

# Disclosure of Harmful Medical Error to Patients: A Review With Recommendations for Pathologists

Yael K. Heher, MD, MPH, FRCPC\*†‡ and Suzanne M. Dintzis, MD, PhD\*†‡

**Abstract:** Harmful error is an infrequent but serious challenge in the pathology laboratory. Regulatory bodies and advocacy groups have mandated and encouraged disclosure of error to patients. Many pathologists are interested in participating in disclosure of harmful error but are ill-equipped to do so. This review of the literature with recommendations examines the current state of the patient safety movement and error disclosure as it pertains to pathology and provides a practical and explicit guide for pathologists for who, when, and how to disclose harmful pathology error to patients. The authors provide a definition of harmful pathology error, and the rationale and principles behind effective disclosure are discussed. The changing culture of medicine and its effect on pathology is examined including the trend towards increasing transparency and patient engagement. Related topics are addressed including the management of expected adverse events, barriers to disclosure, and additional resources for the implementation of disclosure programs in pathology.

**Key Words:** patient safety, error, disclosure, apology, pathology error, quality improvement

(*Adv Anat Pathol* 2018;25:124–130)

A surgeon calls with an urgent concern about a breast biopsy you signed out as benign, but the surgeon was expecting a malignant diagnosis. You review the patient slides and confirm they are in fact benign. To further investigate, you pull the blocks for comparison. Based on the differing tissue profiles and the grossing log, you discover that the histology laboratory mixed up the labels with another breast biopsy performed on the same date by a different surgeon. The case which you signed out as benign is in fact malignant. The case with which it was switched (actually benign) was signed out as malignant and that patient proceeded to an unnecessary lumpectomy, which was benign. The patient with breast cancer has received false reassurance, remains unaware of her diagnosis, and has had no further counseling or treatment.

How do you handle this? What do you tell the surgeon? What do you tell the patients?

## A CHANGING CULTURE: SAFETY, ENGAGEMENT, AND TRANSPARENCY

In 1999, the Institute of Medicine (IOM) published its landmark white paper, “To Err is Human: Building a Safer Health System.”<sup>1</sup> The report’s estimate of 99,000 annual

US patient deaths because of preventable error shook the medical establishment and set the modern patient safety movement in motion. A culture change ensued in health care, with a focus on systems science and human factors contributing to error, rather than on blame and punishment.<sup>2,3</sup> A subsequent modification to the “blame-free” patient safety model, known as the “Just Culture,” has since evolved and aims to understand and manage error through a balance of the systems approach and personal accountability.<sup>4</sup>

Many hospitals and physicians have embraced the safety movement, adopting practices that center on patient safety and quality improvement. Regulatory bodies such as the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), the Accreditation Councils on Graduate and Continuing Medical Education (ACGME), and physician organizations including the College of American Pathologists have pushed hospitals, physicians, and training programs to adopt quality and safety principles through mandates. Similarly, insurers and governmental payors have embraced payment models that advance safety culture goals and milestones.

Responding in part to concerns about safety, patients themselves have become increasingly involved in their own care—a movement known as “patient engagement.” The goals of this parallel movement include making care more consistent with the patient’s goals (patient centered). Proponents of increased engagement also argue care is more effective when patients are involved in decision making. The safety movement’s goals dovetail with increased patient engagement, and thus most health care organizations interested in safety have also embraced engagement. Online portals allow patients access to their test results, including pathology reports, and are the most widely adopted proof of increased engagement. Programs such as OpenNotes, which allow access to physician notes, may become widespread in the near future.<sup>5,6</sup> As engagement increases, inevitably so does transparency. Patients who have direct access to information are likely to be become more aware when errors occur.<sup>7</sup> Physicians are obliged to respond to these errors through disclosure and discussion.<sup>8</sup> The development of error disclosure skills is therefore a crucial and necessary next step for health care professionals, including the pathology community, in this era of safety, engagement, and transparency.<sup>9</sup>

## PATHOLOGY IN THE SAFETY ERA

In 2015, the IOM (now known as the National Academy of Medicine) published a follow-up to its 1999 report and for the first time put the field of pathology right in the middle of the safety culture. Entitled “Improving Diagnosis in Healthcare,” the 2015 report specifically called on pathologists to join the patient safety movement, assume a more prominent role as care providers, and collaborate more

From the \*Department of Pathology at Beth Israel Deaconess Medical Center; †Harvard Medical School; and ‡University of Washington Medical Center.

The authors have no funding or conflicts of interest to disclose. Reprints: Yael K. Heher, MD, MPH, FRCPC, Quality and Safety, Department of Pathology FN201, Beth Israel Deaconess Medical Center, 330 Brookline Avenue, Boston, MA 02215 (e-mail: ykheher@bidmc.harvard.edu).

