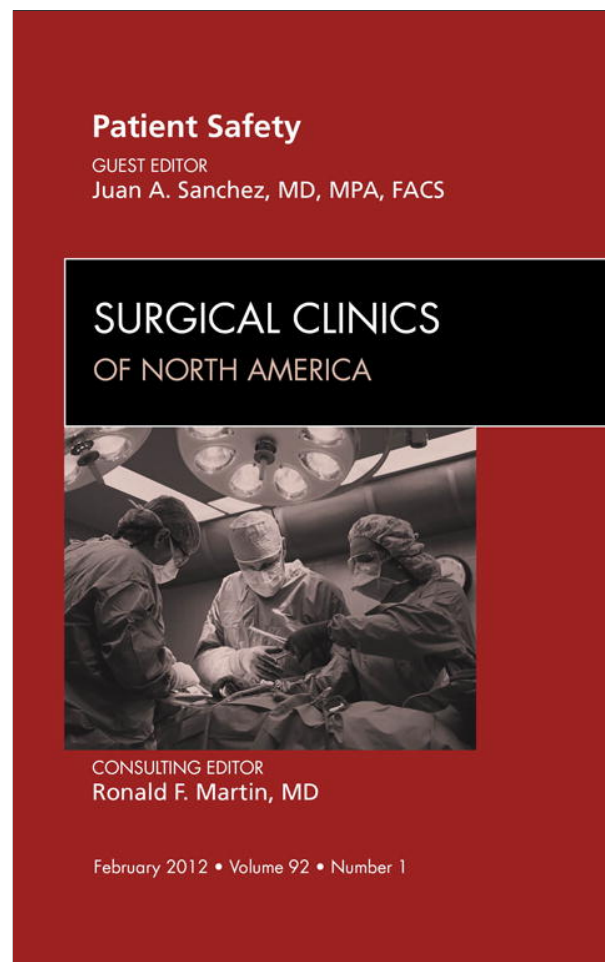




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Open Disclosure of Adverse Events: Transparency and Safety in Health Care

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KEYWORDS

- Disclosure • Transparency • Patient safety • Ethics
- Professional • Legal

In the Veterans Health Administration (VHA), adverse events are defined as untoward incidents, iatrogenic injuries, or other adverse occurrences resulting in patient harm directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other medical facility. The phrase disclosure of adverse events refers to the forthright and empathetic discussion of clinically significant facts between providers or administrators and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future.¹

Disclosure of adverse events can be counterintuitive to physicians, especially if there was no suspicion of any problem in health care delivery perceived by the patient. Why invite trouble? In the past, the practice of medicine supported by professional medical societies and health care organizations advised physicians to remain silent on these matters or limit discussions to their malpractice defense attorneys and hospital administration when things went wrong. Health care organizations, spurred on by the acrimonious relationship between the legal and medical professions, frequently denied and defended the occurrence of an adverse event.

A consequence of this institutionalized secrecy was patient confusion and fear about what was happening and what the future held for their health and well-being. At a time when a patient and family needed their health care providers the most, they were adversaries. Patients and their families resorted to legal means when left with more questions than answers and a growing suspicion that the physician was not telling the whole story. The American College of Surgeons Closed Claim Study

The authors have nothing to disclose.

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Surg Clin N Am 92 (2012) 163–177

doi:[10.1016/j.suc.2011.11.001](https://doi.org/10.1016/j.suc.2011.11.001)

0039-6109/12/\$ – see front matter Published by Elsevier Inc.

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showed a significant association between tort claims and the lack of transparency between surgeons and their patients.² Reducing the patient and provider adverse event experience to a lawsuit exacerbates the unmet expectations of both parties and, in some cases, furthers harmful consequences from health care.

This article rejects the old paradigm of silence and secrecy following an adverse event and makes the case for open disclosure of adverse events to patients and their families as part of the routine practice of medicine. Adverse event disclosure to patients should be part of the expected course of managing a health system, without exception. We establish the ethical, professional, and legal basis for disclosure and share our perspectives on how to operationalize disclosure in the practice of medicine and in the standard operations of managing a medical center in the VHA.

WHY DISCLOSE ADVERSE EVENTS?

In 1987, the Chief of Staff of the Lexington Veterans Affairs Medical Center (VAMC) and the Staff Attorney for the US Department of Veterans Affairs (VA) Regional Counsel Office in Lexington, Kentucky, discovered that a patient had succumbed from a mistake made in the medical care provided in their facility. They made the decision to disclose what happened to the family, who had no knowledge of this mistake in care, because it was the right thing to do. At that moment, the humanistic risk management program, called the Lexington Model, was born.^{a,3}

Steve Kraman and Ginny Hamm, who had the courage and vision to see the wisdom of honesty and transparency as the most effective means of managing adverse events in health care, started the informal practice of disclosure with patients. In Lexington, when an adverse event occurred, there would be an early case review, full disclosure in a face-to-face meeting with the patient and/or family, an authentic apology with acceptance of full responsibility by the organization for what happened, an offer of fair compensation, and sharing of an action plan to prevent a similar occurrence in the future. Over the following 23 years, Lexington continued to have tort claims (Lexington ranked in the top quartile of tort claims among VAMCs), but they also ranked in the bottom quartile for litigation costs.⁴

The humanistic risk management approach envisioned by the Lexington VAMC was not driven by a rationale that open disclosure in health care prevents lawsuits, but rather the desire to facilitate just outcomes for patients and providers. Just outcomes as a moral good in this context emanate from the ethical, professional, and legal duties health care professionals owe to their patients.

