

Vision for Safety:

Insights from Cataract Cases to Reduce Adverse
Events using a Systems Approach

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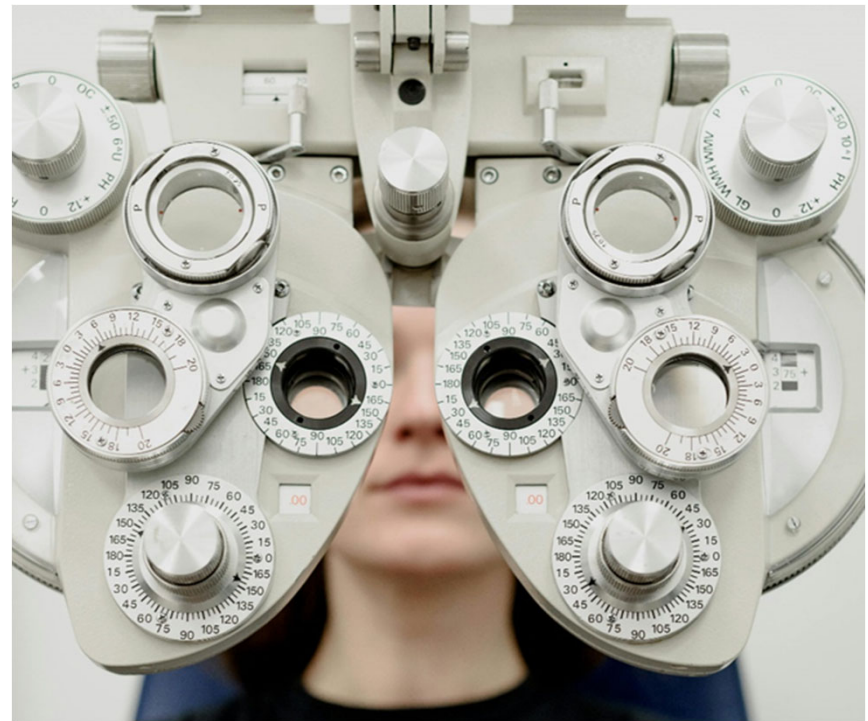
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Learning Objectives

- Introduce a systems approach to the review of adverse events and unanticipated outcomes
- Identify systems factors that contribute to patient harm
- Use a systems approach to apply lessons learned from malpractice claims to risk management and patient safety strategies to prevent similar events.



Claims Statistics

OMIC Cataract Case History

Top Allegations

IOL incorrect power

Capsule problem

Diminished vision

IOL displacement

Retinal detachment

Blindness

Corneal damage

Endophthalmitis

Financial Impact

- \$61.7M total indemnity payments
 - \$9.2M for wrong lens claims
- 15% of total indemnity payments
 - 18% are wrong lens events

Applying a Systems Approach to Manage Risk

Systems Approach



Recognizes that errors happen and reinforces the importance of integrated teamwork among physicians and staff.



Most errors do not occur due to the actions of one, but multiple failures in the system.



Goal is to make safety a team effort and proactively identify failures in the system and improve.

