Preventing Adverse Events in Cataract Surgery: Recommendations From a Massachusetts Expert Panel

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Massachusetts health care facilities reported a series of cataract surgery–related adverse events (AEs) to the state in recent years, including 5 globe perforations during eye blocks performed by 1 anesthesiologist in a single day. The Betsy Lehman Center for Patient Safety, a nonregulatory Massachusetts state agency, responded by convening an expert panel of frontline providers, patient safety experts, and patients to recommend strategies for mitigating patient harm during cataract surgery. The purpose of this article is to identify contributing factors to the cataract surgery AEs reported in Massachusetts and present the panel's recommended strategies to prevent them. Data from state-mandated serious reportable event reports were supplemented by online surveys of Massachusetts cataract surgery providers and semistructured interviews with key stakeholders and frontline staff. The panel identified 2 principal categories of contributing factors to the state's cataract surgery–related AEs: systems failures and choice of anesthesia technique. Systems failures included inadequate safety protocols (48.7% of contributing factors), communication challenges (18.4%), insufficient provider training (17.1%), and lack of standardization (15.8%). Choice of anesthesia technique involved the increased relative risk of needle-based eye blocks. The panel's surveys of Massachusetts cataract surgery providers show wide variation in anesthesia practices. While 45.5% of surgeons and 69.6% of facilities reported increased use of topical anesthesia compared to 10 years earlier, needle-based blocks were still used in 47.0% of cataract surgeries performed by surgeon respondents and 40.9% of those performed at respondent facilities. Using a modified Delphi approach, the panel recommended several strategies to prevent AEs during cataract surgery, including performing a distinct time-out with at least 2 care-team members before block administration; implementing standardized, facility-wide safety protocols, including a uniform site-marking policy; strengthening the credentialing and orientation of new, contracted and locum tenens anesthesia staff; ensuring adequate and documented training in block administration for any provider who is new to a facility, including at least 10 supervised blocks before practicing independently; using the least invasive form of anesthesia appropriate to the patient; and finally, adjusting anesthesia practices, including preferred techniques, as evidence-based best practices evolve. Future research should focus on evaluating the impact of these recommendations on patient outcomes. (Anesth Analg 2017;XXX:00–00)

No procedure in medicine is free from error—including procedures as common as cataract surgery. Fortunately, better adverse event (AE) reporting in recent years provides an opportunity to learn from mistakes when they happen. From 2011 to 2015, Massachusetts received 37 reports of serious cataract surgery–related AEs,[1] including 5 globe perforations during eye blocks performed by 1 anesthesiologist in a single day.

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The literature on AEs in eye surgery describes several contributing factors, including insufficient team briefings,[2–4] transcription errors,[3,5–7] and inadequate site markings.[6,8] A 2012 survey of cataract surgeons in the United Kingdom found that only 54% used a checklist to confirm intraocular lens selection.[4] Even with standardized protocols in place, AEs often result from inconsistent adherence to them, including skipped or poorly executed time-outs.[3,5,9,10] A retrospective analysis of 106 AEs during eye surgery found that 86% could have been prevented by conscientious application of standardized preoperative verifications, site markings, and time-outs.[10] Lapses in protocols may stem from factors such as alterations to the surgical schedule[3,7,9,10] and time-pressured environments experienced by many care providers.[3,11]

The goals of anesthetic care for cataract surgery include analgesia of the eye, rapid recovery from anesthesia, and minimizing risk of complication from both surgery and anesthesia. There are several anesthesia techniques described in Supplemental Digital Content 1, Appendix A, http://links.lww.com/AA/C43 that can accomplish these goals, including topical anesthesia, needle-based blocks (peribulbar and retrobulbar), sub-Tenon's block, and general anesthesia. While the overall risk of patient harm during cataract surgery is low,[12,13] there is evidence that the risk differs by anesthesia technique.[12,14–18]

The safety challenges in cataract surgery are similar to those in other types of surgery. As perioperative physicians, anesthesiologists play a critical role in preventing patient harm, not only by maintaining knowledge and skills as evidence evolves but also by acting as observant, thoughtful, and vocal members of care teams. Moreover, anesthesiologists have the opportunity to advance patient safety more broadly, through cross-disciplinary initiatives that reflect the multidisciplinary nature of the care we provide. Coordinated safety efforts across specialties, and including patients, may have the greatest potential for improving patient safety.

A multi-stakeholder effort in Massachusetts illustrates how providers and patients can work together to improve patient safety. The work was initiated by the Betsy Lehman Center for Patient Safety (the Center), a nonregulatory Massachusetts state agency with a mandate that includes using data reported to the state to catalyze safer health care. While the Center receives reports of serious reportable events (SREs) from the Massachusetts Department of Public Health, it does not conduct investigations into AEs. The Center's enabling statute contains a confidentiality provision (M.G.L c. 12, § 51c) under which information it receives from providers and others is not public record and is not subject to disclosure through discovery or subpoena, or admissible as evidence in judicial or administrative proceedings.

A recent series of cataract surgery–related AEs reported to the state[1] provided an opportunity for the Center to work toward 1 of its goals: to develop a better process to quickly analyze and respond to SRE data collected by the state. To do this, the Center convened an expert panel involving anesthesiologists, ophthalmologists, administrators, patient safety experts, and patient representatives to evaluate the cataract surgery–related AEs and recommend strategies for preventing similar events in the future. The purpose of this article is to identify contributing factors to the cataract surgery–related AEs reported in Massachusetts and present the panel's recommended prevention strategies.

