distracted and wouldn't follow the policy."

-Ophthalmologist at a hospital

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RISKS 1-3 Shared contributors

The first three risk areas—wrong lens, wrong patient, wrong eye—share common contributing factors that cut across all provider types, settings, and steps in a cataract procedure. These include:

1. Time-pressured environment
2. Inadequate communication
3. Lack of close adherence to policies, particularly time-out procedures

CROSS-CUTTING RECOMMENDATION Perform robust time-outs with at least two care team members before *every* key step in the procedure

The concept of time-outs is far from new. All facilities in Massachusetts practice time-outs to some degree in the course of cataract surgery. But the quality of time-outs varies across facilities, and those performed inadequately—or not at all—can result in serious patient harm.

Time-outs work because they force a collective pause in the action. In the fast-moving atmosphere of a surgical facility, many moving parts have to fall into place perfectly time and again each day, despite such challenges as cancelled or out-of-order cases and on-the-spot changes to lens selection. Strong time-out practices are likely to catch a wrong lens or a surgery about to be performed on the wrong eye or wrong patient before harm ensues.

Among other points, effective time-out practices should address:

1. ***Who* is involved?** Each time-out should involve all care team members present at the time, as well as the patient when possible. Time-outs should always include at least two team members with different credentials and roles. For instance, if anesthesia is administered in a holding area outside of the operating room, the clinician administering the anesthesia should be joined by an additional staff member.
2. ***When* in the process?** At three distinct points:
   - Upon patient arrival to the pre-op area (nurse and technician confirm patient, operative eye, procedure)
   - Immediately prior to a nerve block (nurse or technician and anesthesia provider confirm patient, eye)
   - Immediately prior to the surgical start (nurse, surgeon and anesthesia provider confirm patient, eye, procedure, lens style and power)

> *"It's a lot of pressure to keep yourself on the ball every single second of an 8- hour day and do it fast, do it correctly and do it right every single time…And for the most part, we do work very quickly and efficiently and then you see something like this come up and you say 'wow'. What is that a result of? A little bit too fast?"*
>
> *- Circulating nurse at a hospital-affiliated surgery center*
>
> ***
>
> *"Make sure you stop, don't be afraid [to say], 'Everybody just stop what you are doing,' because it is very serious. It will make a difference."*
>
> *- Nurse at an ambulatory surgery center*

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3. ***How* performed?**
   - *As a team*, using *pause points* where the whole team is present and focused on the question at hand
   - With *active* verification rather than passive questioning to avoid confirmation bias
   - *Uniformly* for all surgeries at the facility, regardless of the particular physician performing the block or surgery
   - In a manner in which every team member (medical student, technician, nurse, physician) *feels empowered* to call a "hard stop" to the time-out when they suspect something may be wrong, knowing that their concerns will be taken seriously regardless of whether they are well-founded

> *"Even if it was one patient, it would have been upsetting. But five? Five in one day? It was hard to wrap your head around that. How did this happen?"*
>
> *- Nurse at an ambulatory surgery center*

INJURIES RELATED TO ANESTHESIA: FINDINGS AND RECOMMENDATIONS

RISK 4 Anesthesia choice and administration

In addition to anesthesia injections to the wrong eye as discussed above, the Massachusetts data contain numerous reports of injuries stemming from both improper nerve block technique and the inherent risks of retrobulbar and peribulbar blocks. Among the SREs reported to DPH in 2014 are 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.* Confidential reports to QPSD at BORIM also include five additional reports of complications related to retrobulbar and peribulbar blocks: two cases of retrobulbar hemorrhage or hematoma, and three cases of systemic reactions including bradycardia, hypotension, and unresponsiveness.

Although the risk of an anesthesia-related error or serious complication is small in any given case, the large volume of cataract surgeries means that even small risks can translate into large numbers of patients harmed at the population level. And when a catastrophic outcome strikes, the fact that the overall risk is small or that the harm arose from an inherent risk of the procedure is of little consolation to patients and providers.

