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

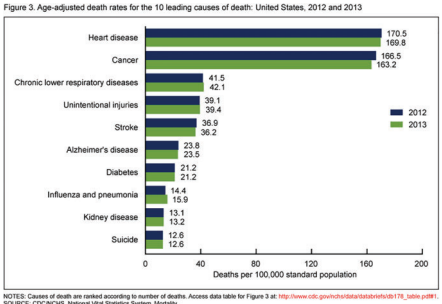
Beth Steele, OD, FAAO
bsteele@uab.edu

Disclosure Statement

- None

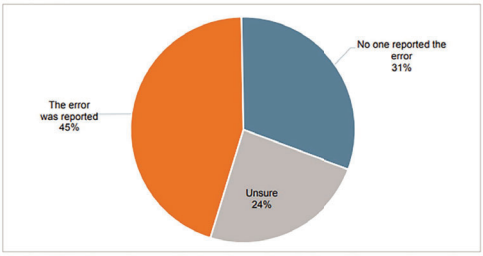
CDC – Deaths Due to Medical Errors

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



Truly Unknown Occurrence Rates

Nearly half of survey respondents who say they experienced a medical error say that it was reported to medical personnel, other health care facility staff, or to someone else.



Question: Did [you/you or the person close to you] report the medical error, did someone else report it on [your/their] behalf, or did no one report it?

Institute for Healthcare Improvement; https://etactics.com/blog/medical-error-statistics

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.

A failure of achieving the intended outcome in a planned sequence of mental or physical activities when that failure is not due to chance.

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 → ***need for 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

State-wide Medical Liabilities Acts/Laws

https://www.ncsl.org/research/financial-services-and-commerce/medical-liability-medical-malpractice-laws.aspx

In Alabama for example….

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

Failure to Diagnose

- Almost all are tied to failure to dilate
  - Retinal condition, Glaucoma
    - Photos vs. exam
    - Advanced imaging
- Misdiagnosis
- New technology / standards of care

Failure to Refer

- Suspicious / unclear findings
- New treatments available -- new (standards of) care
  - New drugs for Geographic AMD
  - Genetic therapy for RP
  - Corneal crosslinking for Keratoconus or Pellucid

Documentation Errors

- "possible optic disc edema" – no proper follow up or referral
- "flashes" – no proper follow up or RTC
- Incomplete documentation of care provided

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

When *Errors* Lead to Malpractice

Optometric Malpractice Claims (Classe' 1998)

- 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

Types of Medical Errors

Diagnostic

Surgical

Prescription

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

Table 1. Definitions of Different Types of Medical Incidents

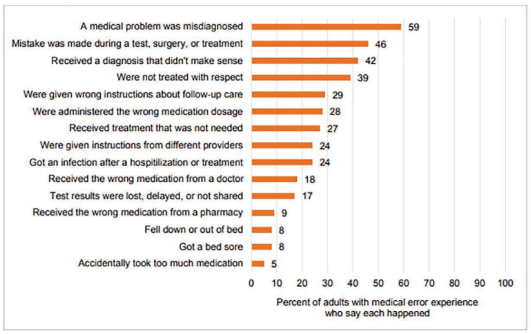
Definition
Near Miss
Unsafe conditions. The event did not reach the individual because of chance alone. The event did not reach the individual because of active recovery by caregivers.
Nonharmful Event
The event reached the individual but did not cause harm, or an error of omission, such as a missed medication dose, reached the patient. The event reached the individual, and additional monitoring was required to prevent harm.
Harmful Event
The individual experienced temporary harm and required treatment or intervention. The individual experienced temporary harm and required initial or prolonged hospitalization. The individual experienced permanent harm. The individual experienced harm and required intervention necessary to sustain life.
Death
The individual died.

Chamberlain C et al. Arch Surg, 2012.

Medical Errors Usually Due To:

- Communication breakdown
- Error in diagnosis
- Poor judgment
- Inadequate skill
- *Rarely due to inadequacies of one individual*

Six in 10 adults with medical error experience say a medical problem was misdiagnosed and 4 in 10 say they weren't treated with respect.

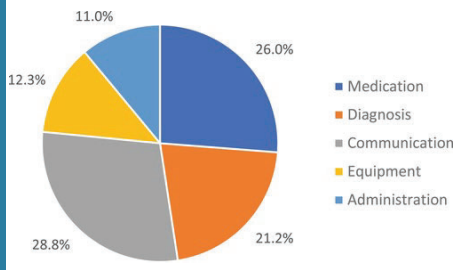


Question: Again, thinking about the most recent time a medical error was made in [your care/the care of someone close to you], for each of the following, please indicate whether or not it is the sort of medical error that occurred.

Institute for Healthcare Improvement; https://etactics.com/blog/medical-error-statistics

Eye Care Providers were Surveyed on the Most Common Sources of Error

MacFarlane E, et al. Ophthalmic and Physiological Optics. July 2022.



