Error in Anatomic Pathology

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Abstract

Error in anatomic pathology is a topic that is currently making the difficult transition from a problem peculiar to a subset of poorly trained or otherwise inadequate pathologists to a problem shared by the specialty of pathology. This transition will involve a number of difficult steps, including sorting error from both inherent diagnostic uncertainty and from variations in practice patterns from which no evidence-based best practice has emerged. Identification of error will require scientifically valid diagnostic gold standards, and in those areas of diagnosis without such a standard, the identification of and response to error will continue to be heavily influenced by hindsight bias and subjective opinion. The pathologist, like other physicians, has limited options to “make things right” following a significant error. The silver lining is that many errors have the potential to prompt changes that will prevent future patient harm. Unfortunately, a dysfunctional legal system that values punishment and transfer of assets over future improvements in health care has wrung much of the positive potential out of error, leaving only the damaged patient and damaged pathologist.

Most people’s perception of science is that it deals with certainties, an understandable misconception given that elementary scientific education deals with well-established theory derived from substantive research.¹

A malpractice suit grows like kudzu. It climbs any available support, smothers it, and winds off in new directions as far as opportunity and obstacles allow.²

Just a few years ago, writing an article on error in anatomic pathology was an easy task. The available scientific literature was relatively limited, and there were few regulatory or legislative initiatives to keep track of. Conventional wisdom held that pathologists rarely made errors and that errors were so easily explained that the topic was hardly worthy of discussion. Errors seemed to fall into 3 main categories: (1) a diagnosis different from mine, (2) a diagnosis that was contradicted by a higher authority, and (3) a diagnosis that was contradicted by outcome. Pathologists made indubitable diagnoses using the binary benign or malignant system, and diagnostic categories were distinct from each other, separated by bridgeless gaps in a manner similar to the gaps that separated each species from all other species before Darwin. In 1996, a pathology educational association succinctly synthesized common wisdom when it turned down a proposal for a course on error by pathologist Ronald Sirota, citing “…the narrow focus and nature of the subject matter.”

How fast things can change. The literature on error now includes a vast potpourri of political, sociologic, regulatory, and psychological information admixed with miscellaneous contributions such as the signed public confessions that appear regularly in the journal Lancet. Many national
pathology meetings now devote at least some time to the topic of error.

How did this change come about? Wind filled the sails of the topic of error in medicine when in November 1999 the Institute of Medicine (IOM) released a report claiming that as many as 98,000 hospitalized Americans die every year because of medical mistakes. Although the information in the report was not new, the messenger, the timing of the report, and the recommendations for addressing the problem of medical error were new. The report’s release immediately precipitated what the American Medical News referred to as a “furious interest in medical errors,” and soon almost everyone with a word processor felt compelled to share their views on the topic. As time passed, reporters and politicians even began poking about in areas of medical care that seldom are noticed. Approximately 4 months after the release of the IOM report, the limelight was even directed toward anatomic pathology when The New York Times published an article discussing a study of pathology second opinion review of cases referred to Johns Hopkins Medical Center. The pathologist senior author of the Hopkins study was quoted by The Times as stating he would recommend a second opinion for any malignant diagnosis or for any benign diagnosis for an organ known to have a high error rate. The Times article used the Hopkins study to estimate that because of pathology errors, approximately 30,000 cancer diagnoses a year in the United States were “wrong.”

Approximately a year and a half after the initial IOM report on error, a study from the Veterans Administration challenged the method that previous publications used to identify such high estimates of deaths from medical errors. In fact, it now seems likely that the figures that so captivated politicians, the public, and the news media ignored the fact that many of the deaths that had been attributed to medical errors occurred in patients whose health status was so precarious that they had a very short life expectancy even with optimal medical treatment. However, the exact number of errors causing patient harm is relatively unimportant. It is clear to most physicians that the correct number is higher than any of us would like it to be, and it is also clear that the 1999 IOM report represented a substantial shift in how both medicine and the broader society view medical error. Of importance to the long-term view of medical error, a 2001 follow-up IOM report on medical error came and went with only “muted” interest. The initial shock and can-do enthusiasm of late 1999—reflected in headlines such as “Clinton to order federal agencies to reduce error”—have been replaced by stories noting that the efforts to improve patient safety are “slow-going.”

The present article is written with the assumption that, like other complex areas of medical care, interpretation of anatomic pathology specimens is subject to error. Although acknowledging the importance of this error has the potential to help us improve our diagnostic performance, we have to be aware that fighting error can also be used to cause harm to individuals and the specialty. For example, if requesting outside review of 5 years’ worth of Dr X’s prostate biopsy cases because “concerns have been raised” becomes the format for weeding out error, what will appear to outsiders to be a concern about quality will turn into an exercise with all of the benefits of a witch hunt. Furthermore, some individuals or organizations may see the increased interest in error as an opportunity to rearrange the practice of pathology in a manner that may not be in everyone’s best interests. Although some aspects of tissue examination would be expected to raise unique issues, a practical approach to understanding and reducing anatomic pathology error would be to look at what has been learned about error in other fields and then modify and adopt the best ideas. Any attempt to review the topic of error will inevitably result in “spectrum bias,” meaning important details and entire subtopics will be left out. I would contend that at this point, a review of medical error cannot simultaneously present all aspects of the topic in any depth and at the same time be short enough so that any pathologist would actually read it.