* In describing these incidents, the Betsy Lehman Center and the panel have relied exclusively upon information reported by the facilities in their SRE submissions to DPH. The Center did not conduct independent investigations or develop its own findings or conclusions.

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The safety profiles of eye anesthesia techniques

What do the data show about anesthesia practices, patient preferences, and the relative benefits and risks?

Until about 25 years ago, retrobulbar nerve block administered by a surgeon was the predominant form of anesthesia worldwide.[25, 26, 27] Since then, several other options—including less invasive techniques—have become available and more widely used. Another significant practice change relates to who is responsible for administering and monitoring the anesthesia. Many cataract surgeons now rely upon anesthesiologists and certified registered nurse anesthetists (CRNAs) for these purposes. It is worth noting that while all ophthalmologists are trained in eye anesthesia, including nerve blocks, during their residencies, such training is not a required part of an anesthesiology residency.[28] Many anesthesiologists who perform eye anesthesia learn how to perform blocks through training or experience outside of a formal residency program.

The five major anesthesia techniques currently used in cataract surgery in Massachusetts, along with their relative benefits, limitations, and risks as documented in the literature, are presented in Table 2.

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Table 2. Cataract surgery anesthesia techniques and their documented patient safety profiles from lowest to highest risk

Compiled by Betsy Lehman Center Expert Panel

Technique	Benefits	Limitations and Risks
1. Topical Anesthetic *Drops, pledgets, or jelly*	• Pain-free administration • Most cost and time efficient (can be administered by a nurse) • Shortest duration of action • Patients have useful vision immediately after procedure[29] • Lowest risk of sight-threatening complications [30-35] and very low risk of any other complications if minimal or no sedation is used	• Short lasting, so less appropriate for longer or complex cases • Eye is not immobilized, so patient must be able to follow instructions and look straight ahead during procedure • Patients may perceive visual phenomena[36] • Some patients may require additional intracameral local injection or sedation to be comfortable[37]
2. Sub-Tenon's Block *Injection using blunt irrigation cannula to deliver anesthetic into sub-Tenon's space*	• Performed with direct visualization • Likely lower risk of sight-threatening complications as compared to sharp-needle blocks[38-40]	• Likely to require slightly more time to administer preoperatively than sharp-needle blocks • More chemosis[41] and minor conjunctival bleeding[42] than other block techniques • Sedation may be required • In the U.S., has not been widely adopted for cataract surgery
3. Peribulbar Block *Sharp needle extraconal injection*	• Temporarily immobilizes eye and often blocks vision[43] • Provides complete anesthesia • Shorter needles (≤1.25 inch) lower risk of severe systemic and sight-threatening complications.[44-46] Needle insertion into the extraconal space likely lowers risk of globe perforation for patients with long axial length[47, 48]	• Blind injection technique • Greater risk of sight-threatening complications compared to topical drops or sub-Tenon's block [49, 50] • Compared to retrobulbar block: - Requires higher volume of anesthetic - Slightly longer wait time to be effective [51] - Increased incidence of chemosis [52] • Frequently combined with sedation
4. Retrobulbar Block *Sharp needle intraconal injection*	• Similar to peribulbar block, temporarily immobilizes eye and often blocks vision • Provides complete anesthesia • Shortest wait time to be effective	• Blind injection technique • Greater risk of sight- threatening complications as compared to topical drops or sub-Tenon's block [53, 54] • Greater risk of globe perforation for patients with long axial length or recessed eyes [55, 56] • Longer needles (typically 1.5 inch) and injection into the intraconal space increases risk of: - Cerebral spinal fluid spread[57, 58] of local anesthesia causing brainstem anesthesia and retrobulbar hemorrhage - Postoperative strabismus from extraocular muscle injury[59-61] - Optic nerve injury[62, 63] • Frequently combined with sedation
5. General Anesthesia	• Immobilizes patients who cannot lie still during cataract surgery • Reduced risk of sight-threatening complications from anesthesia	• Much higher incidence of postoperative nausea and vomiting,[64] and transient altered mental status • Small risk of more serious complications such as cardiovascular or respiratory events