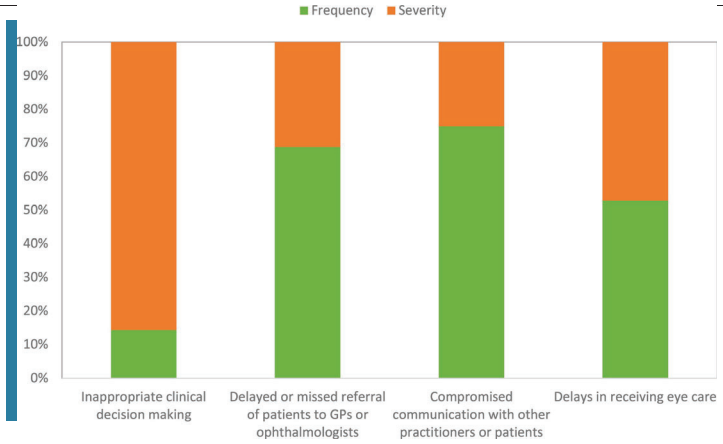


Table 1. Definitions of Different Types of Medical Incidents

Definition
Near Miss
Unsafe conditions.
The event did not reach the individual because of chance alone.
The event did not reach the individual because of active recovery by caregivers.
Nonharmful Event
The event reached the individual but did not cause harm, or an error of omission, such as a missed medication dose, reached the patient.
The event reached the individual, and additional monitoring was required to prevent harm.
Harmful Event
The individual experienced temporary harm and required treatment or intervention.
The individual experienced temporary harm and required initial or prolonged hospitalization.
The individual experienced permanent harm.
The individual experienced harm and required intervention necessary to sustain life.
Death
The individual died.

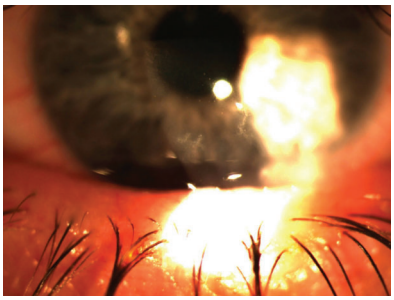
Chamberlain C et al. Arch Surg, 2012.

Diagnostic Errors

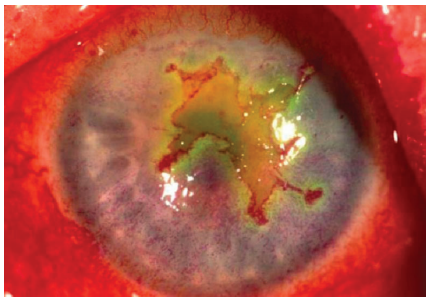
- Approximately15% diagnostic inaccuracy amongst general medical providers
  - Less likely with specialists
  - 5% of adults have experienced a misdiagnosis
  - Associated with approximately 10% of deaths in the US
- Leading (or 2nd) type of medical malpractice claims resulting in payment
  - Least preventable
  - 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….



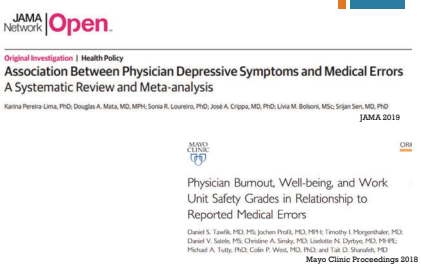
Overconfidence as a Cause ?!

- 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

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

Physician Burnout, Depression….

- Association with higher risk of medical errors among physicians with:
  - Positive screening for depression, suicidal ideations
  - Symptoms of burnout
  - Excessive fatigue
- Physician well-being should be a focus


JAMA Network Open.

Original Investigation | Health Policy

Association Between Physician Depressive Symptoms and Medical Errors
A Systematic Review and Meta-analysis

Karina Pereira-Lima, PhD; Douglas A. Mata, MD, MPH; Sonia R. Loureiro, PhD; José A. Crippa, MD, PhD; Livia M. Bolsoni, MSc; Srijan Sen, MD, PhD

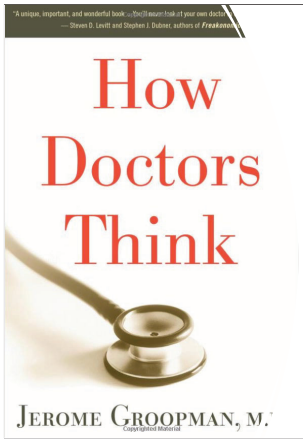
JAMA 2019

Physician Burnout, Well-being, and Work Unit Safety Grades in Relationship to Reported Medical Errors

Mayo Clinic Proceedings 2018

Cognitive Factors

- Individual is at the "core" of any taxonomy of error
  - Triggers the error, but not necessarily the root cause
- Memory loss
- Attention
- Deviations in performance/actions
- Decision biases
- Reasoning error
- Cognitive load
- Faulty heuristics

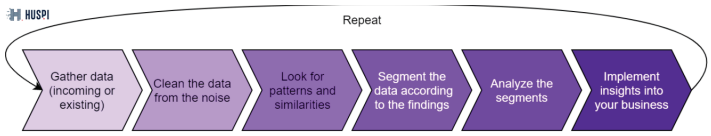


Common Vulnerabilities in Clinical Decision Making

- How Doctors Think - Groopman

Pattern recognition in the clinical setting

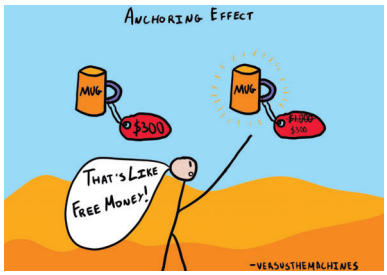
- Vs. Linear thinking



- Most mistakes are cognitive (vs. knowledge gaps)
  - Cognitive traps

Anchoring

- Stuck on first diagnosis that comes into your mind based on first sentence patient says/ first impressions
- *Example:* Middle schooler with trouble reading, eyestrain, headaches, double vision, presumed CI w/o a careful look at refractive error
- **+2.00 – 1.25 x 037**
  +3.00 – 2.00 x 116

