Review

Quality and patient safety in the diagnosis of breast cancer

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Abstract

The media, medical legal, and safety science perspectives of a laboratory medical error differ and assign variable levels of responsibility on individuals and systems. We examine how the media identifies, communicates, and interprets information related to anatomic pathology breast diagnostic errors compared to groups using a safety science Lean-based quality improvement perspective. The media approach focuses on the outcome of error from the patient perspective and some errors have catastrophic consequences. The medical safety science perspective does not ignore the importance of patient outcome, but focuses on causes including the active events and latent factors that contribute to the error. Lean improvement methods deconstruct work into individual steps consisting of tasks, communications, and flow in order to understand the affect of system design on current state levels of quality. In the Lean model, system redesign to reduce errors depends on front-line staff knowledge and engagement to change the components of active work to develop best practices. In addition, Lean improvement methods require organizational and environmental alignment with the front-line change in order to improve the latent conditions affecting components such as regulation, education, and safety culture. Although we examine instances of laboratory error for a specific test in surgical pathology, the same model of change applies to all areas of the laboratory.

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Introduction

In recent years, anatomic pathology diagnostic errors have been a source of headline news revealing sentinel events involving patients who had incorrect diagnoses. A sentinel event is defined as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related...
to the natural course of the patient’s illness. For some patients who had incorrectly diagnosed breast lesions, the consequences were devastating and resulted in delays in diagnosis with interval advancement of cancer and/or death or unnecessary invasive surgery, such as a mastectomy for a benign condition. Some of these headlines are documented in Table 1. From a medical perspective, cases 1 and 2 are examples of specimen identification error, case 3 is a communication error, and case 4 is a cognitive interpretation error.

There are several reasons why these errors achieved such high prominence in the media. First, the media focuses on patient outcomes and understandably, the errors leading to catastrophic outcomes are important to understand. By highlighting these errors, attention is brought to bear on the problem. Second, patients place their trust in physicians and hospitals and a medical error with tragic consequences sometimes is viewed as a breach in that trust. The medical legal perspective evaluates error in terms of human “negligence” or the failure to exercise the care that a reasonably prudent person (healthcare professional) would exercise in similar circumstances. In tort law, the standard of care is the degree of caution or prudence required of an individual who is under a duty to provide such care.[1,2] The media often directly or indirectly portrays sentinel events as instances of negligence in daily healthcare work activities.

Unfortunately, partly as a result of this perspective, the public and healthcare personnel associate medical error with incompetence and react with blame. This view is counterproductive to improvement, as it magnifies the focus on individual responsibility rather than an examination of all the underlying root causes. In tort law, the standard of care is the degree of caution or prudence required of an individual who is under a duty to provide such care[1,2]. The media often directly or indirectly portrays sentinel events as instances of negligence in daily healthcare work activities.

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Table 1

<table>
<thead>
<tr>
<th>Case 1: Cancer-free woman underwent double mastectomy because of lab mix-up</th>
<th>Source: Today.com</th>
<th>Date: October 4, 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>• In 2006, she was told she needed to undergo a radical double mastectomy because she had an invasive form of breast cancer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• “I just broke down and cried,” she recalled of the moment she got the diagnosis.</td>
<td></td>
<td></td>
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<tr>
<td>• The patient went to another doctor for a second opinion, and was again told she had cancer. The doctor relied on the same misplaced tissue sample.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case 2: Pathologist mix-up of breast biopsies leads to unnecessary lumpectomy</td>
<td>Source: Pathology Blawg</td>
<td>Date: May 12, 2012</td>
</tr>
<tr>
<td>• The pathologist involved in the case switched biopsy samples and gave the correct diagnosis to the incorrect patient, which led to a lumpectomy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case 3: Case Out of Canada</td>
<td>Source: Pathology Blawg</td>
<td>Date: February 3, 2012</td>
</tr>
<tr>
<td>• Interestingly case out of Canada.....</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Although the pathologist’s pre-operative report on the breast biopsy did not indicate malignancy, apparently it was worded in a fashion that was confusing, and led the surgeon to believe there was cancer; a mastectomy was subsequently performed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The plaintiff is seeking a total of $2 million in damages.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case 4: Case out of Canada</td>
<td>Source: New York Times</td>
<td>Date: July 19, 2010</td>
</tr>
<tr>
<td>• Nearly a year earlier, a pathologist at a small hospital had found the earliest stage of breast cancer from a biopsy. Extensive surgery followed....</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Now she was being told the pathologist had made a mistake. Her new doctor was certain she never had the disease, called ductal carcinoma in situ. It had all been unnecessary — the surgery, the radiation, the drugs and, worst of all, the fear.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This review examines quality, medical error, root cause analysis, and patient safety improvement initiatives in a laboratory medicine test (i.e., breast core biopsy) for a patient who has a breast lesion suspicious for cancer. Although we evaluate the specific types of error highlighted by the headlines reported in Table 1, the framework for this analysis could involve any laboratory test. In addition to contrasting the ways media and Lean quality improvement practitioners perceive diagnostic errors, another goal of this review is to discuss personnel and system components of error and the development of improvement strategies.

