Dealing with Medical Errors

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School of Medicine
Our mission is to teach ethics & professionalism to medical students & health professionals while nurturing empathy and humanitarian values.

www.texashumanities.org
Ruth Berggren, MD, MACP, has no relationships with commercial companies to disclose.
Learning Objectives

- **Define**: medical error & adverse events, distinguish preventable, non-preventable and negligent adverse events.
- **Understand**: the magnitude of adverse events in the United States
- **Review**: professional ethical codes on error disclosure
- **Develop**: familiarity with model programs for dealing with medical error
Patient Study

- 61 y.o. involved in high speed MVC
- Normal abdominal CT
- Femur and tibial fractures
- OR for fracture repair
- Post-op transferred to orthopedic floor with persistent abdominal pain
- Distention, fever, leukocytosis
- Wife at bedside asking for evaluation for more than 24 hrs.
- Seen and re-examined 36 hrs later. Sepsis and acute abdomen
Instructions from very angry wife – “You fix him and don’t let anything happen to him or I promise I will be on your doorstep.”

OR—terminal ileal mesenteric tear with dead cecum and right colon

Right hemicolecctomy with ileotransverse colostomy

Complete disclosure and apology for the missed injury and the delay in diagnosis

Pledged a plan to prevent this type of occurrence from happening in the future -- atonement

Then…

POD# 7 – Abdominal pain, fever – re-explored – anastomotic leak
Story Continued...

- Sepsis, ARDS, open abdomen, tracheostomy, controlled ventral hernia... to rehab 2 months after injury

- Ostomy closed....hernia repaired by local general surgeon

- Delayed infection of the mesh

- Returned to the initial treating surgeon six years later to have mesh removed -- coag negative staph
Outcome

- The patient died ten years after initial injury from an unrelated illness
- The patient’s wife calls the surgeon each year on the anniversary of her husband’s death to thank the surgeon for everything done for her husband
Patient 2

- 65 year old man with a lumbar T12 spine fracture
- Multiple rib fractures
- Paraplegia
- Undergoes spine stabilization
- POD 6 has fever, drainage from surgical wound
- Scheduled for return to OR for exploration of wound and probable washout
Operating Room

- Cardiac Arrest on induction of anesthesia
- Following dose of succinylcholine
- Serum K+ 7.8
- Eventual return of pulse and rhythm with treatment of hyperkalemia
- CPR 30 minutes
- Recognized hyperkalemia related to succinylcholine administration
Faculty surgeon did not discuss with the family

Family believes they were incompletely informed of the facts surrounding the arrest – very angry

POD 2 – full family meeting with complete disclosure of the succinylcholine mediated hyperkalemic arrest
Ramifications of the Initial Communication

- Anoxic brain injury – care withdrawn POD# 8
- Tenaciously and relentlessly pursued litigation
- Two years of depositions
- Eventually settled for $2.5 million
- Persistent anger and hatred of all who cared for the family member
Medical Error vs Adverse event

- IOM (NAM): the failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim

- An injury caused by medical management rather than the underlying condition of the patient

- An adverse event attributable to error is a ‘preventable adverse event’
Definition of Medical Error

- Medical errors are preventable adverse medical events
- Negligent AE are a subset of preventable AE that satisfy legal criteria for negligence (STD of care)

“Careful - that new bed is a little touchy.”

Is this medical error?
Of Errors and Adverse Events

Adverse Events

Medical Error

Near Misses

* Negligent adverse events

27%

Adapted from Truog et al: “Talking with Patients and Families about Medical Error”
How patients vs doctors see error:

- Physician Concepts:
  - Skill
  - Knowledge
  - Rule

- Patient Concepts:
  - Relationship breakdown
  - Difficulty accessing care,
  - Poor communication,
  - Lack of time and attention
**Problem:** your car stops in the middle of the road.

1. **Why** did your car stop?
   - Because it ran out of gas.

2. **Why** did it run out of gas?
   - Because I didn’t buy any gas on my way to work.

3. **Why** didn’t you buy any gas this morning?
   - Because I didn’t have any money.

