Objectives

Review the impact of preventable unanticipated medical outcomes

Identify commonly used rational which limit actual disclosure of unanticipated medical outcomes

Discuss practical strategies to facilitate disclosure and apology

My Mom's story

"It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm. It is quite necessary, nevertheless, to lay down such a principle."

Florence Nightingale, 1863

Background: Harvard Medical Practice Study 1990

Assess adverse events of hospitalized patients in New York, 1984

Overall 3.7% of 2.7 million pts (98,609) experienced medical error

- 57% minimal or transient harm
- 17% moderate impairment
- 7% permanent impairment
- 14% death

Brennan *N Eng J Med* 1991

Background

In 1999, the Institute of Medicine released the report "To Err is Human: Building a Safer Health System"

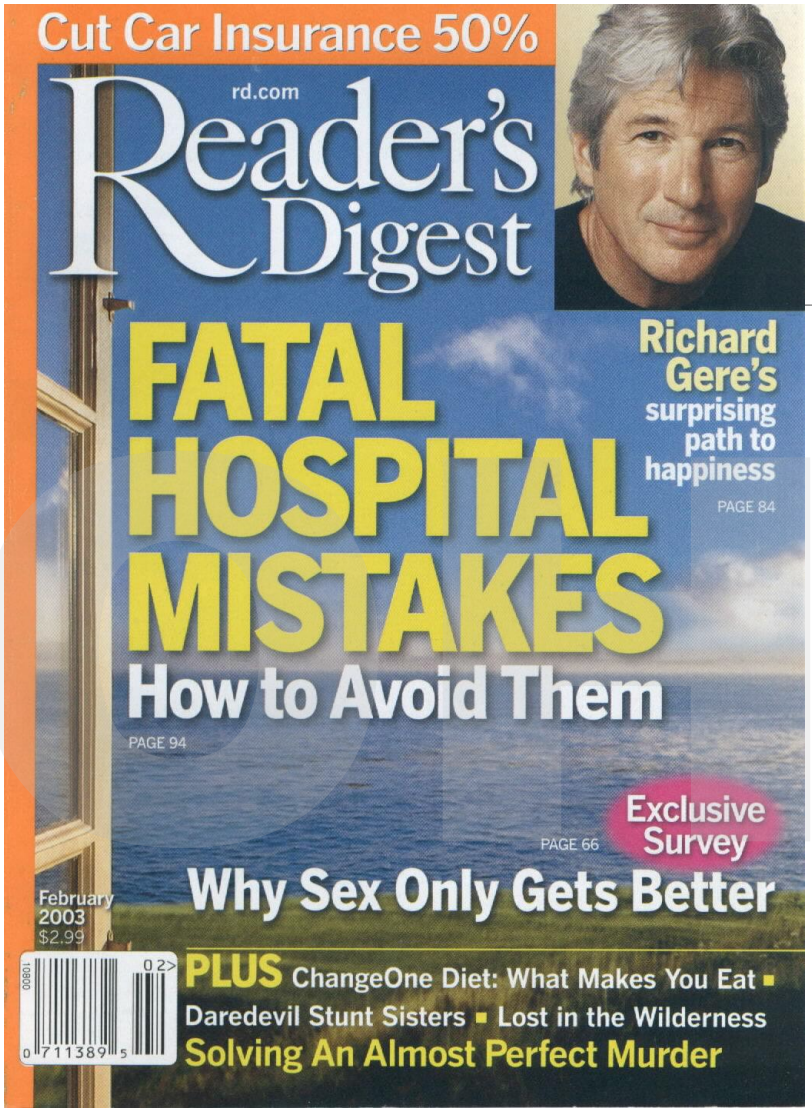
Since this report, the magnitude and impact of medical errors have become more apparent

To Err Is Human: Building a Safer Health System Institute of Medicine 2000.

