Lessons Learned from Glaucoma Claims: Closing the Loop, Medical Record Amendments, and Comanagement Guidance

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OMIC Risk Manager

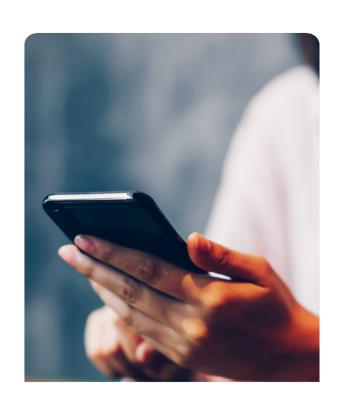


Ohio Ophthalmology Society March 15, 2025

Financial Disclosures

Michelle Pineda, MBA
 OMIC Risk Manager





OMIC insureds will earn a 5% Risk Management discount by scanning the QR code that will be shown at the end of the course.

If you are unable to capture the QR code on your phone, please let me know.



Learning Objectives

Upon completion of this course, participants should be able to:

- Understand the role of communication in promoting patient safety and reducing malpractice exposure.
- Implement referral and follow-up safety protocols to close the loop.
- Define the role and responsibilities of healthcare team, including licensed and unlicensed staff.



Claims Statistics

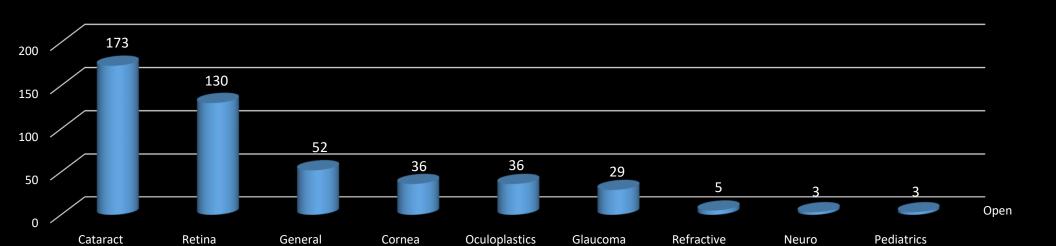






Open Claims

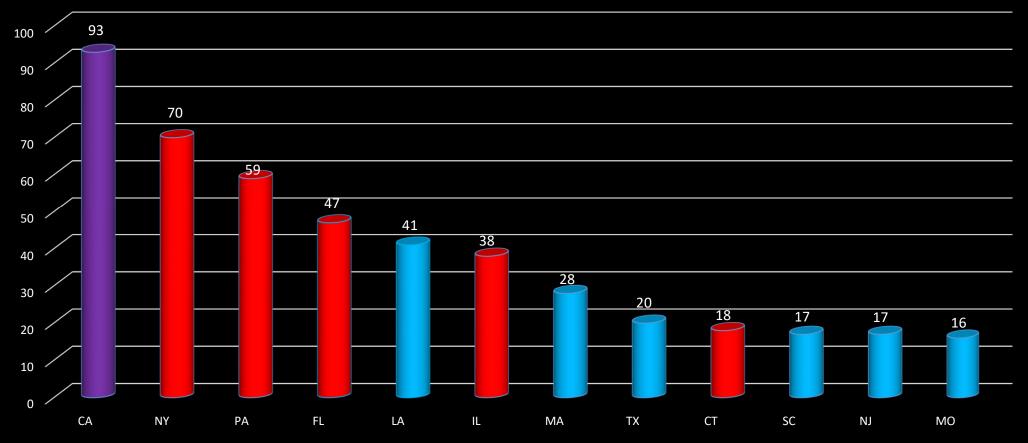
BY SPECIALTY through September 1, 2024



Will get updated slides through end of 2024 Jeannette Domask, 12/16/2024 JD26

Open Claims by State As of September 1, 2024

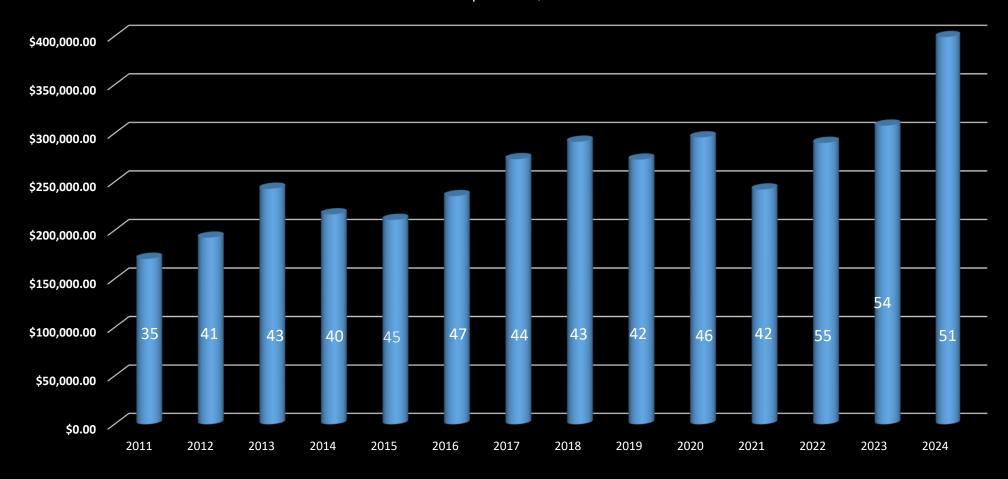
OPHTHALMIC MUTUAL INSURANCE COMPANY A Risk Retention Group



Average Indemnity Payment



WITH NUMBER OF SETTLEMENTS PER YEAR 2011- As of Septmeber1, 2024



Case #1

Delayed referral in a young patient with chronic uveitis



Nov 22	 32 y/o female, established patient Ocular hx: chronic bilateral non-granulomatous intermediate uveitis, treated with topical & subtenon steroids; posterior subcapsular cataracts; denies family hx of glaucoma; secondary open angle glaucoma, likely steroid-induced. Intermittently elevated IOPs beginning in 2011 (24 OU); sporadic glaucoma drops. Medical and surgery hx: Lyme disease in teens; diabetes, hypertension, migraines, laminectomy, oophorectomy Medications: Topiramate (Topamax), diltiazem, spironolactone (sporadic metformin); Pred Forte drops (2008-present) every day to 6 x daily OU Complaints: hazy vision, worse at night Exam: BCVA 20/20 OU; IOP 25 OD and 27 OS; SLE: quiet AC, trace PSC OD, 1+ PSC OS Impression: Resolved uveitis OU post subtenon injections and prolonged treatment with steroid drops. Plan: Taper prednisolone down every 2 weeks, currently qid OU Return: 4-6 weeks