**Impaired, Error-Prone, and Normal**

Physician impairment raises a variety of issues about medical error that are not necessarily germane to the topic of error committed by physicians who are functioning at their full capacity. In the present discussion, I will concentrate on the problem of keeping fully functioning, highly motivated physicians from committing errors that harm patients and will not deal with the special issues of impairment. However, because error-prone behavior is essentially part of the definition of impairment, it is difficult to discuss error without at least touching on the complex topic of “the problem doctor.” Some idea of the impact of impairment on medical practice is gained from estimates that in the United States, 2.4% of physicians have been disciplined by some state medical board, and during 1999, state medical boards disciplined almost 4,000 physicians. Although experts in medical error like to think of each error as a “medical treasure” that can be used to improve patient care, these same errors are also a marker used to define impairment and to initiate lawsuits. The 1999 IOM report attempts to have it both ways on this issue and essentially ends up talking out of both sides of its institutional mouth. Taking one side, the IOM condemns “faulty systems” that “set people up” to fail, and calls for voluntary
reporting of errors so that systems can be fixed. However, the report also endorses the current tort system, stating that “liability is part of the system of accountability and serves a legitimate role in holding people responsible for their actions.” Leape showed this same ambivalence toward our individual reaction to error when he made the suggestion that physicians should feel “responsible” for patient damage due to error, but should not feel “shame or guilt.” Details of how this should be accomplished within the current tort system were not provided.

It is undoubtedly true that some errors are not system problems and that individual accountability cannot be lost. At the same time, error cannot simultaneously be a medical treasure and the signal to throw a physician to a highly dysfunctional legal system. Currently, discovering a medical treasure can activate the same punitive powers (hospital credentialing committees, state licensure boards, and tort law) that come into play to control the “impaired” physician, and of course this significantly dampens enthusiasm for the discovery and open discussion of errors.

What Is a Pathology Error?

Error is an intuitive “you know it when you see it” phenomenon that is very difficult to define. However, even before attempting a definition, it is important to distinguish between the term error and the term variation. The latter is an umbrella category that lumps (1) error together with (2) the differences predictably arising out of uncertainty and (3) the often multiple (not objectively wrong) ways to approach or complete any task. Leape defined error as “an unintended act (either of omission or commission) or one that does not achieve its intended outcome.” Unfortunately, even this latter definition can be criticized for several reasons:

1. It seems to blame the physician when things go wrong even when everything was done correctly. A bad outcome becomes res ipsa loquitur evidence of error, even though medicine depends on technology that will inevitably fail in a small percentage of cases.

2. It ignores the historic perspective. For example, is a flawless prefrontal lobotomy performed in 1950 an error? Does the practitioner have a duty to judge best practice or just to follow best practice?

3. Most pathologists have had the experience of being “wrong” based on a review by an expert. But is being overruled actually error or just variation caused by difference of opinion? Lawyers think of medicine as hierarchic, analogous to the court system in which they work. However, pathology also has methodologic similarities to science, where ideally, ideas are judged by their merit and not by their sponsoring institution or sponsoring individual.

Obviously, some diagnoses clearly fall outside of even a charitable interpretation of a gray zone and can be considered to be flagrant violations of normative standards. In other situations, error is more difficult to identify. For example, some variation is categorized incorrectly as error when it simply reflects differences of style or terminology—the so-called distinction without a difference. Other diagnoses become errors only in the light of an adverse outcome.

Aspects of diagnosis that are quantitative are usually easy to objectively evaluate for error. For example, a claim that 1 lymph node is positive can be refuted by the presence of tumor in 2 nodes. However, when a claim of error involves subjective judgments, confusion between error and variation becomes common. The marked differences between error and variation can be illustrated by examining fields such as ethics, art, and literature, in which the concept of error obviously is completely different from error in the basic sciences. The claim that Shakespeare painted Guernica would be an error, but which exhibit found in a museum is error, and which is just a variation on the many ways that paint can be applied to canvas? In the field of ethics, the claim has been made that an ethics committee cannot make an error because ethicists have no “shared, collective understanding” of what an error is.

In fields like pathology that are recognized to combine qualitative impressions with science, discussions of error must concentrate on the parts of diagnostic behavior that can and should be standardized. If we are, in fact, subjectively judging someone else’s subjective impressions when we establish the presence of error, then the statement “that diagnosis is an error” becomes the equivalent of “in my mind, that painting is ugly.”

Diagnostic Gold Standard

It would be nice if error could be established by looking at patient outcome or some other clinically valid end point, but because tissue interpretation is an intermediate or adjunctive step in the complex process of patient care, it can often be difficult to establish how differences in diagnosis relate to patient outcome. Unlike clinical medicine, in which many important activities (eg, coronary bypass surgery) can often be easily and rapidly linked to outcome data, the outcome of a pathology diagnosis often depends on many treatment variables and can take decades to establish.