Background

- Preventable medical errors in the US
  - 250,000 to 440,000 deaths a year
  - 3rd leading cause of death after heart disease and cancer
  - Estimated $17 billion in direct medical costs; $735 billion - $980 billion in economic impact

Van Den Bos *Health Affaris* 2011; Makary *BMJ* 2016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AMERICA'S #3 LEADING CAUSE OF DEATH
IS ITS OWN HEALTH CARE SYSTEM
0
DAYS
SINCE LAST PREVENTABLE MISTAKE
TO ERR IS HUMAN
A PATIENT SAFETY DOCUMENTARY

Expectations of Patients and Families

Patients conceive of errors broadly

Desire full disclosure of harmful errors

- Worry that health care workers might hide errors

Gallagher *JAMA,* 2003

Hobgood *Pediatrics,* 2005

Matlow *Arch Dis Child* 2009

Expectations of Patients and Families

Information patients want disclosed

- Explicit statement that error occurred
- What happened, implications for their health
- Why it happened
- How will recurrences be prevented

Importance of an apology

Expectations of Physicians

Physicians theoretically support physician disclosure of adverse events

- Patient and family trust
- Ethical imperative
- Patient safety
- Health provider mental health

Gallagher, *Arch Intern Med,* 2006

Stokes *Emerg Med Clin North Am* 2006

Waite *Health Law J* 2005

Expectations of Physicians

Most clinicians indicated that they would disclose an error to patients

But qualitative analysis revealed that clinicians held a nuanced definition of "disclosure" that most often did not contain the elements desired by patients

Fein *J Gen Intern Med* 2007

Barriers to Disclosure

Fear of failure in the eyes of their peers

Concern that disclosure might harm patients

Fear of malpractice liability

Lack of confidence in disclosure skills

Gallagher *JAMA,* 2009

Gallagher *Arch Intern Med,* 2006

Berlinger *J Med Ethics,* 2005

McDonnell *Ann Intern Med,* 2008

Closing the Gap: Fear of Failure

Physician burnout, fatigue, and work unit safety grades are independently associated with major medical errors

16% of surgeons who had made a “major medical error” contemplated suicide

Nurse Practitioners experience “second victim” phenomena

Shanafelt *Arch Surg.* 2011

Tawfik et al. *Mayo Clinic Proceedings* 2018

Hay-David, *Br J Oral Maxillofac Surg* 2020

Closing the Gap: Fear of Failure

There are two kinds of physicians…

… those who have been involved in a serious incident

… those who will be involved in one at some point in the future, sometimes as a result of their own error, and sometimes due to the circumstances under which they must carry out their work

Change in Focus to Patient Safety

Closing the Gap: Ethical Concerns

Ethical complexities to disclosure

Should I disclose:

- Errors with minor/transient harm?
- Fatal errors?
- Harmful errors in patients who are hopelessly ill?
- Other health care providers' errors?

Closing the Gap: Ethical Concerns

Trust is at the core of the patient-doctor relationship

Hiding from, obscuring, or omitting facts…in conversations… in the face of a medical error, erodes that trust

Patient race/ethnicity, age, gender and education are not related to preference for, or response to, disclosure

Full disclosure, whether it increases malpractice liability or not, is the appropriate ethical path

AMA Journal of Ethics 2008
Hobgood *Qual Saf Health Care* 2008
Berlinger *J Med Ethics* 2005

Closing the Gap: Legal Concerns

Risk managers in the US, Canada, the UK and Europe: up to 80% of malpractice claims are attributed to failures in communication and/or a lack of interpersonal skills

Patients who have sued often cite perception that truth was hidden from them as an important motivators

Huntington *Proc (Bayl Univ Med Cent)* 2003
Joint Commission 2006
Helmchen 2010

Closing the Gap: Legal Concerns

Though only 49% of physicians strongly agreed that serious errors should be disclosed, 70% of risk managers strongly agreed

