Medical Errors in Optometry: Avoiding Them and Facing Them Head On

Beth Steele, OD, FAAO

Disclosures – Dr. Beth Steele

<table>
<thead>
<tr>
<th>Company</th>
<th>Position</th>
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<tbody>
<tr>
<td>Optos</td>
<td>Advisory Board</td>
<td>Honorarium</td>
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<td>Med Op</td>
<td>Consultant</td>
<td>Honorarium</td>
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+ CDC – Deaths Due to Medical Errors

*The 3rd leading cause of death in the US, BMJ 2016*

- Overview and Lecture Objectives

- Definitions / Terminology
- Most Common Errors
- Disclosing Errors to Patients
- Documentation
- Root-Cause Analysis
- Error Avoidance
Medical Error

*A preventable adverse effect of care that may result in patient harm*

1. Error of Execution
   - Unintended act (omission or commission)
   - Failure of planned action to be completed as intended

2. Error of planning
   - Incorrect plan to achieve a particular aim
   - Deviation from process of care

Terminology

- **Unanticipated outcome (adverse event)** = negative or unexpected result from procedure, treatment, judgement or from failure/lack thereof; a mal-occurrence
- **Sentinel event** = serious adverse event attributable to error (e.g. loss of limb or function)
  - Leads to the need to ask why the error occurred → change

→ **Unanticipated outcomes/adverse events may or may not be the result of error or negligence**

→ **Not all errors are malpractice / negligent**
Malpractice

- Behavior that involves unreasonable risk to others; medical negligence; unreasonable lack of skill or fidelity in fiduciary relationship; illegal, immoral conduct
- Medical Malpractice requires all of the following:
  1. **Duty** – owed by doctor-patient relationship
  2. **Breach** - care rendered was below the standard
  3. **Causation** - Link between clinician’s act/omission and the patient’s loss
  4. **Injury** - Patient must have suffered a loss (e.g. vision)
  5. **Damages** – Monetary loss such as lost wages, bills

AL Medical Liabilities Act

- Plaintiff’s legal counsel must prove negligence
- Discovery laws limit what can be asked / shared
  - Confidential information (e.g. incident report, analysis process)
- Damage caps
  - E.g. $250K for non-medical damages
Did an Error Occur?  
*Was the Standard of Care Followed?*

- **Standard of Care** = The level and type of care that a reasonably competent and skilled provider, with a similar background and in the same medical community, would have provided under the circumstances

- Not all errors are malpractice / negligence

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### Top 10 Reasons for Malpractice Suit for ODs

*Classe J, Review of Optometry 2004*

1. Failure to dilate
2. Failure to determine cause of reduced acuity
3. Failure to refer/recall
4. Failure to Rx Polycarb
5. No periodic eye health exam for CL wearers
6. Failure to educate patient about suspicious findings
7. Failure to get informed consent
8. No VF for kids
9. Poor co-management protocol adherence
10. Poor documentation

[https://www.reviewofoptometry.com/article/how-to-be-sued-for-malpractice](https://www.reviewofoptometry.com/article/how-to-be-sued-for-malpractice)
When *Errors* Lead to Malpractice

- Misdiagnosis of Intraocular Disease (58%) – POAG, retinal detachment, mass
- Injuries from Ophthalmic Materials (21%) – CL's (corneal complications), Spectacles (polycarbonate)
- Misdiagnosis of Ant. Seg. Disease (11%) – Corneal disease, FB
- Improper Co-Management (5%) – Refractive surgery, cataract surgery
- Injuries from Ophthalmic Drugs (3%) – Angle closure
- Misdiagnosis of Binocular Vision Anomalies – Failure to treat amblyopia

Optometric Malpractice Claims (Classe' 1998)
**Types of Medical Errors**

*Diagnostic; Surgical; Prescription*

Either:

- **Active errors**
  - Immediate impact
  - Due to actions of an individual

- **Latent errors**
  - Errors in the system, operation, design, equipment

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**Table 1. Definitions of Different Types of Medical Incidents**

