Medical Error*

Learning Objective: At the conclusion of this continuing medical education activity, the participant will be able to describe the myriad factors contributing to harmful medical error, barriers to and benefits of error disclosure, techniques for successful error disclosure and the importance of a supportive organizational culture in health care systems.

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***This AUA Update addresses the Core Curriculum topics of Business/Communication and Ethics, and the American Board of Urology Module on Core/General Urology.**

INTRODUCTION

Prior to the release of the Institute of Medicine report, *To Err is Human*, at the turn of this century the subject of medical error was seldom discussed, either privately or publicly.[1] The belief of the time was that medical error was rare—a belief that went unchallenged by the health care industry, underscoring the at times defensive and image conscious state of medical practice in the United States.[2] Notably the Institute of Medicine report was leaked to the media prior to its intended release, forcing its early publication.[3] The headline was that as many as 98,000 hospital deaths result from medical error each year. The media coverage that ensued generated a frenzied search for someone to blame in addition to a solution to the problem of medical error. Congressional hearings were held to review this concern and governmental agencies, medical boards, insurers and others responded with plans to define and measure error going forward.

While the early leak of the Institute of Medicine report opened a Pandora's box, it also rejuvenated the field of patient safety research. President Bill Clinton signed the Healthcare Research and Quality Act of 1999. This act renamed the *Agency for Health Care Policy and Research* to the *Agency for Healthcare Research and Quality*, with additional funding and a renewed mission to improve the quality, safety and effectiveness of health care.[4] **Renewed interest in quality research spurred the transition from a culture of blame to today's culture of safety.[5]**

DETECTING AND REPORTING ERROR

Difficulty measuring medical error is perhaps the most important barrier to error prevention and presents a challenge to assessing the scope of the problem. **To begin, defining medical error is a non-trivial task.** Medical error and bad outcomes are not equivalent. Within the patient safety literature an entire language has developed to define and classify medical error.[6,7] Moreover, the relationship between an adverse event and an error is not always clear, a point often illustrated by heated discussions at morbidity and mortality conferences. Preventable harm lies at the intersection of medical error and adverse events, and is the target of patient safety efforts (fig. 1).

Measuring medical error presents a separate challenge, primarily because our current system relies almost entirely on voluntary reporting. Voluntary reporting is relatively infrequent, subject to hindsight bias and largely non-standardized.[8] Analysis of the electronic medical record and/or administrative databases is an alternative method of error measurement but is expensive to implement and subject to the programmers' definition of error. Researchers have adopted surrogate measures of error such as iatrogenic illness, critical incidents, adverse events deemed preventable following root cause analysis, malpractice claims and policy violations.[7]

SYSTEMS APPROACH TO MEDICAL ERRORS

Perhaps the best known systems model of medical error is the Swiss cheese model, described by Reason in 2000 (fig. 2).[6] This model visually depicts how, despite layered defense systems, an error can occur due to the unfortunate alignment of flaws in these defenses. A revised classification of the causes of medical error details several of these systemic imperfections.

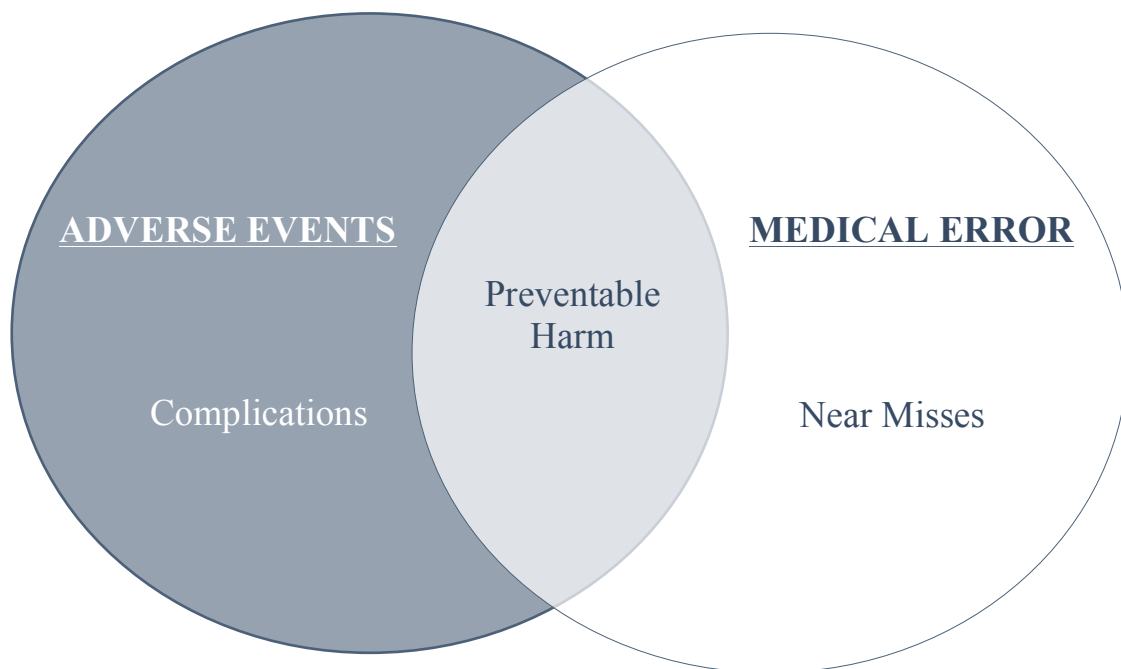*Human error.* Excessive Reliance on Memory: Much of medi-

