Transparency and Truth in Medical Errors

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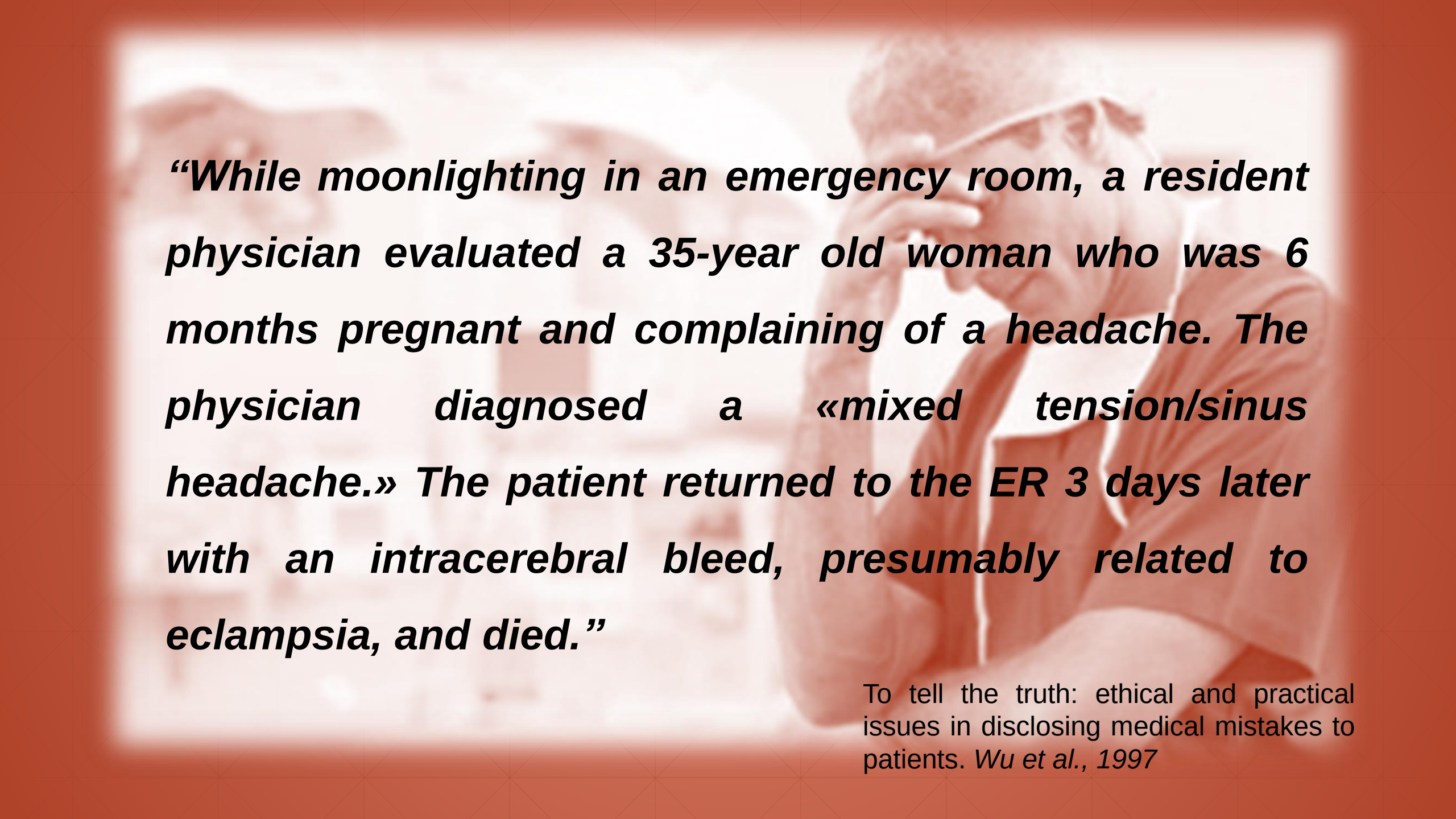


“While moonlighting in an emergency room, a resident physician evaluated a 35-year old woman who was 6 months pregnant and complaining of a headache. The physician diagnosed a «mixed tension/sinus headache.» The patient returned to the ER 3 days later with an intracerebral bleed, presumably related to eclampsia, and died.”