Domains of quality

Medical error is best viewed as a patient safety metric in a healthcare system of multiple quality dimensions. The United States Institute of Medicine (IOM) defines six domains of quality [7]:

1. Patient safety — avoiding injury to patients
2. Timeliness — reducing patient wait times and delays
3. Patient centeredness — providing care based on patient needs
4. Effectiveness — providing care based on scientific knowledge
5. Equity — providing equal access to care

These domains of quality overlap. For example, a “lost” laboratory breast core biopsy specimen may be classified as a failure in the quality domains of efficiency (e.g., the patient needs to be retested, which is a form of waste and results in higher healthcare costs), timeliness (e.g., the diagnosis is delayed until the retested specimen is interpreted), patient centeredness (e.g., retesting causes the patient additional inconvenience), and safety (e.g., the patient must undergo a second biopsy and its potential complications and will have a lengthened period of anxiety until the diagnosis is rendered; pain and anxiety are forms of harm or injury).

A challenge in healthcare is that a quality improvement initiative that positively improves a metric in one domain may negatively affect a metric in another domain. For example, an initiative that improves the efficiency of care may reduce the safety of care. Laboratory waste and inefficiency may be removed by improving work flow. However, this change may inadvertently lead to laboratory front-line technologists feeling more rushed and stressed. In turn, these feelings may contribute to the development of a culture that is less safe, a latent factor that contributes to a higher frequency of medical error and to decreased patient safety.

Consequently, quality domains often compete in healthcare systems with different individuals or system components championing different domains. Healthcare systems often have misaligned hierarchies, and the front-line strives for quality goals that are different from the leadership goals. The lack of knowledge of the latent factors that affect metrics in all quality domains further results in failures in quality improvement initiatives that may have untoward consequences in some quality domains.

Culture plays a large role in driving healthcare organizational quality improvement. The study of patient safety culture has shown that healthcare organizations mature through different levels, as the concept of error moves from one of blame and shame to one of patient safety improvement. Fleming and Wentzell described five levels of patient safety maturity [8]:

1. Pathological — no systems in place to promote a positive safety culture
2. Reactive — piecemeal systems often developed in response to error occurrences and/or regulatory requirements
3. Calculative — systematic approach to safety, although implementation is patchy and inquiry is limited to the investigation of circumstances regarding a single event.
4. Proactive — comprehensive approach to patient safety with evidence-based interventions implemented across an organization.
5. Generative — focused development and maintenance of a positive patient culture; the organization evaluates the effectiveness of patient safety interventions and learns from failures and successes to take action to improve.

The generative patient safety culture may take years to develop. Organizational culture may be shaped by adopted quality improvement methods, as some of these methods involve tools and philosophies that change the organizational and front-line perceptions of work. As organizational leadership and the front-line focus on patient safety, the culture of error reporting and improvement shifts from blame to improvement. Many healthcare organizations have adopted improvement methods that have been used in businesses, such as heavy and light manufacturing and service industries. These methods include Lean and six sigma.[9–11] An overview of Lean methods in respect to patient safety is described below.

### Definition and causes of medical error

The IOM defined a medical error as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. For example, as a breast surgical pathology biopsy provides information to guide appropriate care management, a medical error would be an incorrect diagnosis that leads to the wrong clinical management for a patient with a breast lesion (either a false positive or a false negative error). Based on patient outcomes, medical errors are classified as no harm, near miss, or harm events. The frequency of laboratory medical error is determined by a number of factors, such as method of detection, test type, and gold standard for comparison. The overwhelming majority of general medical and laboratory medicine errors are not associated with an outcome of severe harm.

However, severe harm is a consequence of some diagnostic testing errors and examples are listed in Table 1. In safety science, a goal is to detect and understand the causes of error in order to design improvements that may reduce the frequency of error. For all the cases listed in Table 1, laboratory personnel and other investigators involved in the diagnostic testing process worked diligently to understand the root causes.