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<table>
<thead>
<tr>
<th>Definition</th>
<th>Harmful Event</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>The individual experienced temporary harm and required treatment or intervention.</td>
</tr>
<tr>
<td></td>
<td>The individual experienced temporary harm and required initial or prolonged hospitalization.</td>
</tr>
<tr>
<td></td>
<td>The individual experienced permanent harm.</td>
</tr>
<tr>
<td></td>
<td>The individual experienced harm and required intervention necessary to sustain life.</td>
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<table>
<thead>
<tr>
<th>Definition</th>
<th>Death</th>
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<tbody>
<tr>
<td></td>
<td>The individual died.</td>
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**Diagnostic Errors**

- Approximately 15% diagnostic inaccuracy amongst general medical providers
  - Less likely with specialists
  - 5% of adults have experienced a misdiagnosis
  - Associated with approximately 10% of deaths in the US

- Leading (or 2nd) type of medical malpractice claims resulting in payment
  - Least preventable
  - Physicians tend to overestimate their accuracy with diagnosis

Berner E, Graber M. Am J Medicine, 2008.
Improving Diagnosis in Health Care, from IOM September 22, 2015
Mild FBS, patient reports “trauma” ---
Dx: corneal abrasion

2 days later....
Overconfidence as a Cause ?!

- Most diagnostic errors occur in the synthesizing phase of decision making
  - **Heuristics** = methods that help in problem solving used to rapidly come to an optimal solution
    - "rules of thumb", educated guesses, intuitive judgments or simply common sense
    - Known cognitive errors occurring with heuristics

- Solutions ?
  - Advocating an environment of sharing, learning, growing
  - Self-awareness – slow down and avoid jumping to conclusion
  - Self-reflection
  - Continued education, updating

Berner E, Graber M. Am J Medicine, 2008.

Surgical Errors
***(Procedural Errors)***

- “NEVER events” (WSPE’s)
  - Wrong site
  - Wrong procedure
  - Wrong patient

- Unanticipated outcomes from procedures
**Medication / Prescribing Errors**

- 7 million patients impacted annually
  - >1.5 million patients harmed every year
- Deaths from medication errors went up almost 3x from 1998 to 2005
- Costs $21 billion annually

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Institute of Medicine, 2006, 2015
United States Pharmacopeia
Moore et al, 2007
US Dept Health and Human Services Office of Disease Prevention and Health Promotion, 2014

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**Types of prescribing errors**

*Most often an error in prescribing and administering*

1. Omission errors
2. Dosing errors
   - Knowledge-based
   - Rule-based
   - Memory-based
   - Action-based
3. Unauthorized drug errors
   - Most likely due to:
     - Distractions
     - Inexperienced or insufficient staffing

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71 year old FM
Rx thiothixene (Navane), antipsychotic
instead of amlodipine (Norvasc),
antihypertensive
Took wrong medication x 3 mos
→ Ambulatory dysfunction, tremors, mood swings, personality changes

Prevention

- Computerized Physician Order Entry (CPOE)
- E-Rxing recommended by IOM and ARHQ to *reduce medication errors* and patient harm

“Tall Man” Letters

*Institute for Safe Medication Practices*

- Issues list of FDA-approved drug look-alikes and recommended capitalizations

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Table 1. FDA-Approved List of Generic Drug Names with Tall Man Letters

<table>
<thead>
<tr>
<th>Drug Name With Tall Man Letters</th>
<th>Confused With</th>
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<tr>
<td>aceZOLAMIDE</td>
<td>aceHEXAMIDE</td>
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<td>aceHEXAMIDE</td>
<td>aceZOLAMIDE</td>
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<tr>
<td>buPROPan</td>
<td>buPiracetam</td>
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https://www.ismp.org/recommendations/tall-man-letters-list
Medical Error Reporting

Duty to Disclose
Best Practices
Documentation

Agency Oversight

- Agency for Healthcare Research and Quality (AHRQ)
  - Patient Safety and Quality Improvement Act, became law 2005
  - Established a voluntary confidential reporting system to create a national database of medical errors for analysis and development of evidence-based safety measures