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Malpractice liability and eye blocks

In addition to the clinical risks of retrobulbar and peribulbar blocks identified in the literature, injuries associated with eye blocks are a primary source of eye surgery-related malpractice litigation for anesthesiologists. Published analyses of the American Society of Anesthesiologists Closed Claims Database indicate that performing ocular nerve blocks changes the malpractice liability profile of anesthesiologists, with more permanent injuries and payment than sedation-only claims.[65] This is not surprising given that a separate analysis of the database reveals that in most cataract surgery malpractice claims against anesthesiologists who performed eye blocks, the patients experienced vision loss.[66] Inadequate informed consent is another contributor to anesthesia-associated malpractice claims in cataract surgery. CRICO (malpractice carrier for Harvard affiliates) queried its Comparative Benchmarking System, a national database representing more than 500 organizations and 350,000 malpractice claims, for closed claims related to cataract surgery between 2010 and 2014. Specifically looking at anesthesia-related issues in cataract surgery, communication was identified in 40 percent of claims as a contributing factor, including inadequate informed consent for procedures and inadequate consent for other treatment options.[67]

> *"I've been here 20 years, and I've never heard of anything like that happening. That's a good long time, and a good many eye blocks."*
>
> *- Staff member at an ambulatory surgery center*

Comparing topical anesthesia to blocks

Despite the lower risk profile of topical anesthesia, some physicians express concerns that topical drops may allow for more eye movement during the operation, possibly leading to other injuries, and that patients may also experience more discomfort during and after surgery with this form of anesthesia.

A large British study demonstrated that the great majority of patients having cataract surgery under topical or topical with intracameral local anesthesia did not require additional sedation, and patients having topical anesthesia had significantly lower rates of both sight threatening and potentially life threatening complication than those having needle blocks.[68] Earlier this year, a large study of 21,501 office-based cataract surgeries in which most patients received only oral sedation and topical drops (with or without intracameral lidocaine) found complication rates similar to, or lower than, those reported in other recent studies of cataract surgery.[69] Finally, a 2012 meta-analysis demonstrated the majority of patients preferred topical over block anesthesia for cataract surgery.[70]

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Patient preference for topical drops is frequently driven by anxiety over needle injections and the faster recovery time associated with topical drops. This preference holds despite higher levels of patient-reported pain during and immediately following surgery with topical anesthesia.[71]

Additionally, research shows that preparing patients beforehand to expect visual sensations during surgery significantly helps to decrease any fear that may be associated with intraoperative visual perceptions under topical anesthesia.[72, 73] Overall, these study findings on patient acceptance of topical anesthesia are consistent with the anecdotal conclusions of some Massachusetts surgeons, one of whom commented in a survey response that he or she had started using topical anesthesia over 20 years ago by "doing one eye blocked and the second eye topical and asking patients which they preferred," with "results heavily weighted toward topical." [74]

Cataract anesthesia practices in Massachusetts today

The surveys of Massachusetts facilities and cataract surgeons[75] and in-depth surgeon interviews, conducted by the Betsy Lehman Center and its partners, reveal wide variation in anesthesia practice and preferences:

1. While Massachusetts cataract surgeons say they use blocks less frequently than they did 10 years ago, nearly half still use blocks in 75 percent or more of their surgeries (accounting for about one-third of all cataract surgeries in Massachusetts)
2. Cataract surgeons who prefer eye blocks most often cite the fact that blocks are long-lasting and well-suited to complex cases
3. Surgeons who prefer topical drops most often cite reasons related to patient safety and lower risk of complications
4. Intravenous sedation is used in almost all cataract surgeries in Massachusetts, regardless of the type of eye anesthesia used
5. Most patients are not offered more than one anesthesia option, even when alternatives are mentioned during the consent process (only about 20 percent of surgeons say they "always" or "often" offer their patients a choice)
6. Several surgeons who do not administer their own anesthesia also commented that they defer to the preferences and skills of the anesthesiology staff at a given facility