ADVERSE EVENTS

Preventable Harm

Complications

MEDICAL ERROR

Near Misses

Figure 1. Visual representation of relationship between medical error and adverse events.
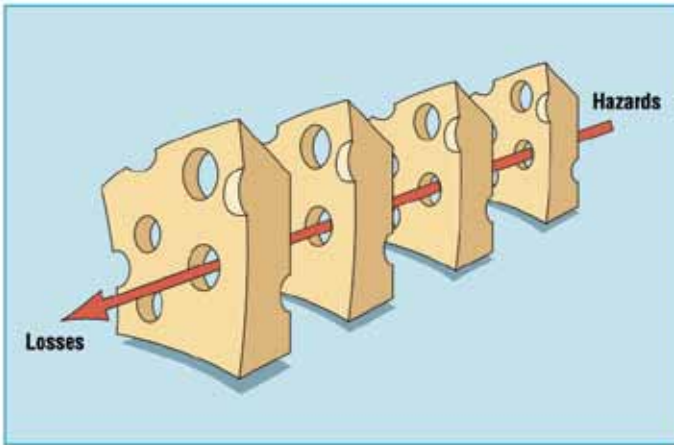
Figure 2. Reason's Swiss cheese model of human error.[6] Reproduced with permission.

cal practice relies on short-term memory, also called working memory. For instance a urologist may see several patients prior to documenting each encounter, relay the plans to a medical assistant who may be busy rooming a patient, or review the list of equipment needed for a surgical case with a circulating nurse who doesn't have a pen on hand. Working memory relies heavily on cognitive *heuristics*, or mental shortcuts based on pattern recognition, which ease cognitive load and allow for rapid decision making.[9] One can think of heuristics as rules of thumb—they are at once helpful and imperfect. Innumerable heuristic flaws affecting working memory have been described, including availability bias, recency bias, confirmation bias, misinformation effect, list length effect and context effect. Integrity of working memory is further compromised by stress, distraction, interruption, lack of sleep and cognitive overload—familiar concepts for training and practicing urologists alike.[10, 11] **Given our reliance on flawed cognitive functions, including working memory, it is no surprise that error is not only human, but common**.

Knowledge Deficits: Physicians can make mistakes in diagnosis and decision making due to lack of information or knowledge.[2] Technology is playing an important role in minimizing this as a source of error. Advances in medical knowledge are becoming increasingly accessible to practicing physicians through online journal access, medical summary sites (e.g. Up-to-Date), and publication of regularly updated guidelines. Informaticists are continually working to improve the electronic medical record to facilitate instant access to patient data. It is clear that automated internal reconciliation of data can lead to error detection and prevention.[12] On the other hand, data overload and copied-and-pasted notes can obscure and/or propagate error.[13, 14] The optimal strategy for implementation of the electronic medical record remains a work in progress.

