Course Title: PREVENTION OF MEDICAL ERRORS

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Professor Emeritus of Optometry and Vision Science, UAB

"A lie gets halfway around the world before the truth can gets its pants on."
-Sir Winston Churchill

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DISCLOSURE STATEMENT

Leo Semes, OD, FAAO, FACMO
Consultant - Apellis
Speaker Bureau - Regeneron
Scientific Advisory Board - EyePromise

Stock options - Eye Promise (< 0.01% ownership)

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QUIZ TIME

- The greatest number of deaths annually is highest from which of the following causes?
  - A. Medical errors
  - B. Breast cancer
  - C. Firearms
  - D. Motor vehicle accidents

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QUIZ TIME

- That number for medical errors is…
  - A. 49,000
  - B. 98,000
  - C. 7000
  - D. About 150

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QUIZ TIME

- The percentage of adverse events due to medical errors that were thought to be preventable is about
  - A. 20
  - B. 40
  - C. 60*
  - D. 80

*Mazer B, Nabhan C. No, Medical Errors Are Not the Third Leading Cause of Death - Medscape - Sep 06, 2019.

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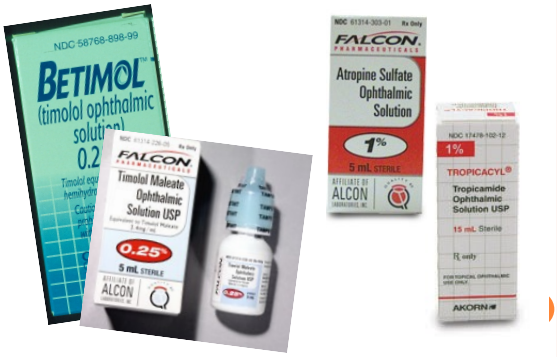
BEFORE WE BEGIN…



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A LITTLE PHILOSOPHY

- To paraphrase Orlando Battista . . .

A mistake does not become an error until you refuse to correct it.

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MEDICAL ERROR REPORTING

- "Medline citations ("medical errors")
  - 1966-through 1996 (n=188)
    - One of the first citations:

      Vogel J. Delgado R. To tell the truth: physicians' duty to disclose medical mistakes. *UCLA Law Review* 1980; 28(1):52-94. [Oct]
  - 1997 through March 25, 2003 (n=1761) ***6 years for 10X*** ⇧
  - *April 21, 2022: 155,817 (now PubMed) NCBI.* So far ⇨ Peaking

2017	7888
2018	7944
2019	7872
2020	7407
2021	6753
2022	1874

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"MEDICAL ERRORS"

- *Google search April 21, 2022*

About 443,000,000 results

- **Featured snippet from the web**

"Medical errors in hospitals and clinics result in approximately 100,000 people dying each year. Medical errors typically include ***surgical***, ***diagnostic***, ***medication***, **devices and equipment, and *systems failures*, infections, falls, and healthcare technology**."

- Jan 4, 2022

2017	7888
2018	7944
2019	7872
2020	7407
2021	6753
2022	1874

Keep the PubMed numbers in mind

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THIS IS SCARY…

Googling "Pharmacy error"

http://www.sgglaw.com/PracticeAreas/Pharmacy-Error.asp

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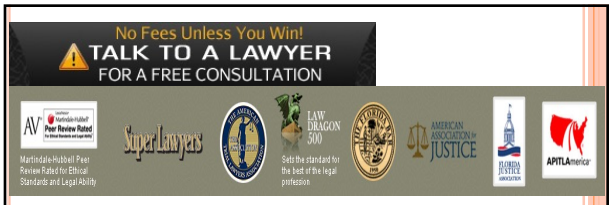

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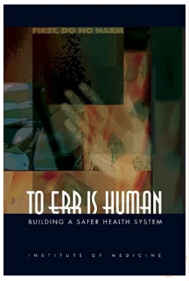
THE WAKE-UP CALL

Institute of Medicine (now: National Academy of Medicine)

landmark report: *To Err is Human: Building a Safer Health System* (1999)



Hardcover
$70.39
- 9 Used from $9.02 2 New from $70.39
- 1 Collectible from $1,260.00 ; Kindle 31.99

(Accessed April 24, 2022)

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IOM LANDMARK REPORT: *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM*

- 50, 000 annual deaths due to medical errors (may be as high as 98,000)
- Up to ½ are preventable (?)
- Impetus for the current national discussion
- Responsibilities
  - Caregiver to patient
  - Nation's responsibility to citizens

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STATE LEVEL - FLORIDA

- Legislation: 456.013
  - requires 2 hour CE course for initial licensure and then biennially for *health-care providers* (ODs are not alone)

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COMMISSION ON EXCELLENCE IN HEALTH CARE

- Established in 2000 by FL legislature
- Chaired by secretaries of:
  - Department of Health
  - Agency for Health Care Administration

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COMMISSION ON EXCELLENCE IN HEALTH CARE (FL) COMPOSITION

- 42 members
  - Professional associations
  - Health lawyers
  - Medical schools
  - Health insurance carriers
  - Consumer advocates
  - Legislators

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STATE LEVEL - FLORIDA

- Requires reporting of mistakes that lead to serious patient injuries, such as life-threatening situations and epidemic outbreaks
- Also report serious adverse events:
  - wrongful deaths,
  - brain injuries,
  - wrong limb removals,
  - incorrect surgeries

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https://flboardofmedicine.gov/forms/frm_AdverseIncident.pdf

Department☐of☐Health☐
Consumer☐Services☐Unit☐☐
4052☐Bald☐Cypress☐Way,☐Bin☐C75☐
Tallahassee,☐FL☐32399☐3275☐
Physician☐Office☐Adverse☐Incident☐Report☐

1. OFFICE INFORMATION

Office Name: _____

Address: _____

Street City State ZIP

County: _____ Office Surgery Center License #: _____

(if applicable)

Physician Name: _____ Name of Licensee Reporting: _____

(if applicable)

2. PATIENT INFORMATION

Patient Identification #: _____ Medicaid

Medicare

Patient Name: _____ Date of Birth:

Gender:

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Other Florida Initiatives

- In 2004, legislation was passed requiring the state to inform the public about important performance outcome indicators for healthcare facilities (eg, volume of cases, average length of stay, complication rates, mortality rates, infection rates for various medical conditions).
  - This information became available online in November 2005 at http://www.floridahealthfinder.gov.
- This same legislation established the Florida Patient Safety Corporation (FPSC), a voluntary statewide reporting program to track and analyze near misses in healthcare.

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Is all that necessary?

