A Fatal Medication Error: Navigating the Legal and Ethical Minefields after a Tragic Outcome.

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Objectives:

1. Discuss processes that should ideally be in place when an adverse event occurs.

2. List the key strategies for effective disclosure to the family.

3. Identify with whom and when you can safely discuss the details of the event.

4. Discuss effective documentation after an adverse event.

5. List the risks and benefits of offering an apology.

6. List coping strategies and available resources that aid providers after an adverse event.

Case History:

You are supervising a new trainee caring for a 4 week old ex 30-week premature infant for an exploratory laparotomy. The infant has been in the NICU receiving total parenteral nutrition containing 28% dextrose through a single lumen peripherally inserted central venous catheter. This infusion was discontinued by the NICU staff and a 0.2% normal saline with 10% dextrose infusion was started by syringe pump prior to transport to the operating room. During the surgical procedure, the infusion runs out and is replaced by the fellow. You have been extremely busy managing other challenging patients and although you had previously discussed checking blood glucose levels during the case, you were unable to obtain an arterial line and access to the patient is severely limited. The surgery is much longer than predicted and after a multiple failed attempts using the handheld glucometer, you discover the blood glucose is 17 mg/dL. All of the appropriate medical management is immediately initiated and the following questions will focus on the legal and ethical components following this incident.

Questions:

Once you identify the low glucose, whom will you first notify?

How will you first describe to the operating room personnel what is happening? Is it appropriate to announce that you may have made an error?

What will you document in the anesthetic record?

What should be communicated to the family and when?

While you are still caring for the infant, the surgeon asks if he can tell the family what happened. How would you respond?

Case History (continued):

The blood glucose has been restored and you have put the family on notice that their child's blood sugar was extremely low during the case and an investigation of this event will take place. The infant had several seizures upon returning the NICU. The surgical team claims that your team has made an error.

You have a meeting with your risk management manager who asks you not to talk to anyone about the case including the surgical team, the nurses, and your resident. You are permitted to only discuss the details of the event with your chairman, risk management department, and your significant other.

Questions:

Why are you being discouraged from discussing the case?

What conversations are protected and what are the consequences of having unprotected discussions?

Would you be completely transparent about the incident with the family?

Is it acceptable to speculate about what may have happened since you are just being honest?

What can be done when multiple providers are in conflict after such an incident?

Case History (continued):

The entire day has been very stressful and you discuss the case over the phone with one of your mentors to gain some clarity. She recommends writing a personal letter to yourself describing the details of the care for this infant and to email a copy to yourself.

Questions:

Is there any utility in keeping a written detailed letter after an adverse event such as this?

Would such a letter be discoverable in court and could it be used against you or anyone involved in the case?

What is Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11101-11152 (HCQIA) and what conversations and documentation does it specifically protect?

Would you seek legal advice outside of your risk management department at this time?

Case History (continued):

The next day there is a great deal of tension among all parties involved in the case. You have some hesitation about whom to trust in the matter. You have a private meeting with your chairman and review the case thoroughly. Although you speculate that a drug error was most certainly made, the chairman encourages you to focus on the facts. Subsequently there is a preliminary investigation meeting with yourself, your risk management department, the surgical team, your fellow, the OR nurse, the NICU nurse, the pharmacist, the NICU attending, and a member of the medical staff review board. There is an open discussion about the events that transpired the preceding day. Evidently the replaced maintenance fluid syringe was not recovered for testing. A discussion about who shall inform the family takes place. You are then advised to provide only the facts to the family during a family meeting. You are specifically instructed to not admit making an error nor an apology, nor that any person made a mistake and then to document that this conversation took place.

Questions:

What is the advantage of having a peer review meeting and what if anything is admissible from such a meeting if a civil case were filed?

Is a lawsuit more or less likely to occur if you provide full disclosure and an apology?

Should an apology be made and by whom? Can an apology be considered admission of guilt?

Can an apology be admissible as evidence in court?

If your liability insurance company declared to you that you are under contract not to apologize, could your coverage be terminated if you do in fact apologize?

How is being encouraged to not apologize nor give any information other than facts be consistent with the American Medical Association's Code of Medical Ethics?[1]

What are the benefits that come from early disclosure and what happens if prematurely disclosed information is later deemed false by the investigation?

Who shall be present for the family meeting and who should lead the discussion?

Case History (continued):

The child unfortunately expires due to severe neurological injury. An investigation team is appointed to perform a root cause analysis. If the investigation determines that the intra-operative care was unreasonable, you will be advised to provide full disclosure, an apology, and offer settlement as a rapid remedy.

Questions:

If the death was secondary to a neurological injury, is this enough evidence to admit that it was due to errors made by the anesthesia team?

What should be the next course of action regarding family interaction and counseling? What counseling is available for yourself and the rest of the intraoperative team?

Should you engage in conversation with the family privately?

How will you cope with the stress of this tragedy?

What shall be done about system improvement?

What type of data can be tracked that would improve the system?

How can the lessons learned through this entire process be incorporated into education? Who may participate in the process of improving a system?