METHODS

The Center convened a 12-person multidisciplinary expert panel (including authors K.C.N., M.G.M., and J.B.) in the fall of 2015 to review the reported AEs in cataract surgery and recommend prevention strategies. The Center reached out to key experts and stakeholders across Massachusetts for recommendations on panel members. The final panel was comprised of 3 ophthalmologists, 4 anesthesiologists, 2 nurse administrators, 1 physician risk manager, and 2 patient representatives. Most panel members (66.7%) had expertise in safety and quality improvement and the remainder were clinicians. Panel members were diverse in gender (50% female), practice location within Massachusetts (41.7% Boston; 16.7% Northeast; 16.7% Southeast; 8.3% Central; 8.3% Cape and Islands; 8.3% Greater Boston), practice type (55.6% teaching hospital; 33.3% independent ophthalmic surgery center, 11.1% hospital-affiliated surgery center), and years of experience (25% 10–20 years; 33% 20–30 years; 25% over 30 years; 17% were patient representatives).

The panel met in-person 5 times, and by conference call 7 times over an 8-month period ending in May 2016. Using a Delphi approach modified to allow communication between experts,[19,20] the panel arrived at a series of recommendations to prevent AEs in cataract surgery based on data obtained from Massachusetts SREs and major incident reports, malpractice claims, clinical registries, and other incident reporting systems, as described in our accompanying brief report.[1] The panel supplemented these data with a literature review of AEs in cataract surgery and complications associated with anesthesia techniques used for the procedure. Separately, we obtained data on clinical preferences and safety concerns through interviews with key stakeholders and frontline staff, as well as online surveys of Massachusetts cataract surgeons.

The key stakeholder interviews were qualitative, semistructured, and designed to last 1 hour (Supplemental Digital Contents 2–5, Appendices B-1, B-2, B-3, and B-4, http://links.lww.com/AA/C44, http://links.lww.com/AA/C45, http://links.lww.com/AA/C46, and http://links.lww.com/AA/C47). Contracted researchers (Mathematica Policy Research, Cambridge, MA) conducted the interviews and recorded field notes in real time. They iteratively reviewed the field notes and analyzed them for common themes around contributing factors and prevention strategies using a grounded theory approach,[21,22] until they reached information saturation, the point at which they felt that no new information or insights were gained from successive interviews. In addition, the Center conducted voluntary semistructured interviews with frontline staff from 4 facilities that reported cataract surgery–related SREs, to elicit contributing factors and prevention strategies. Center staff transcribed audio recordings of the interviews, and 3 members of the Center (including S.R.) iteratively reviewed the transcriptions and analyzed them for common themes using the same methodology as the stakeholder interviews.

The panel also developed an online survey to assess the anesthesia practices and preferences of Massachusetts cataract surgeons and facilities that perform cataract surgery. We iteratively tested the survey instrument with our panel members and the Massachusetts Society of Eye Physicians and Surgeons (MSEPS) executive committee to ensure that it captured the required information (Supplemental Digital Contents 6 and 7, Appendices C-1 and C-2, http://links.lww.com/AA/C48, http://links.lww.com/AA/C49). The panel based its recommendations on analysis of the AEs reported to the state and the literature. Our interview and survey data provided supplementary information on current practices and perceptions of cataract surgeons and key stakeholders. Results are presented as counts with percentages. All analyses were performed using Microsoft Excel 2010 (Redmond, WA).

RESULTS

Twenty-five key stakeholders were interviewed including 13 national and/or international experts (4 patient safety experts, 3 anesthesiologists, and 6 ophthalmologists), and 12 Massachusetts cataract surgeons from diverse geographic and practice backgrounds. The Center also interviewed 32 staffs (1 surgeon, 1 anesthesiologist, 4 nurse managers/directors, 11 nurses, 4 quality and safety staffs, 3 surgical technicians, 3 clinical assistants, 2 materials managers, and 3 administrative staffs) from 4 facilities that reported cataract-related SREs. Additionally, we received 111 responses to our online survey of approximately 280 Massachusetts ophthalmologists. Twenty responses were excluded (9 from ophthalmologists who do not practice cataract surgery and 11 incomplete responses), leaving a final sample of 91 surveys (response rate 32.5%). The survey of approximately 124 Massachusetts facilities received 54 responses. Thirty-three responses were excluded (4 from facilities that do not perform cataract surgery and 29 incomplete responses), providing a final sample of 21 completed surveys. We were unable to calculate an accurate response rate because our survey was distributed through e-mail listservs that included not only facilities that perform cataract surgery but also those that do not perform cataract surgery and whose responses were subsequently excluded from our analysis.

The series of cataract surgery–related SREs reported in Massachusetts from 2011 to 2015 is described in detail in our accompanying brief report[1] and included 15 wrong-lens implants, 2 wrong-eye/wrong-patient surgeries, 5 wrong-eye blocks, 2 retained object/tissue, and 5 globe perforations from eye blocks performed by 1 anesthesiologist on a single day in 2014. All were reported to the state within 30 days of occurrence. The underlying causes of these AEs fell into 2 themes: (1) systems failures and (2) choice of anesthesia technique.

Systems Failures

Systems failures involved 4 subthemes, as described in Table 1: inadequate safety protocols (48.7% of contributing factors), communication challenges (18.4%), insufficient training (17.1%), and lack of standardization (15.8%).

Inadequate safety protocols included inadequate time-out protocols (40.5%), poor adherence to time-outs (37.8%), improper lens storage (13.5%), and other inadequate safety protocols (8.1%). Examples of inadequate time-outs included not engaging a second provider in the time-out or not using at least 2 independent sources for lens verification. Poor staff adherence to time-outs involved time-outs that were incomplete or separated in time from the procedure. For example, 1 SRE report for a wrong-eye block described a 90- to 120-second lag time between when sedation was given immediately after the time-out, and administration of the block. Other SREs involved providers who were distracted by concurrent activities and not actively participating in time-outs. Key stakeholders reported that high surgical volumes and time-pressured environments may drive physicians to develop work-arounds for time-outs, or become complacent with time-outs, weakening their vigilance, and leading to wrong-eye blocks and wrong-lens implants. Finally, improper lens storage also contributed to wrong-lens implant SREs. For example, 1 facility reported that they bring lenses for all scheduled patients into the operating room at the start of the day.