To tell the truth: ethical and practical issues in disclosing medical mistakes to patients. *Wu et al., 1997*

Objectives

- Review essential concepts related to medical error disclosure
- Emphasize the ethical duty of physicians to disclose errors
- Outline the potential risks and benefits of disclosure for patients and physicians
- Describe practical issues in the disclosure of errors
- Discuss recommendations to overcome barriers to disclosure

ESSENTIAL CONCEPTS RELATED TO MEDICAL ERROR DISCLOSURE

What is a Medical Error?

- "*A commission or omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were negative consequences*"
- Excludes:
  - Natural history of the disease that does not respond to treatment;
  - Foreseeable compilations of a correctly performed procedure;
  - Cases in which there is reasonable disagreement over whether a mistake occurred.

System Versus Individual Errors

- **System/latent errors – the “resident pathogens”:**
  - Not within the direct control of the front-line operator
  - Less apparent: defects in the design, organization, training or maintenance in a system due to poor management that leads to operator errors
- **Individual/active human errors:**
  - Derive primarily from deficiencies in the clinician’s knowledge, skills or attentiveness
  - Committed at the level of the front-line staff
  - Effects felt almost immediately

Medical Error Disclosure – A Definition

- 2007 study to understand discrepancy between patient's expectations and physicians' behavior concerning disclosure (24 focus groups, 5 academic medical centers, 204 administrators, physicians, residents and nurses)
- To many, disclosure is not a straightforward description of what happened
- Clinicians hold a nuanced definition of disclosure that often did not contain the elements desired by patients and have a complex view of disclosure that incorporates the competing interests of self-preservation and duty to the patient and institution.
- Conclusion was that error disclosure meant different things to clinicians and patients.

Medical Error Disclosure – A Definition

“Communication between a health care provider and a patient, family members, or the patient’s proxy that acknowledges the occurrence of an error, discusses what happened, and describes the link between the error and outcomes in a manner that is meaningful to the patient”

The many faces of error disclosure: a common set of elements and a definition - Fein et al., 2007

Medical Error Disclosure – Current Context

- Hospitals have traditionally followed a "deny-and-defend" strategy:
  - Providing limited information to the patient and family
  - Avoiding admissions of fault
  - Lack of patient-centeredness
- Growing number of institutions encourage "communication-and-response" strategies that emphasize:
  - Early disclosure of adverse events
  - More proactive approach to achieving an amicable resolution.