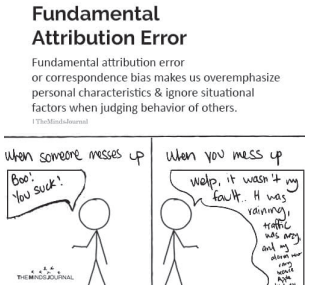


Availability

- Grabbing onto whatever is available in your mind
- Example: 24 year old grad student complains of blurry vision going from near to distance. The last 3 patients had latent hyperopia. You assume latent hyperopia and cycloplege before measuring amps/facility.
- **Amps – normal**
  Facility – 2cpm OU (struggles with +)

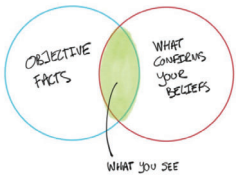
Attribution

- Allowing culture/stereotypes to cloud your judgement
- *Example:* Your patient, currently living in a homeless shelter, struggles to describe "colorful flickers" that have been happening for 2 weeks. You assume a background with little education and minify the symptom based on poor communication.
- ***The patient was highly educated but suffered from drug addiction, and was suffering from retinal migraine.***



Confirmation bias

- We rationalize what we know
- Example: 32 year old complains of blurry vision and wants new glasses. He is adamant that his glasses, now -3.25 are not strong enough.
  - CC 20/20-1
  - Refraction -4.00 20/20+1



Diagnosis momentum

- Once the diagnosis is put into play and received by someone with credentials, taken at face value…not questioned)
- "cut and paste" with EHR year after year
- Example: Dr. Swanson called it glaucoma 10 years ago, must be glaucoma today

Satisfaction search

- Satisfaction search (we're tired; it's hard being a doctor; Occam's razer – if you find one answer that can explain, you go with it)
- Example: 27 year old complaining of "distorted vision" in his glasses. You measure uncorrected cylinder and finalize Rx.
  - **Corneal topography shows early keratoconus**

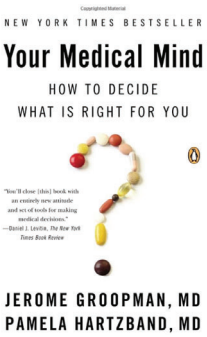
Patients and Doctors: Medical Mindsets

6 Medical Mindsets

Dr. Pamela Hartzband and Dr. Jerome Groopman

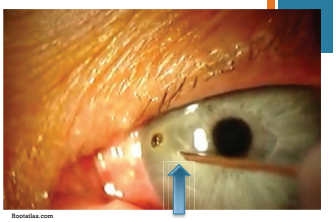
- Maximalist vs. Minimalist
- Naturalist vs. Technologist
- Believer vs. Doubter

- ***Patients vs. Doctors***



Surgical Errors *(Procedural Errors)*

- "NEVER events" (WSPE's)
  - Wrong site
  - Wrong procedure
  - Wrong patient
- Unanticipated outcomes from procedures



Medication / Prescribing Errors

- 4.9% error rate for all prescriptions
- 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

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

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

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

Aronson J. Br J of Clin Pharm, 2009.

Top 10 – Crompton A, et al. Pharmacy Journal 2019

1. Rx omitted or delayed
2. Anticoagulants
3. Opioids
4. Insulin
5. NSAID
6. Drugs that required regular blood test monitoring
7. Known allergy (e.g. antibiotic)
8. Drug interaction
9. Loading doses
10. Oxygen

Medical Error Reporting

- Duty to Disclose
- Best Practices
- Documentation

Agency Oversight

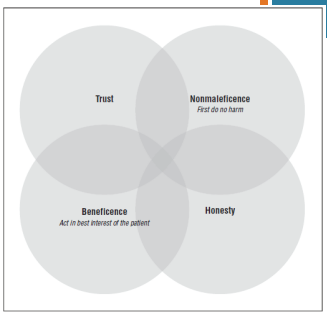
- Agency for Healthcare Research and Quality (AHRQ)
  - Patient Safety and Quality Improvement Act, became law 2005
  - Established a voluntary confidential reporting system to create a national database of medical errors for analysis and development of evidence-based safety measures
- Joint Commission
  - 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
  - *Some larger institutions/hospitals: Risk Management and/or Patient Safety Committee*
- Provider Education
  - Some states (e.g. FL) – 2 hours Medical Errors initially and then q2years

And more importantly…

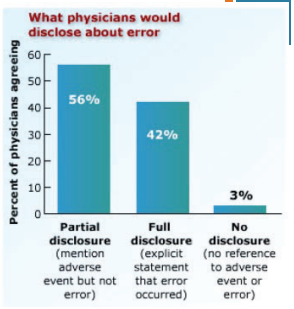
- Doctor-patient relationship
  - Full disclosure fosters a patient-centered approach
  - Patient has a right to know
  - Builds trust
- AOA Standards of Professional Conduct
  - "…telling the truth is a necessary component of a trusting optometrist-patient relationship"
- Optometric Oath, Am Board of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



Chamberlain C et al. Arch Surg, 2012.

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



Gallaher TH, et al. Arch Internal Medicine, 2006.

Patients 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

Disclosing Medical Errors to Patients: It's Not What You Say, It's What They Hear.
Wu, A. J Gen Intern Med., 2009.

