Lessons Learned from Cataract Surgery

Southern Eye Congress
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OMIC
OPHTHALMIC MUTUAL INSURANCE COMPANY

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Financial Disclosures

Dr. Fouraker:

- Consultant and speaker for Alcon.
- OMIC Board Member

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Learning Objectives

Course Goal: Identify professional liability risk exposures associated with cataract surgery procedures and provide ophthalmic surgeons and their practice with risk management strategies to mitigate those risks.

Objectives

1. Identify the types of information and tasks that should be included in a **pre-op protocol** including billing for cataract surgery patients. Be able to develop a written pre-op protocol for this procedure.
2. Identify the purpose of the **informed consent process**, and the benefit of using procedure-specific consent forms for cataract surgery. State how the informed consent process can mitigate liability risk and how it is used in the event of a claim.
3. State steps in the pre-op protocol that should be used to confirm that the cataract surgery **patient's expectations** are in line with the **operating surgeon's expectations** for outcome.
4. Identify **anesthesia liability** risks in cataract surgery, specifically the potential risks when using CRNAs and Anesthesiologists to render anesthesia care. State how to maintain the separation of care between these anesthesia providers and the operating ophthalmologist during the cataract surgery.
5. State how **documentation** of patient care benefits patient safety and provides defense against medical malpractice claims. Be able to include steps to ensure correct lenses are ordered and pre-operative tests are accurately filed in the patient's medical record.
6. State why **surgical time-out procedures** prior to surgery are important. And be able to develop a time-out protocol for cataract surgery.
7. State the importance of **timely resolution of patient complaints**.

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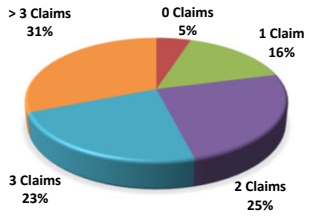
Probability of a claim in a 30-year career



Probability of a claim in any given year is 8%

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OMIC Claims History 2011-2020

- **ALL OMIC Claims 2011-2020**
  - **80%** claims closed with no indemnity payment
  - average settlement $226,101
- **OMIC Cataract Claims 2011-2020**
  - **83%** claims closed with no indemnity payment
  - average settlement $148,496
  - 4 plaintiff verdicts ($2,649,466 total)

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Cataract Claims

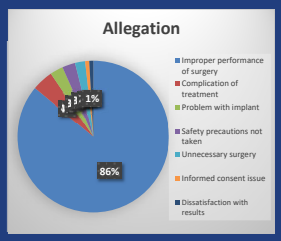

TABLE 1. NUMBER OF CATARACT CLAIMS (2016-2020)	
ALL cataract claims	299
Litigated claims (lawsuits)	136 (85)
Non-litigated claims	163
# indemnity payments	49
This study: claims involving ONLY premium IOLs and premium services	99
Litigated claims (lawsuits)	32 (19)
Non-litigated claims	67
# indemnity payments (litigated)	13 (9)
# cases	80

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Legal Elements of Medical Malpractice

"The Four D's"

to a medical malpractice case that must be met by a plaintiff

- Duty of MD to treat patient
- Deviation from standard of care (requires expert testimony)
  - What would a reasonably prudent ophthalmologist do in the same or similar circumstances?
- Direct causal relationship between deviation and the alleged injury/damages (i.e., proximate cause)
- Damages: actual economic and non-economic
  - If paid = "indemnity" payment

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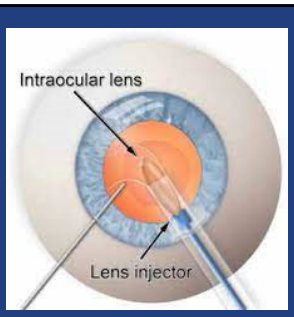

Case #1
Wrong IOL

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Preop Evaluation

- 65 y/o female c/o blurry vision OU x 6months, OD>OS
  - UCVA= 20/40 OD, PH 20/50; 20/40 OS, PH 20/40
  - Dx: 3+ NS cataracts OU
  - Plan: phaco with PCIOL OS; no noted complications
- Lens Implant Data Sheet completed same day with order for ZLB multifocal lens, +25.5 diopters

