Medical Error Disclosure

How To Do It Right!

Scripps System Wide Grand Rounds
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In Consultation with Ellen Pels Esq, Scripps Legal
Audience Response Question

- Have you made a medical error disclosure?
  - Yes
  - No
Deny and Defend, Time-honored Approach to Patient Injury

- Care givers are conditioned to avoid discussion about what happened and never, ever offer judgment about how it happened, or discuss whether the outcome was the result of a true mistake.
- Claim comes, often months-to-years after the adverse outcome.
The Status Quo

- Repeated malpractice crises
- Deep fear about “disclosures”, reporting
- Increasing regulatory/accreditation intrusions
- IOM sees no change in medical error rates
What Drives Patients to Sue Their Care Givers?

Four common themes:
1) The need for an explanation
2) A desire to ensure the safety of others
3) A sense of accountability
4) Compensation

Vincent, C., Young, M., Phillips, A.
Why do people sue doctors?
A study of patients and relatives taking legal action.
Lancet 1994; 343:1609-13
Patients Harmed by Medical Errors Want Three Things

- Explanation
- Apology
- Assurance that changes have been made to prevent harm from being done to someone else

Leonard J. Marcus
Director of the Program for Health Care Negotiations and Conflict Resolution,
Harvard School of Public Health
(analysis of malpractice mediation sessions)
Basis for Disclosing Adverse Events

- Positive obligation to disclose—informed consent
- Honesty/Truth-telling—“Fair and Just Culture”
- Regulatory requirements—Joint Commission RI.2.90: “the responsible licensed independent practitioner or his or her designee”
- State Statutes/Regulations—
  - Health & Safety Code Section 1279.1/California Code of Regulations, Title 22 Sections 70737 and 70746
Basis for Disclosing Adverse Events (continued)

- Medical Staff Bylaws Compliance Responsibilities
  - *Scripps Health S-FW-LD-1003, Date: 01/10, Page 5*
- Required Reporting to CDPH; Leadership Responsibilities
  - *Scripps Health S-FW-LD-2002, Date: 11/12, II. E., Page 2*
- Attempt to mitigate malpractice suits
Mitigation of Lawsuits?

- Expression of compassion, support = reduced likelihood of lawsuit
- Failure to provide expression of compassion = increase likelihood of lawsuit
Who is Responsible for Disclosure?

- **Joint Commission**: “the responsible licensed independent practitioner or his or her designee”
- Attending physician with assistance of hospital administrative staff or risk manager
Where and When Should We Disclose?
Within 24 hours of recognition that a medical error has occurred, advise that:
- Medical error has occurred
- Actions taken to care for patient and minimize consequences
- Investigation in progress
- Disclosure should be done in location that guarantees privacy and confidentiality
Immediate Response

- Attend to the immediate needs of the patient
  - Get medical assistance, including consultants prn
  - Change in treatment required?
  - Be available to staff for notification/consultation
- Assist with preservation of evidence for the initial investigation (guide wires, syringes, vials, tissue, IV bags, supplies, equipment, disposables)
- Notify/facilitate call to risk management staff as soon as possible
Subsequent Response

- Risk management staff to meet with administration to discuss disclosure plan
- Report to additional appropriate individuals
  - Medical staff and administrative staff
- Recognize and acknowledge your own emotions
- Plan for your coverage as needed
Parallel Response and Investigation

- Risk Manager will initiate investigation and assist with:
  - Obtaining resources to assist with patient care/transfer
  - Support for patient and/or family
  - Employee and medical staff documentation
  - Decision and notification if event meets requirements for mandatory reporting (CDPH;FDA)
  - Preserve evidence
  - Review event investigation checklist to help so you don’t have to think of everything
Mandatory Reporting

- CDPH Adverse Events–highlights. Death or serious disability related to:
  - **Surgical Events** (wrong patient/body part/procedure, retained foreign objects, death within 24 hours of anesthesia)
  - **Product or Device Events** (contaminated device/drug, device used other than intended, air embolism)
  - **Patient Protection Events** (infant security, patient disappearance, suicide)

California Health & Safety Code 1279.1 and 1280.15
California Code of Regulations 70737 & 70746
Mandatory Reporting (continued)

- **Care Management Events** (med errors, hemolytic blood rx, maternal deaths, pressure ulcers)
- **Environmental Events** (falls, burns)
- **Criminal events** (impersonating healthcare providers, patient abduction, sexual assault)

California Health & Safety Code 1279.1 and 1280.15
California Code of Regulations 70737 & 70746
Mandatory Reporting (continued)