AHRQ
Vincent C et al. The Lancet, 1994.

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?

.vs

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

Table 1. Definitions of Different Types of Medical Incidents

Definition
Near Miss
Unsafe conditions.
The event did not reach the individual because of chance alone.
The event did not reach the individual because of active recovery by caregivers.
Nonharmful Event
The event reached the individual but did not cause harm, or an error of omission, such as a missed medication dose, reached the patient.
The event reached the individual, and additional monitoring was required to prevent harm.

Chamberlain C et al. Arch Surg, 2012.

Prescribed Zylet instead of Alrex…..

.vs

- "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

Early, open, and full disclosure that an "error occurred" and why it occurred

1. Apology for poor outcome
2. Nature of condition and how the error's effects will be dealt with/minimized
3. 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***
- ***Result: decline in malpractice suits***

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

Step 1: 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

Step 1: Full Disclosure – if event was preventable and what you believe to be due to error….

- Carefully consider before using the word "error" or "mistake"
- Consider instead… Telling the patient what should have happened:

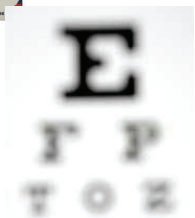
"This is outside of what we expected", or

"This outcome was not anticipated"…

Ex - Wrong drop instilled in-office ?

Mom brings 7 year old back in 48 hours after exam because vision is blurry and pupils are still dilated.

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 son's vision is still blurry.



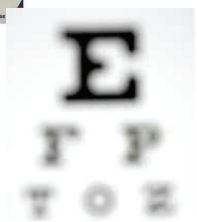
Step 2: Apology

- 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

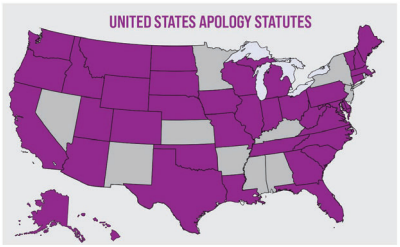
Step 2: Apology
We are so sorry that this happened.



Apology Laws

- 36 states with "apology laws"
  - apology not admissible in court
- However…

States with Apology Laws



https://www.reviewofoptometry.com/article/protect-yourself-from-malpractice

Step 3: Nature and Consequences of Mistake/Condition

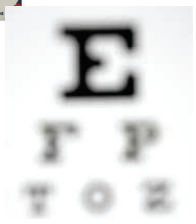
- What is the nature of the mistake?
- Describe the potential consequences for the patient and/or family.
- What will be done now to care for the patient?
- What will the organization do to mitigate the impact on the patient, and is it committed to preventing recurrence?

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.



Step 4: 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

Should we practice "defensive medicine" to protect ourselves?

Medical errors, malpractice, and defensive medicine: an ill-fated triad

Leonard Berlin

From the journal Diagnosis
https://doi.org/10.1515/dx-2017-0007

American Medical Association Journal of Ethics
March 2016, Volume 18, Number 3: 299-310

POLICY FORUM
Medical Malpractice Reform—Historical Approaches, Alternative Models, and Communication and Resolution Programs
Joseph S. Kass, MD, JD, and Rachel V. Rose, JD, MBA

What is confidential, and therefore non-discoverable?

- Anything labeled "quality assurance" or "peer to peer"
- Incident reports/discussion
- Process improvements

"Can I see a copy of the incident report?"

- Rarely helpful to share all event analysis
- Preferred: only share the most important root causes and the prevention plan
- Balance transparency with a need to maintain some information as confidential.

"Who is to blame for this?" "Who is getting fired?"

- i.e. "How could this have happened?" "Are you taking this seriously?"
- Avoid blaming anyone.
  - Explain your own role.
  - Highlight the analysis process that will investigate.
- Do not offer opinion of care provided by others
- Acknowledge the issue and redirect the conversation toward a shared goal of ensuring that a similar event does not happen again.
- Most adverse events have multiple causes
  - human and system elements

What about an error made by another clinician?

- Co-management
  - Anti-kick back
  - Stark Law
  - Careful documentation / transition of care documents
- 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…

- In the *medical record*, include o*bjective* 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

Should you document….. ?

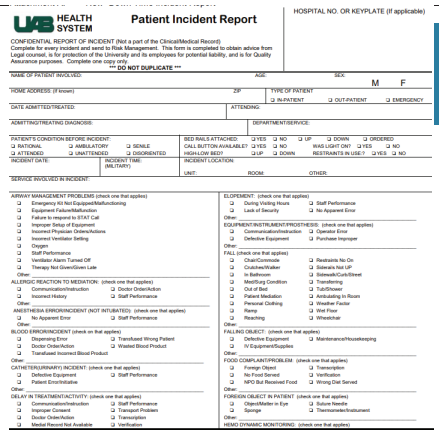
- Disclosure discussion
  - Apology?
  - and names of person(s) in the room at the time
- It depends –
  - unnecessary items in the patient's *medical records*
  - may admit liability
  - and/or create admissibility for those items in court
- Best to stick to facts and objective findings , plan for patient's care

Documentation of an Unanticipated Outcome

- ICD-10 codes:
  - "unknown"
  - T codes - "poisoning/underdosing/overdosing by adverse …"
  - Y95 – Nosocomial condition
  - Iatrogenic

Incident Reporting

- To be completed by person most familiar with incident
- Most important section: DESCRIPTION
- For Internal Use Only
  - Do NOT discuss incidents outside of "formal" analysis meetings or with those that are not "need to know"
  - Do NOT add to medical record



UAB HEALTH SYSTEM

Patient Incident Report

HOSPITAL NO. OR KEYPLATE (If applicable)

CONFIDENTIAL REPORT OF INCIDENT (Not a part of the Clinical/Medical Record)
Complete for every incident and send to Risk Management. This form is completed to obtain advice from Legal counsel, is for protection of the University and its employees for potential liability, and is for Quality Assurance purposes. Complete one copy only.