THE ETHICAL OBLIGATION FOR DISCLOSURE

In *Principles of Biomedical Ethics*, Beauchamp and Childress⁵ outline 4 principles of bioethics that offer a common morality approach to health care ethics by eliminating contentious or marginally relevant metaphysical concepts and distilling the basic common moral framework held by persons with differing belief systems. This approach to health care ethics, also known as principlism, establishes specific duties

^a In 1987, after losing 2 malpractice judgments totaling \$1.5 million, senior management of the Lexington VAMC decided to become more proactive with investigating clinical cases with the potential for tort claims and be better prepared for defending against those claims. In the course of investigation, there were several cases in which negligent care had been delivered that was unknown to the patient's next of kin. The Lexington Risk Management team was confronted with an ethical dilemma that they resolved by meeting with the family to inform them what had happened: that negligent care contributed to the death of their loved one. The Lexington Model of humanistic risk management was born.

owed by medical providers and, by negative implication, bestows associated rights on patients. Arguably, the 4 principles of autonomy, nonmaleficence, beneficence, and justice form the foundation for all generally accepted ethical norms in health care and apply to all patients and members of the medical profession.⁵

The duty to respect patients' rights to direct the course of their own moral lives and make medical decisions is encompassed in the principle of autonomy. The duty to provide benefits that are reasonable in relation to the risks of medical treatment and the correlated rights of patients to have their medical providers act for their benefit is the principle of beneficence. The principle of nonmaleficence is described as a patient's right to be free from avoidable harm at the hands of the medical provider and the duty of the provider to avoid causing harm. The duty to be fair in the distribution of benefits and risks is the justice principle, which corresponds with the patient's right to receive a fair and equitable share of benefits and burdens.

Numerous professional societies codify medical providers' ethical requirement to disclose adverse events to patients in accordance with the common morality approach of the 4 principles, including the American College of Physicians' Ethics and Human Rights Committee,⁶ the International Council of Nursing,⁷ and the American Medical Association (AMA).⁸ Of particular note is the influential moral imperative contained in the AMA Code of Medical Ethics. The code states that "It is a fundamental ethical requirement that a physician should at all time deal honestly and openly with patients... Only through full disclosure is a patient able to make informed decisions regarding future medical care... Concern regarding legal liability that might result following truthful disclosure should not affect the physician's honesty with a patient."⁸

The principle of autonomy is contained in the AMA's ethics code when it counsels medical professionals to provide truthful information about patient care in order for patients to make future medical decisions. The principles of beneficence and justice are shown by the requirement to put patients' interests before their own concern for legal liability, thus ensuring that patients do not shoulder the burden of the adverse events alone. The duty of nonmaleficence applies even after the harm caused by the adverse event, because the provider could exacerbate harm by not being honest with the patient about what happened.

Our experience in Lexington VAMC with disclosure of adverse events to patients or their personal representatives is not only consistent with these ethical norms, it is also informed by our organizational ethics, which are derived from our commitment to care for veterans. The VHA as a health care provider has a fiduciary responsibility to its patients, employees, affiliates, and the communities in which it exists. The organizational core values of integrity, commitment, advocacy, respect, and excellence guide our employees and institutional leaders. Honestly discussing the difficult truth that an adverse event has occurred shows respect for the patient and a commitment to improving care.

PROFESSIONAL DUTY

Similar to the VHA's institutional responsibility to its patients by virtue of its position, health care providers have a fiduciary duty to disclose adverse events to their patients. This duty is inherent in the health care profession's contract with society. The health care professional has expert knowledge, training, and technical skills that the public must trust will be applied to enhance their health and well-being. Information asymmetry between the medical profession and the community places the medical provider in the role of the patient's fiduciary. Trust is a critical element to the success of the therapeutic relationship.

The high degree of privilege that society has bestowed on the health profession carries the expectation that the profession will be self-regulating with standards established to benefit patients. The health profession has been permitted the latitude to regulate the practice of medicine by defining education requirements, granting or revoking licenses to practice, and forming medical specialty societies to establish standards of care. The act of professionalism is to uphold the standards that are defined by the profession.

Professional standards include being truthful and trustworthy, treating all patients respectfully and without bias, and avoiding conflicts of interest. Michael Woods,⁹ a Colorado General Surgeon, defines professionalism as commitment, caring, and competence. In his words, “acting in a professional manner includes offering an apology when there has been an unexpected outcome... Apology is about the provider showing respect, empathy, and a commitment to patient satisfaction.”⁹ Clinical and administrative staff members have a professional duty to protect the welfare of patients by preserving and supporting appropriate professional behavior. Therefore, disclosure of adverse events to patients should be a routine part of patient care.

LEGAL AND REGULATORY MANDATE

Any breach of professional standards of care that result in patient harm, including the failure to disclose, qualifies for legal remediation. Patients have a fundamental right to prevent unwanted bodily interference. This concept, called the doctrine of informed consent, grants a qualified legal right to competent patients to direct what happens to their bodies. In turn, health care professionals have a legal right to collect fees for services they provide and a legal obligation to refrain from nonconsensual medical contact with patients. To ensure that the contact between the parties is consensual, medical providers have an affirmative duty to involve patients in a process of shared decision making for all medical treatments and procedures. Providers also have an affirmative duty to inform patients of all relevant facts about their treatment so that they can make decisions that are consistent with patients wishes and values.

In the case of an unexpected outcome, such as an adverse event, the patient has the right to be informed about the event with its implications to current and future health. Without full and open disclosure, patients may be unable to make informed consensual decisions, including whether or not they wish to continue treatment with their providers. Withholding information or misleading patients about relevant medical information violates patients’ legal right to bodily integrity and may even breach contractual duties between the parties.

