5 The practice of error prevention in anatomic pathology

Stephen S. Raab, MD

Introduction

The formal practice of surgical pathology and cytopathology error prevention involves the performance of several sequential process steps, which has been described in the patient safety literature. The first step involves understanding the work of anatomic pathology to determine when work is safe or unsafe in all testing phases. The total testing process (TTP)[1] describes three main testing phases: (1) the preanalytic phase, composed of clinical decision making of test choice and test procurement; (2) the analytic phase, composed of anatomic pathology laboratory activities, such as tissue processing and interpretation; and (3) the postanalytic phase of clinical decision making based on the test result.[2] The anatomic pathology test pathway comprises hundreds of steps, consisting of technical and cognitive tasks/activities and connections/hand-offs among laboratory personnel and technologies.

One standardized approach to error prevention and reduction is the continuous quality improvement method best known as the *plan, do, check,* and *act* (PDCA) cycle, popularized by Deming.[3] *Planning* involves the activities of defining the problem, establishing the level of the problem, determining the root causes of the problem, developing a target goal based on an ideal state, and designing initiatives that target specific causes of the problem. *Doing* involves the implementation of these initiatives using formal or informal methods described by implementation science. *Checking* involves the activities of evaluating the effect of the implementation. *Acting* (or adjusting) involves the activities of continuing or changing the implementation strategy and quality improvement initiative. The PDCA cycle is optimized when performed by frontline personnel and is sometimes characterized as single loop learning.

The current practice of the PDCA cycle of surgical pathology and cytopathology error reduction is discussed below.

Planning steps

Definition of medical error

The Institute of Medicine (IOM) defined a medical error as the failure to complete an action as intended or the use of a wrong plan to achieve an aim.[4] Medical errors are further classified as near-miss, no-harm, or harm events based on the assessment of patient outcomes. *Near-miss events* are errors detected and prevented prior to having a possibility of affecting the patient (eg, a specimen mislabeling error made at the time of tissue procurement is detected and corrected in the gross room). *No-harm events* reach the patient, without harmful consequences. *Harm events* are errors that cause patient harm, which is graded using a scale that ranges from mild to severe, with the most catastrophic occurrences termed *sentinel events.*

Based on the IOM definition, the following are examples of anatomic pathology errors in the TTP cycle:

- A Pap test specimen is lost in transportation (eg, in the hand-off between the clinical team and the laboratory).
- On a lung fine-needle aspiration biopsy procedure, a radiologist obtains a very bloody specimen and a definitive diagnosis cannot be rendered.
- A labeled and opened tissue cassette is found on the floor the following morning adjacent to the tissue processor. The tissue cannot be located.
- A gastroenterologist does not receive a copy of the diagnostic biopsy report.

The concept of medical error is hardly new, as early medical practitioners recognized that one cause of disease originated from the treatment itself (ie, the Greek term *iatrogenesis* or originating from the physician). The IOM report highlighted the current level of error and harm in medical practice and spearheaded efforts to reduce error frequency and consequences.

As each anatomic pathology test step involves the completion of a single or small set of activities or hand-offs, the failure to complete any step could lead to an error. As the TTP involves plan development in preanalytic, analytic, and postanalytic testing phases, the use of a wrong plan in any phase also could lead to an error. Therefore, error prevention begins with understanding the work and reducing the probability of failure in each step and plan.[5,6]

Patient harm is just one potential consequence of medical error. The IOM defined six domains of quality: safety, efficiency, timeliness, effectiveness, equity, and patient centeredness.[1] Aside from safety, medical errors may cause a breakdown in care delivery in the other five quality domains. For example, laboratory personnel may perform additional work to prevent harm from occurring as a consequence of some medical errors, such as mislabeled specimens. This extra work lowers the laboratory efficiency and may affect the timeliness of result delivery for other specimens. In anatomic pathology, error prevention generally is discussed in terms of patient safety, although improvement initiatives focused on other quality domains may also represent error prevention.

Most of the existing anatomic pathology literature has been focused on "diagnostic error," or an error associated with the diagnosis itself. Other types of errors also occur in the anatomic pathology TTP and these include errors in test selection and post-test clinical decision making.

