

Disclosing Harmful Pathology Errors to Patients

Suzanne M. Dintzis, MD, PhD,¹ and Thomas H. Gallagher, MD²

DOI: 10.1309/AJCPIO5SHDOD6URI

Imagine this scenario: You receive multiple stomach biopsy fragments showing diffuse surface ulceration, marked inflammation, and reactive atypia. In a small focus of 1 gastric mucosal fragment, there is a subtle, signet-ring adenocarcinoma. You notice on review of the patient's history that she has had multiple previous stomach biopsies for dyspepsia and weight loss. With a sinking feeling, you pull the preceding biopsy specimens and find that signet-ring adenocarcinoma was present in a biopsy you signed out as benign 8 months earlier. After confirming your diagnoses with other pathologists in your department, you call the gastroenterologist to inform him that the patient currently has gastric adenocarcinoma and that the diagnosis was missed on a previous biopsy. You tell the gastroenterologist that you will issue an amended report correcting the missed adenocarcinoma. The gastroenterologist emphatically tells you not to amend the previous report and insists that the missed diagnosis will not alter current care options or patient survival, and that disclosing this information will only serve to upset "his" patient.

As a clinician, and the person responsible for a diagnostic error, how would you handle this situation? Should you issue a corrected report regardless of the opinion of the treating physician? If you decide to issue a corrected report, because the treating physician most likely serves as the gatekeeper for patient information, the patient may never be informed of the delay in diagnosis. Should you contact the patient directly to share this information? Many would argue that because the pathologist has no established relationship with the patient, direct contact between the patient and pathologist in this situation could confuse or anger both patient and treating physician. Yet, does the treating physician have the authority to determine whether the patient is informed of your error?

The topic of medical error became part of the national consciousness in late 1999 following publication of the Institute of Medicine report, *To Err Is Human: Building a Safer Health System*.^{1,2} This report suggested that 2% of hospitalized patients experienced an avoidable adverse event. Pathologists, like all physicians, began changing their practice to improve patient safety and reduce laboratory error. Several articles have been published that seek to define and measure pathology error and examine its root causes.³⁻⁷ The American Society for Clinical Pathology, College of American Pathologists, and Association of Directors of Anatomic and Surgical Pathology have actively promoted education about the causes and prevention of errors.³

Although improving our practice standards will likely increase patient safety, medical errors will happen despite our best effort. What to do then when these errors inevitably occur? The patient safety movement emphasizes not only error reduction but also the importance of greater transparency in the discussion of medical errors with other health care workers and with affected patients.⁸ To date, there has been little discourse and no guidance in pathology on appropriate standards for communication of harmful pathology errors.

Although most health care professional societies recognize disclosure as an ethical obligation, the impetus for transparency is being generated and sustained outside the medical profession. In 2001, The Joint Commission on Accreditation of Healthcare Organizations began to require disclosure of all outcomes of care to patients, including "unanticipated outcomes," as part of its accreditation standards for hospitals and health care organizations.⁹ In 2006, the Full Disclosure Working Group of the Harvard Hospitals released a consensus statement suggesting that patients be informed of what,

how, and why an event happened, including an admission of responsibility for harmful errors.¹⁰ Also in 2006, the National Quality Forum, an organization that develops standards for the provision of health care, endorsed a new guideline on disclosure of serious unanticipated outcomes to patients.¹¹ In addition, 35 states have adopted legislation protecting apologies from being used as evidence of liability, and 8 states require disclosure of serious adverse events to patients.¹²

In response, many hospitals and health care organizations have developed or are developing programs to promote disclosure. Relatively little is known about the effectiveness of such initiatives. In fact, there is a difference between the consensus that harmful errors should be disclosed and current practice. In a national survey of patients who reported experiencing harmful events during their health care, only 30% said the error was disclosed to them.¹³ Survey research suggests that physicians endorse the principle of disclosure but are often very cautious when talking with patients about errors. Many physicians remember having been told by risk managers that they should “never admit fault” and “never apologize” in order to avoid lawsuits. The factors contributing to physicians’ behaviors and attitudes toward disclosure are complex and include fear of litigation, the nature of the error, the content of the disclosure, and fear of damage to reputation.¹⁴

