

## IN THE LITERATURE

### Error Disclosure in Pathology and Laboratory Medicine: A Review of the Literature

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#### Abstract

Since the 1990s, the fields of anatomic and clinical pathology have made strong commitments to improving patient safety, including the creation of formal and informal guidelines for assessing and reporting quality lapses. Unfortunately, some medical errors are inevitable. Patient safety experts advocate full and complete disclosure of all serious medical errors in an effort to preserve the patient-physician relationship and minimize the risk of harm to patients. While evidence suggests that most pathologists disclose serious medical errors, many do not disclose such errors to patients. A literature review of articles published on diagnostic error disclosure in pathology and laboratory medicine suggests that there are in fact persistent barriers to the disclosure of diagnostic errors that are specific to pathology. A number of these barriers are considered here, followed by recommendations for improving patient safety in pathology.

#### Introduction

Error is defined by the Institute of Medicine as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim” [1]. Of particular relevance to pathology are [diagnostic errors](#), which might be revealed by pathologists. Regardless of the nature of the error, however, an important component of a clinician’s response after a medical error is full and timely disclosure of that error [2]. Disclosing medical errors not only maintains respect for patient autonomy and supports truth telling but also is strongly desired by patients, particularly if the medical error results in harm or injury [3]. However, existing guidelines for error disclosure offer minimal guidance about how to disclose an error, such as a misdiagnosis or a missing diagnosis by another clinician. Dintzis et al. found that while 95.2 percent of 169 surveyed anatomic pathologists and laboratory medical directors reported having been involved with an error at some point in their clinical practices, only 88.8 percent reported disclosing an error [4]. And a much smaller proportion—16.2 percent—reported disclosing a serious error directly to the patient whom it affected. In the rest of this review, I examine errors in pathology and laboratory medicine, barriers to error disclosure, and opportunities for continued development of this clinically and ethically relevant set of issues.

## Disclosing Errors in Pathology and Laboratory Medicine

Among medical errors, studies historically have demonstrated that diagnostic errors are associated with poor patient outcomes [5-8]. When errors occur in pathology and laboratory medicine, they have the capacity to generate profound diagnostic confusion. These errors can take a variety of forms in different subspecialties of pathology. Errors in laboratory medicine and clinical pathology can occur at any point from specimen retrieval through specimen analysis; they are classified broadly as preanalytic phase, analytic phase, and postanalytic phase errors [9, 10]. Preanalytic phase errors take place before the specimen arrives in the pathology lab and comprise the majority of laboratory errors [10]; analytic phase errors take place during the laboratory processing and analysis of the specimen; and post-analytic phase errors take place during the reporting of the lab results to clinicians and clinicians' interpretation of those results [10]. Errors in anatomical pathology similarly can occur in a variety of settings and might involve reporting an incorrect diagnosis or the absence of a correct diagnosis on a submitted tissue specimen. Diagnostic discrepancies, for example, can occur when the pathologist interprets a "frozen section" within a very narrow timeframe (often less than an hour) for the purpose of determining the best immediate clinical management of a patient or when the pathologist renders a final diagnosis *after* the tissue is permanently fixed in formalin days later. Diagnostic errors in anatomic pathology might be classified as missed (not recognized by a pathologist), near-missed (recognized and communicated to the clinical team), or incorrect (the pathologist identifies the diagnostic entity but misinterprets the diagnosis). In other instances, the pathologist might recognize a diagnostic entity but fail to communicate his or her findings or concerns conclusively [11].

Steps have been taken to improve patient safety and quality in anatomic and clinical pathology. Efforts to minimize the frequency of diagnostic errors and improve patient safety have been implemented by many pathology labs [9, 12-14]. Anatomic pathology has also seen the emergence of interdepartmental consensus conferences in which diagnostically challenging cases are presented and discussed at length prior to the diagnostic results being finalized, clinical- and radiographic-pathologic correlation educational conferences, and multidisciplinary oncologic patient management conferences ("tumor boards") [11]. In clinical labs, implementation of [quality assurance](#) requirements by regulatory and accreditation groups such as Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists (CAP) has led to adoption of measures to improve patient safety, such as increased atomization of specimen processing, standardization of quality control procedures, and proficiency testing [9, 12-14]. These measures hold promise to reduce medical errors in clinical laboratory medicine, which are reported to be as low as 0.045 percent—one of the lowest reported error rates for all specialties in medicine [14]—and in anatomic

pathology, although anatomic pathology labs' published estimated rates of error are much more variable [9, 11].