Dec 20	 Complaints: "I believe my vision is worsening" Exam: BCVA 20/20 OU
Feb 7	 Complaints: Blurry vision OD > OS. One month ago, black cloud over vision, right eye x one hour; returned early last week and remains. Current meds: Timolol qd OU; Pred Forte qd OU Exam: BCVA OD: 20/70; OS: 20/20 IOP OD: 38 (x 3), 26; OS: 14 Plan: increase timolol from every morning to twice daily OD

March 7	 Exam: IOP 35 OD, 12 OS, Plan: Stop timolol, add Cosopt bid and brimonidine tid
March 21	• Exam: BCVA OD: 20/50 Distance, 20/70 Near; IOP 23 OD C/D ratio 0.6 OD.
May 2nd	 Complaints: can no longer see out of OD Exam: HM OD, IOP 32 OD, C/D 0.95 OD Dx: severe glaucoma; glaucomatous progression likely responsible for vision loss Rx: add Rocklatan, continue Cosopt and brimonidine Plan: refer to glaucoma specialist

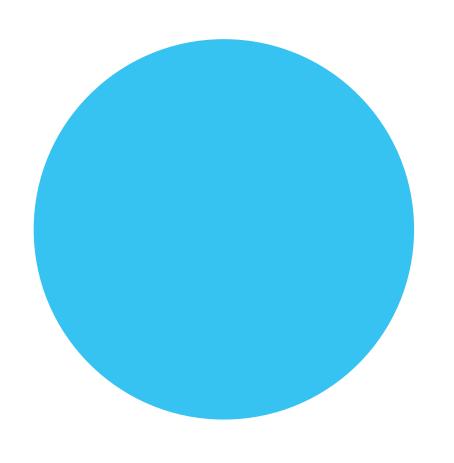
Care by Subsequent Treater

May 5	 1st visit with glaucoma specialist Exam: Vision OD: HM; IOP 35 Plan: offered tube shunt or diode laser; decided on tube shunt
May 10	 Procedure: tube shunt Exam: LP OD and 20/20 OS; IOP controlled

Suit filed Oct 31	 Allegation: failure to timely refer to a glaucoma specialist due to elevated intraocular pressure resulting in permanent damage to the optic nerve and loss of vision in the right eye
Damages	 Patient did not recover vision; remained LP OD Increased difficulty performing job functions; difficulty driving at night Must rely on family for help with many everyday tasks
During Discovery	 Physician recalled telling patient in March that a referral would be made to a glaucoma specialist and office staff would follow up with the patient. The plan to refer was not documented. The referral was made 2 months later, when the patient was HM OD. The referral plan was inserted into the March visit note several months later. The patient's records request made prior to litigation produced records that did not show documentation regarding referral to a glaucoma specialist, and also revealed differences in IOP readings when compared to the insured's records produced during litigation.