- Joint Commission
  - Full disclosure of unanticipated outcomes required since 2001

- National Quality Forum
  - Recommended disclosure of serious unanticipated outcomes since 2006
State level requirements

- Disclosure of sentinel events is required
  - State laws outline “reportable” events
  - UAB Risk Management sends to Patient Safety Committee and determines risk
- 36 states with “apology laws”
  - apology not admissible in court
- Provider Education
  - Some states (e.g. FL) – 2 hours Medical Errors initially and then q2 years

States with Apology Laws

| Arizona    | Nebraska |
| California | New Hampshire |
| Colorado   | New Jersey |
| Connecticut| North Carolina |
| Delaware   | North Dakota |
| Florida    | Ohio |
| Georgia    | Oklahoma |
| Hawaii     | Oregon |
| Idaho      | South Carolina |
| Iowa       | South Dakota |
| Indiana    | Tennessee |
| Louisiana  | Texas |
| Maine      | Utah |
| Maryland   | Vermont |
| Massachusetts | Virginia |
| Michigan   | Washington |
| Missouri   | West Virginia |
| Montana    | Wyoming |

And more importantly...

- Doctor-patient relationship
  - Full disclosure fosters a patient-centered approach
  - Patient has a right to know
  - Builds trust
- AOA Standards of Professional Conduct
  - “...telling the truth is a necessary component of a trusting optometrist-patient relationship”
- Optometric Oath, Am Board of Optometry
  - “I WILL advise my patients fully and honestly ...”

Disclosure of Medical Error to Patient

- One of the most difficult things about practicing
- Physicians may shy away
  - Fear of malpractice suit
  - Embarrassment
  - Apprehension of dealing with patient reaction / emotion
  - Fear of job-related adverse consequence

Patient’s perceptions

- Patient’s want to hear:
  - What happened
  - That you are sorry it happened
  - What you / the system will do to prevent recurrence

- Data shows that patients are less likely to pursue legal action when the physician displayed honesty and sympathy
  - 37% patients said that an explanation and apology would have prevented the lawsuit, AHRQ
Why Else? Benefits the “system”…

- Increased awareness of the problem
  - Reduce mistakes
  - Develop best practices aimed at reducing errors

- Promotes sharing of successful solutions between providers
  - Culture of open discussion
  - Vs. “culture of blame”

- Reduced costs

What if the patient is not aware of the mistake, and no harm was caused?

- Full disclosure fosters a patient-centered approach
- Patient has a right to know
- Builds trust

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Prescribed Zylet instead of Alrex…..

- “These are not the drops that we intended for you to use – we suspect that an error occurred when we distributed the bottle to you. I am sorry this happened. Fortunately, this just had the added component of an antibiotic and did no harm. We will be looking into how this happened so that it won’t happen to someone else.”

Components of a Disclosure

- Disclosure
  - Full disclosure that an “error occurred” and why it occurred
- Apology for poor outcome
- Nature of condition and how will the error’s effects be dealt with/minimized
- Steps the provider/organization will take to prevent recurrences

→ **Provider-delivered**

→ **Sympathetic, non-defensive, and within the shortest period of time from incident as possible**
**Full Disclosure**

- Begin by stating that an error or unanticipated outcome has occurred
  - Prepare the patient for what you are going to say
e.g. “Mrs. Jones, I have something to discuss with you about the procedure.”
  - Describe what happened, in layterms

- Explain what is known about why the adverse event occurred
  - Do not speculate, guess, or assume
  - Instead:
    “We suspect that …”
    “What might have happened was …”
  - Do not comment on care from other providers or care team members

**Full Disclosure – if event was preventable and what you believe to be due to error….

- Consider using the word "error" or "mistake" after consultation with an administrator or risk manager
- Tell the patient what should have happened

  “This is outside of what we expected”, or

  “This outcome was not anticipated”…
Ex - Wrong drop instilled in-office?

Step 1: Disclosure
Mrs. ___ we suspect that instead of the typical dilating drop, one that is stronger was used. This is most likely why your vision is still blurry.