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Informed Consent

- Documentation clearly indicated patient's choice of a multi-focal lens

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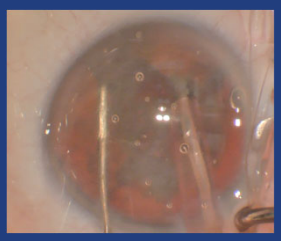
Operative Report

- Phaco and posterior lens implantation OS
- States implantation of PCB00 (monofocal) lens* +25.5 diopters
- No mention of any complications

***** Lens order form indicates ZLB00 multifocal lens ordered *****



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PO Day 1

- Seen by surgeon
- Vision improved
  - 20/40 OS, 20/25 PH
  - PC IOL in good position
  - Return 1 week

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Handwritten addendum dated PO Day 1

- Monofocal lens inserted into capsular bag
- Conducted checklist and verified lens with nurse
- Realized the wrong lens (monofocal) was inserted
- Made medical judgment that explanting lens would harm eye
- Capsular bag showed mild zonular weakness and there was considerable posterior pressure bowing capsular bag forward
- Explantation would risk posterior capsule tear, eliminating possibility of using the planned lens
- Concerned re: retinal tear to myopic & LASIK-treated eye
- Decided it was best to leave lens in place
- No documentation that the error was discussed with the patient

Ongoing Postop Care

1 week
blurry vision OS; VA SC = 20/50 +1, OS, PH to 20/30
5 weeks
seen by optometrist; "blurry vision OS" VA with correction = 20/20
5-1/2 months
seen by insured for pre-op eval, OD
VA 20/40 OD, PH to 20/40; 3+ NS cataract OD
Consented for cataract surgery OD
Lens order sheet = ZLB00 (multifocal) lens, 25.0 diopters

Surgery #2: Right eye

- Femto/ORA-assisted cataract surgery
- Posterior chamber lens
- ZLB00 (multifocal) lens, 25.0 diopters
- No complications noted

Postop Visits

Day 1: seen by insured's partner
Blurry vision OD; VA SC 20/70, pinhole to 20/40 -1
1 week
blurry vision; VA SC 20/50 OD, PH to 20/40
1 month: patient sees a different ophthalmologist
blurry vision continues; may need IOL exchange
6 weeks: last visit with insured
VA SC OD= 20/70, PH to 20/50; OS= 20/60, PH to 20/40

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"Disclosure" of Error

7.5 months after error in eye #1, insured sent and an email to patient stating:

- Your near vision is good despite having only 1 multifocal lens
- A refund check for $1820 for out-of-pocket costs is on its way to you
- No documentation in the medical record regarding the refund, nor discussion with patient about the error.

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The Claim

- Records request
- Notice of intent to sue from attorney
- Theory of liability:
  - Addendum added after 2nd surgery (7 months after event)
  - Insured did not disclose error to patient
  - Fraud and intentional misrepresentation

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Patient's Testimony

- Discovered the error after surgery #2, on PO Day 1, when insured's partner stated during exam that patient had a monofocal lens OS (1st surgery).
- Patient responded "I hope not, because I paid for a multifocal lens" after which the Dr. said "Oh, you do have a multifocal."

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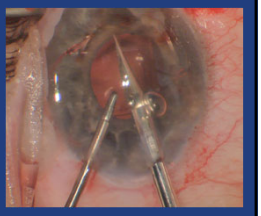
Defense Expert

- Addendum: states monofocal lens was mistakenly loaded, but PCB00 lens is pre-loaded
- Monofocal lens should have been removed immediately & replaced
- Probably not advisable to remove monofocal lens at 13 months



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OMIC Review

- 1st surgery: mistakenly implanted monofocal instead of the documented multifocal lens the patient requested and the office ordered for patient
- No documentation that surgeon discussed the error with patient.
- No documentation that surgeon discussed treatment options after the error.
- Refund should have been discussed immediately with patient, vs. sending 7 months after the error occurred.