*** DO NOT DUPLICATE ***

NAME OF PATIENT INVOLVED: AGE: SEX: M F

HOME ADDRESS: (If known) ZIP TYPE OF PATIENT: ❑ IN-PATIENT ❑ OUT-PATIENT ❑ EMERGENCY

DATE ADMITTED/TREATED: ATTENDING:

ADMITTING/TREATING DIAGNOSIS: DEPARTMENT/SERVICE:

PATIENT'S CONDITION BEFORE INCIDENT: ❑ RATIONAL ❑ AMBULATORY ❑ SENILE ❑ ATTENDED ❑ UNATTENDED ❑ DISORIENTED

BED RAILS ATTACHED: ❑ YES ❑ NO ❑ UP ❑ DOWN ❑ ORDERED
CALL BUTTON AVAILABLE? ❑ YES ❑ NO
HIGH-LOW BED? ❑ UP ❑ DOWN
RAILS LIGHT ON? ❑ YES ❑ NO
RESTRAINTS IN USE ? ❑ YES ❑ NO

INCIDENT DATE: INCIDENT TIME: (MILITARY) INCIDENT LOCATION: UNIT: ROOM: OTHER:

SERVICE INVOLVED IN INCIDENT:

AIRWAY MANAGEMENT PROBLEMS (check one that applies)
❑ Emergency Kit Not Equipped/Malfunctioning
❑ Equipment Failure/Malfunction
❑ Failure to respond to STAT Call
❑ Improper Setup of Equipment
❑ Incorrect Physician Orders/Actions
❑ Incorrect Ventilator Setting
❑ Oxygen
❑ Staff Performance
❑ Ventilator Alarm Turned Off
❑ Therapy Not Given/Given Late
Other:

ALLERGIC REACTION TO MEDIATION: (check one that applies)
❑ Communication/Instruction ❑ Doctor Order/Action
❑ Incorrect History ❑ Staff Performance
Other:

ANESTHESIA ERROR/INCIDENT (NOT INTUBATED): (check one that applies)
❑ No Apparent Error ❑ Staff Performance
Other:

BLOOD ERROR/INCIDENT (check on that applies)
❑ Dispensing Error ❑ Transfused Wrong Patient
❑ Doctor Order/Action ❑ Wasted Blood Product
❑ Transfused Incorrect Blood Product
Other:

CATHETER/URINARY) INCIDENT: (check one that applies)
❑ Defective Equipment ❑ Staff Performance
❑ Patient Error/Initiative
Other:

DELAY IN TREATMENT/ACTIVITY: (check one that applies)
❑ Communication/Instruction ❑ Staff Performance
❑ Improper Consent ❑ Transport Problem
❑ Doctor Order/Action ❑ Transcription
❑ Medial Record Not Available ❑ Verification

ELOPEMENT: (check one that applies)
❑ During Visiting Hours ❑ Staff Performance
❑ Lack of Security ❑ No Apparent Error
Other:

EQUIPMENT/INSTRUMENT/PROSTHESIS: (check one that applies)
❑ Communication/Instruction ❑ Operator Error
❑ Defective Equipment ❑ Purchase Improper
Other:

FALL (check one that applies)
❑ Chair/Commode ❑ Restraints No On
❑ Crutches/Walker ❑ Siderails Not UP
❑ In Bathroom ❑ Sidewalk/Curb/Street
❑ Med/Sorg Condition ❑ Transferring
❑ Out of Bed ❑ Tub/Shower
❑ Patient Mediation ❑ Ambulating in Room
❑ Personal Clothing ❑ Weather Factor
❑ Ramp ❑ Wet Floor
❑ Reaching ❑ Wheelchair
Other:

FALLING OBJECT: (check one that applies)
❑ Defective Equipment ❑ Maintenance/Housekeeping
❑ IV Equipment/Supplies
Other:

FOOD COMPLAINT/PROBLEM: (check one that applies)
❑ Foreign Object ❑ Transcription
❑ No Food Served ❑ Verification
❑ NPO But Received Food ❑ Wrong Diet Served
Other:

FOREIGN OBJECT IN PATIENT: (check one that applies)
❑ Object/Matter in Eye ❑ Suture Needle
❑ Sponge ❑ Thermometer/Instrument
Other:

HEMO DYNAMIC MONITORING: (check one that applies)

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

Quality Assurance Measures

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 ?
  - expertise in the area
  - different levels of superiority
  - unbiased leader
  - interviews and story map
  - cause and effect diagram
  - apply 5 rules of causation

Table 1. Definitions of Different Types of Medical Incidents

Definition
Near Miss
Unsafe conditions.
The event did not reach the individual because of chance alone.
The event did not reach the individual because of active recovery by caregivers.
Nonharmful Event
The event reached the individual but did not cause harm, or an error of omission, such as a missed medication dose, reached the patient.
The event reached the individual, and additional monitoring was required to prevent harm.
Harmful Event
The individual experienced temporary harm and required treatment or intervention.
The individual experienced temporary harm and required initial or prolonged hospitalization.
The individual experienced permanent harm.
The individual experienced harm and required intervention necessary to sustain life.
Death
The individual died.