Loren *Jt Comm J Qual Patient Saf.* 2010

Closing the Gap: Legal Concerns

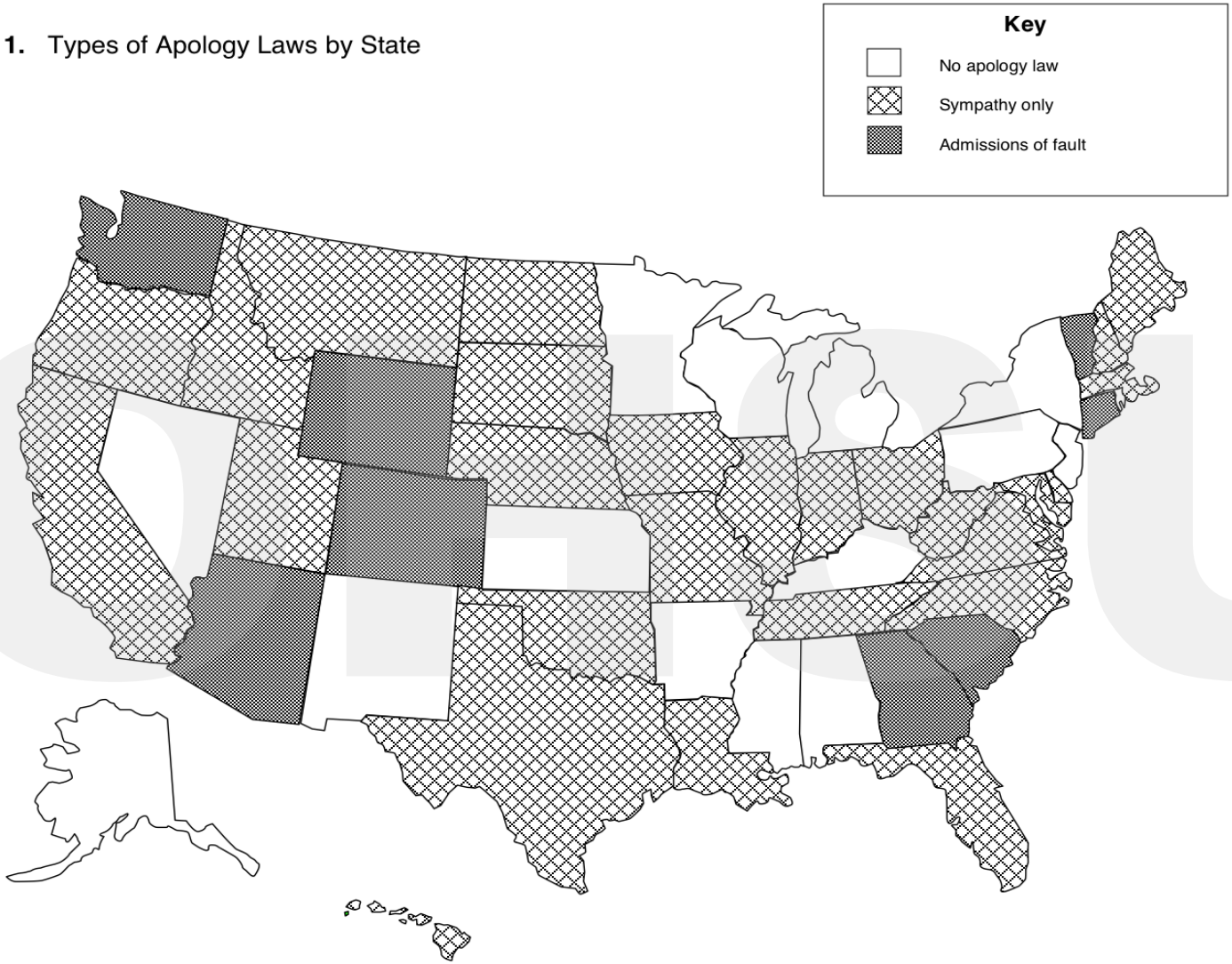
Some lawmakers have attempted to encourage physician disclosure and apology through legislative efforts

Many states have moved forward with disclosure mandates and laws that protect apologies from being considered expressions of legal liability

Clinton *N Engl J Med* 2006

McDonnell *Ann Intern Med* 2008

Figure 1. Types of Apology Laws by State



ORS 677.082[1] Expression of regret or apology

For the purposes of any civil action against a person licensed by the Oregon Medical Board or a health care institution, health care facility or other entity that employs the person or grants the person privileges, **any expression of regret or apology made by or on behalf of the person,** the institution, the facility or other entity, **including an expression of regret or apology that is made in writing, orally or by conduct, does not constitute an admission of liability.**

(2)A person who is licensed by the Oregon Medical Board, or any other person who makes an expression of regret or apology on behalf of a person who is licensed by the Oregon Medical Board, may not be examined by deposition or otherwise in any civil or administrative proceeding, including any arbitration or mediation proceeding, with respect to an expression of regret or apology made by or on behalf of the person, including expressions of regret or apology that are made in writing, orally or by conduct. [2003 c.384 §1; 2011 c.30 §5]