Copyright © 2018 Wolters Kluwer Health, Inc. All rights reserved.

effectively with treating clinicians to make care safer.<sup>10</sup> The National Academy further called on pathologists to define and study sources of error in pathology, to communicate effectively with patients and clinicians, and to engage in error disclosure.

Despite these laudable goals, the practice of pathology presents unique challenges to the patient safety establishment and its goals of greater transparency, error disclosure, and systems improvement. The complexity of workflows in anatomic pathology creates sources of error that are unknown in other branches of medicine. Batch processing creates the possibility for multiple patients to be harmed by a single error, events that can overwhelm even the most motivated safety professional. To make matters worse, clinicians and patients alike often lack basic understanding about the functioning of anatomic pathology departments under normal circumstances. This lack of knowledge creates an additional barrier to error disclosure for pathologists, who must first explain standard operations before addressing deviation and error. Pathologists and pathology departments have often been left out of hospital safety departments, which are commonly run by clinicians who maintain direct relationships with patients. Pathologists themselves often lack the training, experience, and confidence necessary for effective discussions with patients. Finally, many of the payor reimbursement models tied to quality and safety have not included pathology, thus there is neither a reward nor a penalty to motivate pathology departments to embrace the movement. (It is notable that in 2019 this will change and Medicare will include pathology for the first time in its new Quality Payment Program).<sup>11</sup>

Despite these challenges, the potential benefits to pathology of embracing the safety movement are high, as are the potential risks of nonengagement. Isolation from the safety movement would put pathology in conflict with leading health care organizations like the National Academy and eventually will have both regulatory and financial repercussions. It seems likely that if pathology as a field embraces rather than shuns the safety movement, it will gain more authority to ensure that the goals and the supporting regulation and payment models are appropriately tailored to our unique specialty.

### DEFINING HARMFUL ERROR IN PATHOLOGY

Given its nature as a diagnostic field, error in pathology is typically diagnostic error. Any effort to understand, prevent, reduce, and disclose diagnostic error must first define that error. The Institute of Medicine/National Academy of Medicine defines diagnostic error as the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient.<sup>10</sup> By making ineffective communication of a diagnosis synonymous with a diagnostic error itself, the IOM made it clear that in its view the new care model must extend well beyond academic accuracy to include the patient's understanding of the diagnosis.

Despite this call to action from the IOM, a major limitation in understanding error is the lack of a standardized and reproducible error classification system. Definitions of error are variable and overlapping and somewhat reminiscent of the 17th century "Celestial Emporium of Benevolent Knowledge," Jorge Luis Borges's fictitious taxonomy of animals.<sup>12</sup> Error frameworks may be based in different contexts including research, quality control, ethics, insurance, legislative, and regulatory.<sup>13</sup> This variability has encumbered the study of medical error in general. Within

the anatomic pathology literature, attempts have been made to categorize error and document its frequency, though the structure again varies based on goals.<sup>14-17</sup> Some frameworks are based on error impact (harmful, nonharmful, near-miss, unsafe condition or major, minor), prevention (preventable, nonpreventable), and root causes (human factors vs. systems issues). The characterization of error based on the phase in which the error occurred (preanalytic, analytic, and post-analytic) is particularly useful for systems improvement activities in pathology.

In other areas of medicine, the "standard of care" is used to help differentiate negligence from error. This categorization is not particularly helpful for the purposes of error disclosure, in part because little if any anatomic pathology procedures are specified by guidelines or published standards of care. In addition, the term is fraught by its use in the medical-legal context, which is fundamentally different than the broader consideration of error and disclosure.

Some errors are less harmful than others, and some may be characterized as nonharmful error or near-misses. Two gastrointestinal biopsies may be mislabeled, for example, but by chance they are both colonic adenomas. The handling of these errors is more controversial and literature on the topic as it pertains to pathology does not exist. Error can also be distinguished from adverse events, which are rare but expected complications, such as post-operative wound infections. In adverse events, the standard of care may have been met but the outcome is still unfavorable. In practical terms, however, this distinction can be challenging and patients in particular do not recognize the distinction. Consider the case of a biopsy reviewed at an outside institution in which deeper levels ordered by the consultant reveal a new, previously undiagnosed cancer not present on the original levels examined. In some cases this may represent error, in others simply an adverse event.

