Disclosure of Adverse Events

Veronica Carullo, MD, Scott Dingeman, MD, Herodotos Ellinas, MD, Teresa Roberts, MD, Lianne Stephenson, MD

Disclosure

- No relevant financial or non-financial disclosure.

Disclosure-Objectives

- Identify benefits
- List elements of disclosure
- Characterize communication strategies
- Identify barriers
- Summarize available resources

Disclosure

Communication of INFORMATION regarding the results of a diagnostic test, medical treatment or surgical intervention

American Society for Healthcare Risk Management

Unanticipated Outcome

Result that "differs significantly " from what was anticipated to be the result of a treatment or procedure

Joint Commission on the Accreditation of Healthcare Organizations (*JCAHO*)

Unanticipated Outcomes

- Clear Errors
- Perceived Errors
- Recognized complications
- Adverse Outcomes without clear etiology

Adverse Event

- Negative or bad result stemming from a diagnostic test, medical treatment or surgical intervention
- Sometimes called “harm,” “injury,” or “complication”
- May or may not result from an error

American Society for Healthcare Risk Management

History

- Anesthesia Patient Safety Foundation 1985

  "No patient shall be harmed by the effects of anesthesia"

- Institute of Medicine 1999

- BL of Boston Globe dies of chemo overdose
- Willie King has the wrong leg amputated

TO ERR IS HUMAN:
BUILDING A SAFER HEALTH SYSTEM

CURRENT-Dr. Makary (surgeon) writes…

THE SATURDAY ESSAY | Updated September 21, 2012, 10:56 p.m. ET

How to Stop Hospitals From Killing Us

Medical errors kill enough people to fill four jumbo jets a week. A surgeon with five simple ways to make health care safer.

98,000

Annual deaths from medical errors in the U.S.

Source: Institute of Medicine

Transparency can also help to restore the public's trust. Many Americans feel that medicine has become an increasingly secretive, even arrogant, industry. With more transparency—and the accountability that it brings—we can address the cost crisis, deliver safer care and improve how we are seen by the communities we serve.

The Wall Street Journal; Sat/Sun Sep 22-23, 2012

CURRENT

- Medication error, 1: 150-250 anesthetics
- 85% of anesthesiologists reported having involved in a medication error
- 3,700 pediatric hospitalizations Utah-Colorado study
  - 1% adverse events
  - 60% preventable
    - ***EXTRAPOLATE TO US POPULATION***
    - ***70,000 hospitalized children experience an adverse event/yr***
    - ***42,000 preventable***

Orser BA et al Can J Anaesth 2001; 48:139-46
Leonard MS Pediatrics in Review 2010;31:151

NQF-National Quality Forum

- Practice #7 Disclosure

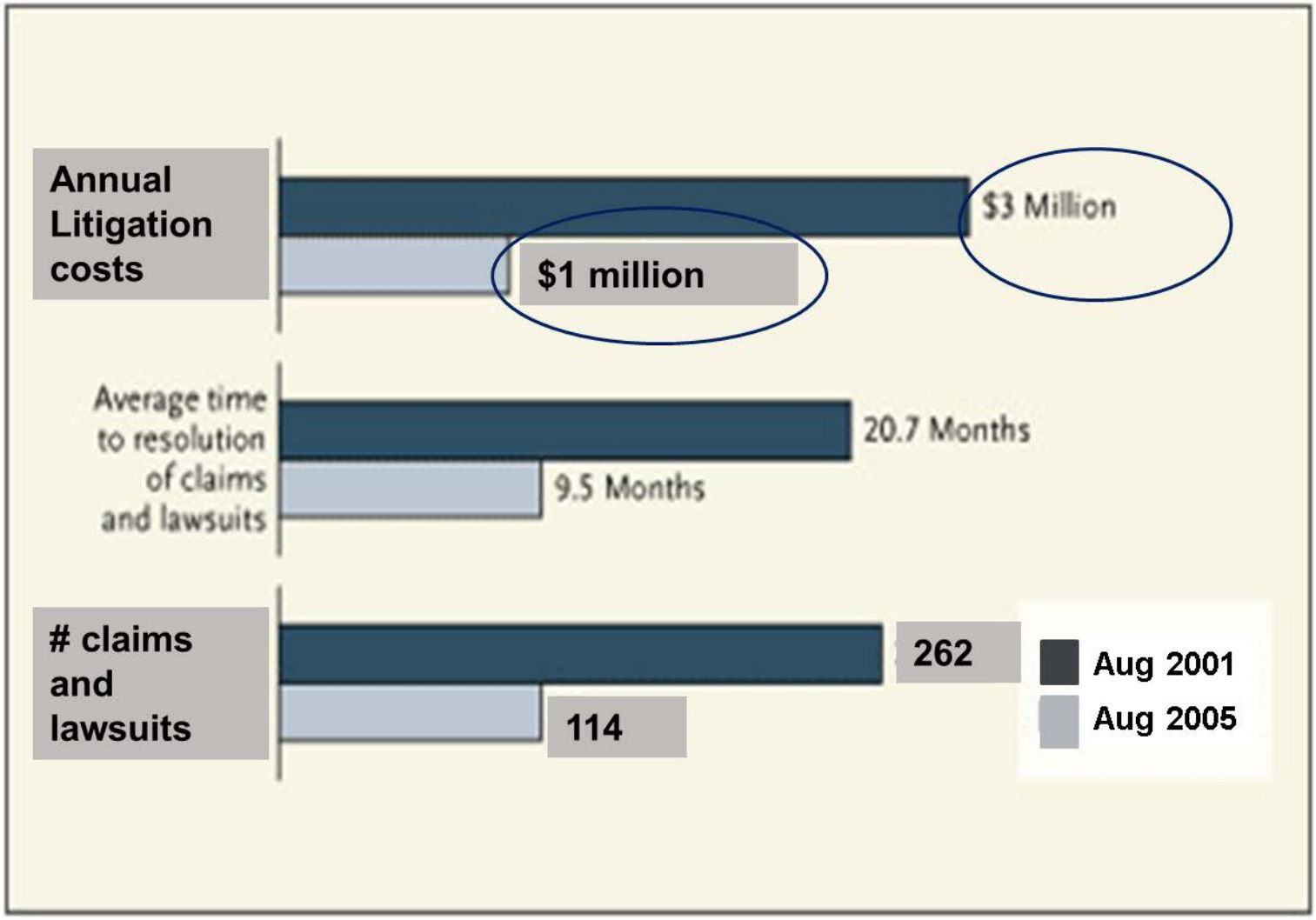
  Provide *open* and *clear* communication with patients and families about serious unanticipated outcomes