Medical Error Disclosure – Current Context

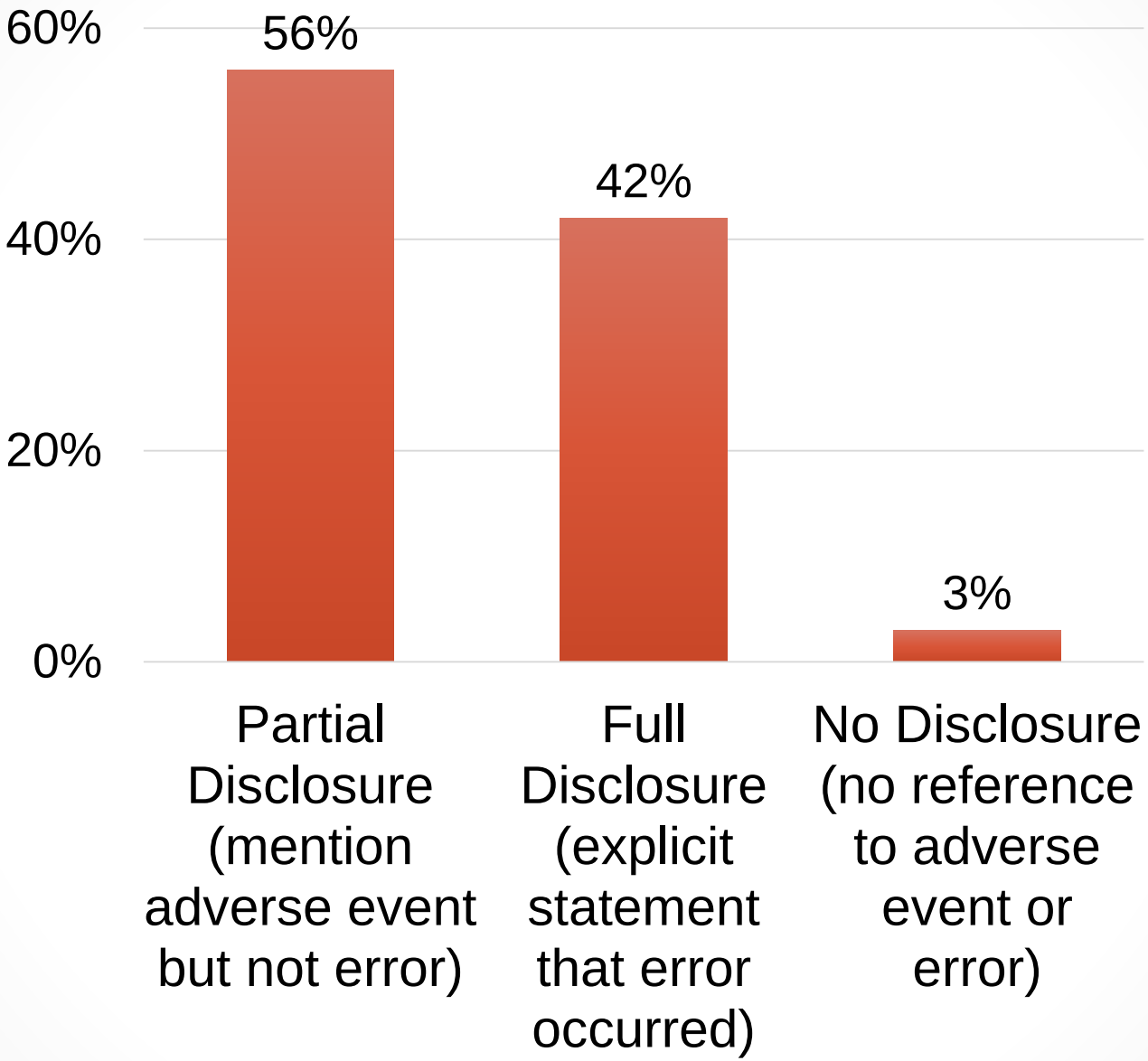
- Patients desire disclosure from clinicians about harmful medical errors
  - Clear explanation they can understand
  - Apology
  - Plan to prevent future errors
  - Care plan, including financial provisions when needed
- Sharing information about error is uncommon in clinical settings
- Roughly 1 in 4 errors disclosed

Choosing your words carefully: how physicians would disclose harmful medical errors to patients – Gallagher et al., 2006

Medical Error Disclosure – Current Context

2006 Study (Gallagher et al.) of 2637 medical specialists and surgeons revealed:

- Most physicians agree errors causing harm should be disclosed
- Only a minority explicitly inform the patient, especially for less clinically significant errors
- Approximately half of respondents would avoid explaining how the error occurred or discuss specific plans to prevent such errors in the future
- Most respondents would explicitly apologize to patients, although surgeons were significantly less likely to do so than medical specialists



What Physicians Would Disclose About Errors

Disconnect between physicians' views of ideal practice and what actually happens:

- Many physicians “choose their words carefully”

- Fail to clearly explain the error and its effects on the patient's health

Gallagher et al. 2006

Full Disclosure of a Medical Error

- Components of disclosure that matter most to patients:
  - Disclosure of all harmful errors
  - An explanation as to why the error occurred
  - How the error's effects will be minimized
  - Steps the physician and organization will take to prevent recurrences
- Full disclosure of an error incorporates these components as well as acknowledgement of responsibility and an apology by the physician.