+ Apology

- Sincerely express personal regret and apologize
  - “I am sorry for your...”
  - “I am sorry that you ....”
  - “I am sorry that this occurred.”
  - “I am sorry that this happened to you.”
- NOT... “I am sorry that I/he/she...”

- Be careful (and get advice first) with things like...
  - “I take full responsibility”
  - “I screwed up”
  - “It's my fault”
  - “I should not have...”
Ex - Wrong drop instilled in-office?

Step 1: Disclosure

Step 2: Apology
We are so sorry that this happened.

Nature and Consequences of Mistake/Condition

- What is the nature of the mistake?
- Describe the potential consequences for the patient and/or family.
- What will be done now to care for the patient?
- What will the organization do to mitigate the impact on the patient, and is it committed to preventing recurrence?
**Ex - Wrong drop instilled in-office?**

Step 1: Disclosure  
Step 2: Apology

**Step 3: Nature of problem**  
The effects are temporary. The blurry vision and dilation will wear off, but it will take longer than normal.

**Commitment to Prevention:** We will also be looking carefully into exactly what led to this so that it can be prevented from happening again.

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**Closing and Follow-Up**

- Discuss next steps and plan for a follow-up conversation
- Ask the patient and/or family if there are any final questions, and provide responses.
- Designate a contact person they can reach with questions or concerns

- Responding to patient/family questions:
  - Quickly
  - Yourself if possible
  - Thanking for bringing concern to your attention
  - Assure taken seriously
Other Tips…

- Contain emotions
- Show open, receptive attitude/posture
  - Arms uncrossed, eye contact, listening skills
- Focus on the patient/family and validate feelings
  - “I understand that you are angry/frustrated”
- Avoid defensiveness, accusatory reaction if your care is questioned
- Avoid blaming other providers, the patient, equipment or “the system”
  - Explain your role in the event to the patient and/or family
- Be careful not to share confidential information

What about an error made by another clinician?

- Co-management
- Intern/resident – attending
- Unrelated physician

35% of malpractice suits are due to something said about another provider
Documentation of an Unanticipated Outcome

*Your best defense…*

- **Include**
  - *Objective* facts about unanticipated outcome – what you see, not why you think it happened
  - Care given in response
  - Treatment and f/u plans

- **Do NOT include**
  - Assumptions, speculations, beliefs of condition or previous care
  - Incident report
  - Comments about analysis procedures

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Should you document…..?  

- Apology ?
- Disclosure discussion
  - and names of person(s) in the room at the time
- It depends – don’t want to put unnecessary items in the patient’s records that may admit liability and/or create admissibility for those items in court

- Best to stick to facts and objective findings, plan for patient’s care
Financial Responsibility

- Avoid statements that create expectations for financial resolution that the organization may not be able to honor
- Waiving / refunding: not an admission of liability however may not always be indicated / appropriate / beneficial
- Discuss with Clinic Administration / Risk Management

Quality Assurance Measures and Prevention
Root-Cause Analysis (RCA)

- Most common method of comprehensive systematic analysis

- Objectives
  - Identify root cause(s) and contributing factors of incident(s)
  - Identify system vulnerabilities that could lead to patient harm
  - Implement strategies that reduce the risk of recurrences
  - Determine ways of effectively measuring and improving performance

- Typically performed after an incident or “close call,” however can be used proactively as well

RCA: Basically --

- What happened?
- Why did it happen?
- What can we do to prevent it from happening again?
Keys to Success with RCA

- Open and honest reporting of errors / close calls
- Risk-based triage system to determine what needs an RCA
- Patient-care committee / Quality assurance committee?
- Assigned to small committee of providers with expertise in the area; members of different levels of superiority; unbiased leader
- Committee conducts interviews and creates a story map detailed event and factors, and a cause and effect diagram; apply 5 rules of causation

5 rules of causation

- Clearly show cause and effect relationship
- Use specific and accurate descriptors for what occurred
- Human errors must have preceding cause
- Violations of procedure are not root causes; but must have preceeding causes
- Failure to act is only causal when there is a pre-existing duty to act
Preventing Diagnostic and Procedural Errors

- Listen to your patient (…history, history, history)
  - Do not make findings fit diagnosis
  - Insist that everything make sense
- Education and Training (…never ends!)
- Gentle yet deliberate approach (….Dr. Lisa Schifanella)
- Don’t assume …
  - No change from last exam (what’s the point of the exam?)
  - Someone else knew better than you (everybody makes mistakes)
- Look again
  - Or let someone else look / refer!