Investigators use a number of methods to determine the root causes of medical error. For example, the front-line staff may be trained to use a Lean method of asking five why’s to determine root cause.[9,10] Asking the five why’s promotes healthcare workers’ understanding that errors often have active individual components and deeper system or latent causes. More complex methods of root cause analysis use categorical error classification or probabilistic error determination. Categorical systems include the modified Eindhoven method,[12,13] which has been used in transfusion medicine and anatomic pathology, and the Ishikawa fishbone method.[14] The different methods provide different levels of understanding and associations of root cause.

Fig. 1 shows an example of the fishbone method applied to a diagnostic interpretation error in breast pathology. The fishbone method classifies root causes of error into six categories, often referred to as the six M’s (materials, methods (process), machinery (technology), milieu (culture or environment), manpower (individuals), and measures). The causes within these six categories may be further sub-classified to produce a hierarchy of immediate and dependent causes. As laboratory tests are categorized by phase (pre-analytic, analytic, and post-analytic), earlier phase failures or breakdowns in process may contribute to later phase failures eventually resulting in an error in diagnostic interpretation. For example, poor quality specimens (originating from a pre-analytic sampling problem) may lead to a diagnostic interpretation error (analytic problem). The fishbone may be applied to each phase in the process to determine the cascade of active errors and component latent factors.

### Quality management system

Many laboratories already have well established quality management programs. A quality management system consists of the activities to direct and control an organization in terms of quality. Quality control activities are those that assure that specific processes and functions meet acceptable parameters, established externally and/or internally. Quality control activities involve the development of standards of acceptable performance and methods of measuring performance. Processes that do not meet acceptable standards are rejected. Quality management systems involve all portions of the laboratory and may broadly be divided into the following components:

1. Organization
2. Personnel
3. Technology/equipment
4. Process control and management
5. Information control and management
6. Occurrence control and management
7. Documentation control and management
8. Inventory control and management
9. Facilities/space
10. Customer service
11. Purchasing
12. Assessment and measure
13. Quality improvement

Quality assurance involves all aspects of work, which are further defined below.

### Quality improvement

Spear and Bowen described that in a Lean model, work may be best understood when it is deconstructed into four basic components [15]:

1. Activities. Activities are technical and cognitive tasks people perform. In the anatomic pathology laboratory, these activities include the accessioning of a breast specimen, gross tissue examination, description, and sectioning, tissue embedding and sectioning, and pathologist diagnostic interpretation using a microscope or viewing a digital image. In the ideal state, all activities are highly specified in terms of content, sequence, timing, location and outcome.
2. Connections. Connections are the hand-offs or communications that occur between individuals or between technologies and individuals. In the anatomic pathology laboratory, these connections include those between two technologists, a technologist and a technological instrument such as a processor, and a technologist and an anatomic pathologist. In the ideal state, connections should be direct and there must be an unambiguous yes-or-no method to send requests and receive responses.
3. Pathways. The overall flow of the patient, specimen, or product is the pathway. In the anatomic pathology laboratory, the pathway flows from accessioning area, to the gross examination room, to the histology laboratory, to the pathologist. In the ideal state, the pathway for every product and service must be simple and direct without loops or forks. The pathway in laboratory medicine testing is displayed by the total testing process (TTP) that includes the pre-analytic and post-analytic testing phases shown in Fig. 2.
4. Improvement. Improvement is an inherent component of work. Improvement to activities, to connections between workers and/or technologies, or to pathways must be made in accordance with the scientific method, under the guidance of a teacher, and as close as
possible to the work being performed. One method of improvement is the plan-do-check-act (PDCA) cycle.

The deconstruction process allows individuals to have a greater understanding of all the components that are inherent in a work process that produces the right result to the right patient at the right time. The active components of medical errors are failures in activities, pathways and/or connections. The latent conditions that contribute to these errors may originate in the work processes or may be conditions within the healthcare system that lie beyond the work processes. Although we do not have enough information to perform a detailed fishbone diagram to determine the root causes of the errors described in Table 1, past experience of similar error types tells us that active failures and latent factors in activities, pathways, and connections and latent factors in the system resulted in these sentinel events.

Much attention has been placed on the levels and systems of healthcare and their effect on patient safety. Ferlie and Shortell [16] defined four systems of healthcare:

1. Patient. The individual patient is the center and first level of the healthcare delivery system and the patients’ needs and desires are the defining factors of a safe system.

2. Care team. The care team is the second level of the healthcare system and consists of the individual physician and a group of care providers. The care team is the basic building block of a “clinical microsystem,” defined as “the smallest replicable unit within an organization (or across multiple organizations) that is replicable in the sense that it contains within itself the necessary human, financial, and technological resources to do its work” [17]. Laboratory personnel are a part of the care team. Currently, many healthcare practitioners recognize that many barriers (i.e., latent factors) limit the effectiveness of these teams to deliver evidence-based care. These barriers include the focus on individual patient needs compared to the needs of patient populations, the lack of supporting information technology tools, the guild structure of the healthcare professions, and the absence of teamwork training.