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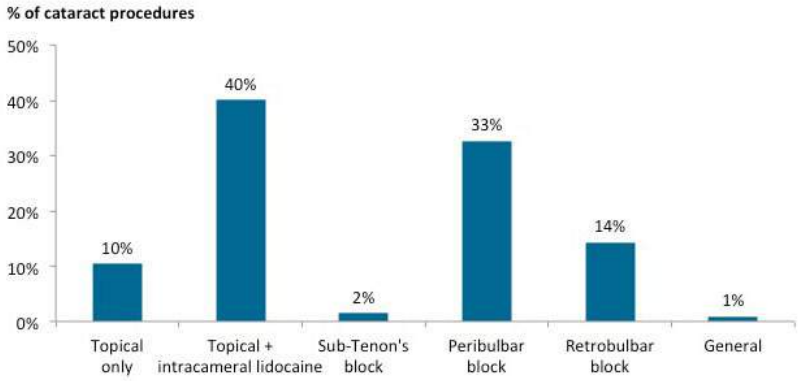
Figure 5. Proportions of cataract procedures performed by survey respondents by anesthesia type



Betsy Lehman Center/Massachusetts Society of Eye Physicians and Surgeons survey of Massachusetts cataract surgeons (2016), N=91 surgeons.

These findings suggest that cataract surgery anesthesia practices in Massachusetts are trending in the same direction as practices in other states—that is, toward greater use of topical drops and away from blocks, retrobulbar in particular. But the data also show that the shift to topical anesthesia may have moved at a slower pace in Massachusetts than at the national level.[76]

It is not clear how intravenous sedation practices in Massachusetts compare to other states. The large study of office-based cataract surgery referenced above does indicate that cataract surgery is now being performed in at least some locations without intravenous sedation.[77]

More information and in-depth analysis of the Massachusetts survey results and interviews can be found on the Betsy Lehman Center's website.

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RECOMMENDATIONS

1. Use the least invasive form of anesthesia appropriate to the case

Despite the relative safety of all types of anesthesia in cataract surgery, any opportunity to reduce the risks of patient harm deserves serious consideration. Toward that end, 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 (for instance, the participation of residents in training). Specifically, the panel recommends the following:

- **For non-complicated cases**, cataract surgeons and anesthesiologists should consider topical anesthesia as a first choice
- **For more complex or longer surgeries**, block injections are an effective and usually safe technique. In these cases, care teams should:
  - Follow the recommendations below for assuring the proper training, credentialing, and orientation of physicians involved in administering blocks
  - Consider using peribulbar over retrobulbar blocks
  - Use needles ≤1.25 inch (31mm) in length to lower the risk of sight-threatening injuries from block injections

2. Seek and apply evidence-based strategies for minimizing the risk of patient harm from anesthesia

The difficulties of moving medical research into practice are longstanding and extend across all of medicine. **Clinical practice at any given facility is more likely to change after a serious incident, when perceptions of what constitutes a tolerably "small" risk may change as well.**

Most clinicians are comfortable with their current practices, and believe that these approaches are serving their patients well. But it is incumbent upon all cataract surgeons and anesthesiologists, whether or not they have experienced a serious incident, to periodically reassess their clinical practices and adopt evidence-based strategies for reducing the risk of patient harm associated with cataract anesthesia and sedation.

> *"[Patients] are all special. They all deserve the best care. And it's what we always want to give them."*
>
> *- Nurse at an ambulatory surgery center*

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3. Engage patients in decisions about anesthesia and sedation

Informed consent is a process that leads to a mutually acceptable decision between a patient and his or her physician. Under Massachusetts law, physicians must present all options, and their associated risks and benefits, about which a reasonable patient would want to know. A discussion of the different anesthesia techniques should therefore be part of the informed consent process in cataract surgery given the significant differences and tradeoffs among the various topical and block techniques.[78] The information presented should include not only the relative clinical risks but also information about patient experience in terms of pain, discomfort, level of consciousness, visual effects, and complications.[79] This discussion between patient and surgeon should take place before the day of surgery. If an anesthesiologist is involved, an anesthesia consent should also be signed before the procedure takes place.

