Lessons Learned: When Safety Protocols Fail

Hans K Bruhn, MHS

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Financial Disclosures

- Hans K Bruhn, MHS- OMIC Risk Manager

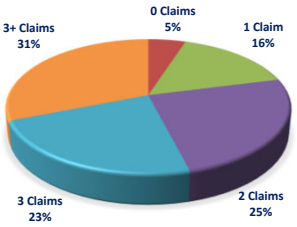
Learning Objectives

- Identify factors that increase the probability of errors.
- Maintain staff engagement in safety protocols.
- Increase effectiveness of checklists and timeouts.
- Understand the link between documentation and defensibility.

"Physicians are in a double bind of expectation: to be human, just like their patients, and to be superhuman, not like them at all, in never making a mistake and knowing everything."

-Sara Charles, MD, 2005

Probability of a Claim in a 30-Year Career in Practice



- **Probability of a claim in a given year is 8%.**

Case #1:
Failure to Review Medical History before Treating

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Chronology: August Visit

Exam	• 61 y/o receiving monthly Avastin injections for wet AMD • Uncorrected VA OD was in 20/40 range • Patient missed July visit due to illness, returned in August • Vision decreased from 20/60 OD to CF with an IOP 44 mmHg OD • Cup to disc ratio 0.3
Impression	• Vision loss attributed to missed appointment in July
Treatment	• Insured administered injection of aflibercept
Note	• ***No mention of high IOP in the chart***

IOP Readings, Prior 6 Months

Date	Vision OD	IOP OD (mmHg) tonopen	Avastin Injection OD
Jan	20/50	26	Y
Feb	20/40	20	Y
March	20/40	35	Y
April	20/50	39	Y
June	20/60	12	Y
July	*Missed appointment*		

Note: *No documentation of elevated IOPs in exam notes.*

Chronology: September Visit

Exam	• VA = LP OD, • IOP 45 mmHg OD; • Cup to disc ratio 0.8; shallow anterior chamber
Diagnosis	• Glaucoma
Treatment	• Paracentesis to lower IOP • Started Vyzulta and Simbrinza • Referred to glaucoma specialist in practice
Apology	• ***The insured apologized to the plaintiff for missing the elevated IOP***

5 Days Later: Glaucoma Evaluation

Exam	• VA = LP. IOP 10 mmHg. Angle closed. Advanced cupping
Diagnosis	• Angle closure glaucoma OD, severe stage
Plan	• Laser iridotomy
Note	• ***Patient never returned to the practice***

Lawsuit

Defendants	• The insured and the practice
Allegation	• Failure to evaluate and treat elevated IOP • Negligent injection of aflibercept
Damages	• Chronic angle closure glaucoma • Loss of vision: 20/50 OD to LP • $550,000 for pain and suffering, and past and future wage loss

Insured's Deposition: Key Testimony

1	• Visual Acuity and IOP are recorded in the EMR but not always available on the summary page. The technician is suppose to alert the physician of any IOP greater than 30.
2	• Never knowingly performed an injection on plaintiff with a pressure over 30 and believes the tech did not communicate the elevated pressure.
3	• Took responsibility for not confirming the IOP before each injection, and admitted to being negligent

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Reviews

Retained Expert	• Failed to timely recognize the high IOP which over time caused optic nerve damage and loss of vision.
OMIC	• Deviated from the standard of care in failing to recognize elevated IOPs at 4 different visits. Failure to evaluate and treat the elevated IOPs was most likely the cause of the optic nerve damage and patient's permanent vision loss.