However, even with implementation of safety and quality measures like those mentioned here, medical errors will still happen. As fiduciaries, pathologists and laboratory professionals are obligated not only to strive to avoid preventable medical errors but also to identify and rapidly report errors. However, there are both individual- and systems-based barriers that pathologists face with respect to disclosing medical errors.

### **Barriers to Disclosure of Errors in Pathology and Laboratory Medicine**

In an article published in the *New England Journal of Medicine* in 2013, Gallagher and colleagues explore some of the challenges clinicians face in disclosing medical errors, including someone else's error, and offer insightful guidelines about how to manage such situations [15]. For example, Gallagher et al. cite as barriers to disclosing someone else's error factors such as embarrassment, lack of confidence in one's own personal disclosure skills, and mixed messages from organizations and malpractice insurers regarding how to handle the incident [15]. The authors also recommend full disclosure of all medical errors that cause harm and identify opportunities for institutions to lead in encouraging clinicians to disclose errors. Gallagher et al.'s recommendation of [full disclosure](#) of errors is laudable. However, its application to the discipline of pathology is complicated by additional existing barriers to error disclosure that are specific to pathology and laboratory medicine.

*Barrier 1: Unclear definitions of "error" in pathology.* A survey commissioned by the Association of Directors of Anatomic and Surgical Pathology (ADASP) Council of 34 ADASP members revealed sizeable differences in what constitutes a medical error in cancer resection specimen assessment [11]. For example, while 74 percent of respondents regarded as an error a discrepancy in a diagnostic report involving a change in the status of a vascular invasion (e.g., from positive involvement of vascular structures with cancer to negative involvement of vascular structures with cancer), 53 percent did not consider omission of the vascular invasion status in a report to be an error. However, positivity of vascular margin status in many cancers such as breast cancer neoplasms often portends a worse prognosis [16-18], and errors and discrepancies in the status of vascular margins have the potential to result in undertreatment or overtreatment of patients. Therefore, efforts are needed to better clarify the definition of error in contexts specific to anatomic pathology and laboratory medicine. With clearer definitions, anatomic pathology labs, health care delivery organizations, and laboratory administrative groups can better work together to develop an atmosphere of transparency and clearer error disclosure plans.

*Barrier 2: Patients might not understand the error.* In a recent study, Dintzis et al. [4] reported that 49.7 percent of 169 surveyed anatomic pathologists and laboratory medical directors indicated that “the patient would not understand what he or she was being told” as an important consideration that might deter them from [disclosing a serious error to a patient](#) [19]. This study demonstrates that some anatomic and laboratory diagnostics information can be technical, complex, and conceptually challenging to lay people. Full disclosure of an error in pathology, like any error, requires sharing appropriate context, which can involve details of not only a pathologist’s individual decision-making process but also specimen processing and laboratory management. All of these factors might be overwhelming to someone without medical or pathology training. Additionally, nonclinical factors such as health literacy levels and the situational context of disclosures can influence a clinician’s or lay person’s capacity to understand a pathologist’s error.

*Barrier 3: Pathologists worry that another clinician might not be able to adequately explain an error to a patient.* With the exception of practitioners of a select few subspecialty pathology services, such as cytopathology and transfusion medicine, most pathologists do not regularly interact directly with patients. Rather, pathologists typically work more closely with clinicians who administer direct patient care. In their role as medical consultant, however, pathologists serve on the clinical team taking care of the patient. Consequently, some critical clinical pathology information is communicated indirectly to patients and their loved ones, mediated by clinicians, who regularly and directly interact with patients. Errors in pathology therefore may be committed not only by the pathologist but also by ancillary staff such as laboratory technicians and managers who work closely with the pathologist and the instruments that process the specimen in the pathology lab. When it comes to disclosure of errors that take place in pathology, this trend of indirect and mediated communication continues; an overwhelming majority of error disclosures in pathology are communicated to the patient by nonpathologists [4].