- **Others:**
  - Restraint related deaths or seclusion
  - Disruption of services or unusual occurrence
  - Unlawful or unauthorized access to and use or disclosure of patients’ medical information

California Health & Safety Code 1279.1 and 1280.15
California Code of Regulations 70737 & 70746
Audience Participation Question

- Should we take someone with us when we do the disclosure?
  - Yes
  - No
It is Scripps Practice that the disclosure of unanticipated outcomes is made by physicians and the appropriate hospital and outpatient administrative staff including:

- Department manager
- Office Manager
- House supervisor
- Risk management staff
On August 14th, 2013 at 12:30 PM, Mr. Jones underwent Right hip reduction under procedural sedation by the orthopedist. His medical history included congestive heart failure and diabetes. Prior to the reduction, he complained of severe hip pain and some mild shortness of breath.
During the procedure, Mr. Jones experienced significant agitation and therefore 10 mg of midazolam was administered over four minutes along with 250 ug of fentanyl. The nurse asked the physician if he really wanted “that much” midazolam. Immediately following the reduction, he became apneic, and suffered a cardiac arrest. A code blue was called and he underwent emergent intubation. He was transferred to the ICU with poor prognosis.
Adverse Response Question

- Would you disclose that there was a medication error?
  - Yes
  - No
Communication

- Sit down and lean in to the patient and/or family
- Make eye contact
- Introduce everyone in the room
- Speak in simple language, not in medical jargon
- Be straightforward, truthful, concise, and respectful
Disclosure Scenario

Dr. Accardi
Arlene Luu
What to Put in the Chart

- “I’m going to sue all of you!”
- “How did this happen, weren’t you being careful...how many others have you harmed?”
- “Who else was there and why didn’t they speak up?”
Disclosure Discussion

- Explicit statement facts of what happened
- Empathic communication of the facts regarding the outcome and its preventability
- Explanation of consequences of the adverse event upon patient’s treatment plan and future health
- Expression of sympathy, benevolence, and/or compassion—California Evidence Code Section 1160
- Commitment to obtain and report on information obtained from ongoing investigation
Legal Questions

- Should legal threats be noted in an incident report and not placed in the chart?
- Do you document how upset the patient/family is in the chart?
Documentation

- Document care and response to treatment
- Summary of facts surrounding event and conversation
- Document meetings
  - Date, time, those in attendance, substance of disclosure, outcome, and next steps
  - Patient reaction and the level of patient’s understanding
  - Questions asked by the patient/family and responses to those questions
Do not refer to occurrence reports
Avoid derisive comments about other providers
Avoid entries that appear self-serving
Be objective
Timely
Sign, date, and time entries
A notation that, as further information becomes available, this information will be shared with patient, family, or legally authorized representative.

Next steps to be taken by the patient and any providers or the facility staff.

Any follow-up conversations.

Legal threats should typically not be placed in the chart but can be placed in the occurrence report.
At 3 PM on August 14th, a family meeting was held and involved the patient’s daughter. Marilyn Smith RN and myself were in attendance. We discussed the necessity of administering additional doses of medication during the procedure due to the agitation Mr. Jones was experiencing. His respiratory distress during the procedure was explained and the informed consent risks were reviewed.
The daughter voiced extreme concern about the events and Mr. Jones’ current, critical medical condition. She has no further questions at this time and we will apprise her as we receive additional information. I have provided her with my cellphone number as a point of contact.
Panel Questions–Ghazala
Apology

- Apology of sympathy
  - “I’m sorry this happened to you.”
- Apology of responsibility
  - “I’m sorry I administered too much medication to you.”
Looking at the Chart

- Immediate vs. delayed chart access
- Copies—where should they be stored?
- Do not access chart of patients in whom you have not provided care for
Post Event Must Do’s

- Notify Risk Management
  - Encinitas–Ana Jackson
  - Green–Cassie Fay
  - La Jolla–Tamara Winkler
  - Mercy–Kathy Seney
  - Foundation–Tony Cardona
  - Home Health–Sandra Hznido

- Notify Your Insurance Carrier
Post Event Must Do’s (continued)

- Disclose the event to the patient and family ASAP
- Document the discussion *factually*. If not sure what to write, use their words in quotes.
- Document all follow-up conversations with the family
Post Event Don’ts

- *Do not* make disparaging comments about other providers
- *Do not* answer questions that you do not have the answer for:
  - “We will provide more information as soon as we investigate further”
- *Do not* disappear!
  - Be accessible and give the patient and family a way to reach you
Follow Up Suggestions

- Preemptive discussion with your respective insurance carrier about medical error disclosure and their specific requirements