A diagnostic error may be further classified as an error in accuracy or an error in precision. In patient safety science, the term *diagnostic error* has no connotation of root cause, patient outcome, or individual blame. In daily practice, connecting error with blame limits error reduction and reflects a lower-level patient safety culture.

A diagnostic error in accuracy is a failure to establish the "truth" or the patient's actual disease process. For example, if a breast biopsy were diagnosed as benign when the lesion actually is malignant, we would classify the benign diagnosis as erroneous. Note that truth is established based on the actual disease and not on a second opinion. The establishment of an accurate diagnosis is challenged by the lack of sufficient "gold standards" in tissue diagnosis.

A diagnostic error in precision is the failure to establish the same diagnosis on repeated measures. A typical example of an error in precision is when two pathologists disagree on the diagnosis. Some categorize this type of error as an error in reproducibility or an error in agreement. It is important to point out that a diagnostic disagreement by definition is still an error, regardless of the description of the level of harm. A diagnostic error in precision also reflects an error in accuracy, as at least one of the diagnoses does not reflect the patient's disease process.

A common method of establishing the level of diagnostic error in accuracy is by the measure of frequency. A common method of establishing the level of diagnostic error in precision is by a measure of agreement, such as the kappa statistic.

Error detection and level

Medical errors may be detected using a variety of methods that vary depending on factors such as timing, people and/or systems involved, and connections between the individuals and the errors detected. Much of the published anatomic pathology literature describes the current levels of diagnostic and nondiagnostic error based on detection methods that are passive, individually based, and retrospective. In daily laboratory practice, ongoing error detection occurs constantly using processes that provide feedback to produce no-harm events and occasional system changes that essentially illustrate front-line, real-time, error reduction. With a few exceptions, real-time detection methods are not used to inform current practice of the existing level and detailed causes of error; corrections simply are made at the front line of care.

Retrospective error detection methods detect a historical level, which generally is assumed to be the current state if an error reduction initiative (or other change process) has not been implemented. A common method of retrospective error detection is through an audit or review of case materials. Secondary, retrospective, diagnostic case review is a method to establish a level of diagnostic accuracy for specific anatomic pathology case characteristics (eg, organ type, procedural type, level of training, degree of subspecialty process).

Well-known examples of retrospective diagnostic error detection are the cytologic-histologic correlation method and the frozen section–permanent section correlation method, in which the diagnoses are compared to determine individual case discrepancies and a frequency of diagnostic accuracy error. For the cytologic–histologic correlation method, Vrbin et al[7] showed a high level of institutional variability in the method of performance, which, of course, limits the ability to compare individual institutional data sets.

Measures of diagnostic precision generally are determined through retrospective studies that involve multiple pathologists who evaluate sets of previously diagnosed cases. Interpathologist kappa values vary widely depending on study design and case and pathologist factors. In the PDCA cycle, the current level of diagnostic error in accuracy and precision serve to establish the benchmark of the problem that is targeted for improvement.

Nondiagnostic errors also may be tracked using retrospective methods, depending on information systems and existing processes such as checklists. Prospective observational techniques may be used to determine baseline frequencies of nondiagnostic errors (eg, mislabeled tissue cassettes).

Safety science is composed of Safety I, which involves the detection of error (or what goes wrong), as described above, and Safety II, which involves the observation of what goes right. As most work is performed without error, the study of Safety II allows systems to understand system strengths and resilience and to make changes to support safe practices.

Root cause analysis

Informal and formal root cause analysis methods are used to determine the causes of medical error. The most informal method is described as a form of story-telling in which individuals discuss and hypothesize the causes of error. Some organizations that use Lean quality improvement methods use a front-line, 5 Why, root cause analysis method that repetitively asks "why" to drill down to deeper causes of error.[8]

Other forms of root cause analysis use categorical or probabilistic methods to identify causes of error. One categorical method is the use of an Ishikawa fishbone to classify error causes into six main groups, as shown in Figure 5-1. By establishing categorical causes, investigators are able to examine the role of system factors that contribute to error.