- WOW!!!
- IOM landmark report: *To Err is Human: Building a Safer Health System* (1999)
- Medscape Medical News
- Medical Error Is Third Leading Cause of Death in US
- Marcia Frellick
- May 03, 2016

Medical error is the third leading cause of death in the United States, after heart disease and cancer, according to findings published today in *BMJ*.

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. . .from MD Linx

https://www.mdlinx.com/family-medicine/medical-news-article/2016/11/22/6953423/?utm_source=in-house&utm_medium=message&utm_campaign=mh-fm-nov16

- **CDC estimates preventable deaths from 5 leading causes**

11/23/2016 *Not necessarily due to medical errors!*

- New CDC research shows that the number of potentially preventable deaths dropped from 2010 to 2014 for three of the five top causes of death in the United States. The five leading causes of death for people younger than aged 80 years in 2014 were diseases of the heart, cancers, stroke, chronic lower respiratory diseases (CLRD), and unintentional injuries, collectively accounting for 63% of all deaths that year. CDC estimates that 15% of these cancer deaths, 30% of these heart–disease deaths, 43% of those unintentional–injury deaths, 36% of these CLRD deaths, and 28% of those stroke deaths possibly could have been prevented. Compared with 4 years earlier, potentially preventable cancer deaths dropped 25%; potentially preventable deaths from stroke declined 11%; potentially preventable deaths from heart disease decreased 4%; potentially preventable deaths from accidents increased 23%, in large part due to drug poisonings and falls; and potentially preventable deaths from CLRD rose 1%.
- "Fewer Americans are dying young from preventable causes of death," said CDC Director Tom Frieden, MD MPH.

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The good news: No, Medical Errors Are Not the Third Leading Cause of Death*

- The idea that 'medical errors are the third leading cause of death' has become a powerful cultural meme immune to correction.
- The methodology applied to arrive at these estimates published in multiple scientific journals falls short of the rigor needed for this important topic.
- These estimates are inaccurate, implausible, and *encourage unwarranted distrust in the healthcare system*.

"A lie gets halfway around the world before the truth can gets its pants on." -Sir Winston Churchill

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*Mazer B, Nabhan C. No, Medical Errors Are Not the Third Leading Cause of Death - Medscape - Sep 06, 2019.

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The good news: No, Medical Errors Are Not the Third Leading Cause of Death*

- Medical error death rates extrapolate from small samples,
  - generalize local data to national contexts,
  - ignore the limited life expectancy of many patients, and
  - gloss over the myriad uncertainties in defining error, preventability, and causality.

"A lie gets halfway around the world before the truth can gets its pants on." -Sir Winston Churchill

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*Mazer B, Nabhan C. No, Medical Errors Are Not the Third Leading Cause of Death - Medscape - Sep 06, 2019.

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Committee

A body that keeps records in minutes but whose meetings last hours

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TYPES OF MEDICAL ERRORS

- IOM definition of error:

"the failure of a planned action to be completed as intended (ie, error of execution)

or

the use of a wrong plan to achieve an aim (ie, error of planning)."

- *Specific topics for today*
  - *Diagnostic*
  - *Surgical*
  - *Prescription / Medication*

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First, some definitions – Types of medical errors

- An **adverse event** is an injury caused by medical management rather than the underlying condition of the patient.
  - e.g., unknown allergy to a newly administered drug
- An adverse event attributable to error is a **preventable adverse event**, also called a **sentinel event**, because it signals the need to ask why the error occurred and make changes in the system.
  - e.g. . . .

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DISCLAIMER . . .

"Operational The Fund is exposed to operational risk arising from a number of factors, including but not limited to, human error, processing and communication errors, errors of the Fund's service providers . . . failed or inadequate processes and technology or system failures."

Not unique to healthcare

Prospectus of van Eck International Investors Gold Fund

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TYPES OF HUMAN ERRORS

- **Active errors** tend to occur at the level of the individual, and their effects are felt almost immediately.
  - Wrong sided operation / attributable to human behavior (HB*)

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TYPES OF HUMAN ERRORS

- **Latent errors** are more likely to be beyond the control of the individual, i.e.,
  - errors in system or process design,
  - faulty installation or maintenance of equipment, or
  - ineffective organizational structure.
  - System Redesign (SR)

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MEDICAL ERRORS - PHILOSOPHY

- Possibility of their existence pointed out early in career (optometry school)
- Potential for consequences pointed out early in career (personal or vicarious experience)
- Desire to avoid errors? Yes

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Medical Errors - philosophy

- Response at various levels of health care?
  - inconsistent
  - mistakes often superficially addressed or hidden
- *Those causing errors are often unaware*
- *Persons often unjustly blamed [scapegoat]*
- *Cycle of inaction or nonproductive action*

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More History

- Neurosurgery subspecialty development (1890-1935)
- Other events
  - Flexner report (1910)
  - Upgrading of Post-grad medical ed.
  - May have lead to the problem as it exists today???
  - Publication of procedures in neurosurgery with outcomes
  - Major question- "What is the root cause of diagnostic errors?"

World's first delivery of intra-arterial Avastin directly into brain tumor (November 17, 2009) -- Neurosurgeons have performed the world's first intra-arterial cerebral infusion of bevacizumab (Avastin) directly into a patient's malignant brain tumor. This novel technique may expose the cancer to higher doses of the drug therapy, while possibly sparing the patient common side effects of receiving the drug intravenously or throughout their body. ...

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Beauty Parlor

A place to curl up and dye

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Who is Watching?

- The Agency for Healthcare Research and Quality (AHRQ)
  - medical errors result most frequently from systems errors—the organization of healthcare delivery and the ways that resources are provided in the delivery system.
  - **Only rarely are medical errors the result of the carelessness or misconduct of a single individual.**
    More on this later

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Error Reporting Issues

- Is there a system to report errors?
- Are near misses being reported?
- Do workers and patients have a mechanism for suggesting improvements for patient safety?
- Do workers feel their concerns are acted upon?
- Is the system truly non-punitive?

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Some other Considerations. . .

- How can I minimize errors in diagnosis?
- How can I obtain a better understanding of my clinical thinking?
- How can I devise cognitive forcing strategies to help my minimize diagnostic error?

Gallagher EJ. Thinking about thinking. Ann Emerg Med 2003; 41:1.

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Why Do We Err?