Second, communication was a common challenge. While verbal communication break-downs (35.7% of communication challenges) occurred most often between staff during lens time-outs, they also involved miscommunication with patients. For example, in 1 wrong-patient event, when the nurse called the patient for the procedure, a different patient responded and was escorted into the operating room. Written communication break-downs (35.7%) involved poor handwriting legibility. Staff hesitancy to voice concerns (28.6% of communication challenges) occurred in high-turnover rooms where there could be a perceived “delay” to address a safety issue. Multiple SRE reports addressed staff communication in their corrective action plans, including training staff to “question illegible orders” and “feel empowered to stop the process,” even if that slows the pace of the room.

Insufficient training was the third most common contributing factor. Several cases noted the involvement of new trainees who may not have been fully oriented. One report stated that a student technologist may have been a factor in distracting the technologist during the time-out. Key stakeholders also reported that without adequate orientation and training, providers who are new to a setting may be at greater risk of missing standard steps in a procedure or misinterpreting communication between staff. The reliance of many facilities on locum tenens or contracted anesthesiologists for cataract surgery may pose a challenge to ensuring familiarity with local practices. Additionally, the facility where the 5 globe perforations occurred reported insufficient training in the administration of eye blocks as a contributing factor. Less than one fourth of anesthesiology residency programs offer ophthalmic anesthesia training,[23] which is not a requirement for certification by the American Board of Anesthesiology,[24] and 91% of third-year residents report being “not confident” performing retrobulbar blocks.[25] Instead, key stakeholders reported that anesthesiologists usually learn ophthalmic anesthesia on-the-job through informal instruction. While this experiential learning may be sufficient in most cases, rare complications or unexpected outcomes may not be adequately addressed.

Fourth, lack of standardization occurred both within and between facilities. Of these, 58.5% involved variations in lens order forms, such as different notations for indicating lens power, and uncommon specifications, such as “multifocal,” handwritten on forms. Key stakeholders also reported that wrong-sided eye blocks and surgeries often stem from nonstandard or unclear surgical site markings. Interviewees indicated that while most facilities mark the eye and perform time-outs, the effectiveness of these techniques depends on their consistent use among providers, and process variations are common, posing challenges to staff who work across multiple sites. Interviewees reported that institutions frequently develop their own safety protocols, regardless of whether they adhere to best practices. Key stakeholders suggested that lack of formal patient safety training may contribute to nonstandardized safety protocols, with many physicians learning safety protocols on-the-job. Poor standardization also extended to lens packaging and labeling. Two SRE reports identified variations in lens packaging as a contributing factor to wrong-lens implants, including similar model numbers and labels for key information such as negative versus positive diopter. Both facilities reported contacting the manufacturers to request improvements, such as changing the labeling of the lens boxes so that the size of the lens, which was displayed as “L” for large and “S” for small, is printed in a larger and bolder font, and not abbreviated, to distinguish it from lens laterality.

Table 1. Systems Contributors to Massachusetts SREs Involving Cataract Surgery, 2011–2015

	SRE Type					
Contributing Factors	**Wrong Lens Implanted (N = 14)**	**Wrong Eye Anesthetized (N = 5)**	**Nerve Block Causing Vision Loss (N = 5)**	**Surgery on Wrong Patient (N = 1)**	**Surgery on Wrong Eye (N = 1)**	**Total SREs (N = 26)[a]**
Inadequate safety protocols	24 (50.0%)[b]	9 (75.0%)	0 (0.0%)	2 (66.7%)	2 (66.7%)	37 (48.7%)[c]
Inadequate time-out protocol	8 (33.3%)[d]	5 (55.6%)	-	1 (50.0%)	1 (50.0%)	15 (40.5%)
Poor adherence to time-out	8 (33.3%)	4 (44.4%)	-	1 (50.0%)	1 (50.0%)	14 (37.8%)
Improper lens storage	5 (20.8%)	-	-	-	-	5 (13.5%)
Inadequate other safety protocol	3 (12.5%)	-	-	-	-	3 (8.1%)
Communication challenges	13 (27.1%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	14 (18.4%)
Verbal communication break-down	4 (30.8%)	-	-	1 (100.0%)	-	5 (35.7%)
Written communication break-down	5 (38.5%)	-	-	-	-	5 (35.7%)
Staff hesitancy to voice concerns	4 (30.8%)	-	-	-	-	4 (28.6%)
Insufficient training	2 (4.2%)	1 (8.3%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	13 (17.1%)
New staff/trainee involved in procedure	2 (100.0%)	1 (100.0%)	5 (50.0%)	-	-	8 (61.5%)
Insufficient training in block administration	-	-	5 (50.0%)	-	-	5 (38.5%)
Lack of standardization	9 (18.8%)	2 (16.7%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	12 (15.8%)
Variation in lens order/verification forms	7 (77.8%)	-	-	-	-	7 (58.3%)
Variation in surgical site marking procedures	-	2 (100.0%)	-	-	1 (100.0%)	3 (25.0%)
Nonstandardized lens packaging	2 (22.2%)	-	-	-	-	2 (16.7%)
Total	48 (100.0%)	12 (100.0%)	10 (100.0%)	3 (100.0%)	3 (100.0%)	76 (100.0%)

Abbreviation: SRE, serious reportable events.