The legal and regulatory duty to disclose any aspect of medical care that affects a patient’s health and well-being has been mandated by several states, accreditation bodies, licensing boards, federal regulations, and national policies.¹⁰ The Joint Commission, which is funded to accredit more than 80% of health care organizations, expresses this rule through the following language: “The responsible licensed independent practitioner or his or her designee clearly explains the outcome of any treatment or procedure to the patient and, when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes.”¹¹ The VHA, which is the largest integrated health care system in the United States, issued a national directive establishing a specific mandate for full and open clinical, institutional, and large-scale disclosure for adverse events.¹

DISCLOSURE LINK TO PATIENT SAFETY

Ethical, professional, and legal duties that health care professionals owe to their patients after adverse events often overlap. When the question is framed as a conflict

of interest between patients' right to know and the providers' or institutions' desire to limit liability or reputational harm, there is a strong presumption in favor of open and honest disclosure.¹² Another argument for open disclosure of adverse events is the advancement of patient safety goals.

Those who choose to draw a line between patient safety and risk management claim that patient safety is focused on systems improvements and learning and that risk management is focused on individual accountability including tort claim management. However, such linear, one-dimensional thinking is not the reality of a modern health care system. Risk management and patient safety are both focused on the risk to the safety and well-being of patients in health care delivery. The 2 terms are linguistically interchangeable in patient-centered organizations and, in the reality of health system operations, they must be fully integrated for optimal patient care.

Patient safety should not be limited to an engineering problem focused only on systems solutions. When a patient has suffered injury as a result of health care, the injured patient's needs are paramount. The patient safety zealots have often preached the mantra of systems while leaving the injured patient's needs in the background. Carol Levine¹³ addressed this problem: "Medical error is more than an engineering problem amenable to technological and systems solutions. Policies put in place to reduce medical error also must address the financial and emotional needs of those who suffer great and often permanent harm."

The patient safety movement in the United States gained momentum with the seminal Institute of Medicine Report, *To Err is Human*.¹⁴ The message from this report was that humans make mistakes and, to make the health care world safer, the focus must be on solutions to improve the underlying conditions that lead competent professionals to make those mistakes. Although this is true, one important element in that model is missing: the injured patient. While focusing on the future in harm prevention, health care systems must not forget the present in addressing the needs of the injured patient. Nancy Berlinger,¹⁵ Deputy Director of Religious Studies at the Hastings Center, makes this point: "If the response to error is 'everyone makes mistakes'... this response is about the person who made the mistake, not about the persons who may be harmed by the mistake, and it utterly fails to address the aftermath of harmful mistakes."

DISCLOSURE LINKED TO SYSTEMS IMPROVEMENTS

Marcus and colleagues¹⁶ queried patients who suffered harm from health care and concluded that patients expressed 3 significant needs from their health care provider after an event. Patients reported a desire for a full disclosure of what happened, a sincere apology, and assurance that actions were being implemented to prevent a similar occurrence with another patient in the future. Another study by Mazor¹⁷ found that 88% of patients wanted an apology from their physicians, and 99% wanted to know that something was being done to prevent a similar adverse event in the future. Boothman¹⁸ reports the benefits of integrating the Risk Management and Patient Safety programs at the University of Michigan with evidence that disclosure invariably becomes a component of broad systems improvement and is closely linked to improving patient safety. A robust risk management program active in the open disclosure of adverse events will be closely linked to an active patient safety program.¹⁹ Patients who have been harmed demand systems improvements to prevent future harm to other patients.

DISCLOSURE: THE INTEGRATED TEAM APPROACH

Our experience in Lexington confirms that transparency and honesty in relationships with patients create opportunities for learning that lead to systems improvements in

health care organizations. In the VHA, there are 3 categories of disclosure: clinical disclosure, institutional disclosure, and large-scale disclosure. The category of disclosure varies with the entity communicating the message, the reason for communicating the message, and the number of patients involved. Disclosures can be on a continuum as more information is learned about the adverse event.

Clinical disclosure exists within the framework of the provider-patient treatment relationship. It is information communicated by the treatment team, in the routine course of health care, for the purpose of providing relevant medical information to patients.^b Institutional disclosure exists within the framework of the institution-veteran relationship, which is fundamental to the social contract the US Government has with the public to provide appropriate health care to veterans in exchange for service to their country. Serious harm or death from adverse events triggers the duty to conduct an institutional-level disclosure. Leaders with authority to speak on behalf of the organization formally accept responsibility for the patient harm, for the purpose of ameliorating the harm and improving the quality of health care in the institution. Large-scale disclosure exists in the context of a public health threat triggered by an adverse event that injures more than 3 patients. Communication of adverse event information is managed at the national level of the organization by coordinating with local medical centers to ensure rapid dissemination of information and remedial measures across the VHA (**Fig. 1**).

To honor our commitment to open disclosure and the legacy of the Lexington Model, we began to develop standardized disclosure practices and implement an integrated Risk Management and Patient Safety program in the Lexington VAMC in 2009. Our program was premised on the assumption that open disclosure is the natural derivative of our robust approach to ethics-based risk management and systems-based patient safety improvement. From November 2009 to August 2011 we conducted institutional disclosures with 20 patients or their personal representatives at the Lexington VAMC. Seventeen of those cases underwent a rigorous root cause analysis resulting in a multitude of systems improvements in the structure and processes of care.

When an incident occurs, it is reported into our electronic patient incident reporting system (ePIR).^c A report can be entered in a few minutes with a simple click of an ePIR icon present on the desktop of all computers in the medical center. ePIR safety report categories are linked to the National Center for Patient Safety database.²⁰ Each report is reviewed and processed by the Patient Safety Manager (PSM) who communicates with the Chief of Performance Improvement (CPI) and the Risk Manager (RM). Should any member of our PSM/RM/CPI safety-risk team receive a report of an incident via informal means such as an e-mail, phone call, or face-to-face conversation, we ask the reporter to enter a report into ePIR. Our ePIR database serves as a final common pathway for incident reporting, creating a composite of all reported events, which allows our office to track events and assess for incidence and trends that may trigger a health care failure mode and effect analysis. All ePIR reports are summarized daily with senior leadership in a morning report as the first order of business.