- Mental functions occur in two modes:
  - automatic
  - problem solving

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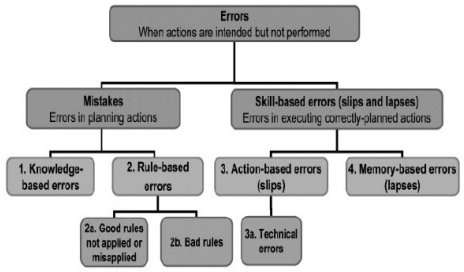
Classification of Medication Errors Based on Psychological Factors



Aronson JK Medication errors: what they are, how they happen, and how to avoid them. QJM. 2009 Aug;102(8):513-21.

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Automatic Mode

- functions quickly
- requires little conscious effort
- draw's on accumulated learning of situation recognition and response
- Can result in "slips"
  - Distraction
  - Breaks in attention at critical moments
  - More frequent [than "mistakes"]

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Automatic Mode -"slips" Example

- Driving home from work on Tuesday and went the "regular way" *almost* neglecting to pick up Margaux at the groomer.
  - The distraction of one slip may lead to another..

- . . . Driving through a red light!
- Slips are more frequent w/competing sensory or emotional distractions, fatigue & stress [like in the 'normal' office setting]

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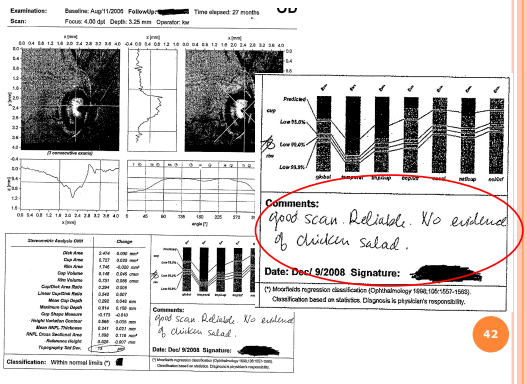
Personal Example



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Diagnostic Errors

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SEPTEMBER 22, 2015

- *Improving Diagnosis in Health Care*, from the IOM), cited these statistics among the impetus for urgent action:
  - 5% of US adults who seek outpatient care each year experience a diagnostic error.
  - Diagnostic errors contribute to approximately 10% of patient deaths.
  - Diagnostic errors account for 6% to 17% of hospital adverse events.
  - Diagnostic errors are the leading type of paid medical malpractice claims, and are almost twice as likely to have resulted in the patient's death compared with other claims.

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Recommendations to Improve Diagnostic Accuracy
from the IOM (8 key areas)

- Facilitate teamwork in the diagnostic process among healthcare professionals, patients, and families.
- Enhance healthcare professional education in the diagnostic process.
- Ensure that health information technologies support the process.
- Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses.

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Recommendations to Improve Diagnosing
from the IOM (8 key areas)

- Establish a work system and culture that supports the diagnostic process.
- Develop a nonpunitive reporting environment and medical liability system that brings improved diagnosis through learning from errors and near misses.
- Design a payment and care delivery environment that supports the diagnostic process.
- Dedicate funding for research on diagnosing and diagnostic errors.

Well, that might just not be new . , , ,

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REVIEWS OF DIAGNOSTIC ERRORS SUGGEST . .

- Overconfidence as a source of errors in medicine.
- Extent of *incorrect* diagnosis *(%)*

2nd opinion & Review

- Dermatology 11% (similar or ↓ and ↓ - 1%)
- Anatomic Pathology 1.5 – 3.8% resulted in a change in treatment or prognosis
- Radiology <5% (but may be higher for ER vs. specialists)

Berner and Graber Am J Med 121; 2008

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REVIEWS OF DIAGNOSTIC ERRORS SUGGEST . .

- It may be safer in New Zealand
  - 6578 inpatient records examined (1998)
  - Diagnostic errors accounted for 8% of adverse events
  - 11.4% of these were deemed preventable

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Latest review of "second opinions"
(It may be safer at Mayo)

- In 12% (36/286) of cases, referral diagnoses were the same as final diagnoses. (Therefore, 88% differed!)
- Final diagnoses were better defined/refined in 66% (188/286) of cases; but in 21% of cases (62/286), final diagnoses were distinctly different than referral diagnoses.
- Total costs for cases in category 3 (different final diagnoses) were significantly higher than costs for cases in category 1 (P = .0001) and category 2 (P = <.0001)

Van Such M, Lohr R, Beckman T, Naessens JM1,4. Extent of diagnostic agreement among medical referrals. J Eval Clin Pract. 2017 Apr 4. doi: 10.1111/jep.12747. [Epub ahead of print]

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Why do diagnostic errors occur?

- Physicians generate hypotheses almost immediately on hearing the patient's chief complaint
- AND follow a pattern based on a "systems" approach
- Additional information when it is sought is to confirm the initial "diagnosis" or other possibilities are often ignored

Berner and Graber Am J Med 121; 2008

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What is the outcome?

- But what if the doctor never recognizes that the diagnosis was incorrect?
- There is no opportunity for correction
- Systematic approach leads to additional errors
- It's a cultural thing – *Outliers*

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Solution?

- If diagnostic processes routinely led to recognized errors…
  - The errors could be corrected by adopting a more contemplative, deliberate approach of alter to strategies to better identify and prevent misdiagnosis

Berner and Graber Am J Med 121; 2008

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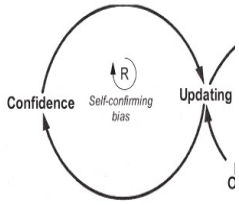
How confidence impedes calibration



R = reinforcing or self-confirming bias

Continuous loop based on confidence in diagnostic certainty without updating

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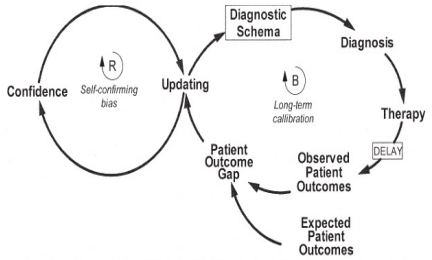
Introducing outcome feedback assists updating and questions self confirmation scheme



R = reinforcing or self-confirming bias

Continuous loop based on confidence in diagnostic certainty

Updating is the key to minimizing diagnostic errors.