4. **Why** didn’t you have any money?
   - Because I lost it all last night in a poker game.

5. **Why** did you lose your money in the poker game?
   - Because I’m not very good at “bluffing” when I don’t have a good hand.
Whether or not an AE is found to be an error by RCA

The patient needs to be informed of what happened & implications for care going forward

- Apology + commitment that event will be investigated AND
- Patient will be informed in a TIMELY manner
A vague, impersonal apology is worse than no apology

Sincere

Personal

Timely

I believe that if you are honest and straightforward with customers, they will treat you like a neighbor when circumstances beyond your control put you in a “one-down” position.

Milton Moore, General Manager, Vision Cable
How NOT to disclose

“Anyway, to make a long story short, the medical examiner who performed your autopsy was fired.”
“Botched attempt is correct. But can anyone suggest a more family-friendly way of describing what happened?”
Effective Disclosure

- Multistep process involving several discussions with the patient/family
- Should go beyond mere words
- Should elicit information from family/pt
- Should provide family with RCA results
- Should include actions taken by hospitals to prevent similar errors
- Involving patients has great potential to meet their needs and improve quality/safety of health care.

What is the magnitude of this problem in America?

- IOM estimated 44,000 – 98,000 deaths/yr from medical errors

- COST: $17 – $29 billion

- 1,000,000
  - excess injuries
  - *To Err is Human*
  - 2000 IOM report
What is the magnitude of medical error in the United States?

<table>
<thead>
<tr>
<th>Leading Cause of Death in United States</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Heart Disease</td>
<td>652,091</td>
</tr>
<tr>
<td>2 Cancer</td>
<td>559,312</td>
</tr>
<tr>
<td>3 Stroke</td>
<td>143,579</td>
</tr>
<tr>
<td>4 Chronic Lower Respiratory Disease</td>
<td>130,933</td>
</tr>
<tr>
<td>5 Accidents (unintentional injuries)</td>
<td>117,809</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preventable Medical Errors</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>98,000</td>
</tr>
<tr>
<td>6 Diabetes</td>
<td>75,119</td>
</tr>
<tr>
<td>7 Alzheimer’s Disease</td>
<td>71,599</td>
</tr>
<tr>
<td>8 Influenza/Pneumonia</td>
<td>63,001</td>
</tr>
<tr>
<td>9 Nephritis/Nephrosis</td>
<td>43,901</td>
</tr>
<tr>
<td>10 Septicemia</td>
<td>34,136</td>
</tr>
</tbody>
</table>
A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care

- Lit review identifies 4 limited studies using a Global Trigger Tool to flag specific evidence in medical records (medication stop orders or abnl lab results), indicating an adverse event

- 210,000–400,000 deaths per year were associated with preventable harm in hospitals

- Serious harm is 10– to 20 X more common than lethal harm
  - James, JT. J Patient Saf. 2013 Sep;9(3):122–8
Fig 1 Most common causes of death in the United States, 2013.
N=251,000/yr


- Cancer: 585k
- Heart disease: 611k
- COPD: 149k
- Suicide: 41k
- Firearms: 34k
- Motor vehicles: 34k

Based on our estimate, medical error is the 3rd most common cause of death in the US.

However, we're not even counting this - medical error is not recorded on US death certificates.

Martin A Makary, and Michael Daniel BMJ
2016;353:bmj.i2139

Data source:
http://www.cdc.gov/nchs/data/nvdr/nvdr64/nvdr64_02.pdf

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What are the errors and whose fault are they?

- Patients being given the wrong medicine.
- Clinician misreading the results of a test
- Not interpreting a test ordered by someone else
- Misinterpretation of ambiguous symptoms such as alteration in mental status, abdo pain or MI
- Clinician not ordering tests indicated by clinical findings.

Many causes, some controllable: fatigue, poor training, lack of communication, time pressure, distraction, and poor judgment.

- 18 errors per 100 ED pts. Only 12% of mistakes are human error; the other 88% are system errors in some sense.
How many of these are surgical?

- 39 X wk a surgeon leaves towels or sponges inside a patient.
- 20 X wk surgeon performs the wrong surgery or operates on the wrong body part.
- 4,044 never events occur annually in the U.S., according to estimates from malpractice claims due to adverse surgical events.