THE ETHICAL DUTY OF PHYSICIANS TO DISCLOSE ERRORS

The Ethical Duty of Physicians to Disclose Errors

- Physician's responsibility to disclose a mistake derives from fiduciary character of the doctor-patient relationship
- Relationship based on trust
- Aligned with principles of:
  - Non-maleficence
  - Beneficence
  - Respect for patient autonomy
  - Justice

To tell the truth: ethical and practical issues in disclosing medical mistakes to patients. *Wu et al., 1997*

Principle of Non-Maleficence

- *Primum non nocere* - “first do no harm”
- Grave responsibility to avoid harming the patient

Principle of Beneficence

- Physician must act for the best interests of their patients' health
- Even if own financial or professional well-being not benefited
- Physician obligation to disclose, especially when harm resulting from a mistake can be reversed or ameliorated.

Principle of Respect for Patient Autonomy

- Full disclosure frees patients of mistaken beliefs concerning their past, present or future medical conditions, thus enabling them to make informed decisions about future medical care.
- Applies when the patient does not need to know of the error in order to make future decisions, as patients have a claim to know their own history.
- Obligation to respect autonomy indicates that a doctor has an ethical duty to disclose mistakes to patients

- Duty to disclose non-remediable mistake so patient can be compensated
- Justice requires that people be given what is due to them
- The more serious the harm the greater the need for compensation, the greater the physician’s responsibility to make amends.

Principle of Justice

- Physicians may feel less obligated (if at all) to disclose mistakes with little marginal impact – Although debatable, main arguments in favor of disclosure:
  - Physician has little to lose
  - Good opportunity for open discussion
  - May strengthen the relationship with the patient or family.

Principle of Justice

The Ethical Duty of Physicians to Disclose Errors

- American College of Physicians Ethics Manual: information "*should be disclosed whenever it is considered material to the patient's understanding of his or her situation, possible treatments, and probable outcomes....However uncomfortable for the clinician, information that is essential to and desired by the patient must be disclosed*."

- American Medical Association's Council on Ethical and Judicial Affairs: "*the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred*."

The Ethical Duty of Physicians to Disclose Errors

- Disclosure of errors now endorsed by a broad array of organizations
- Since 2001, the Joint Commission has required disclosure of unanticipated outcomes of care.
- In 2006, the National Quality Forum endorsed full disclosure of "serious unanticipated outcomes" as one of its 30 "safe practices" for health care.
- The disclosure safe practice includes standards for practitioners regarding the key components of disclosure.

The Ethical Duty of Physicians to Disclose Errors

- Calls for healthcare organizations to create an environment conducive to disclosure by integrating risk management and patient safety activities and providing training and support for physicians.
- Ten U.S. states mandate disclosure of unanticipated outcomes to patients
- More than two-thirds of states have adopted laws that preclude some or all information contained in a practitioner's apology from being used in a malpractice lawsuit.

The many faces of error disclosure: a common set of elements and a definition - Fein et al., 2007

POTENTIAL BENEFITS AND HARMS OF DISCLOSURE

Potential Benefits of Disclosure to the Patient

- Allow the patient to obtain timely and appropriate treatment to correct problems resulting from the mistake and prevent further harm
- Enable close monitoring or undertaking of a medical procedure to mitigate the consequences of a mistake
- Allow documentation of informed consent
- Prevent patient from worrying needlessly about the etiology of a medical problem

Potential Benefits of Disclosure to the Patient

- Provide patients with information needed to make informed decision
- Allow the patient to obtain compensation for lost earnings, payment for care necessitated by the injury or get a bill written off
- Enable compensation through settlement rather than lawsuit
- Promote trust in physicians

Potential Harms of Disclosure to the Patient

- Patient may be harmed by learning about the mistake
- Knowledge may cause alarms, anxiety and discouragement
- Disclosure may destroy patients' faith and confidence in the physician's ability to help them
- Information may cause disillusion with the medical profession

Potential Harms of Disclosure to the Patient

- Disclosure may cause patients to decline beneficial treatments or decrease adherence to treatment regimens
- Not all patients want to know everything about their medical care
- Disclosure of potentially serious but inconsequential mistakes may cause unwelcome confusion

Potential Harms of Disclosure to the Patient

- "*Society recognizes the 'therapeutic privilege', which is an exemption from detailed disclosure when such disclosure has a high likelihood of causing serious and irreversible harm to the patient*" - American College of Physicians Ethics Manual

