

# Disclosing Serious Adverse Events to Patients and Families

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# Disclosure of Adverse Events & Errors to Patients

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## BACKGROUND

- Unanticipated adverse events & harmful medical errors occur
- The way we respond helps maintain trust (multiple levels: patient, family, community, society)
- The way we evaluate adverse events helps to prevent harm to future patients

# Disclosure of Adverse Events & Errors to Patients

- Nearly all physicians (98%) agree that serious errors should be disclosed

Gallagher TH, et al. U.S. and Canadian physicians' attitudes and experiences regarding disclosing errors to patients. *Arch Intern Med.* 2006 Aug 14-28;166 (15):1605-11

- Only 30% of physicians who experienced an error in their own health care said that they were told about the error, a disclosure rate consistent with prior studies of non-physician patients

Blendon R, DesRochies C, Brodie M, et al. Views of practicing physicians and the public on medical errors. *N Engl J Med.* 2002;347:1933-1940

# Disclosure of Adverse Events & Errors to Patients

- 99% of trainees agreed that serious errors should be disclosed to patients
- In a 1984 study, 76% of house staff reported they had been involved in a serious error they had not discussed with the patient
- In a 2006 study 98% of house staff reported they had been involved in a serious error but only 52% of surgical residents and 68% of internal medicine residents reported disclosing the errors to the patient. *Lack of progress noted.*

White A, et al. The Attitudes and Experiences of Trainees Regarding Disclosing Medical Errors to Patients. *Acad Med.* 2008; 83:250–256

- Only 54% discussed adverse events with the attending physician

Wu A, et al. *JAMA* 1991; 265: 208-94.

# Historical Barriers to Disclosure

- 1) Fear of Litigation
- 2) The Culture of Medicine

*"An important barrier to error reporting is a deeply rooted culture that expects error-free practice, emphasizes individual accountability, and tends to blame the individual when he or she fails to perform perfectly"*

Leape LL, Berwick DM. *JAMA*. 2005;293:2384-2390

- 3) Concern about disciplinary action and the potential impact on one's future professional career
- 4) Lack of training in how to disclose, especially for residents and junior faculty

# Barriers to Disclosure—Fear of Litigation

## Open Disclosure Early Results Encouraging

### University of Michigan Health Center: Open disclosure program decreased number of claims - reporting increased

- 2001—**262** open claims (180 lawsuits)
- 2007—**83** open claims (20 lawsuits)
- 2008—**63** open claims (17 lawsuits)
- Legal expenses dropped from \$3M to \$750,000
- Average time to resolve claims decreased from 21 months to 9 months
- 40% increase in clinical activity between 2001-08

Clinton HR, Obama B. Making Patient Safety the Centerpiece of Medical Liability Reform. *N Engl J Med.* 2006 May 25;354(21):2205-8 \* **Numbers updated 5/2009**

# University of Michigan

## Core Principles

- Identify and analyze events quickly, compensate quickly and fairly when unreasonable medical care causes injury
- Defend reasonable care vigorously
- Reduce patient injuries (and claims) by learning from patient experiences
- Voluntary reporting of adverse events has increased as safety culture develops:

2004	2,500
2008	18,000

Richard C. Boothman, et al. A Better Approach to Medical Malpractice Claims? The University of Michigan Experience, *J. Health & Life Sci. L.*, January 2009, at 125

# Barriers to Disclosure—Fear of Litigation

## Does Disclosure Prevent Litigation?

Table 4. Examples of Investigations Examining a Relationship Between Disclosure and Malpractice Liability

Study	Description	Results
Hickson*	Survey of families who had filed suit for perinatal injuries	Approximately 1 in 4 families were suing due to failure of complete honesty or misleading behavior.
Kraman <sup>†</sup>	Adoption of a policy of full disclosure with before-and-after comparison of liability payments in relation to peer institutions	After adoption of the policy, institution moved from being from one of the top-paying institutions in its peer group into the lowest quartile of its peer group.
Shojania <sup>‡</sup>	Systematic review of role of autopsy in quality measurement included question of whether routine autopsies cause more malpractice suits	Only 1 of 47 included studies of autopsy-detected errors in clinical diagnosis reported the impact of autopsy findings on malpractice claims. <sup>‡</sup> This single study found no evidence that errors detected at autopsies lead to more malpractice suits. <sup>§</sup>
Vincent <sup>  </sup>	Survey in England of patients and families that had filed malpractice suits	More than 60% sued for desire of an explanation or because they felt ignored and/or neglected.