A major challenge in patient safety is a cultural belief that traditionally associates the main cause of a medical error as secondary to an individual failing. The current medical-legal culture emphasizes this belief by using a process in which experts evaluate an error to determine if the cause was physician negligence.

Categorical root cause analysis methods evaluate the components of work involved in the activities and connections within the TTP and at higher levels of care that affect the TTP processes. Investigators are able to determine latent causes in addition to the active events. This form of analysis

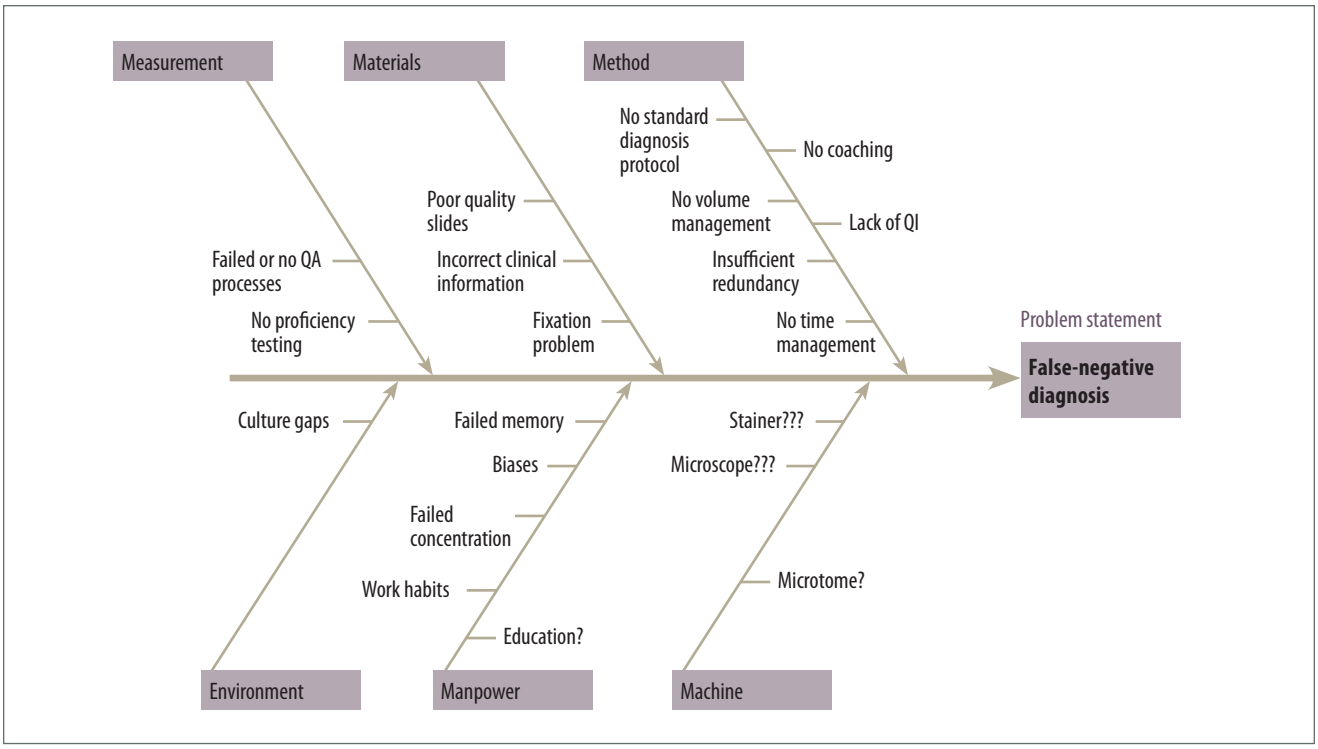

Figure 5-1. Ishikawa fishbone. The point of the arrow points to the problem, and the ribs of the fish describe categories of cause. In this example, the problem is a false-negative diagnosis. Abbreviations: QA, quality assurance; QI, quality improvement.

is based on Reason's "Swiss Cheese" model of error, in which an active failure occurs in the context of a number of latent factors that are generally system based.[9]

Berwick[10] described four levels of health care systems where change occurs:

Level A: The experience of the patient and communities

Level B: The microsystems of care, which are the small units of work that provide the care that patients experience

Level C: The health care organization, such as a hospital

Level D: The health care environment, including systems of regulation, financing, professional education, litigation, and social policy

Pathologists generally work in level B, in a care team that consists of laboratory and clinical service members who work together to provide a diagnosis. In the TTP model, anatomic pathology testing work also includes preanalytic and postanalytic clinical care work, and root cause analysis assesses the clinical activities and hand-offs to determine potential root causes of error within and among microsystems. The high-level system root causes are factors that contribute to front line error and are identified in levels C and D.

Health care levels C and D have a major influence on microsystem quality. For hospital-based anatomic pathology laboratories, the culture of diagnostic care is strongly influenced by overall hospital-based culture. For example, a work culture in which the environment is highly stressful, such as when the volume of work exceeds capacity to perform work, may be a contributing cause of medical error. Many of the factors that affect work, such as educational requirements, legal systems, and system practice scope, are established at level D of care. Consequently, failures at higher health care levels often indirectly contribute to anatomic pathology error.

Patient safety cultures often are established at level C of care. Ashcroft et al[11] described five sequential stages of patient safety culture: pathological, reactive, calculative, progressive, and generative. The safety performance of an organization and the microsystems within that organization improves as the culture matures.

The Quality Chasm report proposed 10 new rules of care for microsystems (Table 5-1) and several of these rules specifically focus on patient safety.[12] For example, many medical errors arise out of variable or nonstandard work (Rule 2), and root cause analysis of some anatomic pathology errors leads to the identification of the lack of standardized activities and hand-offs. Standardized tools and procedures assist in decreasing the frequency of medical error.

The field of diagnostic anatomic pathology is based on the cognitive task of pattern recognition. Pattern recognition is based on learning to recognize that groups of specific morphologic criteria are associated with a specific disease. Root cause analysis shows that failures in the cognitive task of pattern recognition may result in a diagnostic error of accuracy or precision. The current level of diagnostic precision reflects a baseline level of variability in the application of diagnostic criteria and cognitive biases that result in the failure to apply the correct heuristic link of criteria and disease process. The approach to correct these cognitive failures partly lies in the realm of level D involving systematic education and training of pathologists.

TABLE 5-1 Ten rules to enhance the effectiveness of microsystems

Rule	Current practice	New practice
1	Care is based primarily on visits	Care is based on a continuous healing relationship
2	Professional autonomy drives variability	Care is customized to individual patients' needs and values
3	Professionals control care	The patient is the source of control
4	Information is a record	Information is freely shared
5	Decision making is based on training and experience	Decision making is based on evidence
6	"Do no harm" is an individual responsibility	Safety is a system priority
7	Secrecy is necessary	Transparency is necessary
8	The system reacts to needs	Needs are anticipated
9	Cost reduction is sought	Waste is continuously decreased
10	Preference is given to professional roles over the system	Cooperation among clinicians is a priority

Modified from Berwick[10] and Institute of Medicine.[12]

Ideal state identification

From a patient safety perspective, the ideal state is an error-free system. For an anatomic pathology test, all activities and hand-offs in the clinical and laboratory microsystems would be defect free. In addition, health care levels C and D would facilitate safe practices in all microsystems of care.

Although a completely defect-free system may not be attainable, quality management systems strive to improve health care by targeting specific latent and active causes of error. A quality management system consists of processes, procedures, structures, and resources to manage the elements of quality, as described above. Quality management consists of quality assurance and quality improvement, which for patient safety, encompasses the field of improving the existing levels of safety through error reduction processes.

Quality systems use specific approaches or methods consisting of rules, tools, philosophies, and processes. Examples of these approaches are Lean and Six Sigma. Lean uses tools and processes to evaluate the basic components of work to eliminate waste and defects.[5,6,8] Six Sigma involves the use of statistical methods to improve the quality of process outputs to produce a Six Sigma process, reflecting a very low process defect frequency (3.4 defects per million parts).[5,6] Hospital systems often blend the use of these two approaches.