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Resolution

- Clear case of liability
- OMIC was able to mediate the case prior to further discovery
- Settled for $150,000

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Error Management

Preop

1. Insure that lens ordered is: lens received and lens sent to ASC
2. Use safety checklists in OR

Intraop

1. First, take care of the patient

Postop

1. Thorough, accurate, timely op report
2. Factual, timely disclosure of error to patient
3. Objective documentation in medical record with clear plan
4. Financial resolution

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Should you offer a refund?

- Waiving or refunding fees is NOT <u>legally</u> an admission of liability unless "I'm sorry that I…"
- May appease the patient and be seen as caring **OR**
- May convince patient you did something wrong
- Many ophthalmologists consider refunds after cosmetic procedures and premium IOLs a smart business decision

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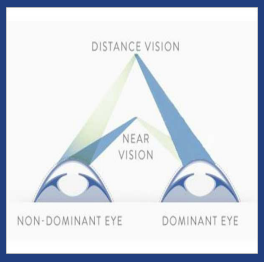
Should you offer a refund?

- Contact Claims if you receive a written demand
- If the outcome resulted from an **error**, waive or refund your fees for all related treatment
- Clearly explain what fees will be waived and for how long

Should you offer a refund?

- If you decide to pay fees of another physician, ask the physician to bill you directly rather than pay or reimburse the patient
- This ensures that payment is only for remedial medical expenses



Case #2
Refractive Error

Preop Evaluation

- Referred by optometrist
- Multiple entries in record indicate patient didn't tolerate monovision in past
- Patient wanted intermediate vision
- Plan: femto-assisted cataract extraction, OS
- Trulign lens target OS -0.75 to 1.00; OD at -0.25

Monovision

Lens	1-2+NS with dense cortical change	2+NS with dense inf c axis
Clarity	Clear	Clear
Anterior Cap	N/A	N/A
Posterior Cap	N/A	N/A
Cortex	Clear	Clear
Nucleus	Clear	Clear

Anterior Segment Exam Notes: referred by Dr [redacted] pt did not tolerate monovision in past

Patient was dilated. Dilation occurred at 10:22 OU with MYD 1%.

Posterior Exam	
OD	
Optic Disc	Normal	Normal

Informed Consent

- Used specific cataract and femto consents
- Patient did not choose a lens option, but did sign the consent:

CHOOSE ONE OF THESE OPTIONS AND CROSS OUT THE OTHER ONE

1) Monofocal IOL/Glasses Option
I wish to have a cataract operation with a monofocal IOL on my _____ eye. I understand I will need to wear glasses or contact at least part of the time

2) Multifocal IOL Option
I wish to have a cataract operation with a multifocal IOL implant on my _____ eye. I understand that although this IOL is designed to minimize the need for glasses, I may still need to wear glasses for optimal vision. I also understand that I will be responsible for a substantial additional charge that is not covered by Medicare or other medical insurance.

Postop Course, OS

- PO Day 1: optometrist sees patient
- PO Day 3: insured sees patient
  - UCVA 20/60 distance, J1 near (OS); refraction is -1.00
  - explains to patient OS was offset by ~ 1 diopter for reading with Crystalens (sic) and OD will be set for plano

Surgery #2, OD

- Surgery: femto-assisted cataract surgery OD with Trulign lens
- PO Day 2: UCVA OD 20/30 +1; J2+ OS; doing well; return 3 weeks
- 1 month: patient complains of constant tearing, burning, poor night vision, stabbing pain OU for several weeks; distance vision is blurred. Refractive testing reveals regular astigmatism OD.
  - Diagnosis: residual refractive error OD; myopia OD
  - Plan: Yag cap OD 1 month, then PRK OD to fine tune distance

Yag capsulotomy

Information Provided By: Patient

Complaint

72 year old female complains of patient returns for yag cap laser treatment in right eye for few months. The timing is described as constant. Quality is worsening. Severity is described as moderate.

