Chapter 9

Patient Safety Issues in Pathology: From Mislabeled Specimens to Interpretation Errors

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Abstract

Catastrophic breaches in patient safety often involve point-of-care settings such as the operating theater or intensive care unit, quite frequently without due consideration given to the elements leading up to such errors. Among such occurrences, wrong site procedures (WSPs) and diagnostic discrepancies continue to result in significant morbidity and mortality among patients. Addressing adverse events is difficult for all stakeholders involved. Furthermore, clinician familiarity with the workflow specific to particular disciplines or procedures may be poor, amplifying communication lapses that precede patient safety occurrences. The patient care paradigm has become increasingly multidisciplinary, and it is important to discuss, improve, and be more cognizant of measures required to achieve "zero defect" performance. Despite the rarity of "never events," their consequences may damage patient and community trust, provider morale, and institutional reputation. This chapter aims to assess current preventive measures and risks in the context of errors involving surgical pathology in the setting of the operating theater utilizing the framework of clinical vignettes. The discussion below will further center on the practical and interpretative errors that occur in the pathological workflow, and the potential for compounding of such errors in the operating theater. Definitions concerning WSP and diagnostic discrepancies will be outlined to characterize potential outcomes of communication errors.

Keywords: never events, patient safety, patient safety errors, safety protocols, pathology, laboratory medicine, diagnostic uncertainty

1. Introduction

The seminal 1999 Institute of Medicine report was significant for U.S. health care, citing that approximately 100,000 annual deaths resulted from medical errors [1]. This report motivated a

cultural shift into the research of various topics including medical errors and their prevention. More specifically, health care initiatives concerning public reporting of outcomes, provider and institutional reimbursement, and methods to improve existing systems, combined with individual accountability, were introduced. Beyond public and private agency investment, government involvement was also increased with the Agency for Health Care Research and Quality providing funds for identification of best practices, in addition to patient safety indicators and standardizing metrics. Despite the above measures, contemporary analyses suggest that medical errors may actually result in over 400,000 deaths per year [2], with the U.S. Department of Health and Human Services Offices of the Inspector General reporting 180,000 deaths resulting from medical errors among Medicare beneficiaries in 2008 [3], and an annual cost exceeding $17 billion [4].

Medical errors continue to illuminate the fragility and complexity of the medical system. Within this context, it is critical to point out that most of these errors are potentially preventable [2]. For example, it has been estimated that roughly 1 in 113,000 surgical procedures involve an incorrect operative intervention [5]. Subsequent analyses performed by the Joint Commission further revealed that communication errors (70%), procedural noncompliance (64%), and leadership (46%) were significant contributors to such events. However, other commonly cited antecedents to sentinel events include team competency, availability of information, organizational culture, failure to mark or clearly mark the operative site, inadequate medical record review, and of paramount importance, deficient continuum of care [6]. It is important to recognize the systemic and procedural breakdowns that often preclude post-diagnostic procedures that may not be operative in nature but may be catastrophic for the patients if improperly conducted (or erroneously delivered and/or interpreted).

There are two broad categories of occurrences in terms of potentially introducing serious medical errors into the arena of laboratory medicine:

- **Practical errors**, which involve the production of patient samples into therapeutically relevant data, and
- **Interpretative errors**, which concern the processing of these diagnostic data into a report for use in the subsequent step(s) along the patient's care continuum.

At the same time, reporting of errors that occur across the various sub-specialties of laboratory medicine often proves difficult. For example, validated studies have demonstrated increased propensity toward error through the inherent systematic complexity (e.g., due simply to the increasing number of process-related steps) [7]. Surgical pathology is particularly vulnerable to breaches in patient safety, in part due to the wide variability in tissue types, anatomic nuances, biologic sampling, inconsistency and human involvement in diagnostic interpretation, as well as time constraints (and pressures) [8]. The Quality Practices Committee and College of American Pathologists (CAP) designed validated guidelines and metrics in laboratory quality, with data collection and peer review initiatives such as Q-PROBES (a peer-comparison quality assurance service offered by the College of American Pathologists that was created in 1989), in order to establish patient safety benchmarks [9]. However, despite increased awareness, the necessity of improving pre-existing pathology paradigms has only been considered recently [10]. Additionally, an expert panel from The CAP, as well as the Pathology and Laboratory Quality Center, in association with the Association of Directors of

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Anatomic and Surgical Pathology, drafted several *recommendations* aimed at avoiding interpretative errors, ultimately designating case review as an effective deterrence to error [11].