Ideally, the informed consent process is viewed as a conversation—not merely the recitation of pieces of information—during which the cataract surgeon takes into account the individual patient's expressed need for a particular level of information and provides the patient with the support necessary to use the information to make choices based on his or her own preferences and values. By sharing the decision-making in this way, the physician and the patient arrive jointly at a determination of what best meets the patient's preferences as informed by the surgeon's professional judgment.

> *"When you get a small group together to discuss how, what, and where ...they get to realize that they are working together as a group to correct the issue to prevent it from happening to somebody else."*
>
> *- Nurse director at a hospital-affiliated surgery center*

4. Strengthen "onboarding" of new, contracted and *locum tenens* anesthesia staff

a. Prioritize credentialing of anesthesia staff

It is incumbent on facilities to ensure that physicians performing eye blocks have proof of appropriate credentials, training, and skills. Extra vigilance may be needed when bringing contracted anesthesiologists to a facility for the first time. Agents that provide anesthesiologists to surgical centers are equally responsible for confirming and documenting that the physicians under their purview have sufficient training and expertise to perform eye blocks.

With the exception of facilities that have the capacity to teach eye block technique, such as teaching hospitals, facilities should ensure that any anesthesiologist brought in to perform blocks has completed a didactic training course in eye blocks, either during or after

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residency, and has experience of successful practice, as determined by reference checks with facilities where he or she has performed blocks previously. In the case of a practitioner who has not completed a course, but who has been practicing blocks for many years, credentialing may be accomplished through thorough reference checks with facilities where that person has practiced recently.

National accrediting bodies such as the Joint Commission and the Accreditation Association for Ambulatory Health Care[80] already require that facilities have written credentialing policies in place, and most do. But facilities may approach the process with varying levels of experience and vigor.

The panel recommends that all Massachusetts facilities review their credentialing policies to ensure that they:

1. Define clear internal assessment criteria
2. Use standardized reference questions developed with input from staff at all levels of the facility
3. Promote due diligence by engaging at least one cataract surgeon in the qualifications assessment who can ask informed questions

b. Formalize the orientation of new clinicians, including temporary and *locum tenens* staff

Locum tenens (temporary) and other contracted anesthesiologists and CRNAs are frequently used to staff cataract surgeries at ambulatory surgery centers. Larger hospitals that employ anesthesia staff also turn to contract medical staff for temporary coverage when needed. Problems can arise when these clinicians begin practicing in an unfamiliar environment without adequate orientation.

Facilities should institute a formal orientation policy for all anesthesia staff who are new to the facility. This process should specify what new clinicians should understand before providing care at the facility and who on staff is responsible for ensuring they understand it. At a minimum, the process should cover team introductions and a review of the facility's process flow from patient check-in to discharge—including the points at which time-outs must occur. The facility's orientation policy should include a contingency process for "last minute" circumstances—for instance, when a *locum tenens* anesthesiologist is filling in on short notice and a full orientation is not possible. In those situations, the facility might assign an established care team member to provide additional support to the temporary anesthesiologist or CRNA.

> *"We designed [a process] and it wasn't until we started using it that we realized there were certain aspects that were silly… we had to go back and redesign it."*
>
> *- Ophthalmologist at a hospital*

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c. Implement an observed eye block assessment policy for anesthesiologists who are new to the facility

Facilities should have policies in place to assess the ability of anesthesiologists to safely administer eye blocks before they are permitted to perform those blocks independently. A surgeon or anesthesiologist experienced in performing eye blocks should observe and modify, if necessary, block technique during the performance of an anesthesiologist's initial blocks at the facility until both parties are satisfied that he or she can perform blocks safely and effectively in that particular practice setting.