Technical Error: Urology is largely a technical field. For surgeons technical missteps are an additional source of human error. **Intraoperative technical errors due purely to lapses in surgical technique are rarely incorrigible when the surgeon is astute. Significant error typically lies in decision making, failure to recognize the error expeditiously, chaos or time pressure in the operating room, lack of an experienced surgical team, equipment failure or other systemic failures.**[15]

Systems error. Cognitive Overload: **Excessive workload and chaotic work schedules have been repeatedly implicated as root causes of medical error.**[2, 16] Distraction, interruption, time

pressure and the need to complete multiple disparate tasks simultaneously all contribute. Emerging science quite clearly indicates that multitasking is cognitively impossible.[17,18] Rather, the attempt to complete multiple tasks simultaneously represents rapid context switching. The unfortunate sequelae of this task switching include detrimental effects on focus, efficiency, short-term memory and problem solving ability, all of which predispose to error.[11, 19]

Communication, Handoffs and Coordination of Care: **Handoffs between health care providers are vulnerable to communication failures, and are a key factor in providing safe patient care.**[20–22] In a 2017 sentinel event analysis the Joint Commission identified communication among staff, administration, and/or patients and families to be a leading cause of medical error, including in 30% of cases leading to malpractice claims.[23] In 2012 Nagpal et al published a qualitative analysis of communication errors across the surgical pathway, breaking down communication errors across phases of care by source, transmission and receiver failures.[24] Increasingly, however, we are realizing that **poor communication is not simply a result of faulty exchange of information.** Communication failures are far more complex and relate to hierarchical differences, concerns with upward influence, ambiguous or conflicting roles, and interpersonal power and conflict, highlighting the need for a multipronged approach to safety culture.[22]

Variability in Practice: Information is not processed in a vacuum. Like all decisions, medical decisions and diagnoses rely on perception, mood and focus, and are vulnerable to bias. Indeed, multiple studies reveal inconsistency in diagnostic interpretation of objective studies (radiological studies, pathology slides, urodynamic tracings) not only between physicians, but by the same physician at different time points or under different circumstances.[25–27] **Without guidelines or protocols to anchor our medical practices, physicians are prone to variability in diagnosis and decision making.**

PREVENTION OF MEDICAL ERROR

Standardization. **Standardization decreases variability in practice as well as reliance on memory.** One salient example of the success of standardization is found the in the ERAS (Enhanced Recovery After Surgery) protocols, which have gained popularity within urology. These protocols are evidence-based standardized perioperative care pathways, and have been shown to decrease perioperative complications, among other benefits.[28, 29] Another example well known to surgeons is the nearly universal implementation of an intraoperative checklist, or surgical time out. In his bestselling book, *The Checklist Manifesto*, Gawande makes an overwhelming case for the benefits of checklists when applied to complex systems; in health care this translates into increased efficiency, consistency and safety at every level.[30] The WHO has recognized standardization as central to patient safety, and the development of standardized operating protocols is the fundamental tenet of the WHO High 5s Project on patient safety, launched in 2006.[31] Standardization of interpersonal communication, such as the SBAR (situation, background, assessment, recommendation) method, has decreased communication related error.[21,32] On a more personal scale standardization of one's own surgical practices is critical; master surgeons are consistent surgeons who "do it the same way every time."[33, 34] **Not only do protocols and standardization reduce error, but they reduce effort, allowing urologists to save**

their mental faculties for complex decision making.

While standardization has been proven to decrease medical error in myriad ways across specialties, it must not be wholly inflexible. Within medicine, tolerance of stylistic variation must be built in so as not to remove physician sense of autonomy, which is inextricably tied to satisfaction and purpose.[35]

A science to standardization has evolved in industries outside of medicine in which systems are similarly complex, tasks are similarly risky and error is similarly catastrophic. Such organizations that have successfully avoided failure over time are referred to as *high reliability organizations*. The classic examples are military aircraft carriers, electrical grid, and nuclear power plants. As with defining medical error, precisely characterizing the high reliability organization has presented challenges; however, the following 5 principles of high reliability organizations are well accepted: preoccupation with failure, reluctance to simplify interpretation, sensitivity to operations, commitment to resilience and deference to expertise.[36] Several models for translating principles of high reliability organizations to the health care setting have been developed, all of which focus on positive organizational culture, effective leadership, transparency, humility and relentless rejection of complacency. **For urologists looking to involve themselves in bettering patient safety within their organization, the Institute for Healthcare Improvement (www.ihi.org) provides a comprehensive library of resources, including a white paper on establishing a framework for safe, effective, reliable care based on the principles of high reliability organizations.[37]**