2. Definitions

In order to familiarize other surgical subspecialties with potential procedural weaknesses within the pathology workflow, a conceptual framework of practical and interpretative errors derived from Meier [12] is outlined (**Table 1**). A brief overview of the taxonomic

Classification	Definitions
Practical errors (in stepwise order)	Patient identification
	Selection of tissue specimens
	Labeling and specimen transport
	Specimen accession
	Receiving sampling specimens
	Fixing, embedding, cutting section
	Mounting, staining, and labeling slides
	Delivery of slides to pathologist(s)
	Examination, collation, and interpretation of slides
	Consideration of ancillary tests, Other information
	Composition of report for subsequent review
	Reception and interpretation of report
Interpretive errors	Errors of commission—wrong or incorrect diagnoses, false positives (i.e., overcalls)
	Errors of omission–mixed diagnoses, false negatives (i.e., undercalls)
Case reports	Amendments—changes that are not pure additions of information
	Addenda—changes that purely add information
	Specimen defects—Specimens that are lost, of inadequate sampling size and/or volume, absent or discrepancy measurements, inadequately representative sampling, absent/inappropriate ancillary testing
	Misinterpretation: **i.** Overcalls **ii.** Undercalls **iii.** Confusion/conflation which results in not altering primary (positive/negative or benign/malignant) or secondary (grade, stage, margin, etc.) characteristics
	Report defects—do not directly influence diagnostic information but often diminish redundancy in information, presented as: **i.** Absent or incorrect non-diagnostic information (e.g., concerning practitioners, procedure, billing) **ii.** Dictation/transcription errors—typographical errors **iii.** Aberrations in electronic formatting (i.e., "computer glitches")

Table 1. A taxonomic framework for discussing errors in pathology; derived from Meier [12].

structure of altered case reports will be provided, which constitutes one way of identifying error in pathology. **Figure 1** highlights significant sources of error in both of these processes [13, 14]. It is of paramount importance for providers to understand the limitations of research in the current literature regarding the preponderance/magnitude of potential and actual error that exists in pathology (as well as the common failure modes in such settings) (**Figure 2**).