One traditional way to get around this difficulty of evaluating pathology diagnoses by linking them to patient outcomes is to consider the diagnosis itself an outcome. The results are available immediately, and diagnostic differences can serve as a surrogate for error. Large numbers of these
“diagnosis as an outcome” studies have been performed in general surgical pathology. As would be anticipated from studies of clinical variation, pathology studies consistently document pathology diagnostic variation. Unfortunately, even simplified studies that concentrate on examining diagnostic differences of opinion are difficult to design in a manner that leads to conclusions that can be generalized to other diagnostic settings. Important factors influencing variation include the individual study’s case selection strategy, the diagnostic skills of the participants, the classification system used, and the availability of special techniques and clinical information. If a study includes large numbers of cases that are either unusually refractory to classification or unusually straightforward, the study’s overall precision results will differ markedly from routine practice. For example, a study of precision in the diagnosis of breast cancer would paint a rosy picture if all diagnostic groups were lumped together for analysis, but this study design would bury the problems with troublesome subgroups.

In anatomic pathology, probably the best “gold standard” to establish either correctness or error is one that relies on the presence of a fundamental characteristic of the disease state, such as a translocation or a distinctive phenotypic abnormality with very high diagnostic sensitivity and specificity. If a scientifically valid gold standard for “correct” cannot be established, the identification of error must rely on some arbitrary political standard such as the diagnosis with the most votes (a normative standard) or the diagnosis made by the highest authority. A political standard means that the discussion has turned to variation, and error may or may not be contributing to the variation.

Variation

The word variation comes from the Latin varietas, which was used to designate deception, wickedness, and even leprosy. In modern usage, the word variation continues to have highly negative connotations in many settings. For example, variation in the standard for how votes for the US president were cast and counted was a source of great concern in the last US presidential election. We were repeatedly reminded that the Fourteenth Amendment to the Constitution guarantees us “equal protection” under the law, and judges questioned how a “uniform standard...can vary from individual to individual.”

One of the paradoxes of science is that advances are built on a special type of variation termed creativity, but at the same time, variation in process is sand in the scientific gears. Ambivalence about variation carries over into clinical medicine. Uniformity of medical process, costs, and outcomes is a consumer expectation, and statistics documenting variation in these areas are typically met with astonishment and even outrage. However, centers of excellence, name brand institutions, and diagnostic superstars—widely considered to be the crown jewels of modern medicine—are a major source of practice variation. In medicine, a center of excellence only becomes excellent when compared with a center that is not so excellent. It would, of course, be wonderful if everyone could be above average, but this happy circumstance is prevented by a statistical reality named the Lake Wobegon effect in honor of the mythical small Minnesota town where all of the children are above average.

In pathology, diagnostic variation arises out of the variation between pathologists, the inherent variation in disease manifestations, and the imprecision built into classification systems. Residency training, journals, textbooks, and consultants do provide a considerable amount of buffering that reduces variation, but in practice, we see the limits of this buffering. For example, it has been correctly noted that pathology training is characterized by “extraordinary variation from program to program,” and this training variation will reliably lead to diagnostic variation.

From a practical standpoint, if controlling the variation currently seen in the practice of pathology is a goal, then variation must first be divided into the following 2 types: (1) variation intrinsic to the processes being discussed and (2) variation that has special causes that are not intrinsic to the processes. For example, if a disease process itself is intrinsically resistant to current methods of classification, educational efforts aimed at improving the skill of the individual pathologist would have no effect on the level of diagnostic variation. However, if a competent pathologist would be expected to consistently make a certain diagnosis given a certain set of data, then searching for system explanations for a misdiagnosis would be a waste of time.

Diagnostic Equipoise

In clinical research, it is considered unethical to enter a patient into a randomized trial unless there is reason to believe that any branch of the trial could be as likely to help the patient as any other branch. Under these conditions of equipoise, the trial can be conducted. Interestingly, this concept of equipoise does not apply to routine clinical medicine, in which patients are “randomized” to providers based on factors such as who is on call that day or who accepts patients for a certain health plan. In fact, it would seem to be impossible to achieve clinical equipoise in areas such as surgery and pathology that are known to be highly
operator dependent but yet often lack the data that would allow the patient to make head-to-head comparisons. Lack of clinical equipoise contributes to diagnostic variation.

**Diagnostic Uncertainty**

A diagnostic situation in which there is negligible uncertainty is characterized by one differential diagnostic consideration that encompasses all of the possible clinical outcomes, and that one diagnostic category can be established with an easily applied gold standard. When a diagnostic situation includes uncertainty, then by definition: (1) the number of possible outcomes exceeds the breadth of any diagnostic category, or (2) the route to the correct diagnosis includes likely opportunities for error, or (3) there would be variation in the diagnostic category to which the case is assigned by various reviewers.