Optimize workflow. **A maximally efficient system has all team members operating at the top of their scope of practice.** Investing in support staff—and convincing hospital administrators to do the same—is crucial to optimizing workflow and reducing error. Urologists on the clinical frontlines do not need to turn to the literature to understand the crippling burden of non-clinical administrative tasks. Still, research increasingly confirms what we experience in daily practice, and a movement to minimize non-clinical tasks for physicians is burgeoning.[38-40] **In addition to preventing physician burnout, reducing non-clinical work for physicians is central to patient safety as it allows physicians to save cognitive bandwidth for high level tasks. As doctors, we are trained that the "buck stops with us," and thus no charge is beneath us if it benefits the patient.** This attitude that has been exploited by health care administrators to the detriment of clinicians and patients alike.[41] **A paradigm shift is needed to recognize the harmful effects of inefficient workflow on safety. All tasks and decisions, no matter how small, require cognitive expenditures that steal from our future stores—a phenomenon known as decision fatigue.[42-44]** Optimizing workflow will require physicians to relinquish some autonomy, learn to delegate effectively, invest in and trust our support teams, and be humble in recognizing that many tasks are better suited to others' talents and abilities.

Leadership and team culture. **Despite difficulties defining and quantifying error, it is clear is that individual lapses are responsible for the minority of preventable harm in medicine. Solutions, therefore, must be systemic, not individualized.** The most promising approach to large-scale prevention of medical error lies within the social sciences. It can be difficult to elicit buy-in to such solutions from clinicians, particularly surgeons, who often consider ourselves objective pragmatists who favor the "hard" sciences. But the data are clear—a "soft" science approach to

patient safety culture can be transformative. The business world recognized the benefits of psychological research in organizational culture a generation ago. In recent decades a spate of best-selling books, Harvard Business Reviews and TED (Technology Entertainment, Design) talks have extolled the benefits of applying cognitive psychology research to business, which include better employee retention and satisfaction, creativity, productivity and ultimately an improved bottom line.[45-49]

Patient safety is our bottom line in medicine, and the health care system must follow the business world in recognizing the importance of organizational culture. The Joint Commission and Agency for Healthcare Research and Quality have recognized the importance of team dynamics and culture in promoting patient safety, highlighting Reason's elements of safety culture (Appendix 1).[50]

The Joint Commission further emphasizes the importance of leadership in promoting a patient safety culture. **Leaders must promote a transparent, non-punitive approach to reporting and learning from adverse events. Moreover, leaders must publicly champion those within their organization who promote patient safety and instate formal assessments of organizational safety culture every 18–24 months to ensure accountability and prevent erosion of engagement.[51]**

DISCLOSING MEDICAL ERROR

"Efficiency must acknowledge truth. Secrecy is a peculiar disease of efficiency. Publicity is the cure for the disease of secrecy."[52]

Ernest Armory Codman, MD
Father of surgical outcomes research

"Doctors hide their mistakes from patients, from other doctors, even from themselves."[53]

David Hilfiker, MD

Barriers to disclosure. Despite ethical and, increasingly, institutional support for disclosure, physicians have a difficult time disclosing medical error.

Personal Barriers: One barrier to disclosure lies within the physician herself, and is perhaps a consequence of the moral imperative embedded in the Hippocratic oath. **While intended to decrease suffering, the command to "first do no harm" implies that error is altogether forbidden, an enormous burden for the budding or practicing physician.[16, 54]** Perfectionistic tendencies familiar to many surgeons can inhibit recognition and admission of mistakes. This phenomenon, sometimes termed "medical narcissism," has been tied to medical error.[55] A recent study of factors affecting physician willingness to disclose errors confirms that injury to one's self-image is a major barrier to disclosure. Perpetuating perfectionism, fearing a sense of personal failure, loss of self-esteem and a threat to one's identify as a healer were also found to be significant barriers to transparency.[56]

Interpersonal Barriers: One of the most commonly cited barriers to transparency in the setting of medical error is communication inexperience and a lack of training in how to disclose error to the patient.[57–59] **Implicit in this is the realization that disclosure is both *difficult* and *unnatural*, as it is often laden with shame, guilt and fear of the patient's reaction.** Training courses in communication and disclosure, once rare, are gaining popularity within graduate medical education curricula.[60]

Encouragingly, data show not only that such successful training can improve disclosure rates, but also that successful disclosure can reduce medicolegal claims, provide doctors with a sense of relief and improve the physician-patient relationship.[61-63]

Disclosure to peers is similarly difficult. Along with a potential sense of embarrassment is a fear that one's reputation will be damaged.[59] Additionally disclosure of a peer's mistakes is considered to be contrary to physician culture and camaraderie, and may be difficult in the absence of clear guidelines regarding when and to whom mistakes should be disclosed. As a result, whistleblowing, or disclosure of others' mistakes, is rare.[64]