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Example

- 34 BM presents with history of apparent FB 3 days earlier
- SL: FL staining typical of corneal abrasion
- TX:
  -
  -
  -

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FOLLOW-UP

- 34 BM treated with topical AB (4G FQ)
  - Not better X 1D
  - Seen by resident not improved @ 2 Days
  - Now what?
- "If it' s not getting better in 2 days, you are barking up the wrong tree." (- J. Toland, MD)

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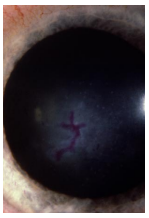
FOLLOW-UP

- 34 BM treated with topical AB (4G FQ)
  - Not better @ 2 D
  - Resident stains with RB; dendrite!
  - DX: HSV Keratitis



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MORE ON DIAGNOSTIC ERRORS

- Misdiagnosis of Acute Conjunctivitis
  - clinical accuracy of adenoviral conjunctivitis varies: 40 – 75%*
- Clinical vs. Laboratory accuracy
  - Of 143 cases, ONLY 31% of presumed bacterial conjunctivitis were culture positive for pathogenic bacteria (Leibowitz et al. 1976)

* ienien TP, et al. Acute conjunctivitis: truth and misconceptions. CMRO 2009; 1953-1961

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ADDITIONAL INFORMATION ON OPHTHALMIC DIAGNOSTIC ERRORS

- 67% of adenoviral conjunctivitis examined in a 3-month period presented unilaterally and the MISDIAGNOSIS rate was 42% (Cheung 2003)
- This may lead to treatment errors . . .

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BACK TO ACUTE CONJUNCTIVITIS

- "The risk of developing HSV keratitis makes the wide-spread use of topical combination agents concerning! "

Obrien TP, et al. Acute conjunctivitis: truth and misconceptions. CMRO 2009; 1953-1961

- LL (8 WF; 1/09; T-Dex X 3 days bid by pediatrician)

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MORE ON DIAGNOSTIC ERRORS

"Traditionally, certain symptoms are presumed to be more likely associated with a viral etiology while others are more likely to be seen with bacterial disease*."

* Obrien TP, et al. Acute conjunctivitis: truth and misconceptions. CMRO 2009; 1953-1961

- Like disc hemorrhage in OHT/glaucoma…

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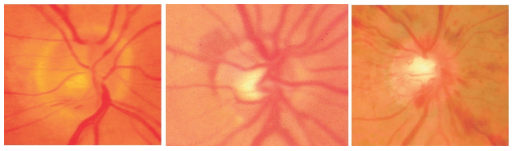
More on Ophthalmic Diagnostic Errors (ONH Hemorrhage in OHTS)



"Twenty-one cases (16%) were detected by both clinical examination and review of photographs, and 107 cases (84%) were detected only by review of photographs (P<0.0001).

Budenz DL, et al. Detection and prognostic significance of optic disc hemorrhages during the Ocular Hypertension Treatment Study. Ophthalmology .2006; 113(12):2137-43.

62

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Disc Hemorrhage in OHTS & *New Paradigms for Detection*

"Twenty-one cases (16%) were detected by both clinical examination and review of photographs, and 107 cases (84%) were detected only by review of photographs (P<0.0001).

"Review of stereophotographs was more sensitive at detecting optic disc hemorrhage than clinical examination."

Budenz DL, et al. Detection and prognostic significance of optic disc hemorrhages during the Ocular Hypertension Treatment Study. Ophthalmology .2006; 113(12):2137-43.

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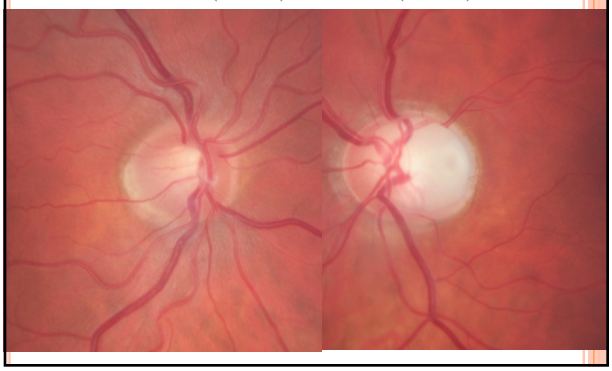
57 W/M -5.50 (20/20) -9.50 (5/350)



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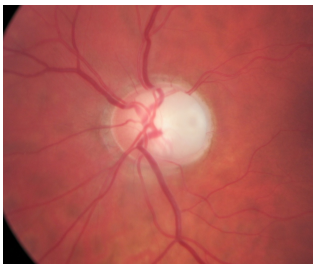
Final Exam Question 64 (Posterior Segment OPT-225)

A. Glaucoma
B. Coloboma
C. Staphyloma
D. Melanoma



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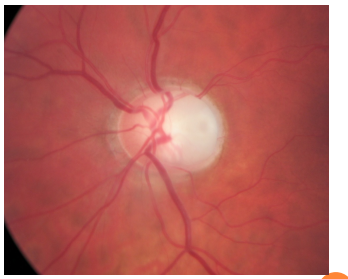
Final Exam Question 31 (Glaucoma OPT-324)

A. Glaucoma
B. Coloboma
C. Staphyloma
D. Melanoma



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Finally . . .(ala John Potter, OD)

- "You see only what you look for; you recognize only what you know." - **Merrill Sosman, MD**

- Sosman was a beloved radiologist and professor at Harvard Medical School. He lived from 1890 until 1959. His maxim is similar to the Buddhist idea that the mind stops with recognition. In other words, once you recognize a possible solution, you stop considering other possibilities.

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CANNIBAL

One who is fed up with people.

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SURGICAL ERRORS

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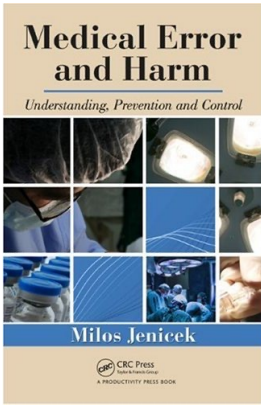

2010

Introduces the term, lathology—ie, the study of lathos (Greek for error) for this scientific field.

Begins a terminology discussion, as well as offering suggestions for improvement.

Surgical errors . . .

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CONTEMPORARY HEADLINE MEDICAL ERROR - JESSICA SANTILLAN (2003)

- Heart-lung transplant patient @ DUMC
- Blood-type mismatch
- How did it happen and how was it handled?
  - Surgery 02/07/03; near conclusion, surgeon realized incompatibility [due to miscommunication United Network for Organ Sharing]

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HOW DID IT HAPPEN AND HOW WAS IT HANDLED?

- Actions
  - Notify family
  - Explain options -> informed decision; public announcement inappropriate at this point
- Outcome – better communication

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HANDOFFS / PATIENT INFORMATION SHARING (MDLINX, MURPHY, J. JULY 10, 2020)

- 7 steps to prevent medical errors during handoffs
  - Talk face-to-face
  - Avoid distractions
  - Make sure all patient info is up to date
  - Communicate methodically
  - Don't do an info dump
  - Use familiar language
  - Get verification

https://www.mdlinx.com/article/7-steps-to-prevent-medical-errors-...KrBIgsXB?utm_source=alert&utm_medium=email&utm_campaign=ajm_50125. Accessed July 14, 2020

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But . . .

