After the Error: Disclosure Responsibilities and Controversies

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Disclosures

• I have no financial disclosures.

• Relationships: ASTRO multidisciplinary Quality assurance subcommittee member; served on AAPM WGPE for safety profile assessment tool
AAPM

- Thank you.
The Background

• Medical Error has been shown to be very common according to the landmark publication by the Institute of Medicine “To Err is Human: Building a Safer Health System” in 2000.
• Medical Error disclosure levels are, in contrast, low, and most say less than ½ of errors are disclosed.
• Medical error disclosure, when embraced on an institutional level such as University of Michigan or the VA system in Lexington, Kentucky has been shown to decrease liability costs (Archives of Internal Medicine, 2010).
• Medical Error disclosure also significantly reduces caregiver stress associated with these errors.
• Patient surveys show they want disclosure of errors.
Error in Radiation Oncology

- Radiotherapy errors are not infrequent, occurring at a rate of 0.6 events per patient, with only 7.8% of these events classified as high severity (>10mm or 10% in dose), and the majority of these are “near misses.”
- Therefore, it would seem certain that errors happen in every practice.
- As such, the radiation oncology community needs to be facile with error disclosure.
Radiation Errors

Radiation Mistakes: One State’s Tally
Even though New York State is the most stringent regulator of radioactive medical devices in the nation, many radiation mistakes go unreported there.

State records analyzed by The New York Times described 621 mistakes from January 2001 to January 2009. On average, there were about two contributing factors for each.

621 RADIATION MISTAKES

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<tr>
<th>Missed all or part of intended target</th>
<th>Wrong dose given</th>
<th>Wrong patient treated</th>
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<td>284 (46%)</td>
<td>255 (41%)</td>
<td>50 (8%)</td>
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32 Other (5%)

1,264 CAUSES OF MISTAKES

- Quality assurance flawed: 355
- Data entry or calculation errors by personnel: 252
- Blocks, wedges or collimators misused: 174
- Treatment plan flawed: 133
- Staffing: 96
- Patient’s physical setup wrong: 77
- Hardware malfunction: 60
- Computer, software or digital information transfer malfunction: 52
- Override of computer data by personnel: 24
- Miscommunication: 19
- Unclear/other: 14

Scott Jerome Parks, who died of brainstem overdose due to failure of export of mlc’s for a head and neck IMRT plan
Some definitions (Courtesy Eric Ford, “AAPM Consensus Recommendations on Incident Reporting Systems”.

- Near miss: An event or situation that could have resulted in an accident, injury or illness but did not either by chance or through timely intervention. Also known as a close call, good catch or near hit.

- Misadministration: Deviation from the intended treatment with the potential to reduce the probability of achieving the treatment goals and which requires action including documentation, notification, and reporting to the proper authorities.

- Latent condition: Underlying inadequacies in the design organization, training or maintenance that have the potential to lead to operator errors.
What about Errors in Judgment?

- This does not mean that we need to disclose error in judgment.

- For instance, choosing to do something within standard of care that eventually is not the right choice for that particular patient is not a disclosable error.

- (Example from my own case: 88 year old man with a recurrent T1 oral tongue cancer, no neck dissection. I made choice to treat ipsilateral clinically node negative neck, and he failed in contralateral neck within a year)

- We are not perfect. We are human. We are allowed clinical judgment of an imperfect nature.
Ethical Rationale For Error Disclosure

• A variety of ethical rationale have been offered for disclosing harmful medical errors to patients.

• Informed Consent: In some respects, error disclosure is a form of informed consent, conveying important information to patients that they need to make informed decisions about their subsequent medical care.

• To that extent, it is important to recognize that informed consent is a positive obligation, i.e., an obligation physicians have to come forward with relevant information that patient should know, rather than waiting for the patient to extract the information from the physician with probing questions.
Rationale

• Truth-Telling: Other ethicists justify the need to disclose errors as a form of truth telling, which suggests such errors should be disclosed even if the information is not essential to informed decision-making.

• Justice and Fairness: Theories of justice also support error disclosure, as such information is often a prerequisite to a patient accessing appropriate compensation for their injuries.

• Non malfeasance: don’t make it worse- after an error, don’t conceal (fraudulent concealment is also a crime); don’t make patient think they progressed if wrong area was targeted
What Does Joint Commission Say?