Notably, the IOM/NAM's definition of error focuses on diagnostic (analytic) and communication (postanalytic) error. Unmentioned are preanalytic errors, such as the one in the vignette above, which are the most frequently encountered error in pathology.<sup>17</sup> Most of the harmful events in the pre-analytic phase occur before the pathologist becomes involved with a patient's specimen. Pathologists may resent taking the blame for preanalytic error if they feel that lab's functioning is beyond their control. Furthermore, preanalytic pathology error can have the additional unique impact of multiplicity of effect. Batch processing through a production line can result in a single upstream error affecting multiple patients. In the vignette above, a single labeling mix-up adversely affected 2 different patients and 2 different surgeons. In the case of errors with processing reagents as well as frame shift labeling errors, dozens or even hundreds of patients can be affected by a single error before it is detected. Error management and disclosure in pathology will require an understanding of preanalytic error. Furthermore, systems designed to guide the disclosure of pathologic error must be robust enough to deal with the multiple patients who might be affected by a single production line problem.

### RATIONALE AND PRINCIPLES OF EFFECTIVE DISCLOSURE

As we have seen, the focus on error which forms the cornerstone of the modern patient safety movement has become inevitably admixed with the goal of greater

**TABLE 1.** Arguments for Disclosure Following Medical Error

Category	Reasoning	References
Patient safety/organizational learning	Thoughtful and thorough examination of factors leading to error allow the system and the providers to learn and adapt to reduce future risk of harmful error	2,3,30
Moral/ethical	Telling patients the truth about harmful error is ethically and morally sound.	7,19,24,29
Fiscal	Disclosure reduces costs associated with claims and litigation.	18–20
Legal	Disclosure reduces the risk of a malpractice claim being filed.	19–21,28,31
Regulatory	The Joint Commission and certain state-based health care regulatory agencies mandate disclosure of medical errors to patients.	31
Emotional: providers	Many direct care providers find honesty regarding error to be a relief and a natural continuation of the therapeutic relationship.	19,22–25,27,32,33
Emotional: patients, caregivers	Patients harmed by medical error seek an apology, an explanation, and assurance that measures have been taken to reduce the risk of the error happening again; these needs can be met by a successful disclosure.	7,19,24–27,34

transparency and resulted in a growing interest in disclosure.<sup>18–21</sup> The risks and benefits of disclosure have been written about extensively and a consensus has emerged that open and honest communication following harmful error restores trust in providers and systems while promoting healing and closure for both providers and patients.<sup>7,19,22–27</sup> In contrast to conventional wisdom, disclosure also reduces litigation, the cost of litigation, and reduces time to case resolution.<sup>7,19,20,28</sup> The American College of Physicians Ethics Manual states “errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may.”<sup>29</sup> In addition to the legal, fiscal, ethical, and emotional arguments for disclosure, disclosure provides the opportunity for improved organizational learning and a reduction in future error, as the analysis of the individual error will reveal systems vulnerabilities which need to be addressed. Table 1 lists the arguments for error disclosure.

Effective disclosure requires involvement of the correct personnel. Data have shown that disclosures are most successful when performed by someone with whom the patient has a relationship, often the treating clinician.<sup>8</sup> Effective disclosure also requires the involvement of someone with a detailed technical understanding of the error, as studies have shown that patients and families want to understand why an error occurred, whether it was preventable, and what will be done to prevent it in the future.<sup>35</sup> The best way to address the patient’s interest in understanding error is to perform and share with the patient a thorough root cause analysis. In the case of error in fields such as pathology or radiology, the treating clinician may lack the technical understanding necessary for optimal disclosure, and yet the literature is generally silent on the role of nondirect care providers in such disclosure.<sup>35,36</sup>

Pathology presents unique challenges to meeting the standards for effective disclosure. Certainly pathologists have the technical understanding to explain the root cause of the error.<sup>35</sup> Pathologists typically lack a relationship with the patient; however, and thus are unable to meet that

standard for optimal disclosure. To make matters worse, pathologists may be reluctant to disclose error and if they are willing, may be ill-equipped to do so. In a survey of practicing pathologists, Dintzis et al identified the major barriers among pathologists to effective disclosure as fear, discomfort with ability to communicate the complexities of pathology effectively, and a lack of clear policies, procedures, and training (see Table 2 for barriers to disclosure).<sup>25,37,38</sup> Cultural factors, inexperience with patient contact and with disclosure, and self-selection of pathologists to a nondirect care specialty have left many pathologists feeling uncomfortable with their communication skills.<sup>36,39</sup> Despite these challenges, most pathologists surveyed generally agree that disclosure following harmful error is appropriate and indicated. A clear gap exists between what pathologists would like to do regarding safety culture and disclosure following harmful error and what they feel comfortable doing. Simulation learning for trainees and pathologists can help address this gap. Another potential solution is to pair the clinician and pathologist together during the disclosure of a harmful pathologic error.<sup>35</sup>