The bad apple paradigm creates a culture of silence. IOM recs:

- Mandatory reporting of AEs
- Funding for safety improvement
- Confidentiality protections for info voluntarily reported
- Non punitive systems within institutions to encourage sharing of information error
- Incentivize and encourage safe practices
- Educate everybody
- Get patients involved in safety movement
- Disclosure is important for improving safety
Other Recommendations:

To curtail harm, (a lay perspective) we must:

- Engage patients and their advocates during hospital care
- Systematically seek patients’ voice in identifying harms
- Transparent accountability for harm
- Intentional correction of root causes of harm
Medical error in surgical literature

“Improving disclosure and management of medical error – opportunity to transform surgeons of tomorrow” A REVIEW OF 52 papers

- WHO: Junior docs more vulnerable to err
- WHERE: Serious errors in ED/ICU/OR
- HOW: Improvements happen from both institutional and individual learning
- WHAT: Need to transform the current culture of: NAME, BLAME, SHAME
- WHY: The rest of this presentation
University of Texas Health
San Antonio

- Written policies on disclosure
- Root cause analysis
Families or authorized representatives must be informed about outcomes of care, including unanticipated outcomes & medical errors.

An unanticipated outcome will be communicated in a timely and appropriate manner by the attending physician with primary responsibility for the patient's care, as soon as reasonably possible taking into consideration the patient's condition.

Communication should occur no later than 24 hours after becoming aware of unanticipated outcome.
Colorado:

Law is broad, covering not only words but also health professionals' actions and conduct. Prohibits outright statements of apology made by physicians and hospitals from being used by the alleged victim to prove liability.

Texas:

Only expressions of sympathy and statements conveying "a general sense of benevolence relating to the pain, suffering, or death of an individual involved in an accident" are inadmissible.
In Texas...

- a communication, including an excited utterance as defined by Rule 803(2) of the Texas Rules of Evidence,
- which also includes a statement concerning negligence or culpable conduct, is admissible to prove liability.
Medical Apology Laws

Key
- No apology law
- Sympathy only
- Admissions of fault
The communication should include an explanation of what occurred, an expression of regret that the unanticipated outcome occurred, followed by an objective statement of the outcome and consequences + actions taken for patient,

Other treatment options available.

Questions should be answered factually and directly, without speculation regarding what is unknown.
What are the underlying ethical principles?

- **Fiduciary relationship obligates MD to be trustworthy and act in the pt’s best interest.**

- **Respect for persons:** act in ways to acknowledge worth and dignity of pt and don’t deceive.

- **Autonomy** (self-determination), doctrine of informed consent requires MD to disclose ALL relevant info for decision-making

- **Justice:** those damaged by error should be compensated for harm; so they must know what happened
What Values and Virtues Underlie the Duty to Disclose?

**Values**
- Truth-telling
- Compassion

**Virtues:**
- Honesty
- Trustworthiness
- Courage
- Humility
- Self-care (alleviation of guilt, shame; maintenance of integrity)
Principle of Consequentialism

- Involves weighing benefits/harms of an action; supports disclosure
- Consoling to know steps are being taken to avoid repeated errors

- Consequences of failure to disclose:
  - Deceitfulness
  - Elevation of self-interests over patients’
  - Undermining of public trust in medicine
Stories of patients and families help us understand the detrimental effects of nondisclosure and emotional withdrawal by clinicians.

Non-disclosure leads to feelings of abandonment, loss of trust, grief, and anger in patients.

Of isolation, inadequacy, depression and grief in MD.
What was your role?

1. Unforeseeable
   - No way to predict
   - Unintended outcome / harm
   - Accident = Sadness

2. Neglected a responsibility
   - Responsible = Regret

3. Intended outcome / harm
   - To blame = Guilt

What did you do & why?
Why didn't you do something else?
What was your intention?
Can ethical duty to disclose conflict with duty not to harm?