Blurry Vision Continues…

- 4 months postop
  - Distance vision constantly blurry; no improvement after Yag
- 5 months postop
  - no change; artificial tears help; insured continued to offer PRK
  - CVA 20/25
  - Assessment: mild myopic prescription that is bothersome to patient
  - Plan: see optom for repeat refraction; return after for PRK right eye
- Patient never returned

Claim

- Insured received intent to sue letter from attorney
- Allegations:
  - Negligent care and treatment
  - Failure to obtain informed consent
  - Breach of warranty of fitness (recommended lenses were not an appropriate choice for patient)

What Did the Patient Understand?

- The Dr. told me the cataract surgeries with intraocular lenses would correct my visual problems with both reading and distance and I would no longer need corrective lenses.
- The lenses would cost $4500 each and would accomplish this.
- My insurance would not pay for the recommended lenses, so I paid out of pocket because the Dr. convinced me that I not only needed them but I would have good vision for distance and reading without glasses.

OMIC Review

- Original surgical plan is a typical one for Trulign IOL
- But why did surgeon choose monovision?
- Chart states in multiple places that patient didn't tolerate monovision in the past
- No documentation to support thought process
- The patient did not indicate lens choice on consent form, which could support argument that patient was not adequately informed of choices.

Resolution

- Insured opted to settle the matter for a nominal amount prior to litigation- $3500

Informed Consent

- An oral agreement reached after the surgeon advises the patient of:
  - Diagnosis and proposed treatment
  - Risks, benefits, alternatives, and potential complications
  - Consequences of refusing treatment
- Informed consent should be documented through a:
  - Note in medical record (always)
  - Procedure-specific consent form (usually)
  - Memorializes the consenting conversation

Informed Consent vs. Surgical Goals

- An informed consent discussion addresses risks, benefits, and alternatives.
- It does not always explicitly include surgical goals.
- What happens if you and your patient have different goals and expectations?

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Managing Patient Expectations

If the patient's goal is unattainable or contraindicated, document the patient's understanding of likelihood of success, complications, and impact on ADLs

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Documenting Surgical Goals

- No documentation that the surgical plan would be similar to the monovision that the patient did not tolerate in the past
- No documentation of the patient's acceptance
- Did the patient understand how monovision would impact her daily life & activities?
- Prior discussion with the patient: What if the goal is not reached? Physician confirmation of expectations.

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Surgical Goals and Patient Expectations

- Be careful with language re: outcomes
- Be clear re: out-of-pocket costs
- Offer all medically-indicated options
- Do not give the appearance of "upselling"

Case #3: Misfiled A-Scans

2 Patients with the Same Surname Walk into the Office…

- …on the same day, for evaluation of cataracts
- A-scans were performed on both patients
- Patient #2's A-scan was misfiled in Patient #1's medical record, and was used to calculate measurements for Patient #1's cataract surgery.
- Fortunately, the error did not impact Patient #2

However….

- Neither the office staff nor the surgeon noticed that the patient name and birthdate were incorrect
- A timeout in the OR was reportedly done
- Patient #1 underwent cataract surgery using Patient #2's measurements

Postop Care (1st eye)

- Only the same-day and PO Day 1 exams were done in the surgeon's office.
- The 1-week exam was done by the comanaging OD, who was not in the surgeon's office.
- The patient was refracted hyperopic, but this was not communicated to the surgeon.

2 Weeks Later…

- The surgeon, unaware of the hyperopic surprise, performed cataract surgery on the 2nd eye using measurements from the misfiled A-scan that belonged to the other patient.
- Again, neither the staff nor the surgeon noticed the incorrect name and birthdate on the A-scan in the medical record, in spite of an OR checklist being used.

Postop Care (2nd eye)

- The patient was seen exclusively by the comanaging OD after surgery #2
- The surgeon remained unaware of any problems until the patient returned over 2 months later after the 2nd surgery, complaining of poor quality vision.

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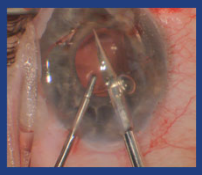
Lens Exchanges



The medical record documents the surgeon's discussion with the patient regarding the need for IOL exchanges.