Kachalia et al. *J C J Qual Safety*. 2003;10:503-511



# Barriers to Disclosure—Fear of Litigation

Malpractice suits often result when an unexpected adverse outcome is met with a lack of empathy from physicians and a withholding of essential information

Clinton HR, Obama B. Making Patient Safety the Centerpiece of Medical Liability Reform. *N Engl J Med.* 2006 May 25;354(21):2205-8

It is not the quality of the medical care...and negligent treatment *per se* that leads to litigation, but, rather, ineffective communication with patients. Factors include:

- *families' perception that the physician was not completely honest;*
- *the inability of family members to get anyone to tell them what happened;*
- *the sense among family members that the physician would not listen;*

Levinson W, et al. Physician-patient communication. The relationship with malpractice claims among primary care physicians and surgeons. *JAMA.* 1997 Feb 19;277(7):553-9

**Concern regarding legal liability which might result following truthful disclosure should not affect the physician's honesty with a patient.**

# A Physician's Guide For Disclosure

## What Patients Want

- An expression of sympathy or apology for what they are experiencing
- An explicit statement that an adverse event or error occurred
- What went wrong and what are the clinical implications
- How recurrences will be prevented from happening to others

Gallagher T. *Arch Int Med* 2005; 165(16): 1819-24

Full disclosure of an adverse event leads to greater trust and more positive regard by patients and family members. Disclosure minus the apology yielded no such benefit.

# WUSM Guidelines for Disclosure of Adverse Events

Approved by WUSM FPP Clinical Practice Committee June 21, 2007

## KEY PRINCIPLES

- Patients have the right to know details of significant events that have the potential to impact their health status
- Timely, honest and sustained communication with patients and/or their families is an essential component of exceptional health care

***It is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients. Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions . . . the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred.***

AMA Code of Ethics E-8.12 Patient Information

# WUSM Guidelines for Disclosure of Adverse Events

## When Disclosure is Appropriate

Adverse events and medical errors that:

- 1) Result in temporary or permanent harm

*Did it harm / hurt patient?*

- 2) Require transfer to an ICU, additional surgery or other medical intervention

*Did it change care—or will it, in the future?*

- 3) Would you want to know about it if it happened to you or a member of your family?

# Definitions

## Adverse Event

Injury caused by medical care not underlying disease

### Examples

- Pneumothorax from central venous catheter placement
- Anaphylactic reaction to a medication (without documented allergy)
- Unintended laceration/perforation

- ✓ **Most adverse events are not associated with a medical error**
- ✓ **Adverse events do not necessarily imply negligence**

# Definitions

## Medical Error

**Failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim**

### Examples

- Ordering a medication for a patient with a documented allergy to that medicine (*act of commission*)
- Failing to prescribe a proven medication with major benefits for an eligible patient (e.g. not administering low-dose unfractionated heparin as DVT prophylaxis after hip replacement surgery (*act of omission*))
- Wrong site or wrong surgery performed (failure of a planned action)

# The Disclosure Process

- 1) The attending MD coordinates the disclosure efforts and should speak with the patient as soon as the patient is stable enough to absorb the information. Residents and fellows should contact the attending physician when an adverse event has occurred prior to any discussion with the patient.
- 2) When more than one attending physician is involved, *confer and collaborate on the disclosure conversation* before speaking to the patient and/or family—*a consistent message is important*

# What To Communicate

- 3) Every physician should be responsible for disclosing medical errors for which they feel personally responsible. *Physicians should not disclose perceived errors made by other caregivers without involving those caregivers in the disclosure process*
- 4) When possible, convene the entire care team (e.g. attending physician, residents, fellows, nurses) in advance to discuss the known facts and to prepare to advise the patient and, when authorized, the patient's *family—a consistent message is important*
- 5) Acknowledge that an adverse event or medical error occurred. Describe the nature of the event in a factual and compassionate manner



# What To Communicate

- 6) If the cause of the event is uncertain, do not speculate or hypothesize - Tell the patient and/or family that further investigation is needed and commit to ongoing communication and follow-up throughout the investigation
- 7) Express your personal concern regarding the adverse event:
  - Patients and families appreciate a sincere expression of regret and sympathy
  - If the adverse event is attributable to a medical error, apologize—say “I’m sorry”
- 8) Ask the patient and/or family if they have any questions and answer them based on what information is known at the time of the conversation

# What To Communicate

- 9) Reach out and emphasize your willingness to speak with them at any time. Follow-up with the patient/family as to the results of any investigation and let them know what steps will be taken to prevent similar events in the future. Identify one contact person (attending physician) for future discussions.
- 10) Identify who will be involved in ongoing patient care. If maintaining the physician-patient relationship appears difficult, it may be appropriate to offer to transfer the patient's care to another provider