The disclosure of errors in pathology by nonpathology clinicians introduces many of the same challenges revealed by Gallagher and colleagues [15]. Clinicians disclosing someone else’s error—in this case, the error of the pathology team—may find themselves with limited firsthand knowledge of the error event and may not be aware of certain pathology-specific relevant information worth sharing with the patient during the disclosure process. Dintzis et al. found that 40.2 percent of 169 surveyed pathologists and laboratory medical directors would be deterred from informing a patient of a serious error if the pathologist or director felt that “the physician would not be able to explain the error clearly to the patient” [19]. This is not entirely surprising since studies suggest that physicians as a whole often do not feel competent disclosing medical errors [2, 15].

Pathologists who directly disclose their own medical errors to patients benefit from effective communication and an [opportunity to express remorse](#) [20]. However, formal

ethics and professionalism training that facilitates communication skills development is currently lacking in pathology graduate medical education programs [21]. Without such training and having limited opportunities to form a rapport with the patients they serve regularly, pathologists might be concerned about introducing complexities into the error disclosure process if they disclose directly to the patient. Similarly, pathologists worry about increased risks of postdisclosure litigation [2, 4, 15].

*Barrier 4: Someone else's error.* To complicate matters further, there are instances in which an error discovered by a practicing pathologist might not be his or her error. Examples include:

1. A pathologist or laboratory director discovers a diagnostic error committed by a technician within his or her medical lab.
2. A pathologist or laboratory director discovers a diagnostic error committed by another pathologist or laboratory worker within the clinician's organization.
3. A pathologist or laboratory director discovers a diagnostic error committed by another pathologist or laboratory director from an outside organization.
4. A pathologist discovers a diagnostic error committed by a clinician in the same organization.

In their roles as medical consultants, pathologists and laboratory directors work with an extensive and heterogeneous clientele base consisting of clinicians and pathologists. In disclosing a referring client's potential medical error, therefore, the pathologist must consider the potential harm to his or her professional relationships. When an error is caused by a technician in the lab, additional layers of complexity in the disclosure process are introduced. These include the responsibilities of the technician, the laboratory manager, the laboratory director, and the health care organization to disclose. However, while error disclosure in such circumstances is encouraged by laboratory accrediting organizations, specific guidelines for laboratory directors detailing particulars on the actual error disclosure in such circumstances are lacking. Standardizing specific guidelines delineating what error events should be disclosed, the timing of error disclosure, and parties to whom the event should be disclosed may prove a helpful resource to pathology laboratory directors.

## **Conclusion**

What is to be done? The CAP's and the ADASP's recently released results of the novel Interpretive Diagnostics Error Reduction Project offer practicing anatomic pathologists the following insightful recommendations to minimize errors [22]: timely mandatory and routine case review tailored to each anatomic pathology lab, followed by investigation of "problematic" cases wrought by significant pathologist disagreements and meaningful steps to investigate and rectify the discordance. While work is underway to prevent medical errors and to design procedures for handling them when they occur, managing communication about errors awaits further exploration in the pathology professionalism literature. The benefits of disclosing medical errors—including effective and open

communication and appropriate management of the patient to minimize any further harm—are well described in the literature [23, 24]. However, barriers to disclosure in pathology persist. Furthermore, to whom the pathologist is obligated to disclose an error directly (e.g., the patient, the clinician who interacts directly with a patient, risk managers, departmental medical director) is still largely uncertain. One survey of practicing pathologists found that 48 percent of anatomic pathologists and laboratory medical directors believe that institutional systems for reporting errors are adequate [4]. More efforts and studies are needed to determine how best to encourage pathologists and laboratory directors to disclose medical errors skillfully. Cohesive efforts in pathology to both reduce medical errors and manage communication about medical errors are important as they serve to further our overall efforts in improving patient safety.

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