[a]Total excludes 3 SREs: 1 wrong intraocular lens event and 2 retained foreign object/tissue events for which the panel did not have enough information to determine contributing factors.

[b]Percentages for the 4 contributing factor categories calculated with denominator of total number of contributing factors.

[c]Contributing factor counts do not equal the total number of SREs because a single SRE may have multiple contributing factors.

[d]Percentages for individual contributing factors calculated with denominator of total number of contributing factors in corresponding category.

Choice of Anesthesia Technique

Choice of anesthesia technique and the inherent complications associated with different techniques, as described in Supplemental Digital Content 1, Appendix A, http://links.lww.com/AA/C43, may have also contributed to AEs in our sample. Fifteen (40.5%) of the 37 AEs reported in Massachusetts over 2011 to 2015 were related to complications from eye blocks. None of the AEs involved topical anesthesia, sub-Tenon's block, or general anesthesia. The anesthesiologist with 5 reported globe perforations was a contracted provider who the facility planned to use as a back-up for its primary anesthesiologist. It was the contracted anesthesiologist's second day at the facility. The facility reported that it used a credentialing service and that the anesthesiologist had been granted privileges corresponding to his or her training. The SRE reports submitted by the facility identified several contributing factors including, "misuse of equipment provided (syringe/needles)," "lack of knowledge/experience to detect cues to warn of possible complications to peribulbar injection," and the provider's qualifications being either insufficiently verified or misrepresented. While the panel did not independently assess these statements, they suggest that contributing factors may have included systems issues such as inadequate credentialing and insufficient orientation to unfamiliar equipment, as well as the inherent risks associated with the type of anesthesia used and individual characteristics of the provider administering it, including lack of knowledge/experience or improper technique.

The event summaries provided by the Quality and Patient Safety Division (QPSD) at Massachusetts's Board of Registration in Medicine for the 5 additional block-related "major incidents" also identified the inherent risks associated with retrobulbar and peribulbar blocks as the primary contributing factor to the AEs. While 2 of the systemic reactions—bradycardia/hypotension after a peribulbar block and tachycardia/hypertension/unresponsiveness after a retrobulbar block—were attributed to the block, the facilities reported that the technique used was appropriate and that no practice changes were recommended. The third systemic reaction—diaphoresis/nausea/vomiting requiring inpatient cardiac management after a peribulbar block—was a vagal response to the block. Cardiac management was required because a new left bundle branch block was discovered during the resulting electrocardiogram. Finally, the 2 cases of retrobulbar hematoma/hemorrhage (1 after a retrobulbar block, the other after a peribulbar block) both involved patients on anticoagulants whose international normalized ratios were not measured preoperatively. In 1 case, the facility reported following recommended best practices, including holding the patient's anticoagulant before the procedure, and using a shorter needle to administer the peribulbar block.

Coinciding with a growing awareness of the comparative risks of anesthesia techniques for cataract surgery, 45.5% (N = 35) of Massachusetts cataract surgeons and 69.6% (N = 16) of facilities who responded to our survey reported increased reliance on topical anesthesia in the prior 10 years. Among surgeons who use eye blocks for cataract surgery, 51.2% (N = 21) reported using retrobulbar less often, and 22.8% (N = 13) reported using peribulbar less often compared with 10 years earlier. Of facility respondents that use eye blocks, 71.4% (N = 10) used retrobulbar blocks less often and 62.5% (N = 10) used peribulbar blocks less often than 10 years earlier.

Yet Massachusetts cataract surgeons still regularly operate with needle-based blocks, as shown in Table 2. Blocks were used in 47.0% of cataract surgeries performed by surgeon respondents and 40.9% of cataract surgeries performed at respondent facilities. Moreover, 46.2% (N = 42) of surgeon respondents reported using blocks in 75% or more of their surgeries; these surgeons perform an estimated 38.4% of all cataract surgeries in the state. Nearly all respondents (94.5% of surgeons, N = 86; 100% of facilities, N = 21) reported that their patients always or often receive intravenous (IV) sedation, regardless of whether topical or block anesthesia is used.

The top reasons providers listed for using blocks were "best for long/complex cases," (36.7%%, N = 40), "safety (lower risk)" (20.2%, N = 22), "common practice at facility" (11.9%, N = 13), "efficiency" (11.0%, N = 12), "patient preference" (6.4%, N = 7), and "other" (13.8%, N = 15). Some commented that blocks offer the patient and surgeon greater comfort, allowing the focus to be on the surgery, rather than on preventing voluntary movements of the eye. Several respondents described specific patient characteristics that influence when they might use a block, including language barriers, tremors, cognitive impairments, or patients who are unable to cooperate.

The top reasons providers listed for using topical anesthesia were as follows: "safety/lower-risk" (41.4%, N = 36),

Table 2. Anesthesia Types Used by Massachusetts Cataract Surgery Providers

	Retro bulbar Block	Peri bulbar Block	Sub-Tenon's Block	Topical Only	Topical + IC Lidocaine	General Anesthesia	Other	Total
Anesthesia type used at any time in past year								
Surgeon respondents (N = 91)	31 (34.1%)	66 (72.5%)	16 (17.6%)	17 (18.7%)	60 (65.9%)	29 (31.9%)	0 (0.0%)	219[a]
Facility respondents (N = 21)	11 (52.4%)	13 (61.9%)	2 (9.5%)	11 (52.4%)	10 (47.6%)	8 (38.1%)	4 (19.0%)	59[a]
Anesthesia type used in 75% or more of a respondent's cases								
Surgeon respondents (N = 91)	12 (13.2%)	27 (29.7%)	1 (1.1%)	4 (4.4%)	23 (25.3%)	3 (3.3%)	0 (0.0%)	70[b] (76.9%)
Facility respondents (N = 21)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (9.5%)	3 (14.3%)	0 (0.0%)	2 (9.5%)	7[b] (33.3%)
Estimated annual total number of cataract surgery cases by anesthesia type								
Surgeon respondents	4465 (14.3%)	10,179 (32.7%)	470 (1.5%)	3264 (10.5%)	12,464 (40.1%)	278 (0.9%)	0 (0.0%)	31,120 (100.0%)
Facility respondents	2350 (17.9%)	3238 (24.7%)	130 (1.0%)	2285 (17.4%)	3855 (29.4%)	283 (2.2%)	968 (7.4%)	13,109 (100.0%)