How many blocks should be observed to verify an anesthesiologist's competence at these techniques? The panel did not find strong evidence in the literature to support a recommendation for any specific minimum number. Yet panelists' conversations with state and national experts suggest that a reasonable range does exist, with the great majority of these experts expressing comfort with "sign off" on new staff after observing about 10 blocks.

> *"Nobody likes to admit that a mistake has been made, but once you get over that and you are able to talk about it you can look to see, 'Why did I make that mistake; why did this happen?' And you have other people who are… saying, 'Well it could have been this, or it could have been that.' You've already started your group analysis by just people talking about it and getting it out in the open."*
>
> *- Staff member at a hospital*

IV. Action steps

Human error is inevitable in cataract surgery, but patient harm from those errors is not. The best practice strategies outlined above will work if they are part of a comprehensive patient safety program that has the support of leadership. Ultimately, leadership is accountable for establishing and ensuring a culture of safety and everything that flows from it. Leaders can set the tone by acknowledging that errors happen, and that it is imperative to put systems in place to prevent them from causing harm.

But, as depicted in the infographic included with this report (pp. 3-4), systems failures can occur at any point in the process, and everyone involved in cataract surgery—from administrative staff to nurses and surgeons—plays a role in ensuring safe and reliable care. The following guidance is intended to help everyone with a role in eye surgery ensure that the work they do is as safe as it can possibly be.

A set of tools is available on the Betsy Lehman Center's website to support implementation.

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1. Facility leaders and administrators

- Communicate clearly, in both words and actions, that patient safety is your highest priority.
- Assess and address your facility's safety culture. Start by surveying staff using free tools such as the federal Agency for Healthcare Research and Quality's patient safety culture surveys.
- Review your facility's current systems for recognizing and then mitigating each type of risk identified in this report.
- Convene staff at all levels to establish or advance a patient safety program and to identify and implement specific process improvements that are well-suited to the facility. Leverage the champions among your staff.
- Insist that all physicians and staff adhere to the standardized processes adopted by your facility; these safety protocols should be posted and staff should be actively trained on new processes.
- Audit practices to measure how well policies are being followed and their impact on patient safety. Draw from one or two sources of data, such as observational audits or electronic health records analytics when available. As an example, this audit tool provides some simple evaluation criteria for observing surgical time-outs.
- Evaluate processes periodically to drive continuous improvement; this might be accomplished through periodic meetings of a standing safety work group and/or the addition of a permanent safety program agenda item at governance meetings.
- Be proactive in identifying and responding to new risks. Focus on near misses and on what could go wrong—even if it hasn't yet.
- Revisit your credentialing and orientation processes for new, contracted, or *locum tenens* anesthesiologists who administer nerve blocks to ensure that those anesthesiologists are adequately prepared to safely practice in your facility.
- Listen and ask. Cultivate open and safe communication by encouraging, not penalizing, staff for voicing concerns, openly addressing mistakes as a learning opportunity. When an adverse event does happen, take steps to conduct a meaningful root cause analysis, communicate effectively with the patient and all members of the care team who were involved, and report the incident to the appropriate state agencies, when warranted. The Betsy Lehman Center offers a set of online tools to guide you through these steps.

> *"I think as an organization from an administrative standpoint, we have a responsibility to make sure our front line care givers have a system in place that's not going to fail them."*
>
> *- Hospital administrator*

* * *

> *"There are a lot of steps in the process that can easily be bypassed. You could easily find a workaround, and we don't allow those workarounds anymore."*
>
> *- Hospital administrator*

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2. Cataract surgeons

- Recognize that other care team members look to your leadership to set the tone, so your participation in implementing safety policies and protocols matters.
- Reassess the systems in your own medical office for ensuring successful patient outcomes and preventing harm associated with systems failures.
- Be proactive—ask your facility about what systems it has in place to prevent patient harm, particularly in areas that may not be under your direct control.
- Observe the standardized safety protocols adopted by your facility…even if your preferred protocols are different. Advocate for new policies if you believe the ones in place do not optimize safe care.
- Be aware of how pressured environments can contribute to systems failures and patient harm. Do your part to avoid exacerbating production pressures and to promote good communication and teamwork.
- Ask about the facility's credentialing, training, and orientation processes, if you rely upon anesthesiologists to administer nerve blocks.
- Reassess your anesthesia practices—consider using topical anesthetic drops instead of nerve blocks in uncomplicated cases.