Discussion:

The specialty of Anesthesiology remains at the forefront of patient safety initiatives since 1983 when the ASA Committee on Patient Safety and Risk Management was formed and closed claims analysis was initiated. Standards on monitoring soon followed in 1986. The anesthetic mortality risk was reduced from a shocking 1:2000 in 1982 to 1:300,000 as of 2011. Although this has been a significant

reduction in anesthetic risk, hospital wide medical errors remain a serious public health problem in the United States causing significant patient harm, economic burden, and severe damage to physician-patient relationships.

Healthcare providers work under extremely stressful conditions and the responsibility they share for the well being of their patients is monumental. An adverse event is devastating for the patient, the family but also for the provider who is occasionally referred to as "the second victim."[3,4] There may be significant psychological suffering for all parties involved and adequate support systems for patients and their providers may not be readily available. Dealing with a critical incident is extremely stressful and requires a prompt and prudent response. Delays in seeking help or incorrectly assessing the risk are possible due to fear and it is important to quickly involve senior members of the team. Asking for help and the confession of errors carries important psychological ramifications. A safe climate is important to encourage people to speak up; whereas if they fear punishment, embarrassment, and reprisal, they will be less inclined to do so and perpetuate "the wall of silence" between families and healthcare.[3,6]

Ideally a serious event such as the one described here should trigger a system that supports rather than blames the staff members and focuses on the appropriate and early disclosure of information to the patient and family. Not only are healthcare providers poorly trained to manage adverse events but there is a paucity of empirical research that provides guidance through the disclosure process. The aviation, oil, and nuclear industries have established protocols for investigating incidents however the medical field has been less reliable in establishing protocols as well as reporting incidents.

In 1987 the Veteran Affairs Medical Center in Lexington Kentucky established a system of early disclosure, apology, and compensation as a means to reduce their malpractice costs. This protocol is not a perfect system for all hospitals and there is still a need for a consistent, well-established system that can be universally adopted in all hospitals. A model protocol from the University of Illinois has recently been introduced and suggests that seven elements are essential in a safety incident system: reporting, investigation, communication, apology with remediation, system improvement, data tracking and analysis, and education.[2] The goals of an effective protocol are to reduce harm through transparency and learning, to reduce lawsuits through early effective communication with all parties, resolve cases early where inappropriate care took place, defend appropriate care cases vigorously, support patient and family engagement, and to support professionals following harmful events.[2]

The Disclosure:

The American Medical Association states "Following an unanticipated outcome, the physician is ethically required to inform the patient of all the facts necessary to ensure an understanding of what has occurred."[1] Adult patients and parents of

pediatric patients want to be fully informed when errors occur and may be less likely to seek sanctions against physicians if they receive both full disclosure and an apology.[5]

Disclosure unfortunately does not occur frequently. In a study of patients and families pursuing litigation in the United Kingdom, there were four major reasons for litigation: to get an explanation and apology, compensation, wanting to see the staff disciplined and held accountable, and to improve the standard of care so that the incident does not occur again.[5] It is however important to note that the number one thing that may have prevented patients from taking legal action in the first place was an explanation and apology.[5] Dishonesty, poor communication, and lack of a timely explanation and apology from the staff after the incident significantly contributed to the decision to take legal action.[5] The timing of the explanation was important where an explanation was given anywhere from several days after an incident up to over a year later and in many cases no explanation was given at all.[5] Furthermore, in the cases where explanations were given, they were often given by more junior house officers and the patients and relatives reported they did not feel that they could adequately ask questions.[5] Therefore it is important to bear in mind that patients are much more likely to accept an original mistake but they are angered and feel bitter when the staff are not willing to explain and answer questions after an incident.[5]

In order to effectively disclose information after an incident patients and families of children should be advised promptly of all significant facts. It is absolutely critical to provide only the facts and not speculate about what might have occurred unless it is obvious, for example operating on the wrong extremity. The main reason not to speculate is that if incorrect information is given to the family, any discovery of new information at a later time that is different than the original information may cause the family to doubt the provider and the hospital. It is important to document in the patient's chart exactly what has been disclosed about the adverse event. The consequences of failure to fully inform the patient or family of the patient's condition could be severe. On top of medical malpractice, a provider could be sued for "intentional concealment" which carries the risk of punitive damages. A provider's credibility may be severely compromised in the eyes of the jury if it is shown that they were not honest or forthright.

The Apology:

An apology for an error is an effective way to reduce lawsuits and demonstrate that providers are loving and feeling humans capable of error whereas the lack of an apology is one of the major factors for intensifying conflict between providers and patients.[7] It is paradoxical then that providers fear the legal consequences of an apology when not apologizing and not calling an error "an error" is irritating to patients and more likely to increase the risk of litigation.[5]

It is ironic that a parent may tell a child that the right thing to do is to apologize for wrongdoings, yet many physicians have been counseled to not give an apology as it makes them look guilty and could be admitted in a civil case as culpability.[7] The paradox here is that the apology is the very thing that patients desire and require for healing and to maintain trust with their provider.