Institutional Barriers: **Institutional barriers to disclosure include unclear guidelines for action when an error occurs, an unsupportive environment for those who do disclose, and fear of disciplinary action or loss of malpractice insurance.**[64-67] Furthermore, when the cause of an error is ambiguous or multifactorial, it can be difficult to determine who should disclose to the patient—a systems glitch that further impedes disclosure.[56]

Medicolegal Environment: The fear of litigation is a powerful motivator behind many behaviors in medicine. **Overwhelming evidence shows that open surgeon-patient communication decreases the risk of getting sued, prompting the oft given advice to** *run toward, not away from, your complications.*[68–70] Moreover, a growing body of evidence shows that institutions with policies to fully disclose, apologize for, and offer compensation for harmful errors have decreased their malpractice suits and overall costs. One illustrative example is found at the University of Michigan Hospital and Health Systems, which in 2001 adopted an "open disclosure with offer" model to medical malpractice claims. At University of Michigan Hospital and Health Systems adverse events undergo rigorous internal review. If care is determined to be within acceptable standards, the institution defends the surgeons and physicians vigorously. If, however, it is determined that the harm was due to an error, the policy is to apologize, and compensation is quickly delivered. All costs associated with the injury are removed from the patient's bill, including outpatient follow-up and supplies. Since implementing this policy, University of Michigan Hospital and Health Systems has significantly decreased the amount it pays litigating and settling malpractice suits; from 2001 to 2005 malpractice claims decreased by 57%, and total litigation costs decreased by 66%.[71]

Techniques for disclosure. While there is no recipe for perfect error disclosure, experts have identified core elements to proper disclosure of error as well as pitfalls to be avoided. Prior to disclosure physicians must wrestle with the following questions:

What is the threshold for disclosure?

What should be disclosed? When? How?

Robert Truog, a bioethicist and pediatric anesthesiologist at Harvard University, has published a comprehensive guide for disclosure of medical error.[72] **In answering the first question he suggests that disclosure of error is indicated when you would want to know about the event had it happened to you (the "Golden Rule") and/or if disclosure may result in a change in treatment.**

Answering the second disclosure is more complicated, particularly *how* to disclose. Truog proposes 5 core relational values critical to successful disclosure of medical error. He refers to these using the acronym TRACK—transparency, respect, accountability, continuity and kindness—which collectively

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DID YOU KNOW?

- Error is ubiquitous in medicine and results from both human factors (cognitive flaws, knowledge deficits, technical error) and systemic factors (excessive workloads, poor communication, lack of standardization).
- Medical error is difficult to define, and even more difficult to measure.
- Disclosing error is ethically and, increasingly, institutionally mandated—but it is difficult. A culture shift within health care systems may facilitate honesty by removing extant barriers to disclosure.
- Open communication between the physician and patient is important and can decrease the risk of medical malpractice lawsuits.
- Surgeons are often "second victims" of medical error, and mutual support from within our profession is important.

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acts as an ethical road map for appropriate disclosure. Truog et al follow this ethical framework with a series of practical guidelines for error disclosure.[72] Appendix 2 contains an abbreviated summary of these practical guidelines.

Legal considerations—apology laws and discoverability. **While medical ethics and institutional policy require disclosure of error, practicing urologists must be aware of how disclosure can hurt them.** Most states have "apology laws" on the books to protect physicians who apologize as part of error disclosure. The goal of these laws is to allow doctors to apologize to patients without this apology being interpreted as an admission of guilt, which could later be used against them in a malpractice lawsuit. While we know apologizing reduces the risk of lawsuits, it is unclear whether apology laws successfully reduce malpractice claims. Most risk managers continue to counsel physicians to word their apologies carefully so as to convey sympathy without taking blame (e.g., "I'm sorry this happened," not, "I'm sorry I did this"). Moreover, the nuances of apology laws vary from state to state, and providers should understand the laws of the states in which they practice.

Another conflict between the physician's self-interest and duty to disclose is found in the venue of disclosure. **Physicians must be aware that conversations with colleagues and/or patients, every aspect of the medical record, institutional error reports and more are all discoverable as evidence for a future lawsuit. There are very few protected venues for disclosure of error. One important protected setting is the morbidity and mortality (also known as M&M) conference, which is fully confidential.** A glaring exception to this protection is found in Florida, where the Sunshine Law allows for full access to this information by anyone who requests it. Excluding this unfortunate exception, we encourage physicians to say openly at morbidity and mortality conferences what they may be afraid to admit elsewhere, and to seek support from colleagues within this privileged venue.