^b Clinical disclosure is indicated for adverse events that are expected to have a clinical effect on the patient that is perceptible to either the patient or the health care team; necessitate a change in the patient's care; have a known risk of serious future health consequences, even if the likelihood of that risk is extremely small; or require the provision of a treatment or procedure without the patient's consent.

^c ePIR (developed for VAMCs by B.R. Smith, Jesse Brown VA Medical Center, Chicago, IL). Currently ePIR is used in more than 50 VAMCs nationwide.

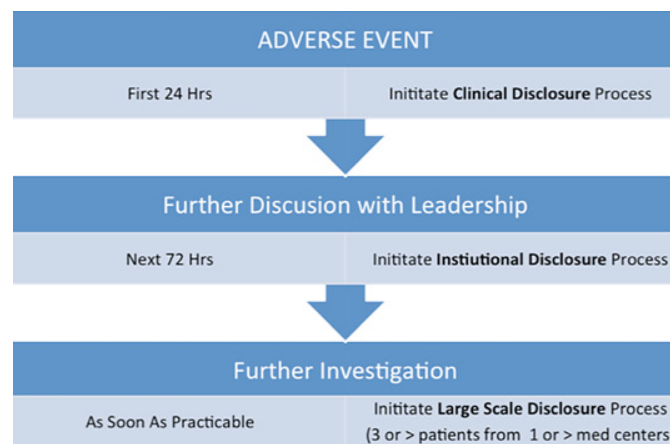


Fig. 1. Disclosure categories in the VHA.

When a report of an incident involves patient injury, our first concern is for the safety and well-being of our patient, and our second concern is to learn why it happened and how we can prevent it from happening again. Our team reviews the incident report and then activates pathways that may lead to disclosure, root cause analysis, or peer review (**Fig. 2**).

Disclosure and review can be a continuum of responses to an adverse event. The first step of the review is to check the veracity of the report and gather facts about the surrounding circumstances. The PSM requests the nurse manager or responsible physician to complete the report to document the clinical care of the patient and mitigation plans, if any had been implemented. After further initial investigation, the reporter or supervisor is invited to the Patient Safety Committee to discuss the case, where a recommendation is made to charter a root cause analysis or to embark on a rapid process improvement (RPI) action. RPIs are small process action teams that

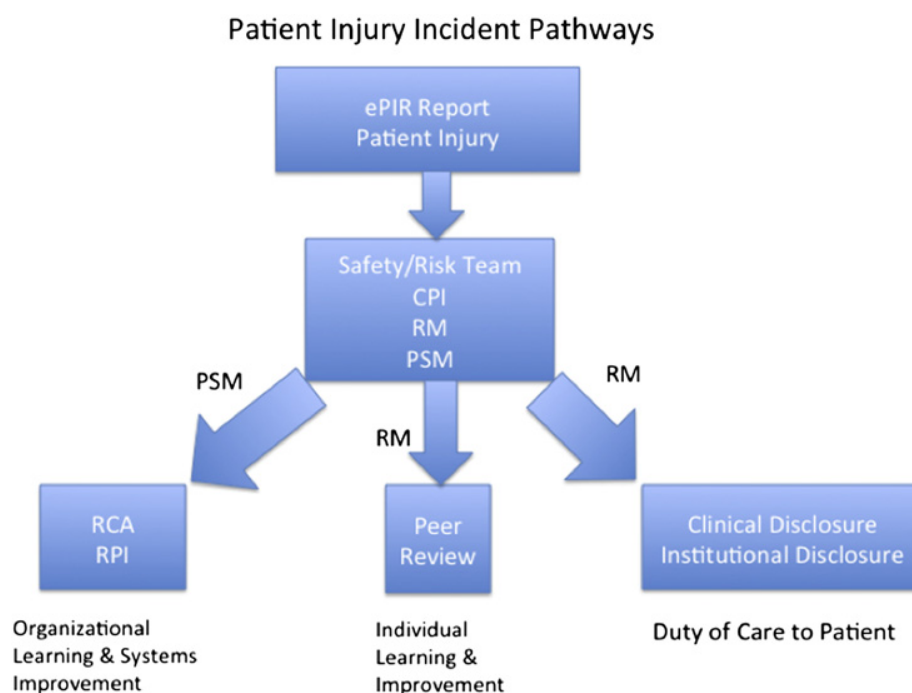


Fig. 2. Lexington integrated model for risk management and patient safety. RCA, root cause analysis; RPI, rapid process improvement.

conduct an intensive investigation and make recommendations to leadership for a mitigation plan in 1 or 2 meetings within 24 to 48 hours.

CLINICAL DISCLOSURE

The RM contacts the clinical team to inquire about the status of the patient and make an inquiry about whether a clinical disclosure had been done by the clinical team responsible for the patient. Clinical disclosures are an informal process for informing patients or their personal representatives of harmful adverse events related to the patient's care. Clinical disclosure is considered a normal activity in the course of medical practice in patient care and should be done within 24 hours of the incident, if possible. The VHA policy on adverse event disclosure requires a clinical disclosure to be documented in the patient's electronic medical record. Memorializing the clinical disclosure in a progress note is consistent with the VHA philosophy that clinical disclosure is like any other routine part of care and so should follow standard medical record documentation procedures.