OMIC Review	 Long course of topical and subtenon's steroids with periodically elevated IOP and no HVF/OCT NFL is below SOC More aggressive treatment required in Nov/Dec when IOP rose to mid 20's and 30's Documentation and EHR issues Some notes in EHR signed 6-8 months after date of visit Cannot defend records alteration Insured consented and early resolution was pursued
Result	

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Result	Settled for \$2 million



Risk Management:

Delayed: referral or testing > diagnosis > treatment In Litigation...

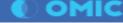
86% of OMIC glaucoma claims that resulted in a settlement included one of these allegations:

- ➤ A failure or delay in diagnosis
- Improper management of the treatment plan, including delayed referral to a glaucoma specialist
- Improper performance of surgery
- Improper management of surgical patients



Implement Protocol to Close the Loop

- Assess Processes: Identify bottlenecks and risks (e.g., missing test results, delayed notifications, patient compliance failure).
- Office Readiness: Evaluate team attitudes, communication, and use of policies and procedures for patient safety and quality improvement.
- Patient Engagement: Understand patient experiences and provide educational materials to involve them in the process to ensure compliance.
- **Documentation Audits**: Ensure accurate and complete labs, tests, and referral documentation to prevent errors.
- **Electronic Health Records (EHR)**: Assess EHR capabilities in supporting tracking systems to close the loop for ordered labs, tests, or referrals.



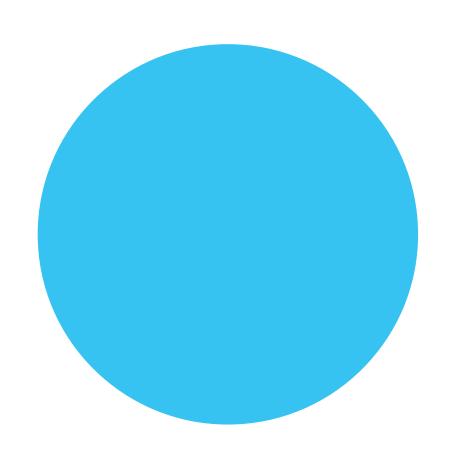
Follow-Up Strategies



- Explain your recommendations, including when to obtain labs, tests and referrals, and the importance of compliance.
- Describe potential consequences to vision if treatment is delayed or declined.
- **Document** the discussion.



- Implement tracking systems to verify that patients obtain recommended labs, tests, and referrals.
- Establish policies and procedures to close the loop.
- Goal to ensure timely diagnosis and treatment.
- Terminate patient as a last resort.



Risk Management

Late sign-offs in the medical record



Late Medical Record Entries and Sign-off

Risks

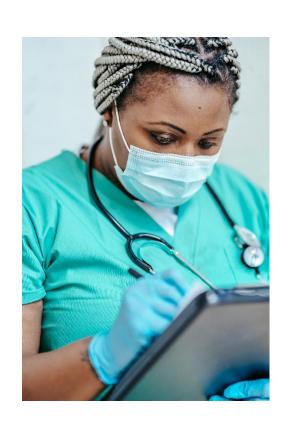
- Compromises credibility, accuracy, and completeness
- May lead to
 - Incorrect diagnoses
 - Delayed treatment and referral
 - Medication errors
 - Inappropriate treatment plans
- In litigation, late entries can cause the credibility of the entire medical record to be questioned

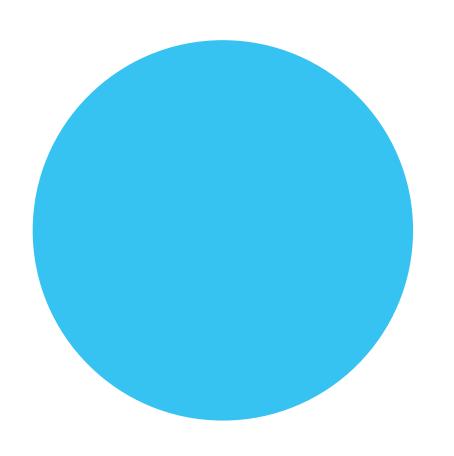
How to Avoid

- Review:
 - Review documentation to insure accuracy and thoroughness.
- Complete ASAP:
 - Sign off at the end of each day or as soon as possible to ensure timely completion.
- Utilize system reminders:
 - Leverage EHR features such as automated prompts to remind you to complete and sign off on patient records.