- In 2001, the Joint Commission promulgated Standard RI 2.90, which requires that patients and their families be informed of all “outcomes of care, treatment, and services, including unanticipated outcomes.” Nat’l Quality Foundation requires serious only, JCOH requires all

- At a minimum, the serious unanticipated outcomes addressed by this practice include
  - (a) sentinel events as defined by the JCAHO (any unexpected occurrence involving death or serious physical or psychological injury or risk thereof; serious injuries specifically include a loss of limb or function);
  - (b) serious reportable events as defined by the NQF (one that results in death or the loss of a body part, disability, or loss of bodily function lasting more than 7 days or still present at the time of discharge from an inpatient health care facility or, when referring to other than an adverse event, an event that the occurrence of which is not trivial);
  - (c) any other unanticipated outcomes involving harm requiring substantial additional care (such as diagnostic tests, therapeutic interventions, or increased length of stay) or causing loss of limb or function lasting 7 days or longer.
Senate Bill 1237 of California, passed September 2010 legally mandates disclosure of:

- CT or therapeutic exposure that results in unanticipated permanent functional damage to an organ or a physiological system, hair loss, or erythema, as determined by a qualified physician;
- A CT or therapeutic dose to an embryo or fetus that is greater than 50 mSv (5 rem) dose equivalent, that is a result of radiation to a known pregnant individual unless the dose to the embryo or fetus was specifically approved, in advance, by a qualified physician;
- Therapeutic ionizing irradiation of the wrong individual, or wrong treatment site; and, the total dose from therapeutic ionizing radiation delivered differs from the prescribed dose by 20 percent or more.
- Require a report in any instance where the dose administered exceeds 20 percent of the amount prescribed in a situation where the radiation was utilized for palliative care for the specific patient.
- Require the radiation oncologist to notify the referring physician that the dose was exceeded.
What should be disclosed?

- Anything that results in a perceptible clinical effect (SSD patient set up to SAD with diarrhea and thrombocytopenia)
- Anything that changed your diagnosis or treatment course or management (more CBCs, extra fractions to make up for shorter field)
- Anything with a chance of future harm
So are all errors necessary to disclose?

- Ethicists agree that only harmful or potentially harmful errors should be disclosed.

- So minor “variances”- bolus left off, slightly wrong SSD on electron boost, etc are unlikely to cross the threshold for disclosure.
Why do errors occur? Incompetence?

• Drawing from lessons learned in other high risk industries such as nuclear power and aviation, patient safety experts assert that most medical errors are due not to incompetent providers but rather due to flaws in the systems of care.

• These flaws, often referred to as "latent errors," represent the breakdowns in the healthcare system that made the error itself more likely to happen.
Swiss Cheese Model of Error
Human factors engineering...

- is the discipline of applying what is known about human capabilities and limitations to the design of products, processes, systems, and work environments.
- It can be applied to the design of all systems having a human interface, including hardware and software. Its application to system design improves ease of use, system performance and reliability, and user satisfaction, while reducing operational errors, operator stress, training requirements, user fatigue, and product liability.
- HFE is distinctive in being the only discipline that relates humans to technology.
The Disclosure Gap

• A variety of studies have documented error disclosure rates of approximately 30 percent.
• Multiple barriers inhibit disclosure, ranging from fear of malpractice to shame and embarrassment from admitting to a patient that one has made an error.
• Furthermore, few physicians have had formal training in error disclosure, and therefore may feel quite uncomfortable conducting such conversations.
• Difference between theories espoused and theories practiced!
Closing the Disclosure Gap

- Emotional support for caregivers and administrators. Serious unanticipated outcomes upset not only patients and their families but also the involved caregivers and administrators, distress that can last for weeks and months.
- Education/skill building. Few caregivers have had training in disclosing unanticipated outcomes to patients. Thus, institutions should invest in educational programs to teach caregivers how to conduct these difficult conversations.
- Coaching- Disclosure coaches can help the health care team discuss the event in a blame-free way and decide how to disclose the serious unanticipated outcome to the patient. This disclosure planning process will include rehearsing the disclosure and anticipating questions.
Benefits of Disclosure

• University of Michigan has seen a 50% decrease in legal expenses since the full disclosure policy instituted 5 years prior. Number of claims was also decreased

• One of the reasons patient safety advocates argue for disclosure is because transparency helps identify systems errors, which in turn leads to prevention strategies.

• Reduce clinical team stress and shame
Once Error is confirmed....

- Call Risk management.

- In addition to their need to know, they often give excellent “just in time” coaching to help the team talk to the family.
A critical step in this is investigating the incident

- [http://www1.imperial.ac.uk/resources/C85B6574-7E28-4BE6-BE61-E94C3F6243CE/londonprotocol_e.pdf](http://www1.imperial.ac.uk/resources/C85B6574-7E28-4BE6-BE61-E94C3F6243CE/londonprotocol_e.pdf)

- The London Protocol: Systems Analysis of clinical incidents

- A systematic method for investigation of clinical incidents
- Excellent framework for investigation
• Clinical Context: what was happening with patient—dropping BP, intubated, in pain

• Contributing factors: like patient factors (unable to speak english); task and technology factors (poor equipment, lack of standardized procedure), individual factors (staff member poorly trained, inexperienced), team factors (personality clash, poor communication), work environment factors (inadequate staffing, high workload)