When deciding whether to and how to apologize, it is important to have a discussion with your risk management manager and insurance company as there are many variables to consider. When a clear error was made, it is often best to apologize early and does not increase any risk but rather reduces litigation risk. When it is not clear if an error was made then it is not advisable to apologize since nothing was done wrong and actually can be interpreted as an admission of guilt. It is acceptable to apologize, provide sympathy, or a general sense of benevolence that an event has happened to the patient and this is inadmissible as evidence pursuant to Rule 408 of The Federal Rules of Evidence. It should be understood that any statement of fault however could be admissible.

From: *Rule 408 of The Federal Rules of Evidence*

> Rule 408. Compromise and Offers to Compromise. Evidence of (1) furnishing or offering or promising to furnish, or (2) accepting or offering or promising to accept, a valuable consideration in compromising or attempting to compromise a claim which was disputed as to either validity or amount, is **not** admissible to prove liability for or invalidity of the claim or its amount.
>
> Evidence of conduct or statements made in compromise negotiations is likewise **not** admissible. However, this rule does not require the exclusion of any evidence otherwise admissible merely because it is presented in the course of compromise negotiations.
>
> This rule does not require exclusion when the evidence is offered for a purpose other than the proof of liability for or invalidity of the claim or its amount, such as proving bias or prejudice of a witness, negativing a contention of undue delay, or proving an effort to obstruct a criminal investigation or prosecution.

Protected Information:

It is important to know the law in the state where you practice as these can vary. For example, in the state of California, Evidence Code § 1157 provides that any information submitted to or considered by a medical staff peer review committee is privileged and confidential and does not have to be disclosed in a lawsuit. This creates an open environment during peer review meetings where providers can discuss the details of events without having to worry about anything they say being admissible in court.

If a letter containing the details of the event is prepared after the event for the benefit of oneself in anticipation of litigation, it is inadmissible in court pursuant to *The Federal Rules of Civil Procedure* 26(b)(3)(A):

Trial-Preparation Protection for Communications Between a Party's Attorney and Expert Witnesses. Rules 26(b)(3)(A) and (B) protect communications between the party's attorney and any witness required to provide a report under Rule 26(a)(2)(B).

Therefore it can be to the providers benefit to write a summary of the details of the event. If a trial takes place five years later, it would be unlikely that any person could recall with any accuracy the details of a case as well as they could the day the event occurred.

The peer review meeting and discussions with your chairman are protected information pursuant to the Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11101-11152 (HCQIA). Conversations outside of these settings which include private talks in the hallway, phone conversations with mentors, and any other types of discussion about the event are not protected. Confiding in a friend or mentor is common and provides emotional support but they could be called in to court to testify about what you said to them. It would be ideal to have a form of protected support as providers can feel severe pain after an incident.

The patient's chart and anesthesia record are extremely important. Make sure the record is accurate. After an event, the anesthesia record is unlikely to be accurate given that you were caring for the patient and not focused on the clerical details of the record. Thoroughly review the record right after the case while the details are fresh in your mind. If the case were to go to undergo litigation many years later, an accurate record speaks for itself.

System Improvement:

Injured patients are concerned that something will be done about medical errors so that such errors will not be repeated.[5] Improving the system is done to prevent future errors. This is only feasible through a conscientious effort to report errors and quality improvement efforts. In many cases patients and families can play a role in quality improvement which can be therapeutic for them. This step in the process requires reporting of errors, tracking data, and analyzing the data to see whether interventions have helped reduce events.

Summary:

In a climate of rising malpractice premiums and highly complex and changing medical care, one of the most important things that can be done not only to reduce litigation but to treat patients better is to explain things clearly and offer a sincere apology when appropriate. Further research is needed to investigate what consequences come from various disclosure processes. Systems should be in place in hospitals for the benefit of the patient as well as the providers when adverse events occur and hopefully the transition of blame on the individual to blaming the system will increase transparency, reduce patent and provider suffering, and improve patient-provider relationships after adverse events.

From *ASHRM's Risk Management Pearls*:

Review the medical record
Identify directly involved staff
Review the case with risk management
Distinguish between factual information and conjecture
Identify participants for disclosure meeting
Identify a private and quiet location for meeting

Avoid:
Assuming you can speak for other clinicians without soliciting their input and including them if they are primarily involved
Initiating the communication until you have removed noise and interruption

Discussion:
Begin by asking what the family understands about the situation and determine if they are able to participate.
Communicate in clear and simple terms:
What happened and the likely effects on the patient
What steps are being taken to provide care for the problem
What ultimate outcome is expected, if known and when it can likely be determined if unknown
What steps if identified might prevent the problem in the future
An expression of sympathy for the suffering of the patient and family
An apology for an error if one occurred
When more information will be available and an anticipated timeline for a subsequent meeting
Whether the family has questions

Avoid:
Bringing a crowd to the meeting
Speaking loudly, rapidly, or using medical jargon
Confusing facts with theories
Unhelpful body language such as crossed arms, standing over family

Closing:
Summarize the main points and questions
Identify the primary contact person and provide contact information
Provide a time frame for the family's next contact

Documentation:
Document a summary of the communication and questions answered
Document who was present, both staff and family
Document any pertinent facts about the family response

Avoid:
Documenting conjectures or opinions about the case or about the family or staff involved

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