# Disclosure Considerations

- Prepare by getting help if needed
- Be yourself
- Be aware of body language—Sit at the patient's level
- *Do not criticize the care or response of other caregivers*
- Speak in layman's terms – avoid medical jargon but don't oversimplify or be vague
- Allow ample time for questions – do not monopolize the conversation – acknowledge what you have heard
- Don't avoid the patient or family, even if you don't have all the answers yet
- Initiate conversation—don't take advantage if they don't ask
- Done well, disclosure is usually a series of conversations
- Remember to keep the patient's medical needs at the forefront

# Guidelines for Documentation

- 1) The patient's medical record should contain a complete record of pertinent clinical information related to the event, including:
  - Details of the event, including date, time and place
  - The patient's condition immediately before the event
  - Medical intervention in response to event including therapies initiated, studies ordered, medications administered and requested consultations
  - Patient's response to the medical intervention
  - Future treatment plan

# Guidelines for Documentation

- 2) Disclosure discussions with patients and/or their families should also be documented in the medical record, including:
  - Time, date and place of discussion
  - Names and relationships of those present at the discussion
  - Documentation of discussion of the event
  - Patient/family responses
  
- 3) Any follow-up conversations with the patient and/or family should also be factually documented in writing in the medical record

# Guidelines for Disclosure of Adverse Events

- In some cases it may be appropriate to waive or adjust a patient's bill
- Please speak to Risk Management before making any such offers
- WUSM Risk Management should be notified of all adverse events, errors and patient disclosures (362-6956). Residents contact BJH Risk Management (454-7566) or SLCH (454-4614)
- WUSM Risk Management coordinates communications with BJH and SLCH patient safety/risk management, as appropriate

# Impact of Adverse Events on Physicians

After medical errors, physicians have reported feeling upset, guilty, self-critical, depressed, and scared

90% of physicians disagreed (37% strongly) that hospitals and health care organizations adequately support them in coping with stress associated with medical errors

Waterman A., et al. The Emotional Impact of Medical Errors on Practicing Physicians in the United States and Canada. *Jt Comm J Qual Saf* 2007 Aug; 33(8):467-476

For many physicians, the most difficult challenge was forgiving themselves for the error

Gallagher T, et al. *JAMA* 2003; 289(8): 1001-07

# Impact of Adverse Events on Physicians— Resident Study at Mayo

Quarterly surveys over 3 year period showed significant associations between distress and another error in the subsequent 3 months.

Feeling responsible for a serious medical error enters a vicious cycle by provoking burn-out, depression and reduced empathy, which in turn often result in suboptimal patient care and higher odds for future errors.

West CP, Huschka MM, Novotny PJ, Sloan JA, Kolars JC, Habermann TM, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. *JAMA*. 2006;296(9):1071–8.



# Impact of Adverse Events—Future Plans

Almost every physician and nurse has their story, their case and their night. They remember the details as if it were yesterday, even if it was 10 or 20 years ago. They tell their stories with an intensity of emotion that brings tears to the eyes of both the storyteller and the listener. Many have never shared their stories with anyone; some, with only a spouse or close friend. These stories usually end with expressions of shame, isolation and lack of closure. The counsel received at the time of the incident, if any, included: “Stuff happens,” “You can’t dwell on it,” “You’ll just have to do it better the next time,” and “Go back to work.”

Given that the vast majority of errors are due to failures of bad systems and not bad people, providing support to clinicians and other staff is simply the respectful and compassionate thing to do.

*James B. Conway, M.D.  
Harvard School of Public Health  
Institute for Healthcare Improvement*

# Next Steps: Struggling with Standards

## Uncertainty about exactly how much information to share with patients is one key barrier to disclosure

- Should we allow the patient or family determine the content of disclosure?
- Should there be a consensus about what is “material” information to be shared, regardless of what patients/families ask?
- Material facts: facts regarding the unanticipated outcome and its preventability (National Quality Forum standard)
- Material facts: considered material if that information were essential for a reasonable patient or family to be *free of fundamental misconceptions about what transpired*

Gallagher TH, et al. Disclosing Harmful Medical Errors to Patients: Tackling Three Tough Cases. *Chest* 2009;136:897-903

# For More Information

For access to the Guidelines, Powerpoint, video, and literature cited in this presentation, please go to:

<http://fpp.wustl.edu>

> *Patient Safety* > click on “*Disclosure of Adverse Events*”

***WUSM Patient Safety Website***  
<http://patientsafety.wusm.wustl.edu>

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# Questions and Answers

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