If You Use a Scribe...

- Responsibility: Ultimately, the physician remains responsible for all clinical decisions and actions taken based on the documented information, even if a scribe assisted in the documentation.
- **Review Documentation**: Review and sign off on all documentation completed by the scribe to confirm accuracy and thoroughness.
- **Confidentiality**: Emphasize the importance of confidentiality and compliance with HIPAA and ensure adherence.
- Feedback and Evaluation: Providing regular feedback to the scribe can help improve their performance and ensure they are meeting the expectations of the role.





Risk Management

Amendments

- > Late entries
- Addendums
- Corrections

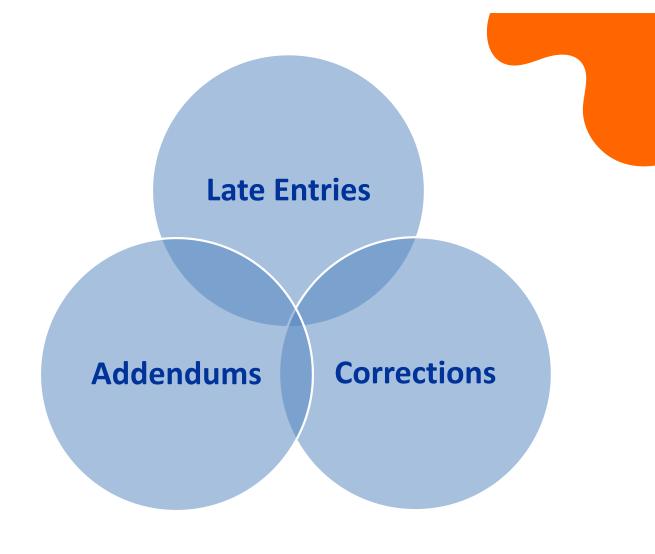


In Litigation...

- ➤ Medical records, both paper and electronic, will be scrutinized by the plaintiff's attorney for any entries that suggest credibility is in question.
- ➤ EHR audit trails and forensic evaluations assist plaintiffs in proving an allegation of medical records credibility.
- Records alterations cannot be defended.

These changes can be legitimate but must be done correctly to avoid any appearance that the change was intended to conceal or falsify what occurred.

Such changes to the medical record should occur infrequently.





Late Entries, Addendums, and Corrections

When might these be necessary?

- The original note was not completed at the time of the patient encounter.
- Crucial information was inadvertently omitted.
- There are errors in the documentation.
- The documentation does not provide sufficient detail for one or more elements of the note, such as the differential diagnosis, plan, informed consent discussion, instructions to the patient, etc.



Making Amendments in Medical Record

Addendum

Entries added to a health record to provide additional information in conjunction with a previous entry. The addendum should be timely, bear the current date, time, and reason for the additional information being added to the health record, and be electronically signed.

Correction

A correction is a change in the information meant to clarify inaccuracies (incorrect, invalid, or made in error) after the original electronic document has been signed or rendered complete.

Deletion

A deletion is the action of permanently eliminating information that is not tracked in a previous version. Most EHRs do not allow permanent deletion.

Late Entry

An addition to the record when a pertinent entry was missed or was not written in a timely manner. The late entry should be timely, bear the current date, time, and reason for the additional information being added to the record and be electronically signed.





- ➤ If you think you need to add to the record, be sure you understand how to do so correctly.
- Policies and procedures should be established to provide guidance.
- > Contact Risk Management for assistance.

Case #2

Emergent referral for topiramate (Topamax)-induced angle-closure glaucoma



Jan 24 Referral by treating neurologist	 35 y/o with history of migraine, calls treating neurologist at 10:00 am to report awakening with severe vision loss after double-dosing on topiramate (Topamax) the day before; then developed severe headache, nausea, and vomiting. Neurologist calls ophthalmologist's office, speaks with scheduler, and requests that patient be seen that day for suspected topiramate-induced glaucoma. The patient was scheduled as a work-in at 3:15 pm for "blurry vision."