Frequency of disclosure ONE in FOUR

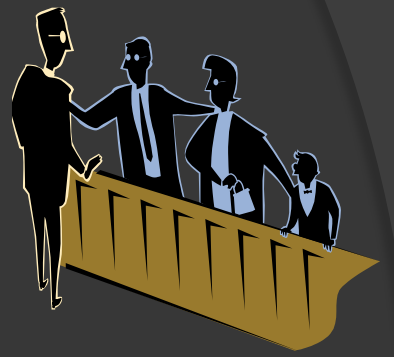
University of Michigan

- Decrease in pending lawsuits by ½
- Reduction in litigation costs per case

Results of Medical Error Disclosure Program at the University of Michigan Health System.


Annual Litigation costs
$3 Million
$1 million
Average time to resolution of claims and lawsuits
20.7 Months
9.5 Months
claims and lawsuits
262
114
Aug 2001
Aug 2005

Benefits of Disclosure



- May avoid claim or lawsuit
  - Diffusing anger
  - Answering questions
- If claim or lawsuit
  - May avoid being named as a defendant
  - May reduce amount of settlement
- May avoid complaint to the Board of Medical Practice

Benefits of Disclosure

- Improve doctor-patient relationship
- Improve communication and trust
- Repair reputation of doctors and hospitals
- Lower costs to institutions due to malpractice
- Develop error-prevention strategies

Truog RD et al. Baltimore MD: Johns Hopkins University Press, 2011

Why Disclose?

- Legal requirement
- Ethical and Professional “requirement”
- If not, will you REGRET it in the long run?

Elements of Disclosure

- Respond immediately
- Report
- Communicate
- Investigate
- Begin Quality or Performance improvement process
- Follow up

Anesthesiology Newsletter May 2009; 73 (5) 20-22

Elements of Disclosure Reporting

- Internal
  - Department Chair
  - Risk Management/Legal Department
- External
  - Joint Committee-Sentinel Event
  - Insurance Provider
  - State

Elements of disclosure communication what to say!

- ***AREA***
  - ***A***cknowledgement
  - ***R***egret
  - ***E***xplanation
  - ***A***ssurance

YES

Peluso APSF Newsletter Spring 2006

Elements of Disclosure Communication
What NOT to say!

- Do NOT speculate about what happened.
- Do NOT blame others
- Do NOT accept fault unnecessarily based on emotions

NO

ELEMENTS OF DISCLOSURE COMMUNICATION

How to confront patient and family!

- Be honest, calm, concerned, direct
- Sit down, make eye contact
- Keep it simple
- Ask for questions or concerns
- Participants
  - Family and friends if family wishes
  - Surgeon/Healthcare team members

ELEMENTS OF DISCLOSURE FOLLOW UP

- Remain accessible
  - Respond to phone calls, letters
- Continue care or arrange for continued care
- Don’t pester
- Don’t avoid
- Follow Risk Management Recommendations

Barriers of disclosure

- Fear of breaking pt-doctor relationship
- Fear of litigation/financial ruin
- Professional reputation
- Shame and embarrassment
- Loss of privileges, licensure, malpractice
- Inadequate training to effectively disclose

Resources

- When things go wrong: Responding to Adverse Events
- National Quality Forum (NQF)
  - http://www.qualityforum.org/about/
- CRICO/RMF
  - http://www.rmf.harvard.edu/patient-safety-strategies/communication-teamwork/disclosure/disclosure-support-materials.aspx
- The Sorry Works! Coalition
  - http://www.sorryworks.net