3. Organization. The organization is the third level of the healthcare system and consists of the hospital or clinic that provides the infrastructure and resources to support the care teams and microsystems. The organization encompasses the decision-making systems, information systems, operating systems, and processes to coordinate the activities of multiple care teams and supporting units and manages the allocation and flow of resources. The patient safety and quality improvement culture are determined by a number of organization factors.

4. Environment. The fourth level of care is set by the regulatory, educational, professional societal and financial structures that affect the performance of healthcare organizations and ultimately all other levels of the system.

Using this model of levels of healthcare, many of the latent factors that contribute to error are based in the organizational and environmental structures. These two levels affect education and cultures, which strongly influence front-line healthcare work (i.e., the activities, pathways, connections, and improvement) at the care team and patient level.

**Lean improvement**

Lean improvement methods involve the use of specific tools that are focused on the different components of work. Some of these tools are discussed below.

**5S**

In the Japanese language, the 5S’s stand for seiri, seiton, seiso, seiketsu, and shitsuk and in the English language the 5S’s stand for sort, set in order, sweep or shine, standardize, and sustain.
1. Sort. Eliminate all unnecessary tools, supplies, equipment, and process instructions (standard operating procedures).
2. Set in order. Arrange all tools, supplies, equipment, and process instructions so that they are easily located. Setting in order eliminates wasted time in looking for necessary items.
3. Sweep or shine. Clean and organize the workspace and all tools and equipment. This step assigns all work components to proper places.
4. Standardize. Standardize all work areas and job responsibilities. Work stations and activities for a specific job should be identical.
5. Sustain. Continue the processes after the establishment of the previous four S’s. Continually review the first four S’s and determine if improvements may be made.

Hiroyuki Hirano developed the 5S method within his overall approach to work systems [18]. The 5S method may be used to develop best practices, continually challenge these best practices to develop better practices, and standardize these best practices within systems. For example, the errors listed in Table 1 are secondary to failures in at least one of the 5S components. Root cause analysis would help to determine the specific process components that failed leading to the error.

For example, the mix-up or failure to maintain proper identification of patient specimens (cases 1 and 2 in Table 1) often occurs because of the failures in all of the 5S’s. In an ideal work environment, the work-place is structured to prevent individuals from working on different patient specimens (activities and pathways) at the same time and thus markedly limits the risk of specimen mix-up. Many pathologist–clinician communication errors (case 3) are secondary to the failure to develop standardized communication methods, such as checklists that provide standardized diagnoses, which have well-defined meanings for both the pathologist and the clinician. Many diagnostic interpretation errors (case 4) also are related to failures in standardizing diagnostic practices. Many of the latent factors contributing to these failures originate in the organizational and environmental structures of pathology training, regulation, and laboratory hierarchy.

**Observations**

In the Lean process, a failure or work problem is quickly followed-up with a Gemba, which consists of individuals going to the area in which the problem occurred to see the work. In this process, individuals on the front-line and individuals experienced with Lean methods observe the detailed activities, pathways, and connections of work processes to determine steps that are prone to failure. Through observations, the front-line personnel use another Lean tool, known as a process map to better detail the components of work.

**Process mapping**

Fig. 3 shows a high level process map of the steps in anatomic pathology. Each box represents a main step in producing a pathology diagnosis. We also have included some pre- and post-analytic steps...
in the process. By using observations, Smith and Raab developed a more detailed process map of the accession and gross examination components of an anatomic pathology laboratory that handled breast biopsy specimens. Fig. 4 is a spaghetti diagram outlining the flow of a single specimen from accessioning through the gross examination room, histology, and into the immunohistochemical section of the lab.

Specimen mix-up quality improvement

Specimen mix-up may occur anywhere in the pre-analytic or analytic steps in specimen procurement, processing, and interpretation. Smith and Raab categorized latent factors and active events in 335 specimens [19]. Latent factors within the workflow included poorly designed specimen bags, inaccurate and complicated standard operating procedures, occurrence of unprofessional behaviors tolerated by leadership, and poorly designed information systems. The near miss events were a result of active operator failures and included such events as writing illegibly, matching requisitions and specimens incorrectly, and knocking over containers.

Smith and Raab found that every specimen, including breast biopsy specimens, experienced an average of 5.8 near miss-events during just the initial phases of analytic processing. Of these near miss events, on average, the observers identified that each specimen had 5.2 latent process conditions occurring in the workflow and 0.6 active operator dependent events, occurring outside the standard workflow.