Later that Patient arrived at 3 pm, but not brought to an exam room until 4:50 pm. day... • A **technician** dilated the patient with Neosynephrine 2.5%, Cyclogyl 1%, and Mydriacyl 1%. (Record later changed to Mydriacyl 0.5%.) **Exam by ophthalmologist**: IOP 54 mmHg OU; unable to perform a complete exam due to pain, discomfort, and photophobia; mild injection of the conjunctiva and corneal edema OU, anterior chamber shallow in the periphery; VA was count fingers at 1 foot OU. Tx: Alphagan, Azopt, Lumigan, Betimol, lopidine, Diamox, and Valium. Glaucoma meds given at 4:58 pm and 6:30 pm; no steroids administered. • **Results**: at 6:49 pm, IOPs 49 OD and 52 OS. **Impression**: acute glaucoma, malignant glaucoma versus angle-closure glaucoma **Plan**: physician called glaucoma specialist at university, who agreed to see the patient the next morning. (The university is a 2.5-hour drive away.)

Jan 25	 Patient seen by university glaucoma specialist. Exam: IOP 44 OD and 46 OS; mild lid edema, pupils dilated OU. Impression: angle closure, history of topiramate use; advised laser iridotomy. Treatment: patient desired bilateral iridotomy the same day, which was performed. After iridotomies, IOPs were 24 OD, 18 OS.
Ongoing treatment and course	 The patient continued care with glaucoma specialist(s). One year later, vision was relatively stable at 20/80; silicone plugs placed for dry eyes. Two years later, the cup to disc ratio of the right eye had increased to 0.5-0.6 OD; IOPs remained stable in the 17-18 range. Initial note was "rewritten" when patient requested a copy of medical records approximately one year after event.



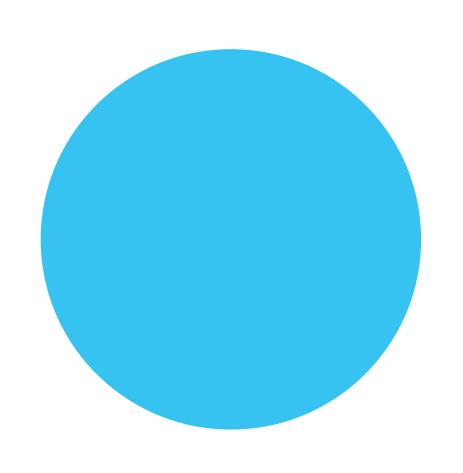
Lawsuit	 Allegation: delayed treatment of glaucoma and failure to lower IOP in a timely manner resulting in irreparable damage to the optic nerve and permanent decrease in visual acuity.
Damages	 Independent Medical Exam: severe peripheral and central vision loss; VA 20/100 OD, 20/200 OS, no pinhole improvement. Mild cataracts. IOP 22 OD, 23 OS; cup to disc ratio .52 OD, .49 OS; OCT without significant nerve fiber layer loss.
Retained Expert Opinions	 Patient should have been seen sooner than 2 hours after arrival at office. Dilated by technician before physician advised of IOPs. Failed to diagnose topiramate-induced glaucoma. Should have stopped topiramate and started cycloplegics/atropine, as well as steroids to address corneal edema and presumed choroidal swelling. Below SOC to send patient home with elevated IOPs, when appointment with glaucoma specialist was not until 11:30 am the next morning. Patient should have been sent to ER for IV mannitol. Cannot defend alteration of medical records.

OMIC Review	Agreed with retained experts.
Result	



OMIC Review	Agreed with retained experts.
Result	• Settled for \$450k.





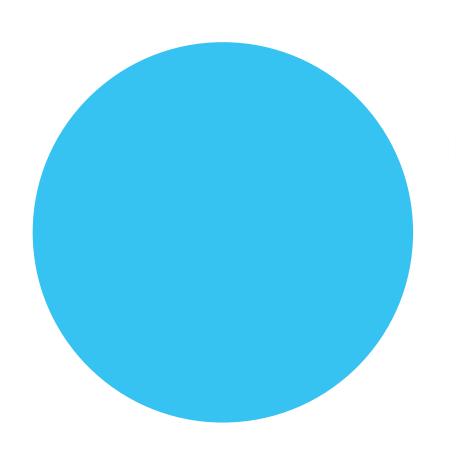
Records alterations



The prior case illustrated the risk of an improper <u>late entry</u> in the medical record, while this case illustrates the risk of a late and improper <u>change</u> to the medical record.

Legal Risks:

- An improperly-executed change to the medical records that is made in close proximity to a medical records request, and a long time after the event in question, will raise suspicions about the motivation for the change and its veracity.
- If you think a change to the medical records is indicated before producing a copy of your records, we strongly advise you to speak with Risk Management at your carrier, or your practice attorney.