INSTITUTIONAL DISCLOSURE

The RM convenes the medical center senior leadership who form the permanent Disclosure Team, the VHA staff attorney for the Regional Counsel Office, and any other necessary health care professionals, to discuss the appropriateness of an institutional disclosure. The Disclosure Team outlines the relevant information and identifies who should convey it to the patient. Institutional disclosures are a formal process of acknowledgment from the organization to patients or their personal representatives regarding harmful adverse events related to the patient's care. If the decision is to proceed, the RM office schedules an initial institutional disclosure meeting to be done within 72 hours of the incident, if possible. In most circumstances, it is difficult to ascertain the underlying cause of the incident without conducting further investigations. For this reason, institutional disclosure frequently requires a series of Institutional Disclosure Conferences (IDCs) or other personal contacts between the Disclosure Team and the patient to address the ongoing needs of the patient and family and to report the results of the investigation after it is completed (**Fig. 3**).

The IDC is conducted by the Chief of Staff, or designee, CPI, RM, and subject matter experts, such as the involved providers. Family members or friends may also attend at the discretion of the patient. If the patient chooses to have an attorney present, the VHA staff attorney for the Regional Counsel will also join the meeting. In the IDC meeting, the Disclosure Team divulges what happened to the extent that it is known, makes a sincere and empathic apology, and accepts responsibility on behalf of the medical center for what happened. The CPI provides a brief explanation of how the event will be prevented in the future or informs the patient that an investigation will be conducted for the purpose of preventing a future recurrence of a similar event.

The patient, family members, or friends affected by the adverse event are given an opportunity to express their feelings and thoughts about the experience and are encouraged to ask questions. Patient insight into the event commonly yields essential information about the underlying system issues. The RM advises patients of their rights to a second medical opinion, private legal representation, and to seek a remedy, if appropriate, by filing a federal tort and/or disability claim. After the IDC, the facility revenue manager is advised regarding the cancellation or hold on first-party and third-party billing for the relevant episode of care until the investigation has been

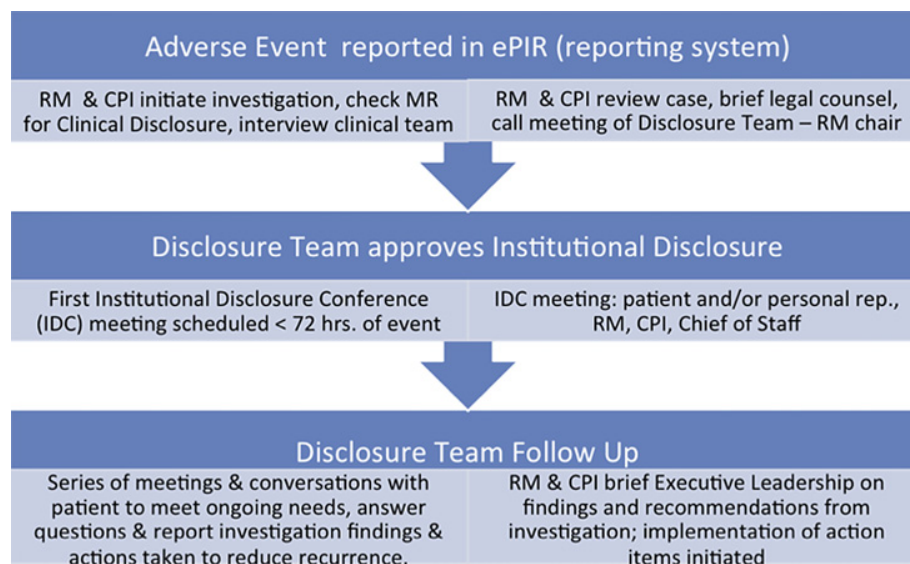


Fig. 3. Lexington model disclosure program from adverse event report to institutional disclosure.

completed. This process is described in the Lexington policy for disclosure of adverse events.²¹

After the initial IDC meeting, an investigation is launched and is usually completed in 4 to 6 weeks. The findings and recommendations from this process will be shared with the patient and family in a future meeting. In the meantime, interim measures are often taken to reduce the risk of recurrence and to mitigate further harm. The patient or personal representative is provided with contact information for members of the Disclosure Team and encouraged to call with any questions or concerns. All IDC conversations are documented in a special administrative institutional disclosure note that becomes a part of the patient's medical record. Key elements of the IDC meeting are described in **Fig. 4**.

Institutional Disclosure Conference Providing for Patient & Family Needs	
Informational	Emotional/Psychological
• Disclosure of what happened to the extent known • Inform health implications & treatment options • Report findings & implemented actions from investigation • Arrangements for consultations (e.g. mental health, social worker, chaplain) • Notice of right to hire attorney • Notice of right to 2nd opinion • Process for compensation in VA – Federal Tort Claim Act – 38 USC 1151 Disability Claim • Cancellation of 1st and 3rd party billing for relevant episode of care and for ongoing care related to adverse event	• Listen to patient and family narrative • Full apology • Acceptance of responsibility • Expression of concern/remorse • Encourage the expression of feelings, perceptions, ideas re: adverse event • Offer for bereavement support

Fig. 4. IDC.