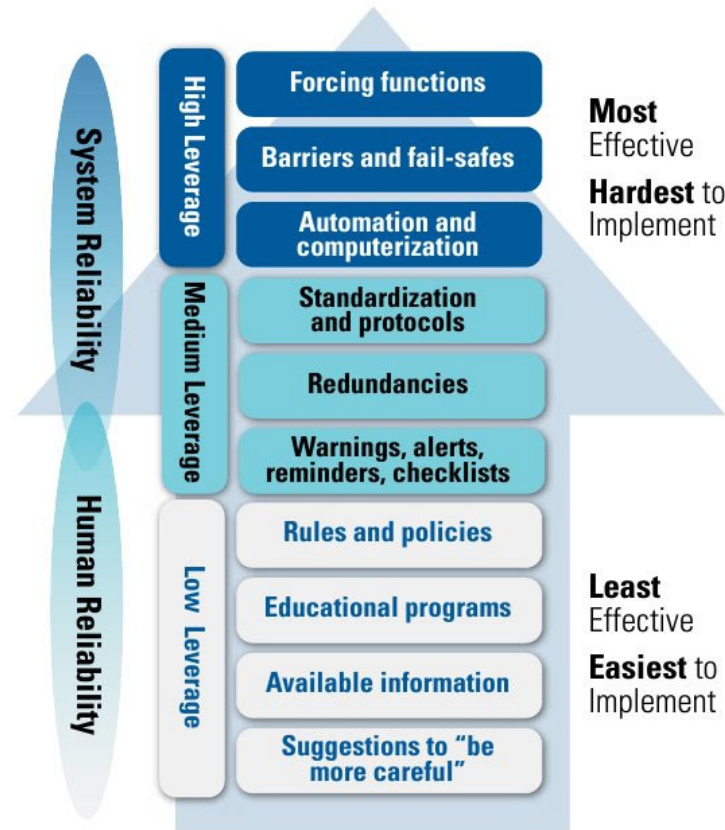
Swiss Cheese Model

- Each slice = defense in place.
- Holes = defense failure.
- Layering multiple defenses helps to mitigate exposures.
- When multiple holes lineup, an adverse event may reach the patient.



<https://psnet.ahrq.gov/primer/systems-approach>

Hierarchy of Effectiveness



Culture of Safety

Everyone is responsible for safety implementation and reporting unsafe conditions.

A blame-free environment for individual reporting of errors or near misses without fear of reprimand or punishment.

Encourages collaborative decision-making across all staff levels and disciplines to seek solutions to employee and patient safety problems.

Organizational commitment of resources to address safety concerns.

Systems and Processes

in Cataract Surgery

Preoperative assessment

Perioperative communication

Informed Consent Process

Surgical safety checklist

Postoperative care

Review of Closed Claims

Case: IOL Contraindicated

**System Issue:
Perioperative Communication**

IOL Contraindicated

Medical History	Surgery	Postop	Referral	Outcome
• 37 YO c/o foreign object sensation, pressure, and blurred vision OS. • Dx: Cataracts OU. 20/80 OS, 20/25 OD. • Pentacam: early keratoconus OU but not addressed. • Cataract surgery recommended.	• Cataract surgery with multifocal toric IOL OS.	• Postop c/o decreased vision, glare, and trouble reading. • 20/25 OS, 20/20 OD. Surgery to reposition IOL 1.5 months postop. • 2nd Petacam 2 months post op • Dx: keratoconus; referred to cornea.	• 4 months postop • Cornea MD exchanged lens to monofocal IOL and performed iridoplasty with cerclage to address glare and halos	• Patient reported continued issues with light sensitivity and halos • Possible future artificial iris procedure. • Settled \$235,000

Litigation

Keratoconus not identified prior to cataract surgery, which led to poor choice of multifocal toric.

Missing office visits documentation; operative note to reposition IOL describes a Lasik procedure.

The patient developed iris TID and a sluggish pupil following the use of intracameral moxifloxacin

Repositioning of multifocal toric IOL and IOL exchange was due to failure to diagnose keratoconus

Alleged poor vision likely related to the multifocal toric IOL, iris atrophy/TID and the presence of a toric IOL in an eye with keratoconus.

System Approach

Preoperative Assessment



Policy and procedure
for consistency and
reduce gaps.



Measurements and
IOL choices.



Patient selection
criteria, medical
clearance, and review
of medical history
and diagnostic tests.



IOL
recommendations,
costs, set
expectations.

Risk Reduction Strategies

Medical Record/Documentation



Review medical history, medications, tests, consults, intake forms.



Document items that could impact surgical planning and outcomes.



Office notes and operative reports should be reviewed carefully for accuracy and signed off within set timeframe.



Establish standard practices for medical record addendums and amendments.

Risk Reduction Strategies

Preoperative assessment and planning

Review results of
examination and
testing

Clearance from
other providers

Holding and
restarting any
prescribed
medications

Pre-op instructions

Risk Reduction Strategies

IOL Selection & Recommendations

The key is setting expectations.