Telephone screening by unlicensed staff



Telephone Screening by Unlicensed Staff

Key Concepts:

- The role of unlicensed staff is limited to gathering and transmitting information and assigning an appointment category.
- Unlicensed staff cannot:
 - engage in independent decision making or interpretation.
 - offer an opinion on cause of symptoms or treatment needed.

Legal Risks:

- Inadequate documentation and misinterpretation of patient information can lead to legal liabilities if a patient's condition worsens as a result.
- Plaintiff may allege that screening calls without policies and physician supervision is the unlicensed practice of medicine.



Telephone Screening Policies and Procedures

Create policies for:

- Handling postop complaints
- Patients who want to be seen ASAP
- Physician referrals: emergent, urgent, and non-urgent
 - And, how to handle emergent- and urgentappointment patients when they arrive at the office
- When physicians want to be interrupted
- Missed appointments and no-shows

Provide staff with:

- Physician-approved written policies and procedures
- A mechanism to report challenges or concerns encountered during screenings and with applying the policies
- Ongoing training and supervision



Patient Telephone Screening Form

Phone number New patient: Yes/No Time of call Date of call New referral from Dr. Name and title of staff member taking call		New refe	rral from Dr	
	is your problem?			
When	did your problem begin?			
How s	uddenly did it begin?			
Has th	e problem worsened, improved, or	remained unchange	ed?	
Does i	t affect one eye or both?	If one eye, which	one? Right/Left	
Have y	ou recently had surgery or a proce	dure? Yes/No		
0	Type and date of surgery/procedu	ure		
Has yo	our vision changed? Yes/No			
0	Loss of vision? Yes/No			
	 If yes, describe loss 			
	Flashes? Yes/No Floaters? Yes			es/No
0	Change in vision? Yes/No. (circle			
F0.20	■ Double vision? Disto		0000000	001
	in? Yes/No Location, description,		202	
	Has the pain worsened, improved		_	
	Did nausea and vomiting accomp	12 Table 1	10	
0	Is there any other type of pain? Y	150 NO 150	Other	
A	Headache Facial pain	Jaw pain or ache	other	
	ur eyes red? Yes/No Has redness worsened, improved		nas.d2	
	arge from the eye? Yes/No. If ye		10.77(1)	
	Eyelids stick together? Yes/No.	es, describe	- 	
	urn/injury to the eye, forehead, or f	Face 2 Ver/Nie		
	Eyelid damaged? Yes/No Pain?		occ2 Voc/No	
	Describe how burn/injury occurre	그렇게 하다 뭐 하는데 하다 그 그렇게 된 어떻게 된다면 다 없다.	Full (1995) - 14 Full (1975)	
0	Describe now burnyinjury occurre	=0	55 45 33 55 55	
Do you	u wear contact lens? Yes/No	Glasses? Yes/No		
Any of	her problem?	***************************************	>	
			*	
pe of ap	pointment:	Emergent	Urgent	Routine



COMPLAINT	EMERGENT	URGENT	ROUTINE
FLASHES/ FLOATERS	Recent onset of light flashes and floaters in patient with: Significant myopia (nearsightedness): ask about history of LASIK or refractive surgery After surgery or procedure, or Accompanied by shadows in the peripheral vision.	Recent onset of light flashes and floaters without symptoms of emergent category Many ophthalmologists prefer to see these patients the same day. If in doubt, consult with the ophthalmologist.	Persistent and unchanged floaters whose cause has been previously determined
REDNESS/ DISCHARGE	Worsening redness or discharge after surgery or procedure.	Acute red eye, with or without discharge	Mucous discharge from the eye that does <u>not</u> cause the eyelids to stick together
	Redness or discharge in a contact lens wearer	Discharge or tearing that causes the eyelids to stick together.	Mild redness of the eye <u>not</u> accompanied by other symptoms
OTHER EYE COMPLAINTS		Photophobia (sensitivity to light) if accompanied by redness and/or decrease in vision	Photophobia as only symptom
			Mild ocular irritation, itching, burning
			Tearing in the absence of other symptoms
BURN	Chemical burns: alkali, acid, organic solvents. <u>Give burn</u> instructions.		



HB3

This appt should have been marked emergent. Rec these definitions be added to screening protocol. Emergent A condition that requires immediate intervention. Examples include a gunshot wound to the chest, appendicitis, or a perforated abdomen

Urgent A condition that requires prompt medical attention, usually within 24 to 48 hours. Examples include minor injuries, sore throats, earaches, and frequent coughs. Urgent care is available for conditions that need attention quickly but are not life-threatening.