Oregon Patient Safety Commission 2013

Law designed to improve mediation and encourage transparency

A clinician or patient can file with OPSC to bring the parties together, help them find a mediator, and help resolve the claim so it doesn't have to turn into a lawsuit

Settlements reached through this process are not reported to the NPDB

Berthold *Internal Med* 2014

Closing the Gap: Legal Concerns

It seems that if disclosure of medical error is made with compassion, in a timely manner, and with good communication skills both during and after the disclosure process, patients and their families are at least no more likely to seek legal action and some lawsuits may actually be avoided.

Straumanis *Pediatr Crit Care Med* 2007

Closing the Gap: Developing Skills

Few feel prepared for these conversations

- Only 9% of physicians report having had training
- 87% indicated a desire for such training

Gallagher et al. *Arch Intern Med* 2006

"Listen up, my fine people, and I'll sing you a song 'bout a brave neurosurgeon who done something wrong."

Closing the Gap: Developing Skills

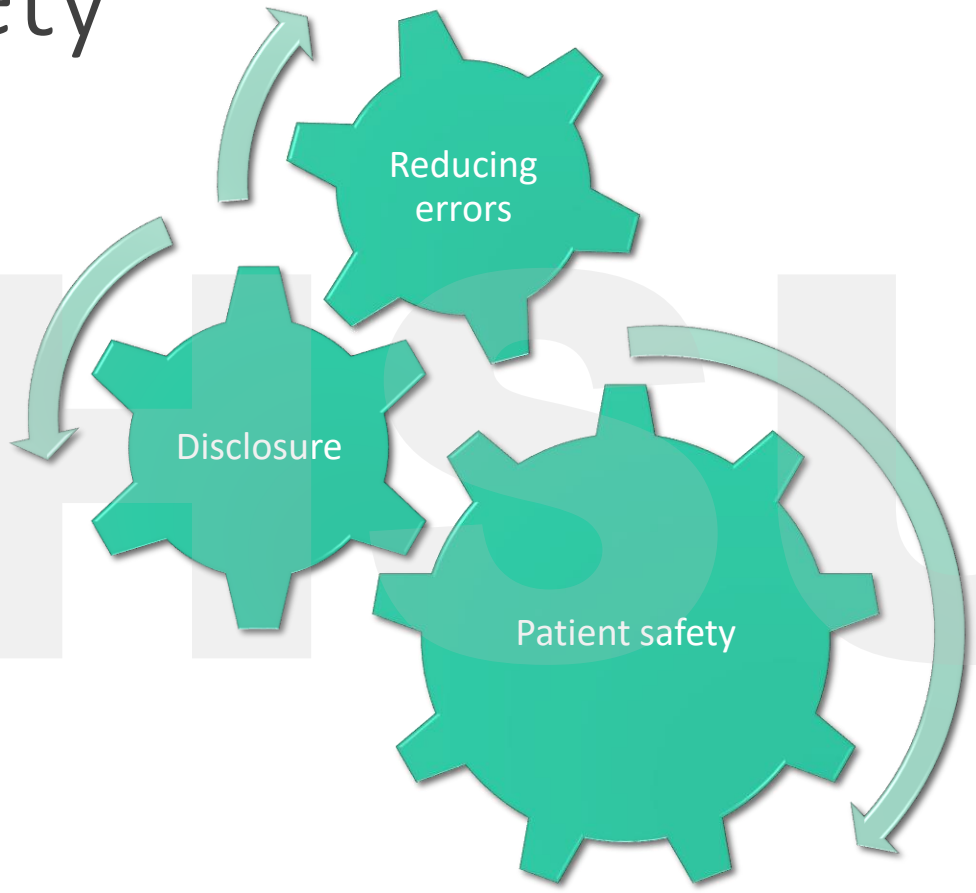
Research suggests training helps

Targeted-skills training can produce sustained changes in physicians' communication behaviors

An education program for disclosing medical errors was helpful in improving confidence in medical error disclosure

Kim *BMJ* 2017
Gardner *J Grad Med Ed* 2018
Levinson *Patient Ed and Counseling* 2013
Fallowfield *Lancet* 2002

The link between disclosure and patient safety



"Open disclosure is the most effective way to reduce errors because it begins the process of learning" -- **Nikki Centomani, R.N., Director, Department of Safety and Risk Management at the University of Illinois Medical Center**

Closing the Gap: Patient Safety

- Talking about mistakes has a strong learning effect

"There is much to learn from the ability of the system to detect and recover from failures and close calls."