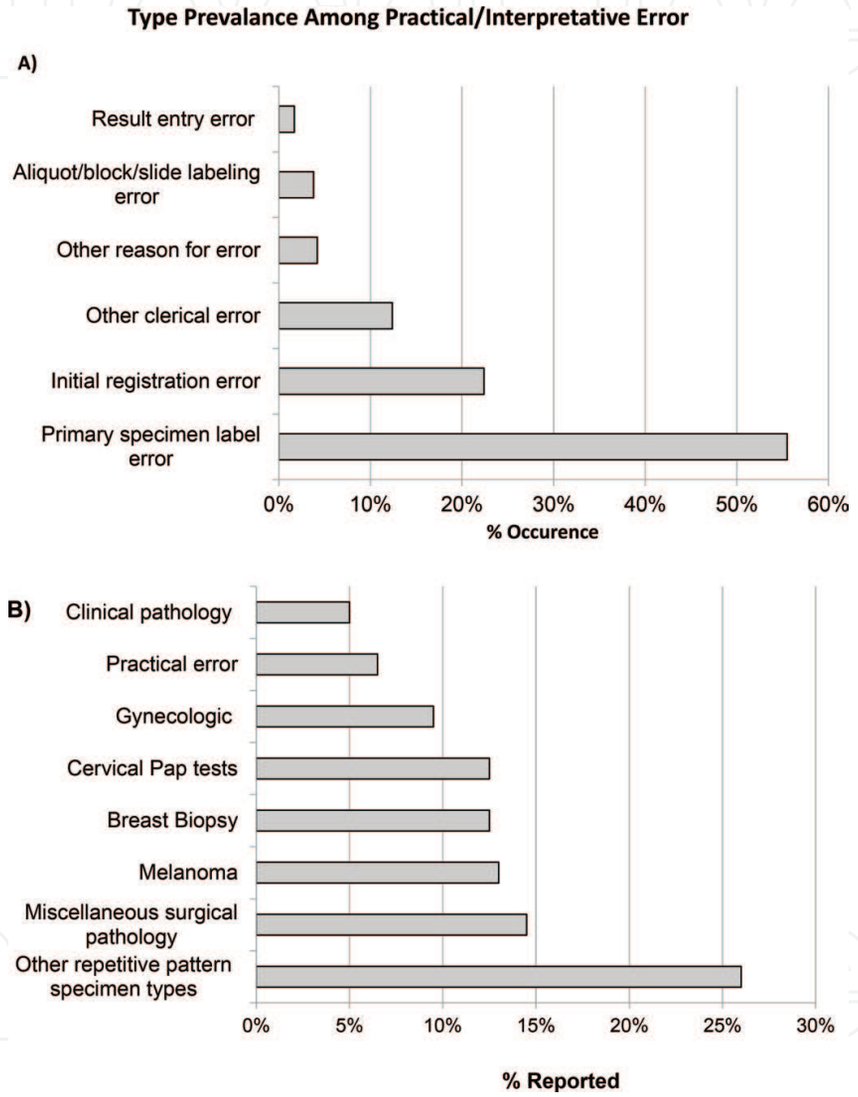

Figure 1. Relative frequency of errors occurring during practical/systemic and interpretive/diagnostic processes. (**A**) Reasons for clinical lab error prior to delivery of sample for interpretation. These errors are not differentiated between pre- and post-verification [13]. (**B**) Data for cases of medical negligence resulting in practice considered below the standard of care. Clinical pathology refers to laboratory error, practical error refers to system errors, miscellaneous surgical pathology errors refer to claims which show no pattern in specimen diagnostic criteria and are considered random, and other repetitive pattern errors include sarcomas, lymphoma, lung, gastric, fine need aspirates, prostate, bladder, and nongynecologic cytology errors; 57% of claims are from practical errors, melanoma, breast, Papanicolaou, and gynecologic samples [13, 14].

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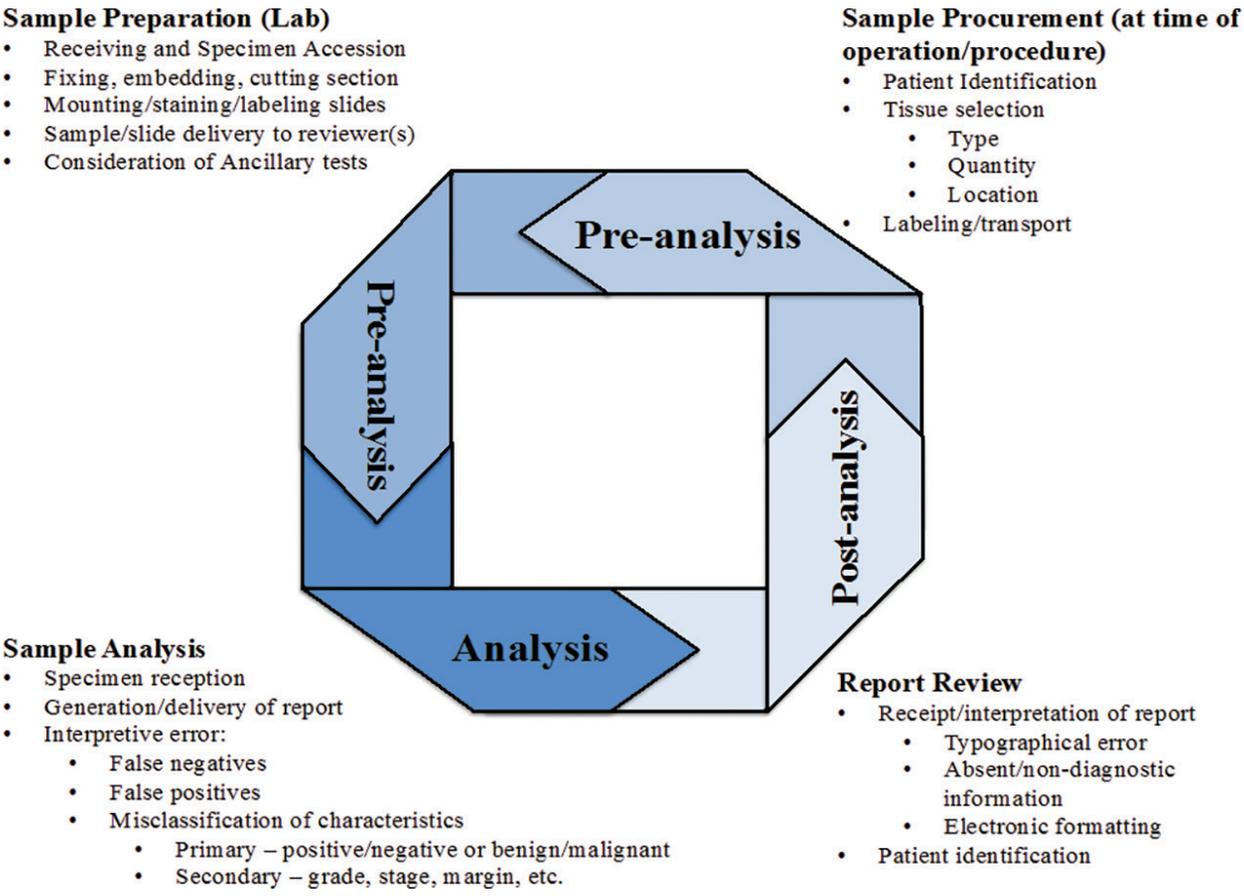