Routine A procedure or surgery that corrects a problem but isn't life threatening. Examples include cosmetic surgery, non-painful hernias, and some reservations.

Hans Bruhn, 12/11/2024

Case #3 Delayed diagnosis of glaucoma in a comanaged patient



Chronology

Patient	 Established patient x 10 years, beginning at age 63. Treated by MD and OD for dry eye with ATs, cyclosporine, punctal plugs, antibiotics, steroids and intense pulsed light (IPL) therapy; history included a sibling with glaucoma. Optomaps were performed annually to assess the back of the eye. Care provided by 2 ophthalmologists and 1 optometrist in the same practice.
2013 September October December	 VA 20/30 OD, 20/50 OS; IOPs 22 OD 23 OS. Cataract surgery OS with Crystalens Trulign IOL Patient drew on Amsler grid a dark gray area superiorly; no visual field test performed. Patient felt dry eye was worse; VA 20/20 OD, 20/40 OS; IOP 9 OD, 12 OS
2014 January March	 Piggyback lens placed. IOP spike to 32 OS; assessed borderline glaucoma with steroid response. Cup to disc ratio documented as .30 OU; 2 weeks later 2nd physician documented as .40 OD and .90 OS Patient complained of grittiness OU and floaters OD; VA 20/20 OD, 20/25 OS; dx=meibomian gland dysfunction (MGD) OU, dry eye; floaters OD; refer to neuro ophthalmologist re: visual field defect.
July	 New diagnosis: normal tension glaucoma (NTG) OS>OD, exacerbated by pigment dispersion from piggyback lens OS Seen by a glaucoma specialist. 2 iStents placed OS and piggyback lens OS removed
August	 Glaucoma remained stable through Patient's last visit at the practice; VA 20/20 OD, 20/50 OS; IOPs 9 OD, 12 OS



Lawsuit	 Defendants 2 ophthalmologists, 1 optometrist, and their practice Allegations Failure to timely diagnose glaucoma Improper refill of medications by staff (no physician oversight) Failure to perform optic nerve exams (relied on Optomaps instead)
Claimed Damages	 Light sensitivity, which inhibits driving, daytime outdoor activities, and computer use Decreased depth perception resulting in tripping and falls. Needs assistance with ADL's.

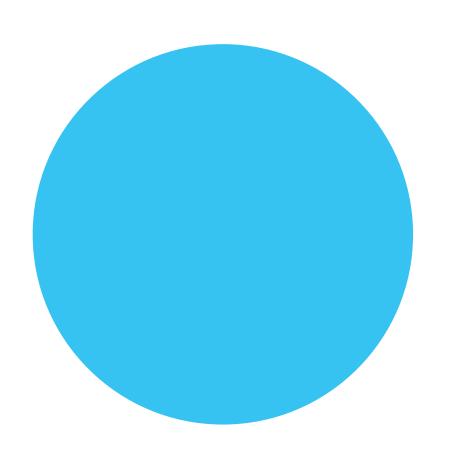


Retained Experts	 Unanimously agreed below standard of care (SOC). Evidence of developing glaucoma several years before diagnosis required visual field studies. Failure to monitor for glaucoma and changes to optic nerve. Physicians allowed the optometrist to perform Optomaps in place of comprehensive eye exams with evaluation of the optic nerve. Concerning changes on Optomaps not addressed. Non-physician staff authorized refills without physician approval. Late diagnosis resulted in additional procedures and caused the condition to progress worsen.
OMIC review	Agreed with retained experts.
Demand	 \$750,000 Defense counsel estimate \$200-250K settlement range
Resolution	



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Resolution	 Case settled for \$162,500 60% of liability attributed to practice secondary to system failures (including OD and vicarious liability), 40% to the physician







Summary of Risk Management Issues

(MD and OD)

*Lack of communication

*Lack of physician oversight of OD providers

*Lack of recognition of early glaucoma

Failure to diagnose

*Failure of OD to do optic nerve exams and follow the patient closely

*Failure to interpret studies

*Failure to conduct proper tests to monitor the patient

*Failure to diagnose

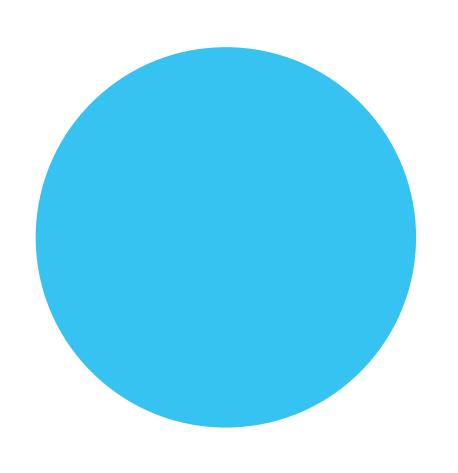
Lack of medication refill protocol

*Refills provided without physician authorization.