Development of error reduction strategies

Anatomic pathology error prevention and reduction occurs through the maintenance of existing safe practices (Safety II) and the development of new safe practices. Safe practices may be classified into the same categories as identified in the Ishikawa fishbone: culture, people, methods, measures, equipment, and materials. Consequently, safe practices are a result of the intersection of all health care levels. For example, health care level D assists in the development of safe laboratories through processes such as accreditation, licensure, certification, and proficiency testing. Health care level C may develop safe practices through strategies that affect the patient safety culture.[13]

Many anatomic pathology laboratory microsystem safe practices are a result of the adoption of standardized procedures and processes that limit the frequency of error. These include a large number of standardized policies and procedures that previously were implemented in all sections of the laboratory. For example, pathologists may use redundant procedures (a method), such as double pathologist sign-off on all first-time diagnoses of malignancy. Alternatively, pathologists may use synoptic checklists (also a method) to report on cancer diagnoses.

Pathologists may develop error reduction strategies based on a newly detected error or as a result of a systematic change process. For newly detected errors, a root cause analysis is performed and specific causes of error are identified. An error reduction initiative is developed that targets a specific error cause.

Doing: Implementation of error reduction initiatives

In clinical practice, the implementation of an error reduction initiative occurs in a variety of ways, although implementation science suggests that specific strategies are more effective in driving sustainable change.

For example, in the Promoting Action in Research Implementation in Health Systems (PARIHS) framework, Rycroft-Malone et al[14] identified three key elements inherent in any implementation plan: evidence, context, and facilitation. These three elements may vary in strength from low to high, and successful implementation occurs when all three are rated as high.

Evidence is the knowledge derived from a variety of sources that has been subject to testing and found to be credible. This concept of evidence is generated by research, clinical experience, patient experience, and local data and information. The importance of local data collection indicates that health care professionals want to see their own data reflecting error and not simply assume that anecdotal or published data are valid in their setting.

Context is the environment or setting in which change occurs and has three components: culture, leadership, and evaluation. A strong context consists of a learning culture (characterized by a clarity of front line roles, decentralized decision making, and high value placed on staff), transformational leaders who enable others to act and make decisions (compared to transactional leaders who tell people what to do), and the ability to evaluate (through multiple sources of evidence).

Facilitation is the enabling of the implementation and is carried out by a facilitator who has a specific purpose, role(s), and attributes. A variety of methods of facilitation have been used in the implementation of error reduction initiatives, and these include external facilitators who help to support the adoption of new activities. Other approaches to facilitation are more grounded in humanistic psychology and enable reflective thinking, identification of front-line needs, and guiding group processes through critical thinking. The role of a facilitator may change during the implementation process.

The PARIHS framework indicates that error reduction initiatives will be variably effective depending on individual and system components. Other implementation methods emphasize various components such as the engagement or measure pieces. The actual implementation strategy implicitly or explicitly involves education (evidence) and change leadership (facilitation) methods.

Measuring (checking) and acting

Following the initial implementation of an error reduction initiative, the effectiveness is measured by tracking the frequency of a specific metric. In safety science, this metric may be the frequency of error. The measuring or checking activity leads to further action to improve the quality of care. The PDCA cycle is meant to be iterative, so that once the hypothesis underlying a change is negated or confirmed, the repetition of the cycle will extend knowledge further. This repetition brings the metric closer to the ideal state, and in the patient safety world, this means lower error frequency or greater precision.

The PDCA cycle is based on the scientific method and builds critical thinking in organizations and a culture of problem solvers.[3] In a Lean system, the PDCA cycle often is described as a *kaizen,* or small improvement event, as small changes in effectiveness measured following the "doing" leads to small changes in the plan and further improvements. The PDCA cycle also may produce better understanding of the problem, which may change the conception of the ideal state.

Summary

The microsystem of anatomic pathology error prevention and reduction is part of a laboratory's quality framework, which is closely linked to the level C organizational and level D environmental networks of quality. The operational success of microsystem error reduction depends on the system capabilities to problem solve and implement sustainable initiatives, based on a quality system approach, such as the PDCA cycle of change.

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