A critical step in the identification of true error is to be able to separate error from the variation caused by the inherent uncertainty of the database. Under conditions of inherent uncertainty, failure of the patient’s outcome to conform to the diagnosis (eg, a child with a metastasis from a Spitz nevus) can be the uncertainty manifesting itself.

The story of scientific and technical advancement is the story of decreasing uncertainty. For example, answering the question “What is it?” has progressed from the sundial to an atomic clock with an accuracy of one part in 10 billion. During that same period, answering the question “Why am I sick?” has gone from mumbo-jumbo to immunoperoxidase stains, but presently the latter question includes likely opportunities for error, or (3) there would be uncertainty manifesting itself.

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**Error Caused by the Quality of the Database**

Whether it is catching a ball while looking into the sun, flying a plane into a fog-shrouded airport, listening to heart sounds with a television on full blast, or looking at a poor-quality portable chest radiograph, it is apparent that performance of any complex or difficult activity will be influenced by “signal to noise” ratio. A person with a very high skill level can compensate to some extent for an adverse ratio, but adverse conditions reliably shift the entire performance curve down. Opportunities for improving the quality of the database range from better slides to better information systems to better communication with clinicians and radiologists. These improvements immediately and directly affect the quality of the pathology report’s diagnostic field.

**The Importance of Hindsight in Error Identification**

When we are evaluated by ourselves, our colleagues, our patients, or a jury of our peers, the central question in the face of an adverse outcome is “Was this something that would have happened even with excellent medical care, or was it an event that a competent physician should have anticipated and taken steps to prevent?” Interfering with an honest answer to this question is the almost universal tendency (referred to as hindsight bias) to allow knowledge of outcome to influence the retrospective review of evidence. Even when outcome-blinded evaluation of evidence indicates a very low probability for a certain outcome, when this outcome is known to have occurred, this same evidence is often mistakenly considered to indicate that the outcome that did occur was either very likely to occur or was inevitable. Unfortunately, no matter what happens, there is always someone who knew it was bound to happen. Hindsight bias has been compared to shooting at the side of a barn and then later drawing a target, perhaps around the hole or perhaps on the other side of the barn. Hindsight leads to what is actually a “hindcast,” which should be sharply distinguished from the prospective nature of a forecast.

Hindsight bias is particularly important in medicine because the complexity of biologic systems often makes it difficult for even the best physician to know prospectively how things will turn out. In retrospect, we can be certain that how things did, in fact, turn out was one of the possibilities, but confusion arises in judging how likely it is that what did happen could have been predicted or prevented. In cytopathology, hindsight bias has been symbolized by the “litigation cell,” which is a nondescript cell type present on virtually every Papanicolaou smear. These cells have low prospective sensitivity and specificity for the establishment of a diagnosis until it becomes known that the patient has subsequently developed a uterine cervical malignant neoplasm. At that point, these “litigation cells” increase markedly in diagnostic value, becoming an obvious clue that should have tipped off any cytopathologist to the impending disaster.
Outcome of Error

Presumably, pathology is similar to clinical medicine in that errors with no effect on patient care far outnumber instances of error that cause significant patient damage. The terms “near error” and “free lesson” have been used to describe errors that do not result in patient injury. For example, if a case is signed out incorrectly, but the mistake is quickly pointed out and corrected, the patient is not harmed by this near error. However, the incorrect diagnosis is just as wrong as if the patient had been killed by inappropriate therapy initiated as a consequence of the original diagnosis. Because of this lack of definitive linkage between error and injury, the tort system has found it necessary to split assertions of malpractice into 2 separate questions: (1) Did the act occur and did it violate the standard of care? and (2) Did the act injure the patient?

If there is no injury to a particular plaintiff, the legal system generally finds against this plaintiff. However, providing excellent medical care requires a system that addresses both the needs of the individual patient and the needs of future patients. The knowledge gained from the study of a near error with no injury to the individual patient must be used to prevent similar future occurrences that may not be “near.”

How Should Error Be Classified?

At the simplest level of analysis, the pathologist functions as a black box, processing information and outputting diagnoses. Most malfunctions occur out of sight within the black box, and there may be a suspicion that errors are a personal or perhaps even a moral failing. It would follow from this view that the classification of pathology errors, except for the purpose of assigning appropriate retraining and/or punishment, is not a useful exercise.

Perhaps reflecting the interest of psychologists in the topic of error, most of the attempts to classify error have concentrated on cognitive failings and on the difficulty of making choices without an agreed-on right answer. The British psychologist James Reason has promoted a method for error classification that includes the following categories: (1) skill-based slips and lapses, (2) rule-based mistakes, and (3) knowledge-based mistakes. This system has been applied to clinical medicine by Leape and to anatomic pathology by Sirota.55

When performing skill-based activities, the pathologist is not engaged in problem solving but is engaged in tasks that are highly automated and require little active attention. The skill-based activity can be accomplished in “background,” even if some other task is capturing the pathologist’s attention. Error occurs when the pathologist inappropriately goes on or stays on “autopilot” and fails to initiate the active intervention that would be needed to respond appropriately to unexpected events.