Chamberlain C et al. Arch Surg, 2012.

Create a Process for RCA

UAB EYE CARE

Quality Assurance Root Cause Analysis

Date of Event:

Nature of Event (e.g. patient safety, patient satisfaction, coding/billing, fiscal responsibility, patient privacy/HIPAA, staff safety/OSHA, infection control):

Person(s)/Group Responsible:

Root Cause:

Contributing Factors / System Vulnerabilities:

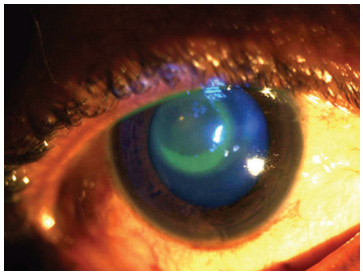
What strategies will be implemented to address it and reduce risk of recurrence?		How will success/performance be measured?
1.		
2.		
3.		
4.		

5 rules of causation

1. Clearly show cause and effect relationship
2. Use specific and accurate descriptors for what occurred
3. Human errors must have preceding cause
4. Violations of procedure are not root causes; but must have preceding causes
5. Failure to act is only causal when there is a pre-existing duty to act

Ex – what happened?

- Procedure / skill
- Disinfection
- Equipment
- Medication
- Patient



Prevention

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!)
- 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 !
- *Gentle yet deliberate*

Solutions to Overconfidence as a Cause ?

- 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.

Preventing Errors with Medication

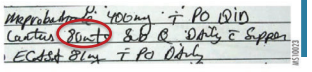
- Review and confirm meds and allergies
- Use EHR system for drug-drug and drug-allergy safety
- Double check Rx
- Comprehensive assessment / low-dose for elderly
- PCP/Pharmacist involvement
- Patient education about concerns, adverse effects
- Non-defensive reactions to patient concerns

Modified from Agrawal A, et al. Br J Clin Pharmacology, 2009.

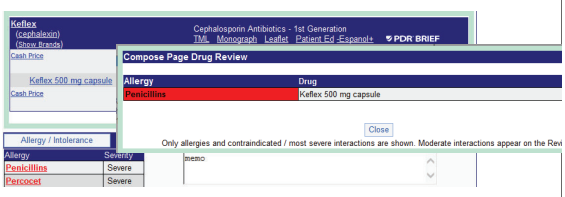
Prevention

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

Figure 3. Order Written for 8 Units of Lantus Insulin Misread as 80 Units

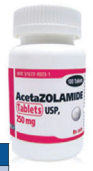


Reprinted with permission from the Institute for Safe Medication Practices, Horsham, Pennsylvania.



"Tall Man" Letters

Institute for Safe Medication Practices



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

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

Drug Name With Tall Man Letters	Confused With
acetaZOLAMIDE	acetoHEXAMIDE
acetoHEXAMIDE	acetaZOLAMIDE
buPROPion	busPIRone
busPIRone	buPROPion
chlorproMAZINE	chlorproPAMIDE
chlorproPAMIDE	chlorproMAZINE
clomiPHENE	clomiPRAMINE
clomiPRAMINE	clomiPHENE
cycloSERINE	cycloSPORINE
cycloSPORINE	cycloSERINE
DAUNOrubicin	DOXOrubicin
dimenhyDRINATE	diphenhydrAMINE
diphenhydrAMINE	dimenhyDRINATE

https://www.ismp.org/recommendations/tall-man-letters-list

Documentation – your best friend, or your worst enemy

Top 4 Documentation Mistakes

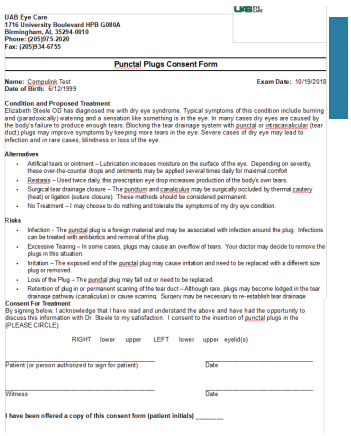
Butler M. J of Am Health Information Management Assoc, 2015.

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."



UAB Eye Care
1716 University Boulevard HPB G080A
Birmingham, AL 35294-0010
Phone: (205)975.2020
Fax: (205)934.6755

Punctal Plugs Consent Form

Name: Compulink Test **Exam Date:** 10/19/2018
Date of Birth: 6/12/1999

Condition and Proposed Treatment
Elizabeth Steele OD has diagnosed me with dry eye syndrome. Typical symptoms of this condition include burning and (paradoxically) watering and a sensation like something is in the eye. In many cases dry eyes are caused by the body's failure to produce enough tears. Blocking the tear drainage system with punctal or intracanalicular (tear duct) plugs may improve symptoms by keeping more tears in the eye. Severe cases of dry eye may lead to infection and in rare cases, blindness or loss of the eye.

Alternatives
- Artificial tears or ointment – Lubrication increases moisture on the surface of the eye. Depending on severity, these over-the-counter drops and ointments may be applied several times daily for maximal comfort
- Restasis – Used twice daily, this prescription eye drop increases production of the body's own tears.
- Surgical tear drainage closure – The punctum and canaliculus may be surgically occluded by thermal cautery (heat) or ligation (suture closure). These methods should be considered permanent.
- No Treatment – I may choose to do nothing and tolerate the symptoms of my dry eye condition.