Vincent et al. *Implementation Science* 2017

Closing the Gap: Patient Safety

- An organizational culture of safety
  Blame-free environment with punishment-free reporting
- Expectation of collaboration across ranks to seek solutions
- Willingness to direct resources to address safety concerns

Boysen *Ochsner J* 2013

The Process of Disclosure

A **continuum** of encounters between the patient, the patient's family and members of the health care institution at which the incident occurred

The first priority must be the patient and the family of the patient

All communications must be culturally and linguistically appropriate.

The Disclosure Process

Process, not an event

- Initial Conversation
- Root Cause Analysis
- Follow-up Conversation
- Plan for on-going conversations with the family over what occurred if desired

Disclosure 101

Patients need

- Truthful, accurate information
- Emotional support, including apology
- Follow-up, potentially compensation

Healthcare workers need

- Disclosure coaching
- Emotional support

Disclosure 101

Certain principles are essential to effective disclosure conversations

But content is not enough – genuine empathy, caring, and concern are essential

- and patients can tell if you're faking it!

Preparation

Stay attentive to the medical needs of the patient

Initial discussion within a few hours of the event

Who will be in the room?

- Clinicians with prior relationship
- Make sure everyone is emotionally capable
- Careful planning around roles

Attending physician usually leads the conversation

What should be told?

Facts should always be disclosed, and generally the sooner the better

- BUT

The first story is usually incomplete and sometimes totally wrong

Avoid natural desire to “put it all together” by connecting a few dots to make a whole picture

Possible “agenda” for conversation

Review of the facts (no speculation!)

Clear, honest communication of regret

Steps to care for the patient

Steps to investigate event, prevent recurrence

Who will speak to the family next, and when

Offer of support services to patient / family

Close with sincere expressions of support, sympathy, concern

American Society for Healthcare Risk Management

“I’m sorry” ≠ “Apology”

“I’m sorry for what has happened to you” is always appropriate

Be careful of apologies that include “buts”

- “I’m sorry but if the nurse had only called me…”

Do not blame “the system” or colleagues.

- “The lab always does this…”

Additional “tips”

Be yourself – it is possible to be “too careful” in choosing your words

Families need to hear a story that “makes sense” and is “plausible,” even when the facts are incomplete

Anticipate potential reactions: quiet or loud anger, sarcasm

Be prepared not to be “forgiven”

Anticipate possible questions:

- “I want a different doctor / nurse”
- “Who’s going to pay for this additional treatment?”

Financial Compensation

Process After the Initial Disclosure

Root cause analysis

Follow-up meeting

- Begin by stating there has been an error;
- Describe the course of events
- State the nature of the mistake, consequences, and corrective action
- Express personal regret and apologize
- Elicit questions or concerns and address them
- Plan the next step and next contact with the patient

Berthold *Internal Med* 2014

Reflection After Disclosure

Has there been appropriate communication and disclosure to the patient and family, most often by a team?

Has the organization made a statement of empathy and issued an apology in cases where there is fault?

Is the organization positioned to never lose sight of the patient and family?

Assessment of the Process

Elicit feedback from the patients, families, and health care providers on the disclosure process

Review the lessons learned and make appropriate systems changes

Provide on-going support services to affected health care personnel

Summary

There is good information regarding the art and the science of disclosure

There remains much to be learned

One thing we do know is that the art of message delivery is as important as the content

"I've learned that people will forget what you said, people will forget what you did, but people will never forget how you made them feel." --Maya Angelou

Resources

- AHRQ Toolkit 2016: provides a structured process for ongoing communication with and care for the affected patient and family, support for healthcare providers involved in the event, and a focus on system-based learning to prevent recurrence
- Oregon Patient Safety Commission https://oregonpatientsafety.org/docs/psrp/PSRP_2019_Annual_Report.pdf

Acknowledgements

My Mom

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Dr. Edward Clark