• Care Delivery problems: problems that arise in the process of care, usually actions or omissions by staff members.
  – these deviate beyond safe level of practice
  – the deviation had at least an indirect or direct effect on the adverse outcome
    – IE failure to observe, monitor, act; incorrect decision; failure to seek help
Conduct interviews

- JUST CULTURE environment
- establish chronology
- Identify care delivery problems
- Identify in detail contributing factors
- Close the interview
Develop an action plan

- The action plan should include the following information:
  - Prioritize the contributory factors in terms of their importance for the safety of future healthcare delivery.
  - List the actions to address these contributory factors as determined by the investigation team.
  - Identify who is responsible for implementing the actions
  - Identify the time frame for implementation
  - Identify any resource requirements
  - Evidence of completion. Formal sign-off of actions as they are completed
  - Identify the date to evaluate the effectiveness of the Action Plan
The Hierarchy of Intervention Effectiveness
What is appropriate full disclosure according to the ethics gurus?

- Statement of what happened with what is known to be factual without speculation or blaming
- Explicit acknowledgement that there was an ERROR
- Promise to investigate the cause of the error and to report back with findings
- Pledge to report back as to what changes where made as a result of the error
- Expression of apology for the error
What are the components of apology?

- A full apology involves:
- Admission of wrong
- Remorse expression
- Explanation of how it happened and steps that will be instituted to prevent a further occurrence
- Restitution for financial or practical burden this causes
Levels of Disclosure

- Full disclosure: detailed description of what happened with explicit statement that there was an error
  - “Your nurse administered 100 units of insulin in error as my order was not clear, and your blood sugar dropped.”
- Partial Disclosure: no information about cause or nonspecific information hinting at the cause
  - “You had too much insulin and your blood sugar dropped.”
- No disclosure: Not mentioning the event’s cause
  - “Your blood sugar dropped.”
There are 2 disappointments:

• 1/ The disappointing medical outcome
• 2/ Disappointing way in which the outcome was handled

• Patients are more forgiving of #1 than #2!
Who should disclose?

- The attending physician.
- Should the attending not do it, it falls to the physician chief of service.
- Should the physician chief of service not do this, the director of risk management. As a JCHAO standard it’s a hospital responsibility too!
The disclosure process- Before (as per Umichigan)

- Acknowledge any self-deprecating emotions that may be surfacing. These may be feelings of personal failure - a sense of incompetence and betrayal of the patient, regret for inflicting further pain on the patient, and fear of legal fallout.
- Approach this process with the attitude that it's the right thing to do and the patient's right to know. Ask yourself: "Is this something that I would want to know if it happened to me or to someone in my family?" Honesty is the best policy.
- Presume good will on behalf of all parties.
- Notify your Risk Management personnel of the occurrence. This should be done immediately if it is clear that an injury to a patient is the result of a medical error.
- Approach this disclosure process, mindful of the need to preserve the confidentiality of patient information.
The disclosure process- Before

- Make certain that the leaders of the clinical team are fully informed
- Gather all the facts. Review the medical record. Any "systems" issues should be recorded and reported through the Incident Reporting System
- Assemble documentation and be prepared to review the chart with the patient/family member. In some cases, a detailed outline should be prepared to ensure that all information of the event is delivered in a concise manner. Gather pertinent studies, if they will help you explain what has occurred.
- Determine who from the medical team should have the conversation with the patient/family. If it is a nursing error, then the Nurse Manager should probably be the one to talk with the patient. The bedside nurse may or may not be present. This varies with the circumstances and is something you will want to discuss with Risk Management.
Try to anticipate questions and/or concerns that may be raised and be prepared with answers.

• Determine who should be present with the patient. This will vary with the seriousness of what has occurred and can be discussed with Risk Management. If the patient is a minor or is incompetent, parents and/or guardians should be present for the conversation.

• Make a thoughtful analysis of the potential harm of disclosure to the patient/family. Give careful thought to the words that you will use in the disclosure conversation. Keep in mind that the patient's reaction may depend more on how the news is delivered than by what is actually said.
The disclosure process- Before

Be sensitive to the patient's ethnic culture. Consult resources to enhance your awareness of ethnic customs around communication, family involvement, and other pertinent issues such as how their culture handles bad news, in particular death.

Prepare a script and role-play - choose the best approach to take with this particular patient/ family, select the right words to be spoken, and rehearse the encounter with someone beforehand.

According to Buckman & Banja, keep in mind that "When the news is painful, you must be prepared to have a conversation."
• Error disclosure involves both communicating information as well as addressing the patient's emotions. Over emphasis of either dimension, such as responding primarily to the patient's disappointment and anger but sharing little information about the event in question, can lead to poor disclosure conversations.