Risks
- Infection – The punctal plug is a foreign material and may be associated with infection around the plug. Infections can be treated with antibiotics and removal of the plug.
- Excessive Tearing – In some cases, plugs may cause an overflow of tears. Your doctor may decide to remove the plugs in this situation.
- Irritation – The exposed end of the punctal plug may cause irritation and need to be replaced with a different size plug or removed.
- Loss of the Plug – The punctal plug may fall out or need to be replaced.
- Retention of plug in or permanent scarring of the tear duct – Although rare, plugs may become lodged in the tear drainage pathway (canaliculus) or cause scarring. Surgery may be necessary to re-establish tear drainage

Consent For Treatment
By signing below, I acknowledge that I have read and understand the above and have had the opportunity to discuss this information with Dr. Steele to my satisfaction. I consent to the insertion of punctal plugs in the (PLEASE CIRCLE):

RIGHT lower upper LEFT lower upper eyelid(s)

Patient (or person authorized to sign for patient) Date

Witness Date

I have been offered a copy of this consent form (patient initials) _____

Patient Must Have Sound Mental Capacity

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

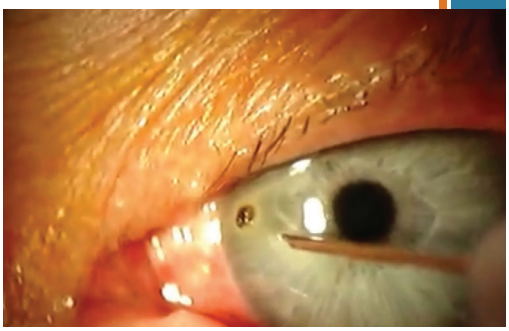
Minors

- 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

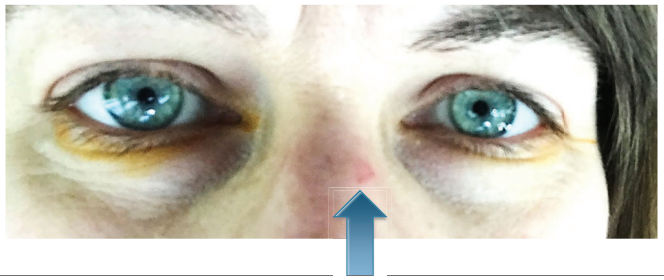
Case Examples

Corneal abrasion during FB removal

Unanticipated adverse event of procedure



Or what about this one?



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
  - (maybe)

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

S05 Injury of eye and orbit

Includes: open wound of eye and orbit

Excludes2: 2nd cranial [optic] nerve injury (S04.0-)
3rd cranial [oculomotor] nerve injury (S04.1-)
open wound of eyelid and periocular area (S01.1-)
orbital bone fracture (S02.1-, S02.3-, S02.8-)
superficial injury of eyelid (S00.1-S00.2)

The appropriate 7th character is to be added to each code from category S05
A - initial encounter
D - subsequent encounter
S - sequela

S05.0 Injury of conjunctiva and corneal abrasion without foreign body

Excludes1: foreign body in conjunctival sac (T15.1)
foreign body in cornea (T15.0)

S05.00 Injury of conjunctiva and corneal abrasion without foreign body, unspecified eye

S05.01 Injury of conjunctiva and corneal abrasion without foreign body, right eye

S05.02 Injury of conjunctiva and corneal abrasion without foreign body, left eye

And of course ….

- You performed an informed consent
- Patient signed written consent

UAB Eye Care
1716 University Boulevard HPB G080A
Birmingham, AL 35294-0010
Phone: (205)975-2020
Fax: (205)934-6755

Informed Consent For Minor Surgery

Name: Compulink Test **Exam Date:** 8/24/2018
Date of Birth: 10/1/1999

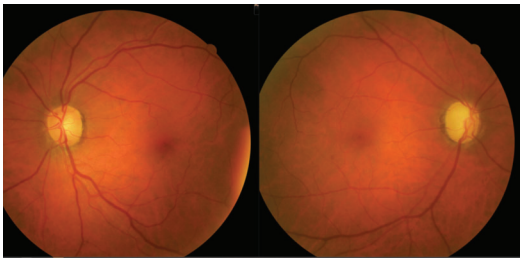
My signature on this form authorizes Elizabeth Steele OD to perform the following procedure:

I have been informed and I understand the nature of the procedure and why it is necessary.

I have been informed and I understand the risks inherent to the performance of any surgical procedure such as loss of blood, infection, reaction to anesthesia, numbness and/or lack of sensation, and the formation of thick or otherwise objectionable scars. I realize that these, or other natural complications may result from the surgical

Progression of POAG after patient lost to follow-up

Unanticipated and unfortunate outcome



What should you say ?

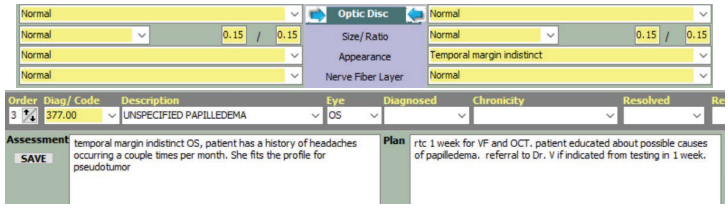
- "Unfortunately your condition has progressed since we last saw you and it appears that you have developed vision loss due to glaucoma."
- Avoid:
  - *"If you had come in sooner… "*
  - *Blaming other practitioners, staff members, or "the system"*

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 …..