Preventing Errors with Medication

- Review and confirm meds and allergies
- Use EHR system for drug-drug and drug-allergy safety
- Double check Rx
- Comprehensive assessment / low-dose for elderly
- PCP/Pharmacist involvement
- Patient education about concerns, adverse effects
- Non-defensive reactions to patient concerns

Documentation – your best friend, or your worst enemy

Top 4 Documentation Mistakes
Butler M. J of Am Health Information Management Assoc, 2015.

1. Mixed messages
2. Copy/paste/forwarding of EHR
3. Incomplete / missing documentation
4. Misplaced documentation

Procedural Informed Consent

- Components:
  1. Verbal – provider must not delegate
  2. Document discussion in record
  3. Written verification – not while dilated

- Must take place when patient is of sound mental capacity

- Must include:
  - Condition
  - Recommended treatment and consequences of not proceeding
  - Risks/complications
  - Benefits
  - Alternatives
In record: “Discussed risks, benefits and alternatives to punctal plug insertion for dry eye. All questions answered. Patient agrees to proceed.”

Sound Mental Capacity

- Physician’s Judgement
- Alert
- Oriented to person, place, time
- Non-impaired
Minors

- State law
  - In Alabama, those aged 14 and older are “consenting adults”
- Does your institution have an internal policy?
  - UAB’s policy is to obtain consent [for invasive procedures] when patient is <19
  - Phone call with documentation is okay

Case Examples
Corneal abrasion during FB removal

Unanticipated adverse event of procedure

What should you say?

“Mr. ___ we were able to successfully remove the foreign body from your cornea and it should heal nicely. There is something the we need to discuss about your procedure, however. Unfortunately, the sharp instrument used to remove the foreign body also touched an adjacent area of your cornea and left a small abrasion. I’m sorry this happened -- we did not anticipate that this would occur. The drops we planned to prescribe for your original injury will take care of this as well, and we expect a full recovery.”

Avoid:
- “Oops”
- “It’s my fault”
- “I’m sorry I gave you an abrasion”
- “It was the intern’s first time removing a foreign body, so it could have been worse!”
- “If you could have held your eye still this would never had happened”
**How should you document?**

- **Objective findings:**
  cornea abrasion 0.5mm x 0.25mm just nasal to pupil; (-) Seidel’s sign

- **Assessment:** Corneal abrasion

- **Plan:** Disclosed to patient that small abrasion occurred as an unanticipated event during foreign body removal; expressed sympathy for the occurrence; explained to patient that condition will be expected to heal nicely from medications already Rxed for FB
And of course ....

- You performed an informed consent
- Patient signed written consent

Unanticipated and unfortunate outcome

Progression of POAG after patient lost to follow-up
What should you say?

- “Unfortunately your condition has progressed since we last saw you and it appears that you have developed vision loss due to glaucoma.”

- Avoid:
  - “If you had come in sooner…”
  - Blaming other practitioners, staff members, or “the system”

Documentation

- Hopefully:
  - Plan: “pt ed seriousness of condition and potential for permanent vision loss”
  - Recall:
    - “reasonable attempt” to schedule patient
    - attempts documented

- Avoid: “pt never came back…”
Another one lost to follow up...
How is your recall system?!

- 20/20
- BMI 38
- ONHs look “mildly elevated

After several attempts to schedule patient, and multiple N/S, R/S by patient, patient returned x 5 years later.....
Wrong solution to rinse CL

Mrs. the reason your eye hurts is because the solution used to rinse your contact is one that is not intended to be put directly into the eyes. We are sorry that this happened to you. The solution does burn and causes temporary irritation to the eye, which may require some treatment and follow up. What we’ll do is.....