3. Anesthesiologists

- Be aware of the risks associated with nerve blocks—and strategies for mitigating these risks—as identified in this report.
- Reassess the efficacy of your own practices at preventing harm from improper block technique (e.g., globe ruptures, optic nerve or extraocular muscle injuries).
- Assess the efficacy of time-out and other processes at preventing harm from systems failures (e.g., blocks on the wrong eye)—and propose improvements as needed.
- Insist upon adequate orientation when starting to practice in an unfamiliar facility.

"If you have a physician champion like [X], somebody saying that we have a problem and we have to talk about it…it speaks volumes. And I'm not saying that the surgeons won't listen to us, they certainly do, but there has to be a physician involved at a leadership level."

- Operating room nurse at a hospital

* * *

"People are having to give up more and more control as time goes by…you can't just do it 'my way' all the time. The surgeon can't be separate from everybody else doing exactly what he wants to do in his little kingdom–it's not going to exist anymore."

- Ophthalmologist at a hospital

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4. Nurses and other clinical staff

- Be a leader in implementing any standardized processes that the facility adopts.
- Be an advocate for your patients whenever you believe that safety protocols are not being observed, or if a patient safety risk has not been recognized by others on the care team.

5. Nonclinical staff

- Recognize that you play an important role in preventing harm in cataract surgery—for example, by ensuring accuracy in lens ordering and patient identification.
- Ask to participate in your office or facility's patient safety program planning discussions.
- Speak up whenever you believe that a patient safety risk has not been recognized by others on the care team.

6. All clinicians and staff

- Support the advancement of a safety culture at your facility in which a shared commitment to patient safety is the highest priority.
- Be aware of the risks that exist at all stages of the cataract surgery process, as identified in this report.
- Participate in your facility's patient safety program planning process.
- Understand that high reliability and safety are achieved through standardization of processes within a facility—and a commitment to continuous improvement.
- Lead by example by adhering to the processes that your facility adopts.
- Promote "just culture" and transparency—where the objective is to improve systems, not punish individuals who make or disclose mistakes.

7. Patients (and their representatives)

- Discuss lens options with your surgeon and make this decision well in advance of the day of surgery.
- Ask your surgeon about anesthesia options.
- Make sure that you understand all you have discussed, before you sign the informed consent form.
- Speak up—ask a question—if something does not seem right.

"To work in [an ASC or a hospital], you need to communicate.... And you need to speak up for your patient. Because they can't."

- Surgical technician at an ambulatory surgery center

* * *

"You have to seek input from the people doing the work. Ask them, 'What do you think we should do?'...It's important to have input from as many different people as possible."

- Anesthesiologist at a hospital

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V. Conclusion

Recent reports by Massachusetts facilities about adverse events in cataract surgery—while unsettling—triggered a collaborative process to assess the actual risks and to generate awareness and vigilance among physicians, staff, and facilities where cataract surgery is performed. As the findings of the expert panel demonstrate, the risks to cataract surgery patients signaled by the SREs are not new. And most if not all of these adverse events—and the resulting harm—might have been prevented with more advanced, dynamic patient safety programs in place.

Adoption of the best practice recommendations included here is a good start. But truly safe and reliable cataract surgery will depend upon the implementation of strong, comprehensive patient safety programs. As many institutional leaders in patient safety have learned, these programs will thrive only with a top-down commitment to establishing a culture of safety throughout an organization. In this way, much of what can be learned from the Massachusetts cluster of cataract surgery errors translates well to patient safety challenges across most health care specialties and settings.

> *"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."*
>
> *- Hospital administrator*

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