- Yes: error of no consequence shakes pt faith in the doctor or the hospital; increases anxiety
- YES: there are so many errors (small ones) that we could do nothing but disclose.
- Threshold for disclosure should be commensurate with harm
A physician shall uphold the standards of professionalism, be honest in all professional interactions, & strive to report physicians deficient in character or engaging in deception...
Principles of Nursing Ethics:

Nurses: duty not to condone attempts to cover up error or attempt to fix blame without correcting conditions leading to the problem.

- Expected to report errors & ensure responsible disclosure to patients.
Physicians should disclose information about errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may.
Code of Professional Conduct

As Fellows of the ACS, we treasure the trust that our patients have placed in us, because trust is integral to the practice of surgery. During the continuum of care, we accept responsibilities to:

- Serve as effective advocates of our patients' needs.
- Disclose therapeutic options, including their risks & benefits.
- Disclose/resolve any conflict of interest that might influence decisions.
- Be sensitive & respectful of patients, understanding their vulnerability.
- Fully disclose adverse events & medical errors.
- Acknowledge patients' psychological, social, cultural, and spiritual needs.
- Encompass within our surgical care the special needs of terminally.
- Acknowledge & support the needs of patients' families.
- Respect the knowledge, dignity, and perspective of other health care professionals.
Overview of Model Programs: Lexington, KY Vet’s Administration

1987: 2 big malpractice cases
1995: VA adopts policy of informing patients and steps to minimize further harm
2003: VA Ethics committee “Disclosing Adverse Events to Patients” summarizes ethical & legal rationale for disclosure
2008: VA continues policy of disclosing AE including non obvious AE & events in which harm not yet manifested.
“Near miss” disclosure not mandatory.
Separation: clinical/institutional disclosure
Won’t disclosures of medical errors increase law suits and litigation costs?
Disclosure policy adopted in 2002

1. Acknowledge cases in which a patient was hurt because of medical error and compensate

2. Aggressively defend cases hospital considers baseless

3. Study all adverse events to determine how procedures could be improved
Results of Medical Error Disclosure Program at the University of Michigan

- Annual litigation costs: $1 Million and $3 Million
- Average time to resolution of claims and lawsuits: 9.5 Months and 20.7 Months
- No. of claims and lawsuits: 114 (August 2001) and 262 (August 2005)

Overview of Model Programs: CO

- COPIC Insurance Company
  - In 2000 adopted the 3Rs program (excludes death, clear negligence):
    1. Recognizing unanticipated event
    2. Responding promptly
    3. Resolving related issues

- COPIC trains & supports MDs in communicating openly with patients
- Financial assistance on a no-fault basis ($30K)
- Payments not reportable to National Practitioner Data Bank
- Patients told how recurrence will be prevented
COPIC outcomes 2000–2006

- 2,853 CO physicians enrolled
- 3,200 events handled in program
- 25% of patients received payments, avg $5,400 per case
- 7 paid cases eventually litigated, 2/7 resulted in tort compensation
- 16 unpaid cases subsequently litigated, 6 of which resulted in tort compensation
- *** ½ insured MDs participate; they experienced no greater claims than non-participants
- Payments are modest, resolution amicable, MD + patient satisfaction is high

The Full Disclosure Program of the Stanford University Medical Institutions

Stanford’s PEARL

The Process for Early Assessment and Resolution of Loss
Stanford’s Journey Into “Full Disclosure”

“Discreet and selective practice” began with in-house claims management (September 2005)

Successes and failures analyzed

Pioneering programs, observations, and peer reviewed research studied (VA, UM, COPIC, Harvard)

SWOT assuming fully instituting a “full disclosure” approach

Formal program launched along side of on-going Stanford and University of Washington research project (September 2007)
Stabilize patient
Take all necessary actions to promote patient safety
Call PEARL Risk & Claims Advisor ASAP, but < 4 hours after PUO
Proceed with documenting the patient’s care after speaking to your PEARL Risk & Claims Advisor
Record PEARL Risk & Claims Advisor name and phone number as exclusive contact regarding PUO, unless instructed otherwise
Stanford’s PEARL