A NOTE ABOUT THE SECOND VICTIM

Often lost in the discussion of adverse events in medicine is how they affect the physician. **Unanticipated adverse events,**

particularly in the setting of medical error, should be recognized as traumatic events for the physician. Frequently we feel personally responsible for a poor outcome, that we have failed the patient, and we second guess our clinical skills and knowledge base.[73] In addition to shame, guilt and frustration, physicians report experiencing difficulty concentrating, poor sleep, decreased self-confidence, depressive symptoms, reduced job satisfaction and avoidance of certain procedures.[74] Such symptoms align with post-traumatic stress disorder and should be treated accordingly.[75] As physicians, we should strive to acknowledge our own suffering and to provide empathy, not judgment, when colleagues are suffering through adverse outcomes.

Appendix 1. Reason's 5 elements of safety culture[50]

Element	Description
Just Culture	An atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety-related information. Clear lines are drawn between human error and reckless behavior
Reporting Culture	People report their errors and near misses without the threat of punitive action
Informed Culture	Managers of patient safety systems have knowledge about human and systems factors patient safety
Learning Culture	Ability to draw the right conclusions from safety information systems
Flexible Culture	Ability and willingness to implement change when needs are identified

Appendix 2. Practical guidelines for error disclosure[72]

First Priorities	Address the patient's medical needs Inform and involve all key individuals, including the attending physician If adverse event was equipment-related, sequester this for later investigation
Preparing to Disclose	Gather information from all involved clinicians. Use the "ask-tell-ask" method for collaborative communication Does the adverse event meet threshold for disclosure? Determine who should be present for disclosure, including attending physician, risk management, and support persons for the patient and family Agree on core information to be disclosed, and decide who will lead the conversation
The Conversation	Apply the Golden Rule Set an agenda for the meeting Apologize when appropriate Explain the plan of care going forward Assess whether existing clinical relationships are viable, and whether second opinions or transition to alternative providers are indicated Assure the patient the event will be thoroughly investigated, and that they will be apprised of all facts as they become known Acknowledge that questions about financial compensation are appropriate and legitimate Offer support services—chaplains, social workers, patient advocates Remember that disclosure may not be greeted with thanks or forgiveness
Documentation and Follow-up	Debrief with a post-conversation huddle Designate who will follow up with patient Assess emotional and psychological needs of clinicians impacted by the event Document the conversation in the medical record If a disclosure "coach" was used, do not document any coaching interventions

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Study Questions Volume 39 Lesson 40

1. An example of a human factor contributing to medical error is
   a. lack of standardized perioperative care pathways
   b. communication lapses during patient handoffs
   c. excessive reliance on short-term memory
   d. excessive workload

2. An example of a systems factor contributing to medical error is
   a. the surgeon slips and cauterizes bowel during a lymph node dissection
   b. a physician in clinic has multiple charts open in the electronic medical record, and orders antibiotics for the wrong patient
   c. a resident orders an angiotensin-converting enzyme inhibitor to control a pregnant patient's hypertension, unaware of the teratogenic side effects
   d. an intern does not write down the plan for Mr. Smith and forgets to order a blood transfusion, resulting in an emergent intensive care unit transfer

3. Interpersonal barriers to disclosing medical error include
   a. fear of medicolegal action
   b. fear of disciplinary action
   c. lack of training in how to disclose error effectively
   d. a sense of personal and professional failure

4. A surgeon performs a nephrectomy on the wrong side. Immediately following the discovery of the error he discusses it with his chairman, who reminds him to file a report through the institutional patient safety reporting system. That evening he discusses the event with his wife as well as with one of his colleagues. The case is discussed at morbidity and mortality conference. A resident refers to the case during a grand rounds conference on medical errors. Six months later the patient files a lawsuit. The only discussion about this case that is confidential and considered not discoverable is
   a. his discussion with his chairman and other colleagues
   b. his discussion with his wife
   c. morbidity and mortality conference
   d. grand rounds conference

5. The "second victim" of medical error refers to
   a. the reporter of medical error who fears retaliatory action
   b. families and friends of patients who suffered harm from medical error
   c. the physician caring for a patient who suffered harm from medical error
   d. the second patient to suffer a repeat error due to failure to report and analyze the first occurrence of a similar error

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