- Communication
- Documentation
- Spectacle reliance vs. spectacle independence
- Alternative language to “premium” IOLs
- Patient’s best interests

Case: Wrong IOL

System Issues:
Perioperative Communication
and Informed Consent

Wrong IOL

Medical History	Surgery	Postop	Disclosure	Outcome
• 54 YO with cataracts, OS>OD. • Significantly myopic patient with BCVA 20/40 -2 OS. • Unknowingly, 2nd IOL testing done with contact lenses in place.	• Planned IOL 9.0 but 17.5 IOL placed. • Error due to using test results with contact lens in place.	• POD1 revealed refractive surprise: VA 20/100. • 3 months postop, surgeon's partner realized error and told surgeon. • Surgeon did not tell patient.	• 5 months postop surgeon wrote off bill. • Surgeon did not disclose error to the patient.	• Patient learned of error. • Offered exchange, since not a candidate for Lasik. • Chose to wear contact lenses. • Settled \$200,000

Litigation

Wrong IOL placed: did not ensure that correct lens was placed

Delay in Diagnosis of Error: did not timely recognize placement of incorrect lens

Poor Documentation: planned course of treatment was not followed, missing plan of care for managing bilateral cataracts

Inadequate Informed Consent: consented for 9.0 diopter IOL (not 17.5 diopter IOL)

Communication: tech did not confirm if patient had CL in place before performing assessment

Failure to Disclose Error: when the discrepancy was noted, not discussed with the patient

Perioperative Communication Failures

Inadequate
informed consent

OR team
discussions pre-
surgery and during
surgery

Disclosure of
adverse events

Pre and postop
patient instructions

Written
documentation
inconsistencies

System Approach

Perioperative Communication



Policy and procedure
for consistency and
prevent gaps.



Written instructions on
stopping and restarting
medication.



Informed consent
process.



Medical history
discussion with
anesthesia.

Risk Reduction Strategies

Informed Consent Process



Includes a discussion, documentation, and completion of a form.



During the discussion, the physician assess the patient's capacity to decide, discloses risks, benefits, and alternatives, and assesses the patient's comprehension of the information.



The informed consent discussion is the physician's non-delegable duty.

Purpose of Informed Consent



Patient autonomy to make informed decisions.



Sets expectations.



Strengthens the physician-patient relationship.



Legal requirement and for defense of treatment.

Risk Reduction Strategies

Disclosure of an adverse event

Consult	Consult with Risk Management regarding response.
Create	Create a plan to remedy and discuss with the patient.
Disclose	Disclose the error to the patient ASAP. Use empathy.
Do not	Do not speculate on how the error occurred if you don't know.
Communicate	Communicate next steps to patient.
Document	Document the discussion in an objective fashion.

Risk Reduction Strategies

Demands and Refunds



- Develop policies and procedures for managing refunds or waivers of copayments and deductibles.

- Notify the Claims Department if the matter constitutes a claim (or potential claim) that must be reported.

- Reach out as necessary to Risk Management or your business attorney for advice on matters that do not constitute claims.

Case: Globe Perforation

System Issue:
Surgical Safety Checklist

Globe Perforation

Medical History

- 60 YOM with longstanding relationship with surgeon. Patient moving out of state, wanted surgery prior to relocation.
- Plan: surgery OS, no complications
- Plan: cataract surgery OD, with retrobulbar block.

Surgery

- Retrobulbar block administered by anesthesiologist.
- Globe perforation recognized.
- Retina performed vitrectomy to treat the vitreous hemorrhage and laser to prevent RD.

Postop

- VA OD from 20/80 to LP

Outcome

- Settled for \$1.6M
- \$560,000 surgeon, \$1,040,000 anesthesiologist

Litigation

Axial length part of ASC orders but not filled in. No explicit documentation regarding a discussion with patient regarding risk of globe perforation with a block.

No discussion with patient about the risks of a retrobulbar block with high myopia and long axial length. No communication with anesthesia about the axial length.