BARRIERS TO DISCLOSURE

Even with a robust integrated patient safety and risk management approach to disclosures, fear remains the major barrier for health care professionals to disclose adverse events. Institutional leaders and providers report fear of defending against a legal claim that is time consuming, embarrassing, and personally humiliating as a disincentive for disclosing information to a patient that might be used against the institution or provider.^{d,22,23} A particular concern for providers is the possibility that a settled claim or a plaintiff jury award could result in the physician being reported to the National Practitioner Data Bank (NPDB). Physicians fear the NPDB report because professional reputation is so critical to successful medical practice.^{e,24,25}

John Banja,²⁶ an ethicist from Emory University, asserts that rationalization and avoidance are psychological defenses to reduce distress and preserve self-esteem in the face of adverse events. Common rationalizations for not disclosing include that it will do more harm than good and that what really happened will never be known. Banja²⁶ argues that medical narcissism blocks disclosure because it emphasizes emotional distance from the patient, the need for clinician control, and an excessive focus on disease and treatment with inattention to the person. As a result, many physicians lack empathic communication skills because they have a strong need to control patients' thoughts, feelings, and decisions. Listening is a critical part of disclosure that is often not well developed among physicians. Banja²⁶ believes that physicians need training in empathic communication, and that senior administrators need training in managing disclosure from a patient-centered perspective.²⁶ The author (EJD), a practicing cardiovascular surgeon for 20 years, corroborates Banja's²⁶ observations from anecdotal experience and observations of colleagues in the hospital setting.

So, are the fears of health care professionals grounded in reality or are these myths perpetuated over time and passed from one generation to the next? Fear of a lawsuit is on the minds of clinicians when making medical decisions, but how much impact does it have? A survey of 2637 physicians and surgeons in the United States concluded that medical liability fears had a minimal impact on the physicians' willingness to disclose an error to the patient.²² Results from the same study were reviewed to see what conditions did affect error disclosure and it was determined that attitudes about error disclosure were dominated by the culture of the physicians more than the fear of being sued.²² In addition, malpractice premiums and awards consume a small percentage of the health economy. Less than 1% of patients who have suffered adverse events from substandard care (ie, negligent harm) have a successful claim against the provider. Most malpractice claims do not involve provider negligence, and most patients who were victims of negligent care never file a tort claim.²⁷

^d Wide variation existed regarding what information respondents would disclose. Of the respondents, 56% chose statements that mentioned the adverse event but not the error, whereas 42% would explicitly state that an error occurred. Some physicians disclosed little information: 19% would not volunteer any information about the error's cause, and 63% would not provide specific information about preventing future errors. Disclosure was affected by the nature of the error and physician specialty. Of the respondents, 51% who received the more apparent errors explicitly mentioned the error, compared with 32% who received the less apparent errors ($P<.001$); 58% of medical specialists explicitly mentioned the error, compared with 19% of surgical specialists ($P<.001$). Respondents disclosed more information if they had positive disclosure attitudes, thought they were responsible for the error, had prior positive disclosure experiences, and were Canadian.

^e Although participants knew they should report errors associated with serious adverse events, both physicians and nurses agreed that reporting was intended to change practice and policy to promote patient safety.

THE COOPERATION CLAUSE OF EMPLOYMENT AND INSURANCE CONTRACTS

A common concern among physicians who do not have protection under the Federal Tort Claim Act is the risk of losing malpractice insurance coverage if an adverse event is disclosed to a patient.^{f,28} The fear comes from the possible interpretation that a disclosure is an admission of wrongdoing that could interfere with the insurer's defense against the plaintiff's claim. Proponents of the deny-and-defend paradigm may view full disclosure of an adverse event as a violation of the insured party's (MD) obligation to cooperate with the insurer and not collude with the injured party. Any contractual provision prohibiting truthful communications with patients about relevant health care issues is clearly against public policy and would be difficult to enforce.^{9,29} In contrast, it is unambiguous that collusion with an insurer to deceive patients is unlawful. When faced with a cooperation clause in an insurance policy, a physician could make a strong argument for a moral obligation to disclose an adverse event.

An employer, such as the VHA, does have the right to require employee providers to cooperate with institutional disclosure policies. Employer rights are qualified by the provider's duty to the patient and ability to practice medicine within the scope of his authority. An employer does not have the right to force or coerce a provider to refrain from a clinical disclosure against the weight of the provider's independent medical judgment about the patient's best interests. The provider's judgment would be measured against the norms established by the profession.

The plausibility of a cooperation clause becoming a deterrent to open disclosure is diminished when compared with the impact of a perceived cover-up. Discovery of a concealed adverse event would likely be far more costly to an insurance company or institution in terms of reputational harm and reduced ability to prevail in court than the settlement of a claim resulting from open and honest disclosure done in a timely fashion.

Behavioral change that embraces adverse event disclosure might only be achievable on a comprehensive organizational level. Such organizational change would be predicated on creating a supportive environment for physicians when their patients sustain adverse events and offering them training in empathic communication skills with strategies for effective disclosure experiences for patients and families. Our Disclosure Team in Lexington supports physicians and nurses whose patients have experienced adverse events, including our presence in clinical disclosure meetings when requested. These meetings can be the most difficult conversations a clinician will ever experience in practice.

REMOVING BARRIERS

A proactive method to address the fear of adverse event disclosure that permeates most health care institutions is to break the code of silence by standardizing the

^f Government liability for a tort is limited by the sovereign immunity doctrine. To preserve the Government's ability to function, which is for the greater good of the public writ large, citizens are prohibited from suing the Government and its employees. An exception to the doctrine applies in cases in which the Government has explicitly or implicitly consented to be sued. The Federal Tort Claim Act (FTCA) explicitly authorizes tort claims, based on state law, to be brought against the Government for tortious conduct against private citizens. This exception allows patients to bring limited medical negligence claims against the Government for care rendered by the VA as health care provider, but shields all employees from being sued if they are acting within the scope of their employment.

⁹ In *Ritter*, the Supreme Court ruled that any insurance policy, "the tendency of which is to endanger the public interests or injuriously affect the public good, or which is subversive of sound morality, ought never to receive the sanction of a court of justice or be made the foundation of its judgment."

policies, procedures, and practice of disclosures and raising the expectation for compliance. The early inspirational work of Kraman and Hamm informed national VHA policy in the open disclosure of adverse events culminating in a national directive issued in January 2008,³⁰ but efforts to operationalize the policy have been inconsistent in facilities across the VHA.