• Clinicians should recognize that error disclosure is more than just giving bad news to patients. Error disclosure involves possible culpability on the part of the clinician and therefore may feel risky to physicians in ways that simply sharing bad news does not. This fact makes it especially important that physicians consciously reflect on their own emotions during the disclosure conversation and consider how these emotions are effecting their communication with their patients.

• Comments perceived by the patient as rationalizations or defensive on the part of the physician, though a natural reaction in response to angry comments made by the patient, can fuel patient anger and are to be avoided.
Schedule the meeting.....

- Should be set at a later date when a clear picture of the most likely sequence of events (note: truth is not always known here) leading up to the adverse event.
- Patients should be encouraged to bring whomever they want to be present.
- The accountable clinicians should be there—RN, dosimetry/physics, MD, etc etc, with a support team!
During Disclosure

- Ensure that the conversation takes place in a private setting, where there is room for persons to walk around, if need be. However, you should remain seated during the conversation.

- Everyone should know who is in the room. Introduce yourself and any support staff accompanying you and find out the relationship to the patient of all persons who are accompanying the patient.

- Ascertain what information the patient may already have, based on his/her own suspicion or on actual knowledge. This is important to dispel inaccuracies and to determine the level at which the discussion should take place.
During Disclosure

• Ascertain how much detail the patient wants to receive or if he/she would rather someone else be the recipient of the information.

• Convey the information slowly in simple terms that are understandable to the patient, avoiding any medical jargon, and in a manner that minimizes distress to the patient. Explain what happened, when and where it occurred, any decisions that were made including those in which the patient participated, any repercussions and recommended corrective action. At this point, you might have some clues as to how it happened, but it may not be feasible to speculate as to why it happened.

• Identify and offer any support that is available to the patient and his/her family, including the venue for future conversations. Work collaboratively with the patient devise a follow-up treatment plan for him/her to mitigate the effects of any injury. Pay attention to patient preferences and cultural considerations.
During Disclosure

• Let the patient/family know what will be done to follow-up, both with regards to preventing this from happening again and how the patient's care will be managed from this point on. This includes an explanation that a full analysis of the events leading to this bad outcome of care will be conducted.

• Express appropriate regret for the error and concern for the welfare of the patient/family.

• Try to avoid making a direct admission of fault at this point. Remember that hindsight bias plays heavily in these circumstances. Only a thorough objective review of facts can give an unbiased determination of fault.
During Disclosure

- You may need to periodically give silent pause, allowing the patient/family time to process the information, rather than feeling the need to fill the void with words and gestures that, once conveyed, can't be taken back. Give opportunity for any questions.

- Special note: If the event is serious, you should have a meeting as soon as possible, even if you can explain only part of what happened. The conversation will most likely focus on what is being done for the patient, not what led to the present circumstance. If the family has questions about what occurred which cannot be answered yet, promise to return when additional facts are known. Explain treatment that may have been necessitated by the error. If tests are necessary, promise to share the results as soon as they are known. Give a general idea of how soon that might be, and be sure to follow up.
After Disclosure

- How you respond after the bad news is given is paramount.

- Acknowledge the patient's/family's emotions upon hearing the bad news. Validate their reaction appropriately so as not to aggravate the situation for the patient/family or for the institution. "This must be difficult for you to hear" might be one appropriate response.

- Do not give any appearance of insensitivity. An empathic and compassionate demeanor is essential. Sometimes the words "I'm sorry" are all that can be articulated.

- If you are met with anger, do not respond in kind. Work hard to avoid defensiveness, rationalizing, sermonizing, or lecturing. Listening to and absorbing feelings, disappointment, anger or frustration may go a long way toward resolving the matter.

- Input from the family is welcomed and valued.
• If the patient or family asks you for information that you don't have because you were not directly involved, be helpful and assist them in getting the information they seek.

• Let the patient/family know who to contact if they have any further questions or concerns and how they can be reached.

• If you are asked about what will happen to the responsible person, you can say that you don't know, but that it will be followed up by the manager/supervisor/supervising physician.

• Let the patient/family know that the institution will handle "systems" problems by referral to the Quality Program for review.
After disclosure

- In some cases, follow-up meetings should be held within 48 hours after the initial meeting to provide updates about the event to the patient/family.

- If a lawsuit is threatened, do not panic. Most events can be resolved short of a formal litigation process. Inform Risk Management about any such declarations or demands for compensation.

- Once the disclosure conversation has concluded, now is the time to continue facilitating the healing process for the practitioner involved in the error. It is expected that practitioners will experience personal emotional fallout from the error and from the disclosure conversation - this will never be easy - yet, it is the right thing to do.
Summary

- Disclosure helps everyone—hospital, patient, provider
- Call risk management early
- True disclosure often requires a lot of prep to have in a proper manner
- In the initial disclosure, do not blame yourself hastily or conjecture about someone else’s care
- Only disclose yourself