- Quaid case

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Reuters. Thu Nov 22, 2007 4:26am EST

- Dennis Quaid twins recovering from medical overdose.

75

75

Heparin @ 1000X the intended dose!

- The two-week-old twins of actor Dennis Quaid were recovering in a Los Angeles hospital on Wednesday after mistakenly being given a massive overdose of a blood thinning drug.
- Cedars-Sinai Medical Center, one of the United States' leading hospitals, apologized on Wednesday for what it called the "preventable error" that led to the twins and another unidentified child being given 10,000 units of the anti-coagulant Heparin, instead of the normal 10 units given to babies.

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Heparin @ 1000X the intended dose!

- How was it handled?
- Dr Michael Langberg, chief medical officer at Cedars-Sinai,
- "This was a preventable error, involving a failure to follow our standard policies and procedures, and there is no excuse for that to occur at Cedars-Sinai. Although it appears at this point that there was no harm to any patient, we take this situation very seriously," Langberg said

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Quaid twins overdosed w/heparin

- @ 11 days of age, stricken with *Staph* infections and intended to get IV Ab, heparin to flush IV lines to prevent clots in the lines) was administered.
  - Heparin was stored in the wrong place
  - Technician was on automatic mode
  - DESPITE 5 opportunities to check on the dosing.

WebMD, the magazine Sep/Oct 2008

78

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Resource for upcoming tables

Clarke JR, Johnston J, Finley ED. Getting surgery right. Ann Surg. **2007** Sep;246(3):395-403, discussion 403-5.

Drexel University, Philadelphia, PA

A look at the root cause of surgical errors – is it the system or is it the individual?

79

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TABLE 1. Suggested Process Improvement for Preventing Wrong-site Errors

Suggestions for Process Improvement	Step	SR/HB	Subsequent Actions
The surgeon should be fully engaged, as a member of the operating team, in the formal time-out, probably in the context of a full preoperative briefing.	Actions of surgeon in OR	HB	Team training to improve the culture of safety.
The surgeon should be explicit in the patient's records about the procedure and its indication, including the side or site if appropriate.	Accurate records for verification	HB	Independent double-check against original source documents.
The consent should be obtained from the patient by the surgeon at the time of the formal recommendation for surgery and should explicitly state the procedure, including the side or site if appropriate.	Consent	HB	A "write-back" section to document the patient's "read-back" of the consent.

SR = System redesign, HB = Human Behavior

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A reliable system for accurately transmitting information from the surgeon's office to the OR nurse should be in place.	Scheduling with OR	SR	Audit or monitor.
Review original definitive diagnostic tests and make them available in the OR.	Report of Dx test information	HB	Note availability of original test in OR on checklist.
Verification should use appropriately phrased questions. Reconciliation should also include schedule, consent, surgeon's records, and patient's records. If discrepancies are noted, the nurse should check all original source documents and contact the surgeon.	Verify with patient/family	HB	Instruction in phrasing questions appropriately.

SR = System redesign, HB = Human Behavior

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Have an initial-time out in the OR before caring for a patient undergoing elective surgery.	Actions of anes. provider in OR	SR	Documentation in the operative and anesthetic records.
Surgeon should reconcile schedule, consent, surgeon's records, patient's records, and patient or family verification independent of nurse before the first time out. If discrepancies are noted, the surgeon should check all original source documents.	Verify by surgeon in OR holding	SR	Audit or monitor.
The marking of the operative site should be reconciled by the surgeon and patient together.	Marking of operative site	HB	Independent verification.
Reconciliation should include schedule, consent, surgeon's records, patient's records, and patient or family verification. If discrepancies are noted, the nurse should check all original source documents and contact the surgeon.	Reconcile by preoperative RN in OR holding	HB	Note on operative checklist.

SR = System redesign, HB = Human Behavior

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The surgeon's records relevant to the operation should be available in the operating suite for verification against primary sources of information.	Verify w/ surgeon's original records	SR	Note availability of surgeon's records in OR on checklist.
The surgeon should discuss new findings and changes in plans with other members of the operating team.	Reconcile w/ intraoperative findings	HB	Team training to improve the culture of safety.
The surgeon should participate in written documentation of specimen, including side and site if appropriate. Reconciliation of labeling should include both the operating technician and circulating nurse. There should be a chain of custody for irreplaceable specimens.	Labeling of specimen	HB	Signoff on specimen information by all involved. Policy for chain of custody procedure for critical specimens.

SR = System redesign, HB = Human Behavior

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Suggestions for Process Improvement	Step	SR/HB	Subsequent Actions
The surgeon should be explicit in the patient's records about the procedure done and diagnosis, including the side or site if appropriate.	Postoperative documentation	HB	Independent written verification by postanesthetic nurse, based on anesthesia report, of surgeon's operative and/or postoperative notes.
Written interpretations of intraoperative images by the appropriate specialist should be available in the OR within the time needed to make decisions.	Review of intraoperative images	SR	Documentation with operative records.
Multiple and ancillary procedures should be included in the formal time-out process.	Include multiple proc. in time-out	HB	Change policies if necessary. Document in the operative record.

SR = System redesign, HB = Human Behavior

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Repeat formal time-out processes for independent procedures.	Repeat time-out for separate procedures	HB	Change policies if necessary. Document in the operative record.
Have a formal sign-out and coverage policy for members of the operating team engaged in the care of a patient in the OR.	Eliminate tasks not related to patient	SR	Audit or monitor.
Have a mini time-out in the OR whenever the patient is repositioned in a different orientation.	Maintaining right-left orientation	SR	Documentation in the operative and anesthetic records.

SR = System redesign, HB = Human Behavior

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STILL IN THE NEWS! - 2009

ORIGINAL ARTICLE

Incorrect Surgical Procedures Within and Outside of the Operating Room

Juka Neily, RN, MS, MPH; Peter D. Mills, PhD, MS; Noel Eldridge, MS; Edward J. Dunn, MD, MPH; Carol Sarnples, BGS; James R. Turner, BS; Audrey Revere; Ralph G. DePalma, MD; James P. Bagian, MD, PE

Objective: To describe incorrect surgical procedures reported from Veterans Health Administration (VHA) Medical Centers from 2001 to mid-2006 and provide proposed solutions for preventing such events.