Three PEARL Cautions

- Do not jump to conclusions
- Do not blame or accuse others
- Never make promises or offer to waive bills or make offer of compensation without express approval of PEARL Risk & Claims Advisor
Stanford’s PEARL

15+1 PEARL Outcomes Measures

- Expenses paid
- Indemnity paid
- Case reserves
- Comparison of Paid v. Reserved
- Pending lawsuits
- Case open time
- Physician well-being
- Patient satisfaction/distress
- Physician satisfaction/distress
- SUMIT staff satisfaction
- Patient forgiveness
- Time of report/recognition
- Report to NPDB & CMB
- Corporate morale/Culture
- Resolution method

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# PEARL Results

<table>
<thead>
<tr>
<th>Metric</th>
<th>Desired Result</th>
<th>Observed Result</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>Reporting Pattern</td>
<td>Faster</td>
<td>Unchanged</td>
<td>Average incident to report lag is one year</td>
</tr>
<tr>
<td>Frequency</td>
<td>Lower</td>
<td>Lower</td>
<td>Annual reported claims dropped from 23 to 15</td>
</tr>
<tr>
<td>Closing Pattern</td>
<td>Faster</td>
<td>Inconclusive</td>
<td>Small number of closed claims</td>
</tr>
<tr>
<td>Severity</td>
<td>Lower</td>
<td>Inconclusive</td>
<td>Some large post-PEARL closed claims</td>
</tr>
<tr>
<td>Overall Cost</td>
<td>Lower</td>
<td>Lower</td>
<td>38% reduction over 5 years</td>
</tr>
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http://theriskauthority.com/

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Recent self–perceived major medical errors were reported by 9% of American surgeons.

- These errors are strongly related to burnout and mental QOL.
- A majority of surgeons attributed their errors to individual rather than system level factors.

- Additional studies on reducing individual factors contributing to medical errors are needed.
- Implementation of system level safeguards are needed.
- Studies to determine how to reduce surgeon distress and how to support surgeons when medical errors occur are needed.

- **Burnout and Medical Errors Among American Surgeons**
  - Tait D. Shanafelt, MD,* et al
  Annals of Surgery • Volume 251, Number 6, June 2010
What to do in the aftermath of complications

Strategy
- Peer with an ear
- Be a (QI) safety advocate
- Seek teaching opportunities
- Understand moral context
- Focus on learning from rather than eliminating errors

Explanation
- Emphasize “holding” vs “solving”
- Participate in fix to promote growth
- Teaching = healing for docs who’ve made mistakes
- Moral context helps docs “do the right thing” p/ complication
- Change personal failing into learning opportunity; prevent future complications

Wisdom in Medicine: What Helps Physicians After a Medical Error? 
Academic Medicine, Vol. 91, No. 2 / Feb 2016
Promoting wisdom after complications

- **Strategy**
  - Universal disclosure training
  - “imperfect, but good doctor” as an acceptable standard
  - Cultivate self-forgiveness
  - Foster reflective practice

- **Explanation**
  - Most are unprepared. Should be mandatory
  - Culture should not perpetuate fear and unrealistic perfection goals
  - Self-forgiveness does not mean lower standards.
  - Medical errors exacerbate burnout.

Wisdom in Medicine: What Helps Physicians After a Medical Error?
Academic Medicine, Vol. 91, No. 2 / Feb 2016
Implications for our practice

- We need awareness and enhancement of existing policies on error disclosure
- Close working relationship with insurance company and our practice site administration
- Professionalism training to include error disclosure
- Physician wellness and patient safety are the key reasons we need to acknowledge, study, and prevent errors
“My job is much more difficult when doctors fall on the sword. The hardest case for me to bring is the case where the defense has admitted error and apologized to the injured patient.”  Andrew Meyer, medical malpractice lawyer
“The good physician knows his patients through and through, and his knowledge is bought dearly. Time, sympathy, and understanding must be lavishly dispensed, but the reward is to be found in that personal bond which forms the greatest satisfaction of the practice of medicine. One of the essential qualities of the clinician is interest in humanity, for the secret of care of the patient is in caring for the patient.”

Peabody FW. The Care of the Patient. JAMA 1927
Thank you!

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