- American College of Physicians cautions "*On balance, this privilege could be interpreted narrowly; invoking it too broadly can undermine the concept of informed consent*"

Potential Benefits of Disclosure to the Physician

- Knowledge of making a harmful mistake can cause great emotional distress
- Physician may be relieved to admit the mistake
- May be a way for the physician to gain absolution for the mistake
- Disclosure may strengthen the doctor-patient relationship
- Candid disclosure may decrease the likelihood of legal liability
- Failure to disclose may place the physician in greater jeopardy if patients brings a lawsuit

Potential Harms of Disclosure to the Physician

- Difficult and painful for the physician - Patient reactions can be highly stressful to doctors
- Exposure to the risk of a malpractice law suit
- If a lawsuit ensues, may result in increased malpractice premiums and psychological stress
- Possible effect on reputation, status and loss of referrals
- Potential impact on hospital privileges, credentialing status and licensure
- Risk of having permanent mark on physician’s record
- Impact on career (poor evaluations, poor letters of recommendation, dismissal)

PRACTICAL ISSUES IN DISCLOSURE OF MISTAKES

- Physician biased against disclosure, and can easily rationalize decision not to tell
- Burden of proof should be on physician to justify not disclosing a mistake
- Decision however should not be left to individual physician's judgment
- Importance of obtaining a 2nd opinion to represent what a reasonable physician would do and be willing to defend in public
- Formal body (ethics committee or quality review board) preferable to informal consultation with peers, who might be similarly reticent.

Deciding Whether to Disclose a Mistake

Timing of Disclosure

- Timing of disclosure should be considered
- Patient might benefit from learning about a mistake as soon as possible
- Disclosure should however take place at a time when the patient is physically and emotionally stable.

Who Should Disclose the Mistake?

- Attending physician
- When a mistake is made by a physician in training
  - Responsibility shared with attending physician
  - Appropriate for physician-in-training and attending physician to disclose the mistake to the patient together
  - May be appropriate to also involve institutional representation (hospital administrator, risk manager, or quality assurance representative)

The Incompetent Patient

- Patients with impaired decision-making capacity can still appreciate an apology
- Not the case for patients lacking mental capacity to understand and appreciate disclosure discussion with physician - even if discussion is simplified.
- Although there may be no need to inform an incompetent patient, family member or surrogate should be informed.

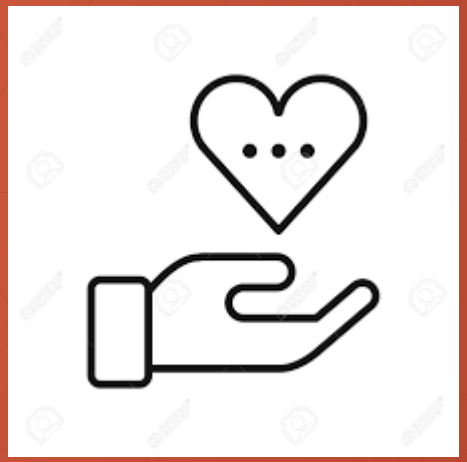
- Disclosure is difficult:
  - Case may be too complicated to be explained easily
  - Facts may not be known precisely
- Instance of “breaking bad news”:
  - Need for medical education about conducting these discussions
  - News and consequences should be presented in a way that minimizes distress.
- Physicians should recognize that patients or families may become upset or angry, and accept this as a natural response, taking care not to react defensively.

What To Say?

“Information should be given in terms the patient can understand. The physician should be sensitive to the patient’s responses in setting the place of disclosure…Disclosure should never be a mechanical or perfunctory process”

American College of Physicians Ethics Manual

What To Say?

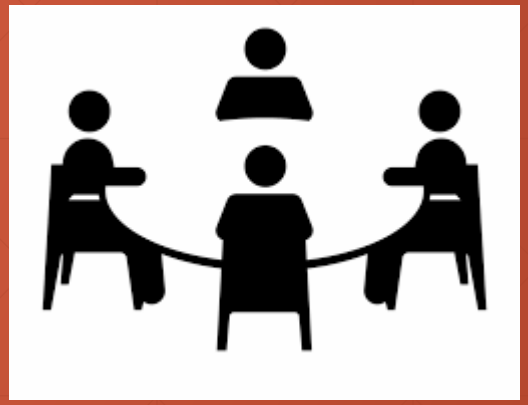


What To Say?