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Outcome

Settled: $360,000

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Risk Management

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Risk Management

- Systems failure: tech failed to notify MD of elevated IOP
- Physician's duty: must review history before treating
- EMR factor: can be more difficult to find IOP values

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Case #2
Distractions in the OR

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Chronology

1st visit	• Patient with diabetic retinopathy, treated with intravitreal injections, presented to the insured with 2-week history blurred vision and floaters on the left • VA = 20/40 OD; 20/200 OS, with peripheral vision present. Diagnosis: retina detachment • Prior to the retina detachment, VA on the left was 20/80 • The patient was consented for pars plana vitrectomy with air/fluid exchange OS
Surgery	• Pars plana vitrectomy, retinal detachment repair, and infusion of C3F8 15% gas • Complication = choroidal hemorrhage.
PO Day 1 (Friday)	• Patient complained of 10/10 pain and severe headaches for 10 hours, not relieved by 1800 mg Tylenol • VA was HM at 8 feet; IOP OS was 85 • Vitreous tap decreased IOP to 24; gas bubble = 95% • RX: Combigan and Maxitrol; appointment on **Monday**

Chronology

PO Day 3 (Sunday)	• 6:45am patient calls the service: "blood keeps filling up in my eye" • Insured sees patient in the office and taps the eye to relieve the gas • *No note* in medical record to document the visit and treatment • Patient admitted to the hospital for IOP management and pain control
Visual outcome	• ***The patient remained NLP OS***

Lawsuit

Defendants	• Surgeon, practice, hospital
Allegations	• Negligent preparation of gas • Failure to formulate and implement a proper treatment plan (postop) • Failure to keep an accurate medical record
Damages	• NLP OS • Need for additional surgery • Past /future medical expenses • Diminished earning potential and quality of life

Discovery

1. The surgery was performed at an ASC the insured rarely used.
2. At this ASC, surgeons are required to prepare the gas.
3. At the "regular" ASC, the techs prepare the gas.
4. There were multiple distractions in the OR:
   - A new scope was being used to repair the macular hole.
   - Two manufacturer's reps were in the OR.
5. The insured concluded that he did not dilute the gas.
6. The lack of a note for the Sunday visit was due to computer problems at the office.

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Reviews

Retained Expert	• The type of surgery performed was appropriate. • Informed consent was proper. • Below SOC to use incorrect gas concentration. • The patient should have been monitored more closely postop. • The insured should have implemented a proper and timely treatment plan, versus responding to symptoms.
OMIC	• Agreed with the opinions of the retained expert.

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Outcome

Settled: $995,500

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Risk Management

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Risk Management

- Be familiar with protocols at ASCs and hospitals.
- Always conduct a timeout when preparing gas.
- Documentation: if you cannot enter a note in the medical record, make a temporary note and add it to the official medical record as soon as possible.

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Case #3
Failure to Perform Patient Identification in the Office

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Chronology

6/29	• High myopia patient underwent emergency retinal detachment repair surgery due to RRD OS following cataract surgery • Prior to surgery, VA OS = HM
9/7	• At follow up visit, patient doing well • VA=20/50 OS • No evidence of re-detachment • Return 6 weeks for OCT of the macula and dilated exam OU
10/19	• Dilated exam; UCVA OS=20/80 • Instead of the planned OCT, patient received bilateral Lucentis injections prepared for a different patient • The patient never asked why she was getting the injections

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Chronology

Later on 10/19	• Staff informed physician of the error after the patient left the office. • The patient was asked to return to the office that day. • The insured disclosed the error and did an exam. • The patient was told that there should be no adverse effects from the injections.
	Subsequently the patient experienced 3 retinal detachments and repair surgeries.

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Lawsuit

Defendants	• Physician and practice
Allegations	• Improper injection of Lucentis • Failure to detect the resulting retinal hole in a timely manner • Failure to take steps to prevent a retinal detachment
Damages	• Three subsequent retinal detachments where injection was given OS • Three additional surgeries to repair detachments • One surgery to remove silicone oil due to high IOP • Out of pocket medical expenses • Ongoing intermittent pain, headaches, light sensitivity • Pain and suffering

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Reviews

Retained Expert	• Bilateral injections are not necessarily below SOC, but carry greater risk for endophthalmitis. • Diagnosis of acute iridocyclitis did not support treatment with Lucentis. • The patient might have experienced the subsequent RDs notwithstanding the injections, although the RDs occurred in the location where intravitreal injections are typically given.
OMIC	• Agreed with the expert's opinions. • The patient was not consented for the injection.