In contrast with the mixed opinions among physicians about disclosure, patients uniformly agree that they want to be told of harmful errors and on the specific information they would like communicated to them after these events.^{15,16} Following errors, patients want an explicit statement that an error occurred, information about why the error happened and how recurrences will be prevented, and an apology. Patients want to be informed of all harmful errors, even when the harm was minor. Disclosing pathology error, therefore, respects patient autonomy and promotes informed decision making. Patients also value error disclosure as a form of truth telling. Communicating openly with patients following errors could enhance patients’ satisfaction with and confidence in the honesty and integrity of their health care providers. Effective disclosure may also reduce the likelihood of malpractice claims, although the relationship between disclosure and litigation remains hotly debated.¹⁷

Although many aspects of patient safety and error disclosure are common to all fields of clinical medicine, pathologists face unique challenges related to disclosure every day. Review of slides received from another institution reveals a missed lymph node metastasis. Should you inform the outside institution’s pathologist? The outside treating physician? Your institution’s treating physician? The patient? All of the above?

One especially difficult issue related to disclosure of pathology errors is what role the pathologist should have

in the disclosure process. Traditionally, pathologists have no direct patient contact. Therefore, disclosure of pathology errors to patients generally occurs through the treating physician. Although it makes sense for the disclosure to come from the physician who has the closest relationship with the patient, this approach also presents problems. When the pathologist is not present during the disclosure, it is not possible for the pathologist to know whether the disclosure was full or whether it was cautious and qualified; how the pathologist’s role in the error was explained to the patient; or whether the disclosure even occurred. Indeed, in our experience, pathologists rarely get feedback about how error disclosure was received by the affected patient. As clinicians, are we comfortable with having our errors disclosed by people other than ourselves?

Pathologists have been shifting the burden of disclosure, and, therefore, many of the difficult ethical decisions regarding disclosure to other health care practitioners. Over time, this approach is likely to become less and less satisfactory. As more mechanisms to report adverse events and monitor disclosure are put into place by health care systems and regulatory authorities, pathologists will be pressed to comply with established disclosure guidelines. Full and frank disclosure of harmful errors to patients will likely be the mandate. Pathologists need to seriously consider how, and by whom, their errors are to be disclosed.

From the Departments of ¹Pathology and ²Medicine, Bioethics and Humanities, University of Washington, Seattle.

Supported by grant RO1HS016506 from the Agency for Healthcare Research and Quality, Bethesda, MD; the Investigator Award in Health Policy Research from the Robert Wood Johnson Foundation, Princeton, NJ; and by the Greenwall Foundation, New York, NY (Dr Gallagher).

References

1. Kohn LT, Corrigan JM, Donaldson MS, eds; 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.
2. Leape LL, Berwick DM. Five years after *To Err Is Human*: what have we learned? *JAMA*. 2005;293:2384-2390.
3. 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.
4. Nakhleh RE. Patient safety and error reduction in surgical pathology. *Arch Pathol Lab Med*. 2008;132:181-185.
5. Raab SS, Grzybicki DM. Measuring quality in anatomic pathology. *Clin Lab Med*. 2008;28:245-259.
6. Sirota RL. Defining error in anatomic pathology. *Arch Pathol Lab Med*. 2006;130:604-606.
7. Zarbo RJ, Meier FA, Raab SS. Error detection in anatomic pathology. *Arch Pathol Lab Med*. 2005;129:1237-1245.

8. Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *N Engl J Med*. 2007;356:2713-2719.
9. Joint Commission on Accreditation of Healthcare Organizations. *Hospital Accreditation Standards, 2007*. Oakbrook Terrace, IL: Joint Commission Resources; 2007.
10. The Full Disclosure Working Group. When things go wrong: responding to adverse events: a consensus statement of the Harvard Hospitals. Boston, MA: Massachusetts Coalition for the Prevention of Medical Errors; 2006.
11. Gallagher TH, Denham C, Leape L, et al. Disclosing unanticipated outcomes to patients: the art and the practice. *J Patient Saf*. 2007;3:158-165.
12. McDonnell WM, Guenther E. Narrative review: do state laws make it easier to say "I'm sorry"? *Ann Intern Med*. 2008;149:811-816.
13. Blendon RJ, DesRoches CM, Brodie M, et al. Views of practicing physicians and the public on medical errors. *N Engl J Med*. 2002;347:1933-1940.
14. 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.
15. Gallagher TH, Waterman AD, Ebers AG, et al. Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA*. 2003;289:1001-1007.
16. Mazor KM, Simon SR, Yood RA, et al. Health plan members' views about disclosure of medical errors. *Ann Intern Med*. 2004;140:409-418.
17. Kachalia A, Shojania KG, Hofer TP, et al. Does full disclosure of medical errors affect malpractice liability? The jury is still out. *Jt Comm J Qual Saf*. 2003;29:503-511.