The record is silent as to whether the error was disclosed to the patient.

Lens exchanges performed, and patient's ultimate VA was 20/20 OU without correction.

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OMIC Review

- This was human error and a clear case of liability
- Several issues contributed to the error
  - Systems issues
    - Misfiled test results (A-scans)
    - Inadequate safety checks in office and at ASC
  - Communication between surgeon and OD

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Claim

- The patient demanded $95,000
- Clear case of liability
- Settled for $36,000

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Safety Checklists

Create a pre-op protocol for:

- Surgery scheduling
- Confirming that correct devices are ordered, received, and sent to OR
- Managing changes to surgical plan: communication amongst patient, staff, surgeon, ASC
- Documenting changes in medical record
- Determining if changes warrant additional discussion or informed consent with the patient

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Comanagement Guidelines

Confirm that the comanaging OD is:

- Qualified to comanage surgical patients
- Knowledgeable about the complications associated with the type of comanaged surgery
- Prepared to contact you promptly about complications or delayed healing, and to immediately transfer care
- Committed to honoring patient requests to obtain care from you

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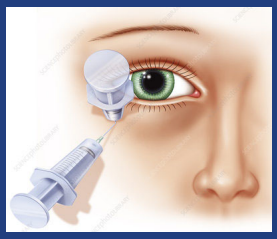
Case #4
Peribulbar Block and the After Hours Phone Call



- Insured performed uneventful cataract surgery OS
- 1 week later, insured performed cataract extraction OD:
  - Procedure at ASC with RN assisting
  - Peribulbar block with monitored IV sedation by CRNA
  - Op report does not mention any complications

Day of Surgery

- Patient left PACU at 10am
- PACU nurse tried to call patient at noon, but line was busy
- 5pm: patient calls office to report pain OD, headache Insured's instructions: remove patch, start Pred and Ocuflox, and use Tylenol #3 for pain
- 7pm: office calls patient, who reports eye still painful, swollen shut, and appears black. Insured's instructions: use cool compresses, elevate head, no activities, and call with any changes.
- 9pm: office calls patient and tells her to come in early the next morning for evaluation.

Postop Care

- PO Day 1: ongoing pain, headache, swelling; can't open OD; periorbital hematoma; IOP 25; no VA recorded.
  - Diagnosis = IOL OU
  - Plan = Zioptan drops; return 2 days
- PO Day 3: retina flat; OD VA=LP; referred to retina
- Final diagnosis (by other provider)=optic neuropathy of unknown etiology; VA OD=NLP

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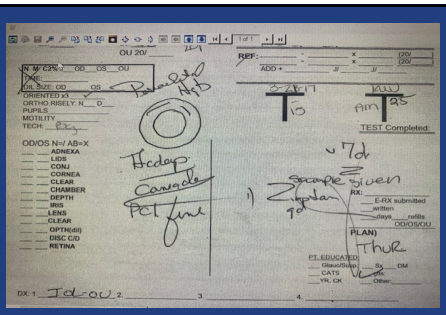

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Allegation

- Failure to timely evaluate post op complaints of the patient who received a retrobulbar block resulting in vision loss due to hemorrhage.

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Legal Action

- Patient filed suit against surgeon and practice
- Patient demanded $1.5M
- Case settled for $750,000

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Plaintiff's Expert Opinions

- Vision salvageable until midnight (day of surgery)
- Insured failed to respond to ophthalmic emergency:
  - Significant pain & swelling were indicative of hemorrhage
  - Required immediate exam and treatment to relieve pressure on optic nerve
  - This failure caused permanent loss of vision, R eye
- Emergency surgery would likely have saved vision R eye

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Defense Expert Opinions

- Poor documentation of postop visits
- No sense of urgency; no clear plan re: declining vision until PO Day 3 when referred to retina
- Retrobulbar hemorrhage should have been suspected as of 5pm call due to swelling and black color around eye
- Insured should have seen patient based on information from 5pm call
- Causation: even if patient was seen following 5pm call on day of surgery, uncertain if VA could have been improved