### HOW TO DISCLOSE ERROR TO A PATIENT: A GUIDE FOR PATHOLOGISTS

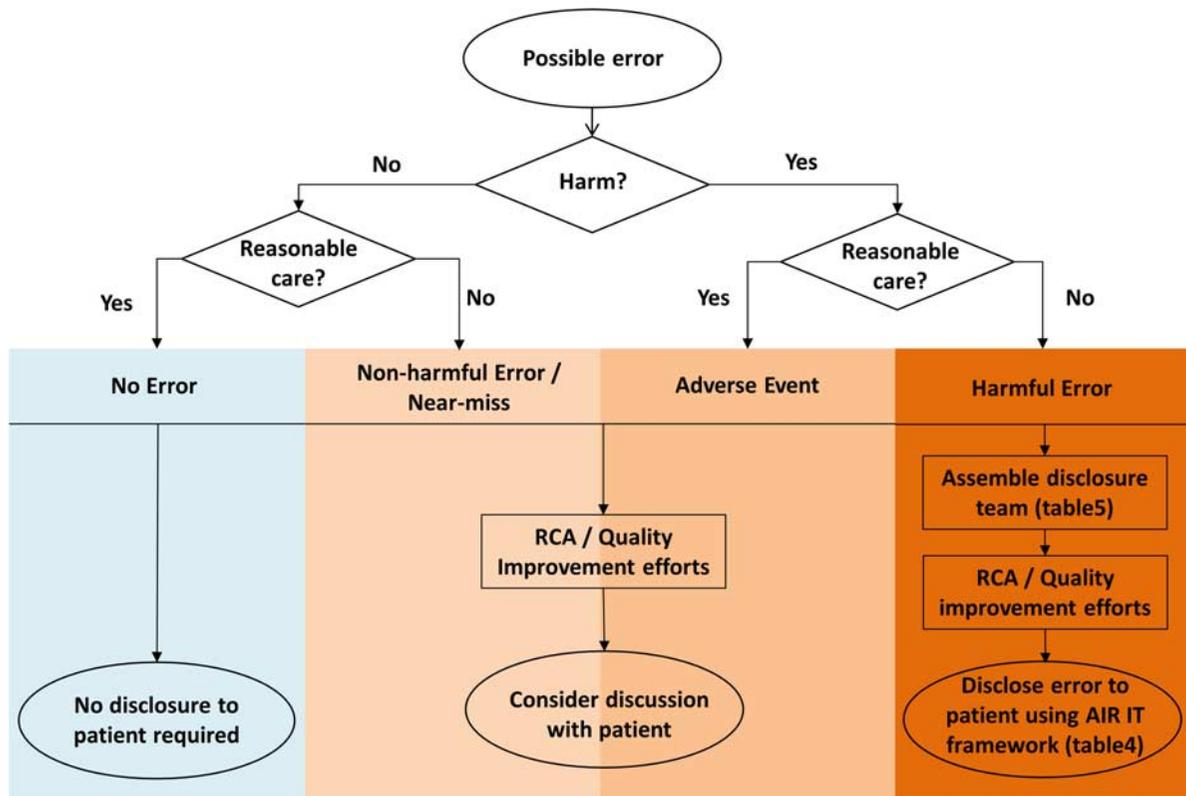
Although disclosure is a worthy goal, its practice presents significant challenges. Who, when, and how to disclose error are questions that command answers. The final portion of the article represents the authors’ recommendations on disclosure as it pertains to the unique practice of pathology. It is our recommendation that pathology departments develop and formally adopt disclosure policies that address each of the issues below. See Figure 1 for a decision tree regarding error discovery, investigation, and disclosure.

### When is Disclosure Indicated?

The authors recommend that pathologists disclose errors to patients when each of the following requirements is met: (a) a pathology error has occurred; (b) the patient was harmed by the pathology error. In the scenario at the start

**TABLE 2.** Barriers to Pathologist Disclosure Following Medical Error

Emotional (Internal) Barriers	Environmental (External) Barriers
Lack of confidence in communication skills	No disclosure guidelines, policies, or education
Lack of relationship with treating clinician and patient	Nonengagement of pathologists with care teams
Shame, isolation following error	Lack of peer support following error
Paternalism, wish to protect the patient	Nonsupportive organizational culture (honesty and learning vs. “deny and defend”)
Fear of litigation	Legal disincentivization



**FIGURE 1.** Disclosure flowchart. RCA: root cause analysis. Harm: the authors recommend a broad definition of harm, including physical and emotional. Reasonable care: the authors recommend asking “Did we meet our own expectations for care?” Disclosure team: may be composed of risk management, patient relations, health care quality department members, patient safety officers, departmental and/or hospital leadership, and peer support officers, as indicated and available. Adapted in part from the Massachusetts Alliance for Communication and Resolution following Medical Injury. Available at: <http://www.macmi.info/blog/forum-slides-and-materials/>. Accessed on May 26, 2017.

of the article, both requirements are met and the authors would recommend disclosure to the 2 affected patients.