*Refills provided for medications that were previously stopped or limited (no reconciliation performed)

*Not all refills were documented





Comanagement



Risks of Comanaged Care

- Miscommunication between providers
- Delayed or incorrect diagnosis due to fragmented information
- Medication errors arising from inconsistent treatment plans or poor documentation
- Difficulty seeing patterns of symptoms and progression of disease
- Poor coordination of care with other specialists
- Patient confusion regarding treatment plan



Comanagement Protocol

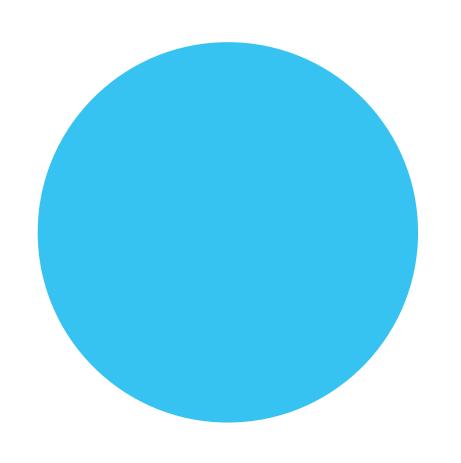
- OMIC recommends that all practices that work with optometrists (whether employees, independent contractors, or participants of a call group) have a written protocol.
- The protocol should include:
 - Role during office hours
 - After-hours call (if applicable)
 - Emergency Department call (if applicable)
 - Ophthalmologist back up
- All members of the practice should be allowed to review and comment on the proposed protocol before it is adopted.
- Once implemented, the protocol should be reviewed and updated on a regular basis. Include an initial and ongoing training plan for staff.



Comanagement Protocol

- Vet optometrists' education, licensure, and certification.
- Understand state laws regarding optometrist scope of practice.
- Define the role of optometrists when managing different categories of patients:
 - Independently within scope of practice
 - Patients that require consultation with an ophthalmologist
 - Patients that require management by an ophthalmologist
- Set expectations regarding documentation.
- Establish protocols for communication between optometrists and ophthalmologists.





Prescription refill protocol



Problem

- *Non-physician staff approved refills without physician review, resulting in:
- 1) refills for medications that had been limited or discontinued by a physician
- 2) patient harm due to greater steroid use than planned.
- *Not all prescriptions and refills were recorded in the medical record.



Root Cause

No standard RX protocol

- No description of roles, responsibilities, or steps for new and renewed prescriptions.
- Lack of physician review prior to submitting prescription.



Prescription Refill Protocol

- Always document the number of refills allowed before the patient must return for a follow-up appointment.
- Define staff's role in handling refill requests.
- Outline steps for:
 - Obtaining physician authorization for refills and new prescriptions
 - How to transmit the order to the pharmacy
 - How to document the transaction in the medical record
 - How to communicate to patients that a refill or new prescription has been denied until the patient comes in for a visit, and how to document the communication.
- Explain your prescription refill policy to patients. You may wish to post the policy under FAQs on your website.



In Closing...

- Develop policies and procedures to close the loop on ordered labs, tests, and referrals.
- Develop policies and procedures for guidance concerning amendments to the medical record.
- Develop policies and procedures for telephone screening for non-clinical staff and for co-management with other providers.
- Train all staff on policies and procedures to set expectations and ensure compliance and patient safety.
- Audit to confirm compliance with protocols or to discover improvement opportunities.

Resources

www.omic.com

- Documentation of Ophthalmic Care
- Coordinating Care with Optometrists
- Comanagement of Surgical Patients
- Telephone Screening Toolkit (includes telephone requests for refills)
- Noncompliance Toolkit
- Terminating the Physician-Patient Relationship Toolkit

AHRQ – Improving your Laboratory Testing Process

IHI – Closing the Loop

HealthIT.gov – Test Results Reporting and Follow-Up



OMIC insureds will earn a premium discount by scanning the QR code and completing the form.

Please allow up to 2 weeks for processing.

Contact us:



riskmanagement@omic.com



800-562-6642

Online resources:



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