Results: We reviewed 342 reported events (212 adverse events and 130 close calls). Of these, 108 adverse events (50.9%) occurred in an OR, and 104 (49.1%) occurred elsewhere. When examining adverse

Overall, the researchers reviewed 342 reported events, including 212 adverse events (any surgical procedure performed unnecessarily, such as a procedure performed on the wrong patient or wrong site) and 130 close calls (in which a recognizable step toward an adverse event occurred but the patient was not subjected to the unnecessary procedure).

Arch Surg. 2009;144(11):1028-1034

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STILL IN THE NEWS!

Of the adverse events, 108 (50.9 percent) occurred in an operating room and 104 (49.1 percent) occurred elsewhere.

When examining adverse events only, ophthalmology and invasive radiology were the specialties associated with the most reports (45 [21.2 %] each), whereas orthopedics was second to ophthalmology for the number of reported adverse events occurring in the operating room."

Arch Surg. 2009;144(11):1028-1034

87

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STILL IN THE NEWS!

"Pulmonary medicine cases (such as wrong-side thoracentesis [removing fluid from chest]) [BREATHTAKING]

and wrong-site cases (such as wrong spinal level) were associated with the most harm.

The most common root cause of events was communication (21.0 %)."

Arch Surg. 2009;144(11):1028-1034

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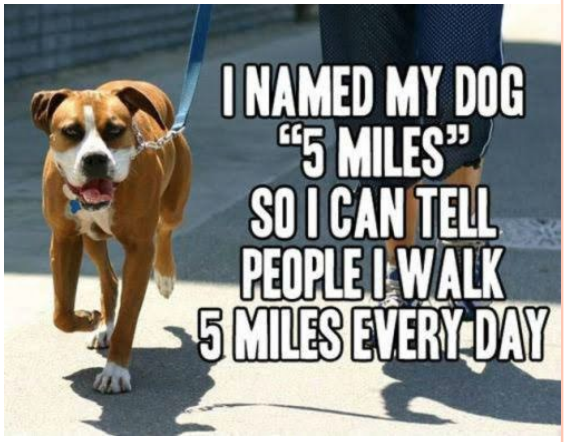
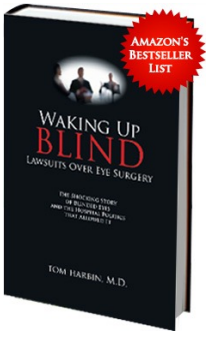


89

A LITTLE CLOSER TO HOME . . .



September, 1983
Emory University

- Dwight Cavanaugh, MD operates on the wrong eye.
- Events follow that are unprecedented.
- Altered records, cover-ups, accusations, career derailments, etc.

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TRIVIA QUESTION

- For what advance in glaucoma treatment is Dr. Harbin known?
- Ocusert®
- Harbin drainage valve
- Pioneering work on PGAs
- Development of the device that became the PASCAL tonometer

91

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TRIVIA QUESTION

- For what advance in the field of glaucoma is Dr. Harbin known?

- Ocusert®
- Harbin drainage valve
- Pioneering work on PGAs
- Development of a device that became the PASCAL tonometer

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SYNOPSIS OF THE FALLOUT

Lawsuits filed / settled / adjudicated

- 6 settled without details revealed (court ordered)
- > $ 7 Million in damages that were public knowledge.

Careers derailed (and not)

- Allen Gammons, MD
- David Campbell, MD
  - and others
- Dr Cavanaugh is Univerity of Texas Southwestern's first Professor Emeritus in Ophthalmology (3/17/2021)

https://www.utsouthwestern.edu/ctplus/stories/2021/cavanagh-professor-emeritus-in-ophthalmology.html

Accessed April 24, 2022

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LESSONS LEARNED (?)

Motivation

- Patients who question a doctor's advice should be offered a second opinion.
- Members of an organization should recognize the high cost of remaining silent about wrong-doing

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LESSONS LEARNED (?)

Impact (author Harbin)

- "A significant deficiency in medical training is the lack of any instruction in practical aspects of running a practice or an academic lab. Not surprisingly, young doctors flounder as they evaluate practice opportunities and enter the real world.
- "My hope was to strengthen medicine by having us confront problems."

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MEDICATION ERRORS

500% growth in medications in last decade of the 20th Century

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"PRESCRIPTION ERRORS"

- Florida –

"Most errors in medicine deal with medication errors. Yet the same safeguards exist with respect to the dispensing of medicine that have been in place for centuries.

…and this activity occurs…

"hundreds if not thousands of times every day."

So, the question to be answered is, "What is the root cause of prescription/medication errors?"

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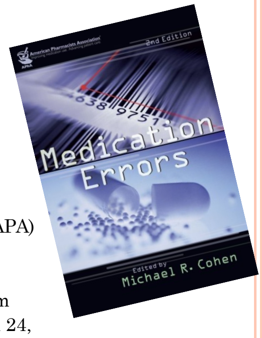
Reference Text

- **Medication Errors, 2 ed. 2006**
  - Edited by Michael Cohen
  - Published by American Pharmaceutical Association (APA)
  - 1-800-FAIL SAF(E) or ismpinfo@ismp.org
  - Also available at Amazon.com ($37.44-97.06, accessed April 24, 2022; *was $35 in April 2016*)



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- *GUESS THE DATE OF THIS NEWS RELEASE*

World Health Organization

Media centre

WHO launches global effort to halve medication-related errors in 5 years

News release

GENEVA/BONN - WHO today launched a global initiative to reduce severe, avoidable medication-associated harm in all countries by 50% over the next 5 years.

The Global Patient Safety Challenge on Medication Safety aims to address the weaknesses in health systems that lead to medication errors and the severe harm that results. It lays out ways to improve the way medicines are prescribed, distributed and consumed, and increase awareness among patients about the risks associated with the improper use of medication.

99

99

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Media centre

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100

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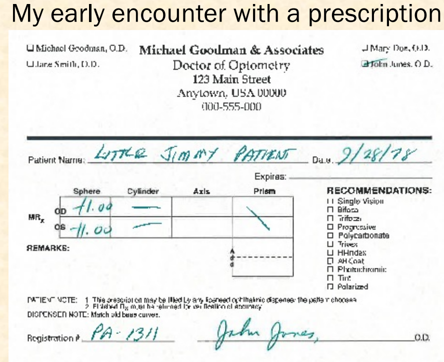
My early encounter with a prescription error



What is the patient's refractive correction?