Resources
When Things Go Wrong

- MA Coalition for the Prevention of Medical Error
- Document organized in 3 parts
  - Pt and Family Experience
  - Caregiver Experience
  - Management of the Event
- Each Major section divided into 3 major parts
  - Recommendations one of them

Resources
The Sorry Works! Coalition

- Launched in 2005
- Adverse Event or Bad Outcome
  - Root analyses
    - If standard of care NOT met-apologize, admit fault, explain, up front compensation
    - If standard of care was MET-explain, apologize, offer empathy, do NOT admit fault or provide compensation

RESOURCES-The Permanente Journal 2013

Disclosing Medical Mistakes: A Communication Management Plan for Physicians

Sandra Petronio, PhD; Alexia Torke, MD, MS; Gabriel Bosslet, MD, MA; Steven Isenberg, MD; Lucia Wocial, RN, PhD; Paul R Helft, MD

- Two step process
- First step: Physician preparation for mistake disclosure
- Second step: Formulating and Delivering

Resources

Patient Safety and Quality Improvement: Medical Errors and Adverse Events

Michael S. Leonard

Pediatrics in Review 2010;31;151
DOI: 10.1542/pir.31-4-151

Table. **Practices to Help Prevent Medication Errors and Adverse Drug Events**

- Obtain a thorough list of the patient's current medications.
- Obtain an accurate list of the patient's allergies and adverse reactions.
- Print legibly.
- Avoid the use of unsafe abbreviations.
- Obtain an accurate patient weight.
- Mind your decimals.
- Include indication for therapy on orders and prescriptions.
- Educate patients and families.

RESOURCES-Journal AMSUS **BICEPS**

- **BREVITY**-brief and focused
- **IMMEDIACY**-grief/guilt confronted soon
- **CENTRALITY**-discussions with ENTIRE healthcare team
- **EXPECTANCY**-affected persons BACK to normal work
- **PROXIMITY**-Discussions and Rx near work place
- **SIMPLICITY**-Discussion and Rx of current problem

Two Victims

- Patient and family
- Provider
  - Feelings of guilt
  - Loss of self-esteem
  - Depression
  - Professional abilities questioned
  - Realistic fear of litigation

ALL LEADING TO SUBSTANCE ABUSE AND EVEN SUICIDE!

Berry APSF Newsletter Spring 2006

Disclosure-Summary

- Barriers to disclosure persist
- Effective communication is paramount
  - ***AREA***
    - ***A***cknowledgement
    - ***R***egret
    - ***E***xplanation
    - ***A***ssurance
- Resources are available
- Education is vital

Disclosure

- “I am indeed amazed when I consider how weak my mind is and how prone to error”
- *René Descartes, French Philosopher, 1596-1650*

TOOLS FOR DISCLOSING ADVERSE EVENTS

SPIKES (developed between MD Anderson and Toronto Sunnybrook Cancer centers)

Setting up
- Mental rehearsal
- Obtain info from involved parties
- Who will disclose
- Arrange for privacy
- Involve family members
- Sit Down
- Make connection with patient
- Silence pagers, phones etc.

Assessing patient's perception
- What does the pt know about the situation?
- What are the pt's expectations?

Invitation
- What does the pt want to hear? All the info, simple info and plan for future

Knowledge
- Warning of bad news coming may ameliorate the shock of what happened

Emotions
- Observe pt emotions, identify the emotion, identify the reason for the emotion, and connect to the emotion with a statement of understanding and empathy

Strategy and **S**ummary

AREA (Dr Anthony Peluso, Chairman of the anesthesiology residency program at University of Connecticut)

Acknowledgement-patients' sentiments

Regret

Explanation-of the events, facts.

Assurance-investigation, follow-up, prevention for future similar events

REFERENCES

1. Should we Tell Parents When We've Made an Error? Bell SK, Mann KJ, Troug R, Lantos JD Pediatrics 135(1) 159-163, 2015
2. Professional Liability Reform: The State of the States. Biggs DA, McClure H. Anesthesiology Newsletter February 2015, vol. 79 (2)
3. The Disclosure of Unanticipated Outcomes of Care and Medical Errors: What Does This Mean for Anesthesiologists? Souter KJ, Gallagher TH, Anesth Analg 2012;114:615–21
4. Talking with patients and families about Medical Error-A guide for education and practice. Troug RD, Browning DM, Johnson JA, Gallagher TH. 2011
5. University of Michigan: A Better Approach to Claims? Journal of Health & Life Sciences Law vol. 2 (2), Jan 2009
6. When Things Go Wrong. A Consensus Statement of the Harvard Hospitals. March 2006
7. What happens when things go wrong? Brandom BW, Callahan P, Micalizzi DA. Pediatric Anesthesia 21 (2011) 730-36
8. SPIKES-A Six-Step Protocol for Delivering Bad News: Application to the Patient with Cancer. Baile WF et al. The Oncologist 2000, 5:302-311