Disclosure practice in Lexington continued in an informal manner with less notoriety in the aftermath of the retirement of Kraman (2003) and Hamm (2009) from the Lexington VAMC. The authors have been managing the Lexington Open Disclosure Program since November 2009. In that 21-month period, 20 institutional disclosures have been conducted. Most of these disclosure cases highlighted significant systems vulnerabilities requiring root cause analysis teams in 17 of the 20 cases, which led to a multitude of improvements in patient safety. However, only 6 clinical disclosures could be documented in the medical records of these patients. Four tort claims were filed and all settled for amounts ranging from \$2500 (minor wrong patient procedure) to \$750,000 (serious injury or death), respectively. One patient filed a federal disability claim. Of the 17 surviving patients, all continue to seek their health care needs at the Lexington VAMC, and many of these patients remain in contact with our office and call if they need help with issues related to accessing services in the medical center.

During that same time period, medical center policies on adverse event disclosure, quality improvement, patient safety, and ethics-based risk management were drafted and implemented. The disclosure practice was formalized, monitored for performance improvement opportunities, and refined based on stakeholder feedback. In June of 2011, education for staff on adverse event policy and procedure was initiated for all employees starting with critical services, defined by tort claim data. The goal of behavioral change that supports the standardization of disclosure of adverse events to patients and their families as part of the routine practice of medicine has moved to a national level.

The authors have developed an Open Disclosure Training Program (ODTP). The program is funded by a Systems Improvement Capability Grant^{h,31} from the VHA to develop a standardized, replicable method for teaching clinicians and administrators how to deliver a disclosure message explaining adverse events or medical mistakes to patients and families. The program uses an integrated structure of classroom instruction with film vignettes depicting health care provider interactions with patients and other providers and disclosure simulations with actors.

The target audience for the program includes physicians, nurses, allied health personnel, health profession students, VHA attorneys, and health administrators. The purpose of this training program is to establish a consistent, high-quality disclosure experience for patients and families in the VHA. We plan to model disclosure practice for adverse events from medical care including events caused by mistakes in the delivery of care. This training program will be offered to the Lexington VAMC and be exportable to other health care institutions. Improvements in patient outcomes of care and provider job satisfaction will be achieved through the implementation of the ODTP. By eliminating waste, improving underlying systems, increasing teamwork coordination, and honoring our ethical duty to disclose, we will enhance the delivery of ethics-based, patient-centered health care.

^h The Lexington VAMC is the recipient of a 3-year Systems Improvement Capability Grant funded by the VHA from 2010 to 2012. A major focus of the grant is on the development of an ODTP based on experiential learning that will culminate in a 2-day workshop of didactics, facilitated interactive dialogue, training films produced by the ODTP team of clinical scenarios to stimulate dialogue on various aspects of disclosure, and simulations of disclosure by attendees with professional actors facilitated by faculty.

SUMMARY

Inspired by the pioneering work of the original Lexington Model, and compelled by our ethical, professional, and legal duties to disclose, this article outlines an enhanced integrated team approach to the Open Disclosure Program in Lexington. From its inception, the ultimate goal of this program was to seek and achieve just outcomes for patients and providers, which remains the goal of our program today. The value of an integrated approach to patient-centered risk management and patient safety is shown by our success in meeting patient and organizational expectations to improve care after an adverse event. Further empirical study is needed to validate our initial observations of the positive organizational impact from standardization of our integrated disclosure practices.

We conclude from our experience thus far that, while focusing on future harm prevention, the present needs of the injured patient must not be neglected. A just outcome requires provider support from the health care institution when an adverse event occurs, improvement of the underlying conditions to enhance the safety of care, an opportunity of forgiveness from the patient for harm caused by the adverse event, and fair compensation. By rejecting the old paradigm of silence and secrecy

Disclosure to a surgical patient

WS, a 70-year-old man, underwent a low anterior resection for carcinoma of the sigmoid colon via open laparotomy. The procedure was complicated by pelvic bleeding, which was controlled surgically and required a 2-unit transfusion of packed red blood cells. The patient did well after surgery for the first 24 hours. On the first postoperative day, a plain film of the abdomen revealed what appeared to be a 4×4 sponge in the pelvis as reported by a radiologist. The surgeon reviewed the film and concurred with this finding. He informed the RM and planned a meeting with the patient and his family as soon as it could be arranged.

The surgeon and RM met with the patient and family at the bedside on the medical-surgical unit. He sat down on a chair at the bedside and calmly explained the radiographic finding. He advised WS to undergo reoperation for removal of the sponge because of the long-term risk of health consequences for leaving a sponge in the abdominal cavity, such as abdominal abscess and bowel obstruction. He apologized and took responsibility for what happened and mentioned that a team was being organized to investigate this case. The patient and his wife were alarmed and questioned how a sponge could be left in the abdomen but accepted the surgeon's recommendation. Later that afternoon, WS underwent an exploratory laparotomy, and the sponge was removed. He did well after surgery and was discharged home in 5 days.

Senior leadership met with the Disclosure Team 24 hours after the event and granted approval to proceed with institutional disclosure, which was initiated 24 hours later. Leadership also approved the cancellation of first-party and third-party billing for services rendered during the current hospitalization. The Institutional disclosure conference meeting was conducted by the Associate Chief of Staff and the Risk Manager with WS, his wife, and their daughter. On behalf of the medical center, the Disclosure Team explained what happened and offered a full apology with acceptance of responsibility. They affirmed the patient's right to a second medical opinion and to hire an attorney. They advised the patient of his right to pursue a legal remedy if he wished via federal tort claim and/or disability claim and would provide the forms for each. The patient was informed that all first-party and third-party billing for services during his present hospitalization were canceled.