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2022 NCBI Medication dispensing errors and prevention - StatPearls

Medication Errors

https://www.ncbi.nlm.nih.gov/books/NBK519065/
Accessed April 23, 2022

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Scope of the Problem

- 6800 prescription medications and countless O-T-C drugs are available in the USA
- Plus supplements, herbs, potions and lotions…
- 7,000-9,000 deaths annually due to medication errors
- 7 million patients are affected, and $40 M is spent treating those
- Major consequences: decreased patient satisfaction and loss of trust in the healthcare system

https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

103

103

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https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

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Common Reasons for Errors

- Failure to communicate drug order
- Illegible handwriting
- Wrong frug selection chosen (from the drop-down menu)
- Confusion over similarly named drugs
- Confusion over similar packaging (pharmacy)
- Errors involving dosing units or weight

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https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

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Medication Error Defined

- "… any preventable event that may cause or lead to inappropriate medication use or patient harm

while the medication is in the control of the healthcare professional, patient, or consumer.

Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

-National Coordinating Council for Medication Error Reporting and Prevention

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https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

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Adverse Drug Reaction vs. Medication Error

- The World Health Organization defines an ***adverse drug reaction*** as "any response that is noxious, unintended, or undesired, which occurs at doses normally used in humans for prophylaxis, diagnosis, therapy of disease, or modification of physiological function."
- ***Adverse drug reactions are expected negative outcomes*** that are inherent to the pharmacologic action of the drug and not always preventable, while *medication errors are preventable.*

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https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

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Adverse Drug ***Event*** Defined

- An adverse drug event is an injury from a medication or a missed or inappropriately dosed medication. An adverse drug event causes morbidity or mortality to a patient.
- Distinguished from ***reaction***
  - An ***event:*** a negative consequence from receiving a drug in the manner it was intended (not inappropriate administration, e.g.)

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https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

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Sentinel Defined

- "an unexpected occurrence involving death or serious physical or psychological injury, ***or the risk thereof***.
- Serious injury specifically includes loss of limb *or function*.

Zithromycin© Post-Marketing Experience:

Special Senses: Hearing disturbances including hearing loss, deafness and/or tinnitus and reports of taste/smell perversion and/or loss.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/050710s44-050711s41-050784s28lbl.pdf
Accessed April 24, 2022

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https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

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When can medication errors occur?

- Ordering/prescribing (50%; 30-70% of which are identified by nurses or pharmacists)
  - wrong: med, route of administration or frequency of dosing
- Documenting
- Transcribing
- Dispensing
- Administering
- Monitoring

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https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

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The most common *system failures* include

- Inaccurate order transcription
- Drug knowledge dissemination
- Failing to obtain allergy history
- Incomplete order checking
- Mistakes the tracking of the medication orders
- Poor professional communication
- Unavailability or inaccurate patient information

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https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

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Types of medication errors

- Prescribing
- Omission
- Wrong time
- Unauthorized drug
- Improper dose
- Wrong dose prescription/wrong dose preparation
- Administration errors including the incorrect route of administration, giving the drug to the wrong patient, extra dose or wrong rate
- Monitoring error such as failing to take into account patient liver and renal function, failing to document allergy or potential for drug interaction
- Compliance error such as not following protocol or rules established for dispensing and prescribing medications

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https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

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Causes of medication errors

- Expired product
- Incorrect duration
- Incorrect strength
- Incorrect rate
- Incorrect timing
- Incorrect dose
- Incorrect dosage form
- Incorrect patient action
- Known allergy
- Known contraindication
- The most common causes of dispensing errors involve
  - workload
  - similar drug names
  - interruptions
  - lack of support staff
  - insufficient time to counsel patients
  - *illegible* handwriting

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https://www.ncbi.nlm.nih.gov/books/NBK519065/
Tariq RQ, Vashisht R, Sinha A, et. al. Accessed April 23, 2022

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Medication error risk factors (speaks to root cause)

- High volume
- Poor handwriting
- Inexperienced staff
- Challenging patient populations
- Lack of follow-up
- Lack of appropriate monitoring
- Lack of policy enforcement
- Medically complex patients
- Medications requiring calculations
- Environmental factors
- Poor communication
- Shift work
- Workplace culture
- Verbal orders
- Interpersonal factors such as external stress

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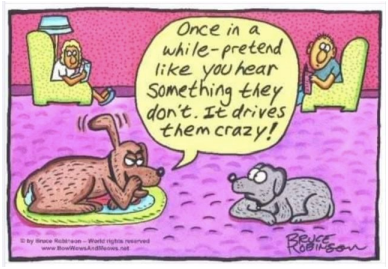
Now the question becomes

- What steps can be taken to avoid the medication errors?



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- Florida took a simple but important step to improve patient safety on July 1, 2003, when s.456.42, F.S. went into effect, making handwritten prescriptions illegal.
- This law requires physicians in Florida to either print legibly or type prescriptions and to include the name and strength of the drug prescribed, the quantity of the drug prescribed in both textual and numerical formats, and the directions for taking the drug.

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Resource: 15 Medication error prevention recommendations

- Medication errors: problems and recommendations from a consensus meeting.
- Members of EMERGE, Erice Medication Errors Research Group, Agrawal A, Aronson JK, Britten N, Ferner RE, de Smet PA, Fialová D, Fitzgerald RJ, Likić R, Maxwell SR, Meyboom RH, Minuz P, Onder G, Schachter M, Velo G. Medication errors: problems and recommendations from a consensus meeting. Br J Clin Pharmacol. 2009 Jun;67(6):592-8

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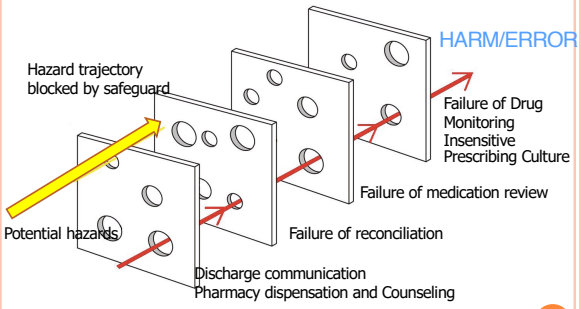
Reason's "Swiss cheese" model of medication errors



da Silva BA, Krishnamurthy M. The alarming reality of medication error: a patient case and review of Pennsylvania and National data. J Community Hosp Intern Med Perspect. 2016 Sep 7;6(4):31758.