As described above, defining harmful error in pathology can be challenging and published standards of care do not exist. When assessing whether an error has occurred, we recommend that pathologists and their quality assurance colleagues ask themselves a simple question: “Did we meet our own expectations for care?” If the answer is no, then it’s likely the event should be treated as a pathology error. Internal or external review of the care provided by local staff may be required to classify difficult cases as error.

Once it has been established that pathologic error has occurred, the next step is to determine if harm has occurred from the error. This may be obvious after case review or may require gathering information from clinical partners.

Nonharmful errors do not in our opinion require disclosure though local practice will vary in this regard. When considering whether an error is in fact harmful, however, we recommend a broad definition that includes the effect of the error on the patient’s emotional state and sense of well being.

Near-misses also do not require disclosure. Nonetheless these events do merit internal discussion and review with other pathologists, members of the laboratory team, and clinical partners and Quality Assurance staff. Thorough review will inform the system changes necessary to avoid future error.

Adverse events in which standards were met but the outcome was poor are an area of controversy with regards to patient disclosure. Because patients often do not perceive the difference between an error and an adverse event, a discussion with patients and treating clinicians may be warranted to facilitate understanding and prevent erosion of trust. The authors recommend that the management, investigation, and policies regarding discussion with patients and clinicians of adverse events should be left up to the discretion of the local leadership and risk management groups.

Table 3 outlines the recommended response to harmful error, nonharmful error, near-miss, and adverse events.

**Who should Disclose Errors to Patients?**

Because optimal disclosure requires both subject expertise and an existing relationship with the patient, the authors recommend that pathologists and clinicians perform disclosure of pathologic error jointly. Risk managers, patient relations professionals, malpractice insurer representatives and hospital attorneys may also be involved, at their discretion and according to local culture, policy, and the gravity of the error.<sup>24</sup>

The pathologist most closely involved in the event does not necessarily need to participate in the disclosure, if another pathologist, for example the director of Quality

**TABLE 3.** Root Cause Analysis, Systems Improvement, and Disclosure Recommendations by Error Type

Event Type	Perform RCA?	Implement Systems Improvements?	Disclose to Patients?
Harmful error	Y	Y	Y
Nonharmful error	Y	Y	Y/N
Near-miss	Y	Y	N
Adverse events*	Y/N	N	N†

\*Adverse events here defined as rare but expected negative outcomes that occurred despite reasonable care being delivered.

†They may merit discussion with patients and clinicians.

N indicates no; RCA, root cause analysis; Y, yes.

Assurance, serves instead. Allowing an experienced designee helps overcome the barriers described above and detailed in Table 2.

Patients may not wish to participate in a disclosure meeting, or may prefer to meet with the clinician alone. Although an initial attempt to disclose should occur in a timely fashion, the decision about who should participate in disclosure and when should ultimately be made by the patient. A patient's initial refusal to participate in a disclosure should not be considered final and a disclosure meeting should be scheduled at whatever point the patient requests it.<sup>35</sup>

### Timeliness

The authors recommend that an initial disclosure conversation occur within a week of error discovery. Silence following harmful error can be perceived by clinicians and patients as incompetence at best, and stonewalling and denial at worst. Because of the complex nature of care delivery, it may not be possible to ascertain the root causes of a harmful event quickly enough to share them in the first conversation. Therefore, initial disclosure, in order to preserve timeliness, may include only some components, such as an apology, and a promise to investigate and meet again to follow-up. It is important not to speculate during a disclosure event but to share only what is known at the time. Incorrect speculation may only further shake trust between providers and patients.<sup>8,27,40</sup>

### Disclosure as a Process

Much like the diagnostic process, or the process of sharing difficult news, disclosure of error should be a process and not a single event. It is important to enter into disclosure conversations understanding the need for future communication and follow-up with both the affected patient (and patient's family) and the affected care team. Ongoing communication is necessary both for effective systems improvement to reduce future error and ensuring patient understanding and satisfaction with the disclosure process. Follow-up is necessary especially because physician perception of the effectiveness of disclosure and apology varies markedly from the patient experience.<sup>26</sup> Although physicians may feel they have completed a disclosure after a single meeting, patients who have experienced harmful error often require more information, support, and follow-up. The authors advise that the disclosure be viewed as a process that continues as long as necessary to meet the patient's needs.