In contrast with skill-based error, the pathologist who makes a rule-based error is aware that there is a problem to be solved but has defaulted to an inappropriate rule set to solve the problem. The pathologist may be using a best-practice approach, but it is being applied to the wrong case.

In Reason’s system, knowledge-based cognitive activity and the associated errors occur when the pathologist recognizes that neither a skill-based autopilot approach nor the application of familiar rules will lead to a correct diagnosis. At that point, the case takes the pathologist into what is recognized as unfamiliar territory. In this diagnostic terra incognita, errors begin to approximate the “hit-or-miss” qualities seen when beginners commit errors. “No matter how expert people are at coping with familiar problems, their performance begins to approximate that of novices once their repertoire of rules has been exhausted by the demands of a novel situation.” The important differences between the expert and the novice occur at the level of skill-based and rule-based diagnosis, where the expert has a much larger stock of successful routines.

The psychological approach to understanding error is interesting and potentially useful but can get in the way of looking at the big picture of error. In fact, the contribution of the individual pathologist’s cognitive function to pathology error is only 1 of 4 different levels of pathology error, and if an analysis of pathology errors does not clarify the level that is being addressed, the result is chaos. The levels overlap, but can be simplified as follows: (1) Operational issues. These include such factors as mislabeled specimens, poor slide quality, lost specimens, and incorrect or incomplete patient information. (2) Specialty of pathology issues. For example, when the specialty has been unable to arrive at best-practice recommendations, this will inevitably lead to differences in the approach to cases that can be misinterpreted as an error committed by the pathologist. (3) Actions of the individual pathologist. If well-established and noncontroversial best practice is familiar to competent practitioners, a pathologist who fails to conform to this practice is at fault. Reason’s cognitive approach can be helpful in understanding error at this level. In addition, for the sake of completeness, a final subtype of error that must be included with pathologist error is “violation,” which is the deliberate choice to behave in a nonstandard way. (4) Health care system level. The current health care system in the United States is designed for the provision of advanced technology at dispersed locations that are conveniently near to most patients. These goals may be in conflict with the goal to provide low-error pathology services.
Diagnostic Bias

A variety of biases have been shown to produce error, and some of these biases are undoubtedly important to diagnostic pathologists.57-59 The one that I have most frequently fallen victim to is referred to as anchoring bias. The latter is the tendency to lock onto a diagnosis (usually early in the workup of a case), and then undervalue data that would either support another diagnosis or refute the favored diagnosis.58

The Role of the System in Error

The traditional view of medical error is that people are the unreliable component in health care provision, and errors can be attributed to their “aberrant mental processes” such as forgetfulness, inattention, poor motivation, carelessness, laziness, negligence, or general incompetence.53 The system in which people work is viewed as a relatively passive and unchangeable part of background, except when it is called on to provide various countermeasures to reduce variation in human performance. A more recent view is that organizational or system factors, including work environment and management decisions, have a major role in the number of errors made by individuals working in systems.60-66 Rather than arising out of the “perversity of human nature,” errors are blamed on system “error traps” and the organizational processes that give rise to these traps.53 System factors that influence the rate of error include design of processes and tasks, training, and conditions of work.67 Reason has noted that “Rather than being the main instigators of an accident, operators tend to be the inheritors of system defects…. Their part is adding the final garnish to a lethal brew whose ingredients have already been long in the cooking.”68

Smoothly running systems match skills to expectations and make it difficult to deviate from best practice. The system is designed with the following objectives: (1) preventing error, (2) making errors as visible as possible so that they can be intercepted, and (3) whenever possible, mitigating the adverse effects of the errors that do occur.69 Management should use tools such as reducing unnecessary complexity, optimizing information processing, implementing appropriate automation, encouraging constraints that restrict unsafe actions, and helping to eliminate the error that often accompanies any significant changes in systems.69

In pathology one of the best examples of system error is flawed classification systems. Widely accepted disease classification systems with inherent low precision can represent an error in process design that “traps” the pathologist into error. Seldom is achieving a low error rate a driving force in the design of pathology classification systems, and it is apparent that the specialty cannot wait until important pathologists have built a career on a classification system before we decide whether the system allows a level of precision that is suitable for patient care. Faulty systems are a particular problem when they divide a continuum (eg, atypical hyperplasia vs nonnecrotizing ductal carcinoma in situ of the breast) into a dichotomy that is linked to major therapeutic decisions.

Another even larger system issue is the number of hospitals in which pathology services are provided. There are strong political and financial pressures to provide a large menu of medical care in a location that is convenient for the patient. We all want this convenient access, especially in an emergency, but convenient access means that there are almost 5,000 registered general hospitals in the United States that have anatomic pathology services “regularly and conveniently available.”70 These hospitals cannot survive by simply stabilizing the condition of patients and transferring them to high-volume regional centers. Furthermore, these thousands of hospitals create demand for the job description “general pathologist,” which arguably is an almost impossibly broad job assignment. One classic manufacturing technique to avoid error is to carefully define the worker’s area of expertise or “scope of practice,” but applying this technique to pathologists is impractical in a system with large numbers of relatively independent, dispersed, and highly varied practice settings.