Outcome

Settled: $575,000

Split 50/50 between physician and practice

Risk Management

Risk Management

- Systems failure: patient identification
  1. Staff called the patient from the waiting room using a first name only. Two patients with the same first name were in the waiting room, and the "wrong" patient walked into the exam room.
  2. No second identification was performed in the exam room.
  3. Staff did not verify the procedure with the patient or the medical record.
  4. No verification that consent had been obtained.
  5. The physician did not do a timeout before administering the injection.

- ***The practice had protocols that required checking this information, but they were not followed.***

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Case #4
Failure of the Surgical Timeout

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Chronology: Day of Surgery

Surgery Schedule	• The patient's cataract surgery was scheduled for the 3rd cataract procedure of the day at the ASC. • On the morning of surgery, the 2nd procedure was cancelled. • The 3rd procedure was moved to the 2nd timeslot.
Timeout	• A nurse gathered the 2nd patient's information and IOL for the timeout. • The record indicates that the timeout was completed. • Surgery was performed using the incorrect lens.
PACU	• The nurse disclosed her error to the surgeon. • Comparison of the intended lens with the implanted lens revealed a significant difference in lens power. • The surgeon proceeded with immediate lens exchange.
Disclosure and Apology	• *When the patient was fully alert, the surgeon disclosed the error to the patient and family.*

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Chronology: Postop Course

PO Day 1	• VA 20/400 without correction • Moderate corneal edema; Durezol prescribed • Reviewed postop care instructions • Plan: return in 2 days
PO Day 3	• VA CF; IOP 25 • Patient expressed anger about error • Surgeon recommended IOL exchange; corneal edema should improve with time
1 month postop	• VA 20/80 -2; IOP 16; OCT normal; retina normal • Dx: persistent corneal edema; continue Muro, Pred Forte, Combigan • Continue to monitor
Note	• ***The patient never returned.***

Lawsuit

Defendants	• The surgeon and the ASC; the surgeon's practice was named but dismissed during discovery.
Allegations	• Incorrect IOL placed.
Damages	• Decreased vision. • Continuing eye pain, light sensitivity, and headaches that interfere with numerous ADLs. • Pain and suffering.

Reviews

Retained Expert	• Placement of wrong IOL is below SOC. • The 2nd procedure caused the corneal edema and endothelial cell loss, but patient recovered vision. • May be difficult to prove that 2nd procedure is the direct cause of ongoing pain, headaches, photophobia.
OMIC	• Deviated from SOC in placing incorrect lens. • Failure to perform an accurate timeout. • No consent obtained for lens exchange. • Extended surgery time and lens exchange contributed to corneal edema.

Outcome

Settled for $750,000

- *$375,000 insured*
- *$375,000 ASC*

Risk Management

Risk Management

- Systems failure: surgical timeout
  - Was the patient identified in the OR before the timeout?
  - Was the patient identification data compared to the operative plan and the lens that was used to conduct the timeout?
  - It seems unlikely that these steps were followed appropriately.

Risk Management

- Systems failure: no informed consent for lens exchange
  - Although the lens exchange was necessary, consent was still required.
  - The surgeon appropriately disclosed the error and elected to apologize.

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Resources

Documentation of Ophthalmic Care
https://www.omic.com/documentation-of-ophthalmic-care/

Responding to Unanticipated Outcomes
https://www.omic.com/unanticipated-outcomes-steps-for-responding/

Surgical Safety Checklist
https://www.omic.com/ophthalmic-surgical-checklist/

Injection Timeout (video)
https://youtu.be/9x7V2zEGIzA?si=sQfut6mm7bVSIW--

Obtaining and Verifying Informed Consent
https://www.omic.com/informed-consent-recommendations/

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800-562-6642

Online Resources:

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

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