Abbreviation: IC, intracameral lidocaine.
[a]Totals more than 100% because surgeons and/or facilities may use more than 1 type of anesthesia.
[b]21 surgeons and 14 facilities reported using a variety of anesthesia types, not a single anesthesia type in more than 75% of cases.

"efficiency" (21.8%, N = 19), "patient preference" (17.2%, N = 15), "common practice at facility" (2.3%, N = 2), "best for long/complex case" (1.1%, N = 1), and "other" (16.1%, N = 14). Respondents highlighted the ability to perform operations faster and also commented on specific factors that favor topical anesthesia, including multifocal lenses and patients on anticoagulants.

Among surgeon respondents, 65 (74.7%) who use blocks reported relying on anesthesiologists to administer them, and 19 (21.8%) administered blocks themselves. Of those who use topical anesthesia, 53 (72.6%) reported relying on registered nurses to administer the drops, followed by themselves (15.1%, N = 11), certified registered nurse anesthetists (CRNAs, 6.8%, N = 5), anesthesiologists (2.7%, N = 2), and residents/fellows (1.4%, N = 1). It is less clear who is responsible for choosing the anesthetic type. Survey respondents described a range of practices with some deferring entirely to the anesthesiologist and others relying on the surgeon's preference. Key stakeholders commented that some surgeons may choose to work exclusively with anesthesiologists who use the surgeon's preferred anesthesia technique.

Only 19 (16.2%) of surgeon respondents reported "often" (15.6%, N = 14) or "always" (5.6%, N = 5) offering their patients a choice on type of anesthesia for cataract surgery. Most reported "rarely" (36.7%, N = 33) offering patients a choice, followed by "sometimes" (33.3%, N = 30) and "never" (8.9%, N = 9). Respondents indicated that a surgeon's comfort level with a particular technique may influence whether patients are offered that option. Key stakeholders noted multiple factors that may inhibit patient engagement in anesthesia decisions, including: the use of complex medical language to describe risks and benefits; nonverbal cues from physicians such as body language discouraging patient questions; and a perception that older patients tend to defer to their surgeon without questioning his or her recommendation.

DISCUSSION

From our analysis of Massachusetts AE reports, interviews, surveys and literature, we believe that most patient harm during cataract surgery can be prevented by following well-established safety best practices. While such principles are often straightforward, their consistent implementation can be challenging due in part to a false sense of security fostered by the relative safety and ubiquity of cataract surgery. The panel identified 6 strategies to help prevent AEs in cataract surgery, summarized in Table 3.[26]

First, providers should perform a distinct anesthesia time-out immediately before administering a block. Like any robust time-out, it should involve at least 2 team members in different roles, such as a nurse and anesthesiologist. When possible, the patient should also be included. Key information, such as patient identity, operative eye, and procedure, should be actively verified against sources such as the patient wristband, chart, consent form, and surgical plan.

Second, all surgical centers should have a uniform, facility-wide policy for marking the operative eye. The site should be visibly and unambiguously marked using a sufficiently permanent mechanism.[27] A second visual cue, such as a clear plastic eye shield taped preoperatively over the nonoperative eye, may further reduce the risk of wrong-side procedures.

Third, facilities should strengthen their credentialing and orientation of new staff. Strong credentialing may involve clear internal assessment criteria, standardized questions developed with input from staff at all levels, and the inclusion of at least 1 physician in the credentialing process. Orientation for clinicians who are new to a practice should include team introductions and a review of the facility's workflow, including time-out and eye-marking procedures. Equally important, contracted and temporary staff should ensure that they have an opportunity to ask questions before practicing at a new facility.

Fourth, anesthesiologists who perform eye blocks should have adequate and documented training, both didactic and

Table 3. Recommendations for Reducing Anesthesia-Related Adverse Events During Cataract Surgery

Recommendation	Contributing Factor(s) Addressed
1. Perform a separate time-out immediately before administering a block, involving active verification by at least 2 team members and the patient, when possible	• Inadequate time-out protocol • Poor adherence to time-out • Verbal/written communication break-down
2. Adopt a standardized, facility-wide policy for marking the operative eye that involves the same unambiguous and enduring mechanism used by all providers within the facility	• Variation in surgical site marking procedures • Verbal/written communication break-down
3. Strengthen credentialing and orientation processes for new, contracted, and locum tenens anesthesia staff, including clear internal assessment criteria and standardized questions to be evaluated by qualified staff; and adequate onboarding that reviews elements such as a facility's work flow, site-marking policy, and time-out procedures	• New staff/trainee involved in procedure • Insufficient training in block administration • Poor adherence to time-out • Variation in surgical site marking procedures • Verbal/written communication break-down • Staff hesitancy to voice concerns
4. Observe the initial blocks of any anesthesia provider who is new to a facility, and require that they have adequate and documented training, both didactic and clinical, on proper technique, management of complications, and identification of high-risk patients	• Insufficient training in block administration • New staff/trainee involved in procedure • Inherent risks associated with needle-based blocks
5. Use the least invasive form of anesthesia that is appropriate for the patient and case, considering the patient's preferences and comorbidities, the planned procedure, and potential complications	• Inherent risks associated with needle-based blocks • Insufficient training in block administration
6. Stay current on evidence-based practices for minimizing the risk of harm from anesthesia, and avoid relying on personal experience to assess the relative safety of techniques	• Inherent risks associated with needle-based blocks