Other latent system factors (outside of the standard work-flow) included the lack of training, a system overly focused on efficiency and not focused on patient safety, and frequent failures in technology.

A fishbone diagram identified a number of causes of specimen mix-up in different steps of the anatomic pathology process for breast biopsy. Some of the analytic phase causes are listed below:

- Accessioning error — failure to adopt standard operating procedures resulting in non-standard activities and pathways.
- Gross tissue examination error — failure to introduce a one piece flow (i.e., one case at a time) system resulting in non-standard activities, pathways, and connections.
- Histology block cutting error — failure to introduce non-consecutive breast biopsy case block labeling or differential case inking, resulting in failures in activities and connections.
- Pathologist interpretation error — failure to implement a 5S workspace or checklists resulting in failures in cognitive activities.

These findings indicate that there are multiple causes of specimen mix-up, and although the mix-up often is secondary to an active error made by an individual, there is a myriad of contributing factors.

Communication error improvement

Communication science shows that there are a number of steps in the communication connection between individuals. Communication breakdown may involve technical components (the accuracy of the message), semantic components (the precision with which the meaning is conveyed), and effectiveness components (the effectiveness with which the meaning affects behavior) [20]. For example, the meaning of particular words may be different for pathologists and clinicians. A pathologist may use the word “atypical” to express a high level of concern that cancer may be present. A surgeon may think that the word “atypical” indicates that a patient has a low risk of
cancer. If a frozen section diagnosis during an intraoperative consultation on a breast specimen is “atypical,” the surgeon may think the patient has a benign lesion and choose conservative management, whereas the pathologist may actually have been indicating that cancer most likely was present.

Barriers in communication may be termed as “noise” and include:

1. Environmental — busy, noisy environments
2. Physiologic impairment
3. Semantic — different word interpretations
4. Syntactical — mistakes in grammar
5. Organizational — poor structured communication
6. Cultural — assumptions and misunderstandings
7. Psychological — attitudes or feelings such as anger.

Communication errors may be investigated using root cause analysis that focuses on these barriers. System design to improve communication may involve implementing new technologies, using checklists (e.g., restricting diagnoses to those that have an agreed upon meaning), altering environments (e.g., using multiple media in noisy environments to limit failures in a single medium), and education (e.g., training pathologists in the best practices of activities, pathways, and connections of communication).

Cognitive error quality improvement

In laboratory medicine, cognitive processes also may be standardized through the use of checklists. Pathology trainees learn to make a diagnosis by first identifying histopathologic criteria associated with that disease. The combination of a number of individual criteria is the pattern of a specific disease. As pathologists learn, they initially identify the criteria and pattern through a very structured cognitive process. Kahneman characterized this process as slow thinking, which consists of a rational, deliberate, methodical, and logical process of reaching a solution to the problem of accurately classifying the disease [21].

As pathologists gain more experience, they develop the ability to employ pattern recognition. In this process, they make the leap from individual morphologic attributes to pattern. Kahneman characterized this cognitive process as fast thinking. An example of driving home from work illustrates how we constantly use fast (driving process) thinking, as we do not rationally examine each step in the process (e.g., Do I turn the steering wheel five degrees to the right to turn right at the next road?).

Causes of pathologist cognitive error include failures in attention, memory, knowledge and fast thinking heuristics (or bias). Biases occur in pattern recognition thinking, as a pathologist makes the wrong leap or connection from pattern to disease. For example, anchoring bias may result in an incorrect diagnostic interpretation if the pathologist places too much emphasis on the clinical history, which “anchors” the pathologist to make the leap from pattern to the incorrect disease.

Like most technical errors, most cognitive errors are secondary to slips in cognition. Cognitive Lean improvement methods also are based on components such as standardizing diagnostic criteria and the implementation of checklists. In some areas, such as transplant pathology, checklists already are widely utilized. Observations of pathologists performing cognitive process assist in the recognition failures and biases. It is important to note that clinicians also are subject to cognitive errors, which may occur in the pre- and post-analytic domains of diagnostic testing.

Summary

Sentinel events in pathology are rare and this is partly due to robust quality management systems and increasing maturity of patient safety cultures [8]. From a safety science perspective, analysis of sentinel events generally shows a large number of latent factors that contribute to an active failure. Quality improvement methods use tools to deconstruct work into its component processes to determine the individual steps that are prone to error and to determine the latent system factors that contribute to these errors. The successful implementation of change depends on a front-line, organization, and higher system focus on both the elimination of latent conditions and the organization of work processes in better ways.

References