Did not document consideration of alternatives to block, topical or sub-tenon block.

System Approach

Surgical Safety checklist



Policy and procedure for consistency and to reduce gaps.



Standardize checklist with simulation drills.



Includes pre-verification step as well as time out.



Encourage staff to ask questions and speak up about inconsistencies.

Risk Reduction Strategies

Informed Consent



Discuss and document if patient has higher risk of complications as part of informed consent discussion.



Communicate with anesthesia provider any pertinent risks.



Develop a process to include high risk issues in your orders or surgical checklists.

Risk Reduction Strategies

Surgical Safety Checklist

Standardize process to facilitate the exchange of critical information among surgical team members.

Pre-Procedure Verification

Ensure all documents, imaging, and required equipment are available, accurate, and checked.

Surgical Time-out

The final safety check of critical information.

Checklist can be adapted to your practice and location of procedures.



SURGICAL SAFETY CHECKLIST

Before anesthesia ▶▶▶▶▶▶▶▶▶▶ Before incision ▶▶▶▶▶▶▶▶▶▶ Before leaving operating room

SIGN IN	TIME OUT	SIGN OUT
☐ PATIENT HAS CONFIRMED • IDENTITY • SITE • PROCEDURE • CONSENT	☐ ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE	NURSE ORALLY CONFIRMS WITH TEAM:
☐ SITE MARKED	☐ SURGEON, ANESTHESIA PROVIDER, AND NURSE ORALLY CONFIRM • PATIENT • SITE • PROCEDURE • ALLERGIES	☐ NAME OF PROCEDURE RECORDED
☐ HISTORY & PHYSICAL REVIEWED	☐ SURGEON AND NURSE ORALLY CONFIRM: • ANTIBIOTIC PROPHYLAXIS • MITOMYCIN-C/ANTI-NEOPLASTICS • IMPLANT STYLE AND POWER • DEVICES • TISSUE • GAS • DYES	☐ INSTRUMENT, SPONGE, SHARP COUNT: ☐ CORRECT ☐ NOT APPLICABLE
☐ IMAGING REVIEWED, IF APPLICABLE	☐ ANTICIPATED CRITICAL EVENTS	☐ SPECIMEN LABELED (including patient name) ☐ YES ☐ NOT APPLICABLE
☐ PRESURGICAL ASSESSMENT COMPLETE	SURGEON REVIEWS • CRITICAL OR UNEXPECTED STEPS	☐ EQUIPMENT ISSUES ADDRESSED
☐ PREANESTHESIA ASSESSMENT COMPLETE	ANESTHESIA PROVIDER REVIEWS • ANY PATIENT-SPECIFIC CONCERNS	SURGEON, ANESTHESIA PROVIDER, AND NURSE CONFIRM:
☐ ANESTHESIA SAFETY CHECK DONE	NURSING TEAM REVIEWS • STERILITY (including indicator results) • EQUIPMENT ISSUES • FIRE RISK • CONCERNS	☐ MANAGEMENT OF PATIENT REVIEWED
DOES PATIENT HAVE:		
DIFFICULT AIRWAY/ASPIRATION RISK? ☐ NOT APPLICABLE ☐ NO ☐ YES: EQUIPMENT/ASSISTANCE AVAILABLE		
HISTORY OF FLOMAX/ALPHA 1-A INHIBITOR? ☐ NO ☐ YES		
HISTORY OF ANTICOAGULANTS? ☐ NO ☐ YES ☐ CONTINUED ☐ STOPPED AS INSTRUCTED		

Case: Delayed Diagnosis of Endophthalmitis

System Issue:
Postoperative care

Delayed Diagnosis of Endophthalmitis

Medical History	Surgery	Postop Day 1 (Fri)	Postop Day 4 (Mon)	Outcome
• 78 YO BVA 20/30 OD, 20/100 OS with amblyopia.	• Cataract surgery OD complicated by floppy iris. • Iridectomy and placement of sutures in 2 corneal incisions.	• Corneal edema, blurry vision, pain pm prior, no signs of infection. • Advised to return Monday. Saturday pt's caregiver called, pt feeling "more washed out". • Surgeon offered to see but pt declined.	• Obvious infection, pt referred to retina. • Dx: endophthalmitis. • OD eviscerated and prosthesis placed.	• Settled \$750,000

Litigation

Alleged cataract surgery on the patient's good eye should not have been performed due to risks.