Even better… ?

- Plan: "pt ed etiology including potential for brain mass and life/vision threatening condition; pt ed need for careful follow up in order to accurate determine cause and appropriate management plan"

Wrong solution to rinse CL

What should you say ?

- 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"*

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 ….

How should you document?

- Objective findings:
  2+ diffuse SPK OD
- Assessment: Punctate keratitis, OD
- Plan: Disclosed suspected adverse effect to patient ….

Poisoning by, adverse effects of and underdosing of drugs, medicaments and biological substances (T36-T50)

Includes: adverse effect of correct substance properly administered
poisoning by overdose of substance
poisoning by wrong substance given or taken in error
underdosing by (inadvertently) (deliberately) taking less substance than prescribed or instructed

Code first, for adverse effects, the nature of the adverse effect, such as:
adverse effect NOS (T88.7)
aspirin gastritis (K29.-)
blood disorders (D56-D76)
contact dermatitis (L23-L25)
dermatitis due to substances taken internally (L27.-)
nephropathy (N14.0-N14.2)

Note: The drug giving rise to the adverse effect should be identified by use of codes from categories T36-T50 with fifth or sixth character 5.

Use additional code(s) to specify:
manifestations of poisoning
underdosing or failure in dosage during medical and surgical care (Y63.6, Y63.8-Y63.9)
underdosing of medication regimen (Z91.12-, Z91.13-)

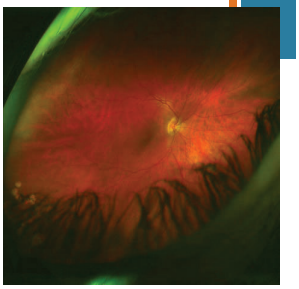
T49 Poisoning by, adverse effect of and underdosing of topical agents primarily affecting skin and mucous membrane and by ophthalmological, otorhinolaryngological and dental drugs

Includes: poisoning by, adverse effect of and underdosing of glucocorticoids, topically used

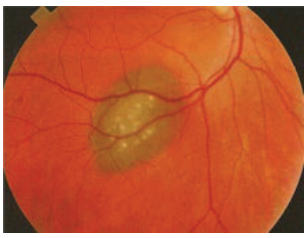
The appropriate 7th character is to be added to each code from category T49
A - initial encounter
D - subsequent encounter
S - sequela

T49.2X5 Adverse effect of local astringents and local detergents

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.



1 year later when you dilate….



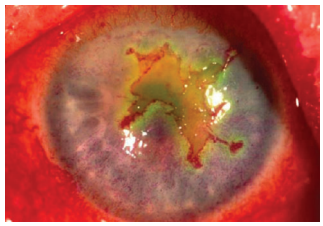
- Best case scenario
  - *You documented the importance of dilation, and that photograph does not ever replace DFE*
  - *You documented that the photograph had a limited view due to eyelashes, and that you educated the patient that she should come back soon for the dilation*
- Avoid:
  - *"We missed it last year because we did not dilate"*
  - *"If you had let me dilate you last year we would have caught it earlier"*

Don't assume…

- It was there before
- It looked the same

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….



Don't assume ..

- That it looked just like this yesterday
- The the steroid did actually make it worse

What should you say ?

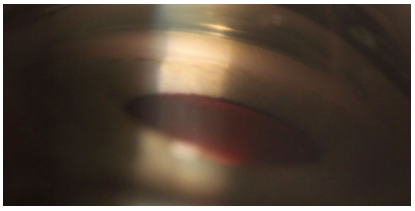
- Mr. ___ based on your history and symptoms, this is not what we expected to see this morning. We need to discontinue the steroid drop, and prescribe a different medication.

- 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?

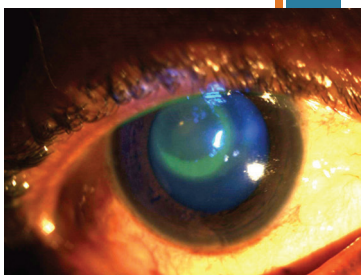
- Objective findings:
  VA 20/50
  Pupil: mid-dilated and sluggish to react to light
  cornea: steamy, folds in Descemet's, 2+ stromal edema
  IOP 45
  Goniosopy: *describe findings….*
- Assessment: Acute Angle Closure OD , pressure under control before leaving office
- Plan: ed pt condition, predisposing factors/etiologies, and importance of keeping; ed pt *and pt understood* risk of permanent vision loss without compliance with medications and follow up appointments; discussed options for referral and patient had no preference; referred to Dr. ____ for immediate LPI, office staff expecting patient now

What if…. Angles were not documented? Your technician forgot to check them.

- Don't assume:
  - Angles were as narrow as you suspect they might have been
  - No other factors involved

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…"*
  - *"my tech probably pushed too hard.."*
  - *"the chemical disinfectant caused a burn…"*

Don't assume…

- Patient did not change position during testing
- Other predisposing factors were not present
- Patient was not over-sensitive to anesthetic

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 …..

Other considerations: Advances in Technology / Treatment

1. Diagnosis
2. Patient education
3. Referral

Other considerations: Refusal to Treat

1. Determine patient capacity to understand
2. Educate patient / caregiver
3. Informed Refusal to Treat Form