hands-on, on proper technique, management of complications, and identification of high-risk eyes and patients. An experienced physician should directly observe anesthesiologists perform their initial eye blocks at a new facility to ensure a safe technique and provide additional guidance on facility-specific processes. While data are limited on the number of supervised blocks individuals should perform before practicing independently, the panel recommended by consensus a minimum of 10 supervised blocks as a reasonable practice.

Fifth, providers should use the least invasive form of anesthesia that is appropriate for the case, considering the relative risk profiles described in Supplemental Digital Content 1, Appendix A, http://links.lww.com/AA/C43. Anesthesia selection should consider the patient's preferences and comorbidities, as well as case-specific factors such as the involvement of surgical trainees, which may necessitate a longer surgical time. Topical anesthesia has been shown to be safer than retrobulbar and peribulbar blocks,[12,14] and is a good choice for short, uncomplicated cataract procedures if akinesia of the eye is not required and the patient can cooperate and lie still for the length of the procedure. Patients with axial lengths greater than 25 mm,[28] staphalomas,[29] a scleral buckle,[30,31] or severe enophthalmos[29] are especially strong candidates for topical anesthesia given their increased risk of injury from needle blocks, particularly retrobulbar. Notwithstanding, there are instances where blocks may be indicated for cataract surgery, including anxious patients who may move during surgery, complicated or prolonged cases, or patient preference in consultation with the surgeon. Some evidence suggests that needles 32 mm in length or less lower the risk of optic nerve injury,[32–34] retrobulbar hemorrhage,[35] and local anesthesia spread to the central nervous system.[36,37]

Clinical guidelines in the United States and United Kingdom acknowledge the risks of serious complications associated with needle-based blocks, but stop short of recommending topical anesthesia.[38,39] We similarly encourage providers to base their decisions on patient and surgical factors; however, we recommend that topical anesthesia be considered a first choice, unless unique patient or surgical factors require a more invasive form of anesthesia. Surgeons often request a particular anesthesia technique after discussion with the patient before the day of surgery. If the anesthesiologist feels a different technique may be indicated after interviewing and examining the patient, he or she should speak with the surgeon preoperatively.

A final general recommendation is for anesthesiologists to regularly reassess our clinical practices and stay current on new safety strategies. Changing familiar practice is difficult—particularly if nothing has gone wrong in our personal practice. Our Massachusetts survey results suggest that providers rely on their own experience with AEs and established institutional norms to assess safety, which may underestimate the risks associated with uncommon complications and prevent providers from adopting best practices as they evolve. Complication rates for severe anesthesia-related AEs during cataract surgery are low enough that most physicians may never encounter them in their personal practice. Yet the events reported in Massachusetts show that AEs from anesthesia for cataract surgery do occur with permanent patient harm.

Our review has several limitations. First, our self-reported data likely underestimate the true incidence of cataract surgery–related harm. Even in states where AE reporting in mandatory, there is evidence of substantial underreporting.[40] In Massachusetts, only 8.5% of ASCs reported SREs in 2014 and 2015,[41] and only 10 hospitals were responsible for 59.1% of all Massachusetts SREs in 2015.[42] Second, the quality of SRE narratives varied widely in both depth of facilities' internal root cause analyses and completeness of their write-ups, and the reports exclusively reflect the opinions of the reporting facilities. Third, the panel did not include any CRNAs. While none of our respondent facilities reported having CRNAs perform eye blocks, CRNAs may have offered unique perspectives on intraoperative sedation/anesthesia.

Fourth, the survey of cataract surgeons was administered by the MSEPS (Boston, MA) via its member listserv, which may not be representative of all Massachusetts ophthalmologists. While we only included responses from cataract surgeons, all MSEPS members received the survey, regardless of their subspecialty. Therefore, the reported response rate (32.5%) underestimates the true rate, as the denominator includes noncataract surgeons who did not meet our inclusion criteria. The survey of Massachusetts facilities that perform cataract surgery has similar limitations. It was distributed via e-mail by 3 organizations: the Massachusetts Association of Ambulatory Surgery Centers (Waltham, MA) to its listserv of member and nonmember ASCs, the Massachusetts Hospital Association (MHA, Burlington, MA) to its members, and the Center to non-MHA member hospitals that perform cataract surgery. Many of the Massachusetts Association of Ambulatory Surgery Centers and MHA recipients did not reply to the survey because they do not perform cataract surgery, making it impossible to calculate a meaningful response rate.

Finally, while our recommendations are based on expert consensus given a comprehensive review of available data, continued research is needed to assess (1) the impact of our recommendations on the incidence of AEs during cataract surgery and (2) any unintended consequences. For example, surgeons who have traditionally relied on blocks for cataract surgery may be less practiced operating on an unparalyzed eye under topical anesthesia. The Center will continue surveying Massachusetts cataract surgery providers to evaluate adoption of the panel's recommendations. Impact on patient outcomes, however, can be more difficult to measure. Changes in the number of cataract surgery–related SREs may underestimate improvements to patient safety as rates of SRE reporting increase with improved vigilance and transparency. The most meaningful evaluation may happen within individual institutions, where clinical data can be better linked to practice changes. Other key areas for future research involve testing options for standardized lens labels and order forms to identify those with the best usability, provider satisfaction, and patient outcomes.