No documentation of Saturday (POD2) call until after evisceration. Caregiver had a different recollection of discussion than surgeon.

There were revisions made to the EHR by other staff which led to questioning the credibility of the medical record.

Postoperative Issues

Telephone screening expectations.

Written postop instructions.

Plan for disclosure of adverse events.

Documentation expectations of all communications with patients in the medical the record.

System Approach

Postoperative care



Policy and procedure
for telephone
screening.



Document calls with
patients – all staff,
during and after hours.



Follow-up visits with
patients and complaint
follow-through.



Discussion and
documentation for
referrals.

Risk Reduction Strategies

Postoperative Coordination



Monitor postop symptoms closely, especially after complicated surgery.



Document after hours calls as soon as possible.



Provide clear postop instructions for symptoms that require emergent follow-up.

Risk Reduction Strategies

Weekend Postoperative Management



Post op Day #1 – plan for managing postoperative period (over weekend or holiday).



Discuss and document plan for postoperative complications and communication over weekend.



Staffing: Define team management of on call service with clinical support.

Conclusion



Standardized Processes

Use checklists and protocols at every stage.



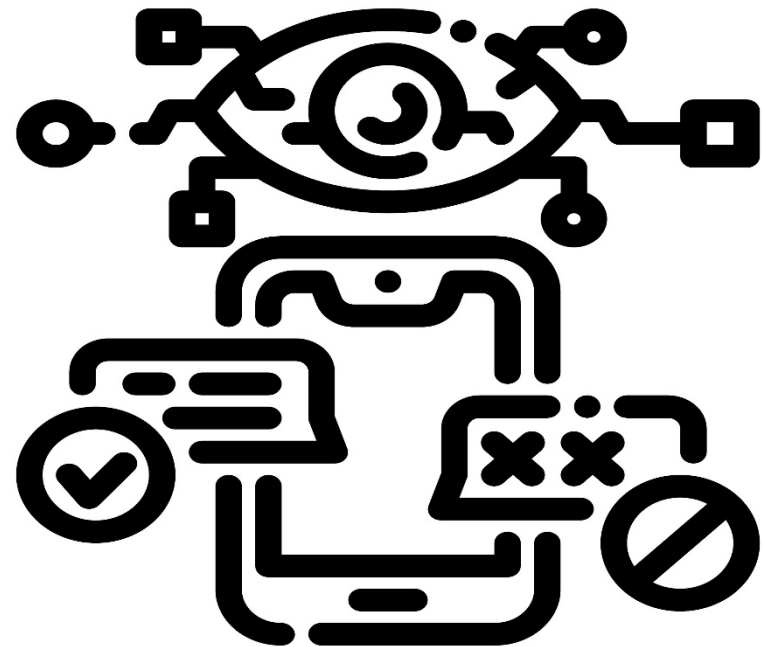
Team Communication

Share critical information before, during, and after surgery.



Patient Safety Focus

Every member of the team plays a role in preventing harm.



Risk Management Resources @ omic.com

Consent forms

- 13 cataract-related forms
- Retrobulbar/Peribulbar consent

Risk Management Recommendations (RMRs)

- Articles on topics discussed in this course, including
 - Cataract Surgery Pre- and Postoperative Interval Guidance
 - Documentation in Ophthalmology
 - Informed Consent Process
 - Hemorrhage Associated with Ophthalmic Procedures
 - Ophthalmic Surgical Safety Checklist
 - Refunds and Waivers
 - Timeout Process for Procedures

Thank You!

Contact us:



riskmanagement@omic.com



1-800-562-6642, option 4

Online resources:



<https://www.omic.com/risk-management/>



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