### Elements of an Effective Disclosure

The authors recommend beginning any disclosure of serious error by first asking the patient what they

understand regarding the error. Having the patient begin the conversation allows the disclosing team to assess both the emotional state of the patient (anger, frustration, confusion, fear) and the patient's level of familiarity with and technical understanding of the medical system. These factors will inform the pathologist's response and ensure that the patient's pressing needs are addressed first. Having allowed the patient to speak, follow quickly with an apology.

An apology is an essential part of an effective disclosure process. An apology does necessitate saying "I'm sorry," but this apology can be either a statement of fault or simply an expression of empathy. For example, a pathologist may apologize on behalf of a general technical laboratory error. Though the pathologist did not commit the error, with the apology the physician is making it clear that he or she is sorry that the error occurred and that the patient was harmed.

After the apology, a discussion should ensue and contain the following (1) honest factual information about what happened; (2) a description of the systems improvements that will be made to prevent the error from happening again.

The authors propose a new framework for disclosure, denoted by the acronym "AIR IT," designating: Apology, Information, Root Causes, Impact of the error, and Targets for improvement. Elements of the "AIR IT" disclosure framework, with examples and language, are outlined in Table 4.

Information is the next important component of the disclosure. The pathologist should explain first, typically in chronological order, a factual account of the events that took place. This may require also explaining standard operating procedure, as well as how the process deviated in this case. The information must be provided in lay terms to improve the patient's understanding.

Root causes should be communicated to the patient next. An in depth review of root cause analysis is beyond the scope of this article, but guides can be found elsewhere.<sup>30,41</sup> A practical limited recommendation includes utilization of the "substitution test" to differentiate systems factors from human error. The substitution test poses a hypothetical question: would a person with a similar background have likely made the same error in this situation? If the answer is yes, then systems factors are likely at play. If the answer is no, the error is more likely the result of an individual mistake. Root causes of serious errors are often numerous and frequently have both systems and human factors.

The patient will be interested in what impact the error had on their care. Will they need a repeat biopsy? Will additional treatment or monitoring be required? How will their ultimate outcome be affected by the error? This portion of the disclosure conversation is often most effectively managed by the clinician partner.

Following the discussion of root causes and vulnerabilities leading to the error, the pathologist disclosing error should proceed to share what targets for improvement have been identified. If changes have already been implemented, this progress should be shared. If major implementation is pending, for example with regards to systems upgrades or a change in practice, then a promise to follow-up should be made.

As part of the disclosure process, an offer of fair compensation because of formal litigation may increase patient satisfaction and reduce costs.<sup>20</sup> Including a risk manager (or other hospital administrator) during the disclosure will allow the patient to have questions regarding payment for services rendered and compensation answered. Because embarking on

**TABLE 4.** Elements of a Successful Disclosure: Acronym = “AIR IT”

Component	Explanation	Example
Apology	Empathic statement, may include personal or systems accountability, or both	“I am sorry this happened to you.” (empathy) “We take full responsibility for this error.” (accountability)
Information	What happened—describe event—facts only	“We are in the process of performing an investigation into how this happened. Here is what we know happened: (state facts only)” If nothing is yet known: “We are in the process of performing a full investigation into what happened. We will share our findings with you as we learn more.”
Root causes	Why event happened: human error and systems factors—do not speculate	“Health care delivery is complex, and involves many steps. Often when something goes wrong, we find > 1 contributing factor to the error. When we looked into what happened in your case, we found multiple issues in our workflow that contributed to the event. (List root causes).”
Impact	Implications for care and outcomes	“Here is what this means for you.” Here the pathologist, the clinician, and the risk management and patient relations team could jointly provide a follow-up plan specific to the patient, including: a clinical plan (joint with clinician), management of hospital services, charges, and offer of fair compensation (joint with risk management, patient relations, and malpractice insurers).
Targets for improvement	Changes to be made in the process to reduce the risk of recurrence, plans for follow-up	“We intend to learn from this event and change the way we provide care to do our best to reduce the risk of this happening to anyone else. Here are the changes we plan to make:” List changes in lay terms. If changes have already been made, share that information. If implementation is pending, promise to follow-up. If data exist regarding preimplementation and postimplementation, offer to share these if the patient is interested.

a formal disclosure, pathologists and clinicians should consult with their local malpractice insurers and risk managers, regarding the advisability of an upfront settlement, which would typically occur within the context of a Communication and Resolution Program (CRP).