No medical procedure is immune from human error, and cataract surgery—1 of the safest and most commonly performed procedures in the country—offers a clear case in point. Lessons learned from safety challenges in cataract surgery may be instructive for other procedures. In particular, our recommendations highlight the important role that anesthesiologists play in preventing patient harm at a systems level. Beyond safely administering anesthesia, anesthesiologists contribute to a strong overall safety culture by engaging in continuous improvement activities, actively participating in time-outs, remaining vigilant, and encouraging staff across ranks to speak up without fear.

Anesthesiology as a specialty can build on its decades of patient safety leadership by collaborating with other medical specialties that are newly defining their patient safety priorities. We can share best practices, convene multidisciplinary workgroups, and foster open communication between specialties from the national level to the individual operating room. In this case, providers from both ophthalmology and anesthesia partnered to identify shared risks and advocate for systems-based solutions to mitigate them. Integrating anesthesia's patient safety efforts with those of peer specialties will strengthen our respective practices and improve the safety of our patients.

APPENDIX A

ANESTHESIA TECHNIQUES

Overview of Techniques

Topical Anesthesia. Topical analgesia is the simplest technique to anesthetize the eye and can be used as the sole anesthetic for cataract surgery. Local anesthetic gel or eye drops are placed on the cornea and conjunctiva shortly before starting surgery. Topical anesthesia does not alter vision, avoids the need for local anesthesia to be injected near the eye, and no or minimal sedation is usually required. However, topical analgesia does not provide akinesia of the eye.

Retrobulbar Block. Retrobulbar blocks are often performed by first administering a topical eye anesthetic, such as proparacaine 0.5%, onto the surface of the eye, followed by an antiseptic, such as 10% povidone-iodine, swabbed over the closed lower eyelid. The antiseptic solution should contact the skin for several minutes to provide optimal antibacterial effect. The patient is usually lightly sedated before the block with short duration IV medications (eg, remifentanil or fentanyl with midazolam) but ideally still able to respond to commands. Standard patient monitors should be used during block placement, with supplementary oxygen if sedation is used. Patients should be instructed to look straight ahead during the block (primary gaze position).[32]

A palpating gloved finger identifies the lower part of the globe and the inferior lateral orbital rim. A needle 32 mm or less (author J.B. prefers a 22 mm, 25 gauge needle) is inserted through the skin, just over the inferior orbital rim, a few millimeters lateral to the "traditional" insertion point, defined as the junction of the middle and lateral third of the lower eyelid just above the orbital rim,[43] as shown in the Figure of our accompanying brief report.[1] Inserting the needle several millimeters lateral to the traditional insertion point may reduce the risk of injury to the inferior rectus and the neurovascular bundle supplying the inferior oblique muscle.[44,45]

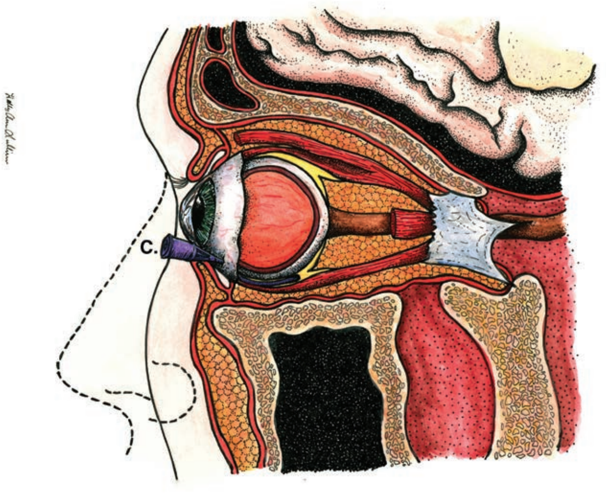

Figure. Injection position for C. sub-Tenon's block. Illustration by Holly Sullivan.

The needle is inserted very slowly with the bevel facing the globe so that the sharpest point on the needle tip is farthest from the globe. Always watch the globe to ensure that it does not move during needle advancement. If it does, the needle may have touched the sclera and should be withdrawn.[46]

Some of our panel members modify this technique to reduce the risk of the needle perforating the globe, by wiggling the needle several millimeter per second (parallel to the surface of the globe) during needle advancement after penetrating the skin. (If touched, the globe would likely move in tandem with the wiggling needle, and the needle should be withdrawn.)[47]

Initially, the needle is advanced horizontally to the orbital floor. There may be slight resistance as the needle pierces the skin, and a slight "pop" after penetration through the orbital septum several millimeters deep to the skin if a blunt Atkinson needle (J.B.'s preference) is used.

The needle tip, after judged to pass under the inferior portion of the globe, is directed superiorly, usually at about a 45° angle, and medially into the intraconal space. Kumar and Fanning[46] recommend that the needle tip, when fully inserted, lie in an imaginary vertical plane from the lateral limbus (the junction of the colored iris and the white sclera) projecting posteriorly.

After the needle is inserted to the desired depth, use the wiggle technique described or confirm that the patient is able to look in different directions, as an indication that globe perforation is not likely. The barrel of the syringe is then withdrawn to assure no blood is aspirated (a sign of an intravascular insertion) and, if none seen, local anesthesia is slowly injected. The volume required for an effective retrobulbar block has been reported to be 1.5 to 4 mL range.[46] When shorter needles are used (25 mm or less), several additional milliliters of local anesthesia may be needed to obtain a successful block.