The Role of the Individual in Error

Although it makes all of us feel better to blame our errors on flawed systems, it is obvious that people who function in the same systems signing out the same number of the same types of cases differ in their error rate. It is also apparent that even though physicians are very highly selected and highly trained, we find the same bell-shaped curve of physician performance that we are familiar with in other activities.71-73 For example, the tens of thousands of talented high school basketball players who would like to play professionally are put through a rigorous selection process that identifies the very best of the very best.74 However, among the best of the best, the performance of the least talented is still dramatically different from that of the most talented.75 Professional sports does not shut down teams in response to this difference any more than pathology departments are shut down when they find that they cannot staff every position with a medical Michael Jordan or Barry Bonds. Furthermore, the medical Michael Jordan is somewhat of a mixed blessing from a systems standpoint, because...
if systems are designed around the talents of superstars working with exceptionally skilled support groups, high rates of failure by less talented workers in less supportive systems are inevitable. As would be expected, it is clear that at least in the approach to certain problems in clinical medicine, low-volume practitioners practicing in a low-volume hospital have outcomes different from those of high-volume practitioners in high-volume institutions.76

A number of industries have attempted to reduce variation by identifying and eliminating the worst performers, using forced “best to worst” ranking systems.77 This concept has some similarities to a system that uses an initial board examination to cut off the bottom performers, followed by board recertification to cut off practitioners who do not maintain or enhance their skills. However, industry has found that even in apparently simple situations, improving the workforce by cutting off the bottom is trickier to implement than it might initially seem.78,79 Therefore, it’s not surprising that in a very broad medical specialty such as pathology, it is extremely difficult to establish the minimal knowledge base required for everyone completing a residency training program and to also develop a valid tool to measure this knowledge. Even more difficult is the task of defining the minimal knowledge base for thousands of pathology practice settings in the United States.

Second Opinion

Perhaps the most important daily diagnostic challenge for the pathologist in practice is to distinguish between a case that has features that are simply outside any evidence-based literature or evidence-based experience and a case that would be given an objectively better diagnosis if referred to another pathologist. Sending any case with an unusual feature off to a consultant “just to be sure” is one approach, and Sirota has pointed out that in nonmedical fields, introducing “redundancy” into a process is a common error-reduction strategy.80 However, sending out every minimally odd case fundamentally changes the practice of pathology, with the community pathologist becoming a screener for the consultants. Furthermore, the point of sending the case out is to improve patient outcomes. Although it is extremely easy to link changed diagnoses to changed therapeutic approaches, for a given patient it can be more difficult to sort out the link between a pathology diagnosis and valid clinical end points. For example, differences in prostate needle biopsy interpretation reliably lead to marked modification of the clinical approach to the patient. However, the various clinical approaches to localized prostate cancer, which vary from watchful waiting to several more aggressive approaches, have not been compared in a randomized trial. If a diagnosis of adenosis is reviewed following the development of metastatic prostate cancer, the pathologist may be sued for not making a diagnosis that led to aggressive therapy. Unfortunately, many patients who have aggressive therapy experience significant complications, and they also can later develop evidence of metastatic prostate cancer.

In the past, dying a “Harvard death” usually meant dying with your electrolytes in perfect balance. If mandatory second opinion were to be instituted, it may also come to mean dying after your slides have been reviewed at Harvard or some other prestigious center. Unfortunately, neither perfect electrolyte balance nor brilliant slide interpretation can prevent the inevitable. On the other hand, it is obvious that the current somewhat informal consultation system has markedly improved the precision of pathology diagnoses, and it is difficult to make the argument that more consultation would not result in even more diagnostic precision. Furthermore, there is some evidence for a pathology placebo effect, with patients and family benefiting psychologically from a second opinion by a prestigious institution.81

What Good Comes Out of Error?

Not all physicians recognize the high potential value of error identification as a tool to improve patient care. Of interest, this value of medical error is analogous to the high value of conflicting or negative data in the basic sciences. In his studies of the validation of scientific theories, the philosopher Karl Popper had the great insight that negative data are much more powerful than positive data in the advancement of science.82 Similarly, in clinical medicine, error identification is critical to many attempts to improve the provision of patient care. Errors prompt system modifications that are designed to make similar errors difficult to commit in the future, and, ideally, modifications are instituted before rather than after patients are harmed.

This positive approach to error, which began as industrial quality management science has now been adopted by the Joint Commission on Accreditation of Healthcare Organizations as an important standard for its review of health care institutions. At the simplest level, such as legible labeling of slides, a failure immediately should trigger approaches that will make future errors less likely. At a more complex level, such as the evaluation of disease classification systems, the importance of failure as a tool to promote improvement is also apparent. For example, if a proposed system works to precisely classify 100 cases, documenting that the system works to classify
the 101st example adds little or no information. In contrast, having the system fail to account for the features of the 101st case tells us definitely that the system will not work for all cases and can suggest ways to update and improve the system.

What Are the Main Barriers to Error-Free Medicine?