- Physician should begin by stating simply that he or she has made a mistake
- Helpful to describe decisions that were made, including those in which patient participated
- Course of events should be described in detail, using nontechnical language: nature of mistake, consequences and corrective action taken or to be undertaken
- Physician should express personal regret and apologize for the mistake
- Finally, physician should elicit questions or concerns from the patient and address them.

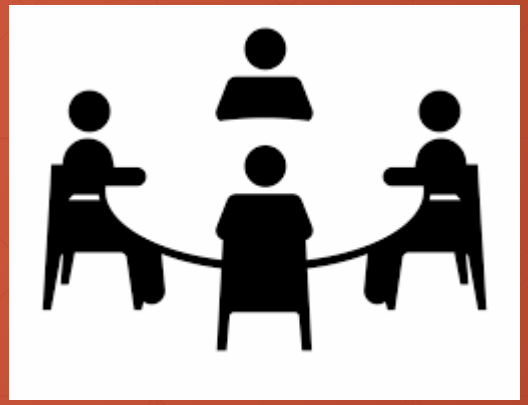
What To Say?

- Harm of disclosing a mistake may be minimized if:
  - Disclosure is made promptly and openly
  - Apologies are offered, and
  - Charges for associated care are forgone
- For mistakes with major impact, offer should be made to cancel charges for subsequent care needed to remedy the mistake and provide the necessary supportive services



- Financial amends should include all extra expenses incurred (physician services, error-generated lab fees, hospital expenses, drug costs etc.)
- Hospital administration should be involved in decisions and negotiations about billing and about whether to bill the malpractice insurance.

What To Say?



OVERCOMING BARRIERS TO DISCLOSURE

Overcoming Barriers to Disclosure

- Physicians may question whether any possible benefits to the patient are worth the possible risks of a lawsuit to their career or livelihood
- May sound unconvincing to exhort physicians to do what is best for the patient
- *“Concern regarding legal liability which might result following truthful disclosure should not affect the physician’s honesty with a patient”* - AMA Council on Ethical and Judicial Affairs

Overcoming Barriers to Disclosure

- Disclosing mistakes may reduce the risk of litigation, if patients appreciate physicians' honesty and fallibility
- Data indicates that patients are less likely to consider filing suit if physicians apologize and fully disclose errors
- Low disclosure rates persist because few physicians have received formal training in how to discuss errors with patients
- Physicians may be unclear about the amount of information that should be disclosed and how to explain the error to the patient.
- Some evidence that formal training in error disclosure can improve physicians' comfort with the process.

https://psnet.ahrq.gov/primers/primer/2/Disclosure-of-Errors

Overcoming Barriers to Disclosure

- Serious mistakes may come to light, even if physicians do not disclose them
- In disclosing mistakes, physicians can take steps to mitigate any harms that may occur to them:
  - Can learn how to disclose mistakes in a manner that diffuses patient anger
  - When applicable, can take the initiative in recommending prompt and fair out of court settlement

Overcoming Barriers to Disclosure

- Early adopters of "communication-and-response" strategies (ex. University of Michigan) observed fewer malpractice lawsuits and lower litigation costs since implementation
- Strategies include full disclosure, appropriate investigations, implementation of systems to avoid recurrences, and rapid apology and financial compensation when care is deemed unreasonable.
- Communication-and-resolution programs although more widely adopted remain complex and must be handled thoughtfully and sensitively

Overcoming Barriers to Disclosure

- Growing body of literature describes the regulatory, legal, and practical considerations with implementing these programs
- Agency for Healthcare Research and Quality CANDOR toolkit
- Communication and Optimal Resolution (CANDOR)
- Designed to help organizations implement communication-and-response programs
- Includes videos, slides, and teaching materials
- Tested in 14 hospitals in several different states

https://www.ahrq.gov/patient-safety/capacity/candor/index.html

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