Peribulbar Block. The initial steps of peribulbar block technique, including sedation, initial position of the needle tip (bevel facing the globe), location of the initial insertion of the needle through the skin, and local anesthetics that can be used, are identical to the retrobulbar technique. Needles 25 mm or less are commonly used for a peribulbar block (J.B. uses a 22 mm, 25 gauge Atkinson needle). After the needle penetrates the skin, use 1 of the techniques described in the "Retrobulbar block" section to confirm that the needle is not in contact with the globe. The needle is then advanced horizontally under the globe, but not more than 32 mm. See the Figure of our accompanying brief report.[1] The syringe is aspirated, and if no blood is seen, the local anesthesia (commonly 6–10 mL) is injected.

Sub-Tenon's Block. Sub-Tenon's block is accomplished by injecting local anesthetic into the episcleral space (the space between the sclera and the overlying sub-Tenon's capsule) via a blunt cannula or needle, as shown in the Figure. The technique is most often performed in the infero-medial or nasal quadrant. After sterile preparation, application of topical anesthetic drops or gel to the surface of the globe, and topical application of 5% betadine solution to the conjunctiva, the conjunctiva is held 3 to 5 mm from the limbus. Blunt Westcott scissors are then used to create an opening in the conjunctiva and Tenon's capsule to access the episcleral space. Specially designed blunt, often curved, cannulas are advanced into the episcleral space, and the local anesthesia mixture (commonly 3–5 mL) is injected. Three milliliters of local anesthesia typically provides analgesia to the globe, and 5 mL will spread to extraocular muscles and provide akinesia.

General Anesthesia. General anesthesia in cataract surgery is typically reserved for patients who are unable to communicate, cooperate, or remain still during eye surgery. It is critical that the patient does not move during the procedure to prevent eye injury. This may be accomplished by either maintaining a continuous deep level of anesthesia or administering muscle relaxants.[48]

Comparative Risks

Complications of retrobulbar and peribulbar blocks include strabismus, retrobulbar/peribulbar hemorrhage, globe perforation, inadvertent brainstem anesthesia, and direct needle trauma to the optic nerve.[12,15,18,38,49] One recent survey put the incidence of serious complications from needle-based blocks at about 1 in 5000 cases.[12] Rates of complications resulting in blindness vary among studies. For example, retrobulbar hemorrhage rates range from 0.1% to 3.0%.[15,49] Globe perforation rates range from 1 in 874 to <1 in 16,000, with half of cases not recognized at the time of occurrence.[39] Retrobulbar blocks may have a higher rate of posterior globe perforation injuries in patients with axial lengths >25 mm,[28] staphalomas,[29] or enophthalmos,[29] and an increased risk of other complications including brainstem anesthesia[36,37] and optic nerve injury if needles longer than 32 mm are used.[32–34] Differences between types of sharp-needle blocks are less clear: while a few small studies report that retrobulbar blocks have higher rates of globe perforation,[15,50] lid hematoma,[51] and severe systemic complications[39] than peribulbar blocks, larger studies and systematic reviews report that the 2 blocks have similar complication rates.[12,51]

Topical anesthesia has the lowest risk of serious anesthetic complications in cataract surgery.[12,14] A 2012 meta-analysis compared outcomes between topical anesthesia and retrobulbar/peribulbar blocks using data from 15 randomized control trials, and found that blocks had higher complication rates, including chemosis, periorbital hematoma, and subconjunctival hemorrhage, than topical anesthesia.[14] While 1 study reported that topical anesthesia led to higher rates of endophthalmitis (0.87%) than retrobulbar block (0.13%),[52] others found no statistically significant difference in the rates of endophthalmitis.[14] A 2015 study of over 21,000 office-based cataract surgeries performed with topical anesthesia without IV sedation reported no intraoperative or perioperative vision-threatening AEs and no cases of endophthalmitis.[53]

Sub-Tenon's block carries a lower risk of serious complication than retrobulbar and peribulbar blocks. While sight- and life-threatening complications are 2.5 times more likely with needle-based blocks than blunt cannula-based sub-Tenon's block,[15,16] many of the same complications that have been shown to occur with sharp-needle blocks have also been reported with sub-Tenon's blocks.[54–57]

Practice Trends

Anesthesia techniques for cataract surgery have shifted over time and remain diverse across states, institutions, and even within facilities. Retrobulbar block was the predominant technique for most of 20th century, preferred by over 70% of US ophthalmologists in 1985.[58] However, with the introduction of phacoemulsification, a quicker and less invasive means of lens extraction, preferences began to shift toward other forms of anesthesia.[59] In 2012, only 6.1% of ophthalmologists preferred retrobulbar blocks for cataract surgery.[60] Increased use of peribulbar block accounts for part of the shift.[49] Yet preference for peribulbar blocks in cataract surgery has also trended downward in recent decades from 38% in 1995[58] to 12.4% in 2012.[60]

Topical anesthesia is the most common technique for cataract surgery in the United States today, following its progressive increased use during the past 2 decades, with 8% of cataract surgeons using it in 1995, 51% in 2000, 61% in 2003, and 77.6% in 2012.[58,60] Of surgeons who use topical anesthesia, 79.6% supplement with intracameral lidocaine,[60] which has been shown to achieve better anesthesia.[61] International anesthesia preferences vary further. For example, in the United Kingdom, ophthalmologists report using sub-Tenon's blocks for 50% of cataract procedures.[12]

APPENDIX B
KEY STAKEHOLDER INTERVIEW PROTOCOLS

- B-1 Ophthalmologist interview protocol
- B-4 Massachusetts cataract surgeon protocol
- B-2 Anesthesiologist interview protocol
- B-3 Patient advocate protocol

APPENDIX C
SURVEY INSTRUMENTS

- C-1 Cataract surgeon survey instrument
- C-2 Facility survey instrument

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