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Telepharmacology

Pharmacy has been practiced over distance for a long time. Telepharmacy is facilitated by computerized physician order entry, remote review, and even remote dispensing. Combining that with video, being able to review medications, and conducting a video consultation with a patient allows the whole pharmacy visit to occur over distance. In one recent study on 47 cancer patients, 27,000 miles of travel were saved because of telepharmacy (Gordon et al., 2012). A… study of six rural hospitals showed that with telepharmacy, about 19 percent of patients had one or more medication errors that were picked up by the remote pharmacists. (Cole et al., 2012)

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Achieving balanced prescribing

- The 9 questions to ask yourself
- Indication , for example
  - Does this patient have glaucoma or OHT and deserves lowered risk for optic nerve and VF damage by decreasing the IOP?

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Achieving balanced prescribing

(Glaucoma medication scenario)

- Effectiveness, for example
  - Will this medication lower the IOP to my desired target?

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Achieving Balanced Prescribing

- Co-morbidities, for example
  - Does the patient have ocular surface disorders that would result in stinging on instillation that may lead to discontinuance?

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Achieving Balanced Prescribing

- Other similar, for example
  - Is the patient taking an oral beta-blocker that may be lowering IOP?

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Achieving Balanced Prescribing

- Interactions, for example
  - Will that oral beta-blocker produce the IOP-lowering effect that my topical beta-blocker would achieve?

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Achieving Balanced Prescribing

- Dosage, for example
  - If I choose to administer a topical beta-blocker, do I start with 0.25% in the AM and titrate the dose from there based on response?

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Achieving Balanced Prescribing

- Orders, for example
  - When writing the Rx, are the dose, frequency, route of instillation, formulation, timing, prescribed amount and refills specified?

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Achieving Balanced Prescribing

- Period (duration), for example
  - For how long is the patient to continue the drop?

(in the case of glaucoma, forever.
OOPS! Did I tell the patient this?)

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Achieving Balanced Prescribing

- Economics
- Well, is the drug cost-effective?

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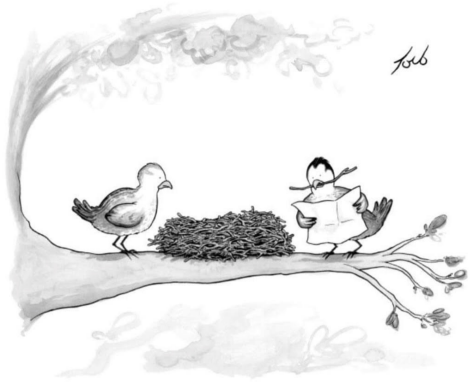

"There's always one annoying piece left over."

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Donald Berwick, MD, president and CEO of the Institute for Healthcare Improvement, (IHI) points out:

- Errors are not a "bad apple" problem where a handful of doctors or other medical personnel are the culprits and need to be rooted out or disciplined.
- Rather it is a systemic problem, where healthcare systems actually produce conditions that lead people to make mistakes or fail to prevent them.
- This means that we need rigorous changes throughout the entire healthcare system that will make it harder for people to do something wrong and easier for them to do things right. (IOM, 2005)

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To that end, *Avoid* These

- "The patient (or Mom) says that's how they take it at home"
- "The dose is from the patient's old chart"
- "It's on the list of meds the patient gave me"
- "We always do it that way"
- "This is a special case"
- *Verify* if it doesn't seem right

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Preventing Prescription Errors

- When names are problematic – use both brand and generic name
- Include product's indication (label ✓)
- Caution patients about error potential when prescribing drugs that have a look-alike or sound-alike counterpart

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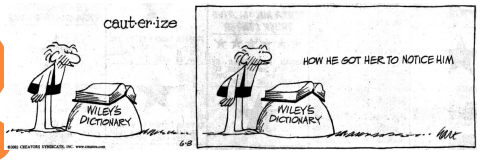
WHAT WE SAY – WHAT WE MEAN



- It's all about communication

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MINIMIZING / PREVENTING MEDICATION ERRORS – OTHER STEPS

- The six "**rights**" followed by nurses when administering drugs:
  - **Right** patient
  - **Right** drug
  - **Right** dose
  - **Right** dosage form
  - **Right** route
  - **Right** time

http://www.tlcprojects.org/NEAT/rights3.swf accessed 8/4/09

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EXAMPLES OF ERROR-PRONE DRUG INFORMATION

Abbreviation	Intended Meaning	Misinterpretation
HCT	hydrocortisone	hydrochlorothiazide
µg	microgram	milligram
o.d. or OD	once daily	right eye
TIW or tiw	three times a week	three times a day
q.d. or QD	every day	q.i.d.
qn	nightly or at bedtime	qh
q6PM	every evening at 6pm	every 6 hours

http://www.medicinenet.com/script/main/art.asp?articlekey=53208&page=3 accessed 8/4/09

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Abbreviation	Intended Meaning	Misinterpretation
q.o.d. or QOD	every other day	q.d. or q.i.d.
U or u	unit	misread as zero or 4 e.g. 4U seen as 40 or 4u seen as 44
IU	international units	IV
Name letters and dose numbers run together e.g. Inderal40 mg	Inderal 40 mg	Inderal 140 mg
Zero after decimal point (1.0)	1 mg	10 mg
No zero before decimal point (.5 mg)	0.5 mg	5 mg

http://www.medicinenet.com/script/main/art.asp?articlekey=53208&page=3

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ADD THE "AT" SIGN TO DANGEROUS ABBREVIATIONS

- $NaHCO_3$ to run @50 cc/h was misinterpreted as 250 mL per hour

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CONVENTIONAL (CULTURAL AND CONFUSING) ABBREVIATIONS

- Concentrated liquid medication was prescribed for sublingual administration
- Order was transcribed with the abbreviation "SL"
- A new nurse misinterpreted SL as "saline lock" and administered the oral solution IV!

"Doc, these contacts don't seem to be any cleaner after using that tablet."

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USE CAUTION, AVOID CONFUSION ("MEASURE TWICE, CUT ONCE")

- May sound alike
- May look alike in print
- May sound alike when orally communicated
- >750 unique drug names reported to cause confusion
  - www.usp.org/reporting/review/rev_76a.htm

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Attempts to cure the latter (FDA initiative)

Ophthalmic	Others
Xalatan	Xarelto
Vigomox	Januvia
Zymar	Kazano
Zymaxid	Farxiga
Moxeza	Tanzeum
Zylet	Afrezza
Zirgan	
Durezol	
Zioptan (NOT: Zopitan Sleeping Tablets	

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And, who has not heard of .. .

- Xiidra?
- Vyzulta?
- Rhopressa?
- Rocklatan?

How about?

- Susvimo
- Tepezza
- Tyrvaya
- Vabysmo
- Nyxol
- Vuity

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At last, the end

- Thank you for your attention
- Questions / Comments?

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