**ADDITIONAL RESOURCES**

Disclosure of error is complex and requires experience and resources that extend well beyond the individual clinician, pathologist, or even pathology department. Risk managers, malpractice insurers, patient safety and quality assurance specialists, and health care quality departments all contribute valuable perspective and should be integrally involved in both the creation of disclosure policy and in individual cases requiring disclosure (see Table 5).

In some areas, alliances called CRPs are available to participate in individual disclosure events and assist hospitals develop disclosure programs. One CRP, the Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI), offers a resource library for those in need of guidance following an event and to those interested in creating their own local CRPs.<sup>42</sup> MACRMI and

other CRPs also perform research on the effects on disclosure on litigation outcomes. Consultation by experts from CRPs can be particularly helpful to safety culture advocates who are struggling to uproot the old model of “deny and defend” in favor of a culture of honesty and transparency.

Pathologists and other physicians involved in error events may experience shame, isolation, and depression and have been recognized as a “second victim.” Peer Support networks exist in some states to provide counseling to affected providers.<sup>43</sup>

**CONCLUSIONS**

Whether they know it or not, pathologists have received a call to action to join the patient safety movement and embrace its goals of patient engagement and transparency. Complete elimination of error in medicine is unattainable and thus increased transparency leads inevitably to the challenge of disclosure. We have reviewed the strong ethical, practical, fiscal, and legal benefits of transparency and disclosure. We have outlined a recommended framework for disclosure of harmful pathologic error, emphasizing the importance of partnering with clinicians and other patient safety professionals. Internal and external barriers presented by practicing pathologists, local leadership, and organizational culture need to be overcome in order to develop an effective disclosure program. In the longer term, effective partnerships between pathology departments, quality assurance professionals, attorneys, insurers, and legislators will be required to allow the full beneficial effects of disclosure to be recognized.

**ACKNOWLEDGMENTS**

*Yael K. Heher: Melinda VanNiel, MBA of MACRMI for providing resources and Yigu Chen MPH PMP CSSBB for providing critical review of the manuscript.*

**TABLE 5.** Possible Resources for Improved Disclosure

Resources for disclosure
Institutional policy for when to disclose
Disclosure training for pathologists and clinicians
Strong organizational relationships between risk management, health care quality improvement, and frontline providers
Patient relations
Supportive malpractice insurers
Communication and resolution programs
Administrative health courts
Legal “safe havens” for standard of care met
Peer support programs for the “second victim”