WS continued to seek his health care from the same medical center with which his primary care provider had an affiliation. He called the RM with a question about his medical bill and also asked for her help to obtain an appointment in the Ophthalmology Clinic. In a follow-up meeting 6 weeks later, the Disclosure Team reported the findings and recommendations from the investigative team. Several measures were being implemented to reduce the likelihood of a retained surgical sponge in another patient in the future.

following an adverse event and making open disclosure of adverse events to patients and their families a part of the routine practice of medicine, real transparency can be promoted. Transparency is the foundation for trust between patient and provider and is also necessary for organizational learning, which is the basis for improving the safety of health care organizations for the patients they serve.

REFERENCES

1. VHA Directive 2008-002. Disclosure of adverse events to patients. (January 18, 2008). Available at: http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1637. Accessed July 27, 2011.
2. Griffin FD. The impact of transparency on patient safety and liability. *Bull Am Coll Surg* 2008;93(3):19–23.
3. Kraman S, Hamm G. Risk management: extreme honesty may be the best policy. *Ann Intern Med* 1999;131(12):963–7.
4. Hamm G, Kraman S. New standards, new dilemmas – reflections on managing medical mistakes. *Bioethics Forum* 2001;17(2):19–25.
5. Beauchamp T, Childress J. *Principles of biomedical ethics*. New York: Oxford University Press; 2001.
6. American College of Physicians. Must you disclose mistakes made by other physicians? Case study by ACP Ethics and Human Rights Committee and Professionalism. 2003. Available at: <http://www.acponline.org/journals/news/nov03/mistakes.htm>. Accessed July 15, 2011.
7. Johnstone MJ, Kanitsaki O. The ethics and practical importance of defining, distinguishing and disclosing nursing errors: a discussion paper. *Int J Nurs Stud* 2006;43:367–76.
8. Council on Ethical and Judicial Affairs. *Code of medical ethics: current opinions with annotations*. 2002-3 edition. Chicago: AMA Press; 2002. p. 217–8.
9. Woods M. *Healing words – the power of apology in medicine*. Oak Park (IL): Doctors in Touch; 2004. p. 16.
10. Sage W, Zivin J, Chase N. Bridging the relational-regulatory gap. *Vanderbilt Legal Review* 2006;59:1263.
11. Joint Commission. *Comprehensive Accreditation Manual for Hospitals*. 2011.
12. Banja J. *Medical errors and medical narcissism*. Sudbury (MD): Jones and Bartlett; 2005.
13. Levine C. Life but no limb: the aftermath of medical error. *Health Aff (Millwood)* 2002;21(4):237–41.
14. Kohn L, Corrigan J, Donaldson M. *To err is human: building a safer healthcare system*. Washington, DC: Institute of Medicine, National Academy Press; 2000.
15. Berlinger N. *After harm – medical error and the ethics of forgiveness*. Baltimore (MD): Johns Hopkins University Press; 2005.
16. Marcus L, Dorn B, McNulty E. *Renegotiating health care: resolving conflict to build collaboration*. 2nd edition. San Francisco (CA): Jossey-Bass; 2011.
17. Mazor K. The health plan members' views about disclosure of medical errors. *Ann Intern Med* 2004;140(6):409–18.
18. Boothman R. Medical justice: making the system work better for patients and doctors. Testimony before the United States Senate Committee on Health, Education, Labor and Pensions, June 22, 2006. Available at: <http://help.senate.gov/imo/media/doc/boothman.pdf>. Accessed December 12, 2011.
19. Boothman R. Integrating risk management activities into a patient safety program. *Clin Obstet Gynecol* 2010;53:576–85.

20. VA National Center for Patient Safety. Ann Arbor (MI). Available at: www.patientsafety.gov. Accessed July 15, 2011.
21. Lexington VA Medical Center. Available at: <http://vawww.lexington.med.va.gov/docs/memo.aspx>. Accessed August 3, 2011.
22. Gallagher TH, Waterman AD, Garbutt JM, et al. US and Canadian physicians' attitudes and experiences regarding disclosing errors to patients. *Arch Intern Med* 2006;166(15):1605–11.
23. Gallagher TH, Garbutt JM, Waterman AD, et al. Choosing your words carefully: how physicians would disclose harmful medical errors to patients. *Arch Intern Med* 2006;166(15):1585–93.
24. Jeffe DB, Dunagan WC, Garbutt J, et al. Using focus groups to understand physicians' and nurses' perspectives on error reporting in hospitals. *Jt Comm J Qual Saf* 2004;30(9):471–9.
25. Kaldjian LC, Jones EW, Rosenthal GE. Facilitating and impeding factors for physicians' error disclosure: a structured literature review. *Jt Comm J Qual Patient Saf* 2006;32(4):188–98.
26. Banja J. *Medical Errors and Medical Narcissism*. Sudbury (MA): Jones and Bartlett Publishers; 2005.
27. Studdert D, Mello M, Brennan T. Medical malpractice. *N Engl J Med* 2004;350(3):283–92 All2.
28. See *Recinto v U.S. Department of Veterans Affairs*, N.D.Cal. 4-28-2011 (2011).
29. *Ritter v Mutual Live Ins. Co.* (Supreme Court 1898), quoted in Dobbyn JF, 1996. p. 107.
30. Veterans Health Administration. Available at: http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1637. Accessed July 15, 2011.
31. Dunn E, Eaves-Leanos, McKinney K, et al. Re-engineering organizational learning to optimize veteran-centered care. Systems Improvement Capability Grant submission in August 2009 accessed on the Veterans Health Administration Systems Redesign. Available at: <https://srd.vssc.med.va.gov/Committee/si/ImprovementGrant/Pages/default-old.aspx>. Accessed December 12, 2011.