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OMIC Review

- Consistent with defense expert opinions

Risk Management Issues

- Documentation
  - Postop visits
  - Postop phone calls with staff
  - Physician orders
- Telephone screening
  - Determine which staff members are equipped to handle postop calls, both during and after hours
  - Develop protocol for giving information to physician and documenting calls and orders

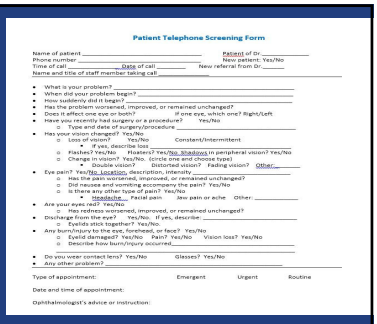
Documentation of Postop Visits

- Exam findings, diagnosis, and plan
  - there was no indication of the surgeon's thought process, differential diagnosis, or plan for a patient who had lost vision
  - Sparse note may be construed by a jury as indicating a physician who was rushed, not thorough, or unknowledgeable

Telephone Screening

- Develop protocols for telephone screening
  - During office hours
    - How are patient complaints and urgent calls triaged?
    - When do physicians want to be interrupted?
  - After office hours
    - Consider the training and experience of your staff and determine who is equipped to handle after-hours calls
    - Special handling for calls re: postop complaints?

Sample Form: Telephone Screening



Patient Telephone Screening Form

Name of patient _____ Patient of Dr. _____
Phone number _____ New patient: Yes/No
Time of call _____ Date of call _____ New referral from Dr: _____
Name and title of staff member taking call _____

- What is your problem? _____
- When did your problem begin? _____
- How suddenly did it begin? _____
- Has the problem worsened, improved, or remained unchanged?
- Does it affect one eye or both? If one eye, which one? Right/Left
- Have you recently had surgery or a procedure? Yes/No
  - Type and date of surgery/procedure _____
- Has your vision changed? Yes/No
  - Loss of vision Yes/No Constant/Intermittent
  - If Yes, describe _____
  - Flashes? Yes/No Floaters? Yes/No Shadows in peripheral vision? Yes/No
  - Change in vision? Yes/No. (circle one and choose type)
    - Double vision? Distorted vision? Fading vision? Other: _____
- Eye pain? Yes/No Location, description, intensity _____
  - Has the pain worsened, improved, or remained unchanged?
  - Did nausea and vomiting accompany the pain? Yes/No
  - Is there any other type of pain? Yes/No
    - Headache Facial pain Jaw pain or ache Other: _____
- Are your eyes red? Yes/No
  - Has redness worsened, improved, or remained unchanged?
- Discharge from the eye? Yes/No. If yes, describe: _____
  - Eyelids stick together? Yes/No
- Any trauma/injury to the eye, eyelid, or face? Yes/No
  - Eyelid damaged? Yes/No Pain? Yes/No Vision loss? Yes/No
  - Describe how injury/injury occurred _____
- Do you wear contact lens? Yes/No Glasses? Yes/No
- Any other problem? _____

Type of appointment: Emergent Urgent Routine

Date and time of appointment:

Ophthalmologist's advice or instruction:

Sample Form: Telephone Screening for Appointment urgency

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 not 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 not 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. Give burn instructions.		

Resources

Procedure-specific consent forms
https://www.omic.com/risk-management/consent-forms/

Telephone screening
https://www.omic.com/wp-content/uploads/2012/11/Telephone-screening-toolkit-with-forms-1.docx

Ophthalmic surgery checklist
https://www.omic.com/wp-content/uploads/2016/02/Ophthalmic-Surgery-Checklist.pdf

AAO guidelines for surgical comanagement
https://www.aao.org/ethics-detail/guidelines-comanagement-postoperative-care

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Thank you!

OMIC insureds will earn a premium discount

Contact us:

riskmanagement@omic.com
1-800-562-6642
Enter 4 for Risk Management

Online Resources:

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

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