## REFERENCES

- Kohn LT, Corrigan JM, Donaldson MS. Committee on Quality Health Care in America, Institute of Medicine. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academies Press; 2000. eds.
- Reason J. Human errors: models and management. *BMJ*. 2000; 320:768–770.
- Reason J. *Managing the Risks of Organizational Accidents*. Hampshire (England): Ashgate Publishing Limited; 1997.
- Dekker S. *Just Culture: Balancing Safety and Accountability*. Boca Raton, FL: CRC Press; 2007.
- Bell SK, Gerard M, Fossa A, et al. A patient feedback reporting tool for OpenNotes: implications for patient-clinician safety and quality partnerships. *BMJ Qual Saf*. 2017;26:312–322.
- Bell SK, Mejilla R, Anselmo M, et al. When doctors share visit notes with patients: a study of patient and doctor perceptions of documentation errors, safety opportunities and the patient-doctor relationship. *BMJ Qual Saf*. 2017;26:262–270.
- Etchegaray JM, Ottosen MJ, Aigbe A, et al. Patients as partners in learning from unexpected events. *Health Serv Res*. 2016;51(S3):2600–2614.
- Powell SK. When things go wrong: responding to adverse events: a consensus statement of the Harvard hospitals. *Lippincotts Case Manag*. 2006;11:193–194.
- Dintzis SM, Gallagher TH. Disclosing harmful pathology errors to patients. *Am J Clin Pathol*. 2009;131:463–465.
- National Academies of Sciences, Engineering, and Medicine. *Improving Diagnosis In Health Care*. Washington, DC: National Academy Press; 2015.
- Cardona DM, Black-Schaffer S, Shamanski F, et al. Medicare's New Quality Payment Program Has Started—Are You Ready? *Arch Pathol Lab Med*. 2017;141:741–745.
- Borges JL. “John Wilkins' Analytical Language”, in Weinberger, Eliot, *Selected nonfictions*, Eliot Weinberger, transl. London: Penguin Books; 1999:23.
- Grober ED, Bohnen JM. Defining medical error. *Can J Surg*. 2005;48:39–44.
- Cooper K. Errors and error rates in surgical pathology: an Association of Directors of Anatomic and Surgical Pathology survey. *Arch Pathol Lab Med*. 2006;130:607–609.
- Nakhleh RE. Patient safety and error reduction in surgical pathology. *Arch Pathol Lab Med*. 2008;132:181–185.
- Zarbo RJ, Meier FA, Raab SS. Error detection in anatomic pathology. *Arch Pathol Lab Med*. 2005;129:1237–1245.
- Nakhleh RG. *Error Reduction and Prevention in Surgical Pathology*. New York, NY: Springer; 2015.
- Mello MM, Chandra A, Gawande AA, et al. National costs of the medical liability system. *Health Aff (Millwood)*. 2010;29:1569–1577.
- Lambert BL, Centomani NM, Smith KM, et al. The “Seven Pillars” response to patient safety incidents: effects on medical liability processes and outcomes. *Health Serv Res*. 2016;51(S3):2491–2515.
- Kachalia A, Kaufman SR, Boothman R, et al. Liability claims and costs before and after implementation of a medical error disclosure program. *Ann Intern Med*. 2010;153:213–221.
- Boothman RC, Imhoff SJ, Campbell CA. Nurturing a culture of patient safety and achieving lower malpractice risk through disclosure: lessons learned and future directions. *Front Health Serv Manag*. 2012;28:13–28.
- Boothman RC. CANDOR: the antidote to deny and defend? *Health Serv Res*. 2016;51(S3):2487–2491.
- Communication and Optimal Resolution (CANDOR) Toolkit: Agency for Healthcare Research and Quality. Available at: <https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/introduction.html>. Accessed April 28, 2017.
- Conway J, Federico F, Stewart K, et al. *Respectful Management of Serious Clinical Adverse Events (Second Edition) IHI Innovation Series White Paper*. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2011.
- Gallagher TH, Waterman AD, Ebers AG, et al. Patients' and physicians' attitudes regarding the disclosure of medical errors. *J Am Med Assoc*. 2003;289:1001–1007.
- Iedema R, Allen S, Britton K, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: the “100 patient stories” qualitative study. *BMJ*. 2011;343:d4423.
- Truog RD, Browning DM, Johnson JA, et al. *Talking with Patients and Families about Medical Error*. Baltimore: Johns Hopkins University Press; 2010.
- Mello MM, Kachalia A, Studdert DM, et al. Medical Liability—Prospects for federal reform. *N Engl J Med*. 2017;376:1806–1808.
- Snyder L, Leffler C. *Ethics Human Rights Committee*. Ethics manual: fifth edition. *Ann Intern Med*. 2005;142:560–582.
- National Patient Safety Foundation. *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm*. Boston, MA: National Patient Safety Foundation; 2015.
- Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *N Engl J Med*. 2007;356:13–19.
- Helmchen LA, Lambert BL, McDonald TB. Changes in physician practice patterns after implementation of a communication-and-resolution program services. *Health Serv Res*. 2016; 51(S3):2516–2536.
- Kaldjian LC, Jones EW, Wu BJ, et al. Reporting medical errors to improve patient safety: a survey of physicians in teaching hospitals. *Arch Intern Med*. 2008;168:40e6.
- Gallagher TH, Etchegaray JM, Bergstedt B, et al. Improving communication and resolution following adverse events using a patient-created simulation exercise. *Health Serv Res*. 2016;51(S3):2537–2549.
- Gallagher TH, Mello MM, Levinson WL, et al. Talking with patients about other clinicians' errors. *N Engl J Med*. 2013;369: 1752–1757.
- Dintzis SM, Clennon EK, Prouty CD, et al. Pathologists' perspectives on disclosing harmful pathology error. *Arch Pathol Lab Med*. 2017;141:841–845.
- Dintzis S. Improving pathologists' communication skills. *AMA J Ethics*. 2016;18:802–808.
- Bell SK, Smulowitz PB. Disclosure, apology, and offer programs: stakeholders' views of barriers to and strategies for broad implementation. *Milbank Q*. 2012;90:682–705.
- Dintzis SM, Stetsenko GY, Sitlani CM, et al. Communicating pathology and laboratory errors: anatomic pathologists' and laboratory medical directors' attitudes and experiences. *Am J Clin Pathol*. 2011;135:760–765.
- 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;166:1585–1593.
- Heher YK. A brief guide to root cause analysis. *Cancer Cytopathol*. 2017;125:79–82.
- Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI). Resource library: [http://www.macrmi.info/resource\\_library](http://www.macrmi.info/resource_library). Accessed May 27, 2017.
- Wu AW. Medical error: the second victim. *BMJ*. 2000;320: 726–727.