Most observers agree that the relatively high error rate in medicine is the result of complex rules being applied to complex biologic systems in complex environments by large numbers of people.83,84 It has been noted that the provision of medical care used to be simple, ineffective, and relatively safe, but is now complex, effective, and potentially dangerous.55 Leape and colleagues62 claimed that “healthcare represents the most complex safety challenge of any activity on earth.”

In anatomic pathology, complexity definitely affects the nature of error. The operational aspects of diagnosis are obviously much simpler than, for example, the pathologist’s cognitive diagnostic component, but even with operations, we find impressive complexity. The efforts of a group of physicians, technicians, clerks and nurses are required before a correctly labeled and technically adequate slide from a single case arrives on a pathologist’s desk accompanied by basic laboratory and clinical data. The number of participants in the case becomes even greater with the addition of special studies and trainees. This division of labor means that rather than being the act of one person, error that harms the patient often involves a series of errors or a system design failure combined with human error.62,86 Each of the multiple errors is necessary, but only together are they sufficient to produce patient harm. Reason illustrated this complexity with his “Swiss cheese model of system accidents.”53 He pointed out that many steps in patient care can function as barriers to error, but each can occasionally fail. Patient harm occurs only when failures in the barriers at each step (slices of Swiss cheese in his model) fortuitously align themselves. When error is viewed as a problem caused by the individual, the person who is closest to the patient (the final slice of cheese) usually gets all the blame, and the various “latent conditions” or “resident pathogens” that led up to the error are ignored.53

A special problem with standardizing pathology is the importance of image analysis. Ideally, the image analysis part of diagnosis would be performed in a manner that extracted only what was objectively on the slide, rather than also telling us facts about the pathologist (eg, do you read? are you careful? do you favor false-positive or false-negative?). When the diagnosis tells us as much about the pathologist as it tells us about the objective features of the image, the slide becomes more of a diagnostic Rorschach and less of an objective medical test.

Several barriers to error-free pathology are a consequence of the approach society has taken to medical error. For example, in its approach to pharmaceutical products, society has demanded that the product be proven safe and effective before it is released for general use, and there is an extremely elaborate system set up to ensure that what it says on the bottle is what is inside the pill. In contrast, there are no precision or accuracy standards for the pathology diagnosis, even though numerous studies have documented that what is in the pathology report’s diagnostic field is not necessarily what is on the slides.

The culture of medicine can also make it difficult to use errors to prevent future errors. Physicians are socialized during training to strive for error-free practice, and because the medical culture simply does not accept the risk of error as a normal part of medical practice, error is often viewed as a “failure of character.”52 Shaming and punishment of the individual “responsible” for an error is widely believed to be an effective approach to the problem of medical error, creating what Wu87 referred to as the “second victim” of the error. Both individuals and institutions respond to error by looking for the flawed individual. For example, when an error becomes apparent, hospitals typically react as if it is an anomaly. The solution is to “ferret out and blame an individual,” and to promise that “it will never happen again.”87

Both this flawed individual approach to error and the punitive and arbitrary nature of the legal system create strong incentives to hide or deny error, making it more difficult to use today’s error to prevent future errors.88 Furthermore, an error that could have harmed a patient but does not is frequently considered good luck—using the “no harm, no foul” approach to analysis—and the error quickly disappears from view.

Physicians and medical institutions have responded to the punitive approach to error with an almost bunker mentality against acknowledging error, especially to “outsiders.” We find that unless people who are involved in errors believe that their reports will be processed by a system that can draw a rational line between blameless and blameworthy action, they lack the trust necessary to participate in either mandatory or voluntary reporting systems.53 This “they don’t understand” reaction is similar to the culture sometimes found within police departments. The result is not one but several major barriers to reporting medical errors, including (1) fear of individual or organizational repercussions, (2) the belief that error is an indication of a practitioner’s incompetence, and (3) the potential for legal discovery of
reports. It is also important to note that pathologists involved in errors committed by other pathologists are caught between the imperative to protect patients and the feeling that only he who is perfect should throw the first stone. It has been repeatedly noted by pollsters that an informal Eleventh Commandment of modern behavior is “thou shalt not be judgmental.” Physicians who make it a habit to point out their colleagues’ errors usually are considered at best meddlesome, and those who testify as experts for plaintiffs are often perceived as simply greedy—being paid to express such statements as “I can’t imagine how anyone could have missed that.”

Establishing best practice with guidelines would seem to be a simple and reasonable approach to controlling variation, but even here there are several problems. For one thing, it has been observed that “some physicians would not be receptive to any guidelines coming from whoever.” Furthermore, although it does not seem to be a controversial position that our immunoperoxidase staining techniques should be standardized, suppressing our diagnostic creative urges is a surprisingly controversial topic.

Finally, it must be admitted that no matter how much attention is directed at preventing error, errors will continue to occur. An Albuquerque pathologist summed up this dilemma when he concluded after reviewing a diagnostic error that “what I learned from this case is that I should not have come to work that day.”