And we will also be looking carefully into exactly what led to this so that it can be prevented.

Avoid:
- “I can’t believe I did that”
- “She/he should have known better”

What should you say?
How should you document?

- **Objective findings:**
  2+ diffuse SPK OD

- **Assessment:** Punctate keratitis, OD

- **Plan:** Pt ed condition and etiology; Disclosed adverse event to patient ....

Patient with Hx of inflammed pinguecula calls and wants a refill on his prednisolone

Monday the patient comes in with increased pain and it looks like this....
What should you say?

Mr. ___ based on your history and symptoms, this is not what we expected to see this morning. We need to discontinue the steroid drop, and prescribe a different medication.

Could say:
- “Do not use the steroid anymore – it can make things worse”
- “It’s possible the steroid made things worse over the weekend, so we need to stop that immediately”

Avoid:
- “I should never have called in the prescription without seeing you”
- “The steroid I prescribed made your condition worse”

How should you document?

Objective findings:
dendritic lesion on cornea, terminal bulbs (+)RB stain, (-)stromal involvement

Assessment: Herpetic keratitis

Plan: ed pt d/c use of steroid and begin therapy with Zyrgan ...... , etc
VH angles 1:1/4, gonioscopy revealed PTM 2+ quadrants before dilating patient...

.....but patient returns with red, painful eye and pressure of 45.

What should you say?

- Mr. ___ we suspect that the dilating drops used earlier today may have contributed to a blockage in the drainage system in your eye, leading a dangerous elevation to the pressure in your eye. Based on our clinical findings, this is outside of what we would have expected to occur. We are sorry that this has happened. We need to get the pressure down as quickly as possible in order to relieve your eye pain and reduce the risk of vision loss.

- Avoid:
  - “The drops we used caused glaucoma.”
  - “That doctor should never have dilated your eyes.”
How should you document?

- **Objective findings:**
  - VA 20/50
  - Pupil: mid-dilated and sluggish to react to light
  - Cornea: steamy, folds in Descemet’s, 2+ stromal edema
  - IOP 45
  - Gonioscopy: *describe findings*….

- **Assessment:** Acute Angle Closure OD, pressure under control before leaving office

- **Plan:** ed pt condition, predisposing factors/etiologies, and importance of keeping; ed pt *and pt understood* risk of permanent vision loss without compliance with medications and follow up appointments; referred to Dr. ____ for immediate LPI, office staff expecting patient now

Round abrasion noticed after Goldmann Tonometry

- **Adverse event**
- **Unanticipated outcome of procedure**
- **Implied informed consent**
  - Description of the procedure
- **Documentation of procedures, and post-procedure notes**
**What should you say?**

- Mr. ___ unfortunately the front surface of your eye has suffered an unanticipated event from the procedure used to checked your pressure. We are noticing a temporary abrasion to your cornea. We suspect that this occurred due to a combination of the anesthetic drop, which can soften cornea, and the instrument used. This is outside of what we would expect to occur. We are sorry that this happened to you. The abrasion will likely cause discomfort today and require some treatment and follow up, however we do expect it to heal nicely. What we’ll do is……

  - **Avoid:**
    - “This was a 2nd year student, so …..”
    - “You have an injury due to the procedure…”
    - “The instrument may have been misaligned…”

**How should you document?**

- **Objective findings:**
  4mmx4mm circular corneal abrasion with +NaFl staining

- **Assessment:** Corneal abrasion

- **Plan:** Ed pt condition and contributing factors. Disclosed to patient that condition consistent with unanticipated outcome during tonometry procedure and that we suspect that …..
38 year old healthy patient was dilated 3 years ago and is in a hurry today. At the patient’s request, you perform a wide-field photograph instead, but the eyelashes are in the way.

Best case scenario
- You documented the importance of dilation, and that photograph does not ever replace DFE
- You documented that the photograph had a limited view due to eyelashes, and that you educated the patient that she should come back soon for the dilation

Avoid:
- “We missed it last year because we did not dilate”
- “If you had let me dilate you last year we would have caught it earlier”

1 year later when you dilate....