**Physician Response to Error**

The “system is the problem” provides a view of error that is less threatening to the pathologist because it is impersonal, and it has the advantage of focusing attention on improving the provision of future health care. However, the patient damaged by error is looking at an event in the past, and the main issues are accountability, punishment, and compensation. How should the physician who has made an error that damages a patient deal with these issues? As much as the physician wishes that the error had not happened, it in fact did happen, and he or she must face the finality of the past. This finality has been a source of anguish since ancient times, eg, the Greek poet Agathon observed that “this only is denied to God—to undo the past.”

Theoretically, apology could be used to address at least the accountability issue, and the General Medical Council in the United Kingdom has recently revised its guidelines on good medical practice to state that after an adverse event, both a full and honest explanation and an apology should be provided. Unfortunately apology has been used and reused by public figures from Jimmy Swaggart to Bill Clinton, becoming almost a standing joke, and the inadequacy of apology in various nonmedical contexts has been acknowledged. Too often the person to whom the apology is addressed hears only “I’m sorry that I got caught” or “I’m sorry that I’m in this mess,” and Hallmark has not developed a product line that that overcomes this barrier. It has been claimed that apology “gives more to those who apologize…than to those asked to accept the apology.” Even before the 1999 IOM report, the chairman of the American Medical Association’s Board of Trustees responded to a series of medical errors by noting that “it has become apparent that we need to say something to our patients other than ‘I’m sorry.’”

Perhaps the most troubling aspect of responding to error is the difficulty that physicians have fixing what they have broken. As Hilfiker pointed out, the very nature of our work means that we often are dealing with elements that cannot be restored in any meaningful way. More recently, a hospital spokesperson acknowledged this same problem at a news conference called to discuss the death of a child caused by an error in administration of chemotherapy at her hospital: “There is nothing that we can do to bring their child back to them, and we are devastated by this knowledge.”

**The Legal System**

Even though many people believe that a final accounting of right and wrong will occur after death, there is also a widespread feeling that when you might have been wronged, you should get resolution in the here and now. The tort system has stepped up to this challenge and has proven itself particularly well structured to deal with the various issues raised when an error may have been committed. Not only can the tort system definitively make a decision about who is at fault but it can compensate the aggrieved party and punish any wrongdoing. The pathologist who is sued lands in an arena that usually combines the jurors’ highly emotional reactions to a negative outcome with these same jurors’ almost complete inability to understand the technical underpinnings of the decision process that accompanied—and may or may not have had a causal relationship—to the outcome.

Of the elements of a malpractice case that make it “bankable” for the lawyer, error (theory of negligence) is much less important than either the degree of damage to the patient or the skill of the expert witness. An ideal witness would be a “nationally acclaimed expert” who has no reluctance to claim the infallibility that comes from absolute knowledge. The expert witness can apparently say almost anything without fear of a charge of perjury, and there is no formal professional venue outside the courtroom to deal with testimony that would not pass any
peer review standard. Interestingly, it is the successful standardization of practice that makes us so vulnerable to the claims of the expert. Physicians cannot be sued for deviating from accepted standards when no such standards exist, but the combination of a poor outcome and a credible expert’s assertion of a failure to perform according to a standard is a very powerful combination. The relative protection from the legal system enjoyed by alternative healers arises in part because they “claim no fixed recipes and make a virtue of treating each case individually.”

Of course, most issues surrounding speeding drunk drivers, spilled hot coffee, and automobile paint jobs that have led to famously incomprehensible jury decisions are much simpler to understand than virtually any allegation of medical malpractice. However, this same jury pool makes the ultimate determination of error or not error in the provision of medical care, functioning as a frequently disoriented gold standard. Not unexpectedly, jurors struggling with conflicting opinions about the technical issues of medical care often seem to be simply lost, but a jury can easily distinguish between a good outcome and a bad outcome. Also, juries can be adept at redistributing resources in response to emotion (eg, plaintiff leaves courtroom crying) or disability.

In light of how the tort system functions, it is quite natural that the fear of facing a jury has permeated medical practice, and this fear certainly affects physician behavior. The rational physician attempting to avoid “error” must to some extent tailor medical decisions to a best guess of the retrospective perceptions of a lay jury. Although it is possible that this “tort deterrent signal” prevents some negligence by physicians, it is more likely that the usual physician response to lawsuits can be compared to that of the business that added the worthless warning label “never iron clothes while they are being worn.”

When plaintiffs’ attorneys attempt to claim the high ground, they talk about not only the tort deterrent signal but also about compensating victims and forcing systems to improve. It is, of course, almost impossible to imagine that a system with the widespread impact of the tort system does not occasionally do something useful. However, most of the evidence is that the tort system is simply an inefficient and expensive mechanism to transfer assets, and that the plaintiffs’ attorneys’ primary goal is imposing their tax on the asset transfer. Because lawyers and their rules control much of the post–error analysis in medicine, the success of error analysis is measured in large part by the lawyers’ standard, ie, the size of the contingency fee, and not by the prevention of similar future errors. As night follows day, any highly complex system operating within these dysfunctional rules would be expected to experience an unnecessarily high error rate.

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