Figure 2. Brief overview of common errors in the pathology workflow; derived from Zarbo et al. [15].

3. Clinical vignette #1

Shahar et al. [16] described a 47-year-old man who presented to the emergency room after reports of progressive right lower extremity weakness. Relevant history included 40-pack-year of tobacco abuse as well as upper-limb dysmetria. Magnetic resonance imaging (MRI) revealed distinct ring-enhancing lesions in the left frontal lobe of the brain, which were biopsied and reported as metastatic small cell lung carcinoma. The patient received radiation treatment for increasing right lower extremity weakness, headache, and blurred vision.

The patient demonstrated worsening lethargy and headache prompting a brain computed tomography (CT) that showed an enlarging mass with midline shift. Histopathological examination suggested glioblastoma with no evidence of metastatic carcinoma. Despite suspicion of a possible rare "collision tumor" (a tumor specimen from a single patient in which pathology reports do not coincide), DNA sequencing of the two biopsies was performed to determine if the tumor was monoclonal. Several genotypic and microsatellite analyses revealed that the samples did not originate from the same patient.

In this particular case, the patient and clinicians were fortunate enough to identify the sampling error early in treatment, which allowed for an appropriate adjustment of the treatment (for the correct diagnosis of glioblastoma).

4. Clinical vignette #2

A 26-year-old man reported intermittent blood in his stool for more than 1 year [17]. The patient appeared well nourished and in no distress. Rectal exam demonstrated scarring from previous anal fissures. Stool examination was negative for occult blood, although laboratory testing did suggest a low mean corpuscular volume and total serum iron. During outpatient colonoscopy, a large ulcerated circumferential lesion was identified in the right colon, which was biopsied and submitted to pathology.

The pathology report had indicated "histologically normal colonic mucosa with prominent submucosal lymphoid aggregates, no malignancy identified" [17]. The lesion had a high probability of neoplastic potential, suggesting a possible false-negative biopsy due to inadequate sampling. A surgery consult was ordered as well as an abdominal CT and barium enema. The CT reaffirmed a mass in the area of the cecum, but did not confirm whether the mass was inflammatory or neoplastic; the barium enema highlighted a mass consistent with malignancy. Following the resection of right colon and terminal ileum, pathology identified a moderately differentiated infiltrative cecal carcinoma with negative margins and metastatic carcinoids in 2 out of 24 pericolonic lymph nodes. The patient did well, although treatment was not initiated until 5 weeks after the procedure.

5. Discussion

The two clinical vignettes highlighted both the ease with which an error can occur, as well as the ability of a well-functioning system of cross-checks to detect errors [17–19]. The above-mentioned cases provide a framework for an in-depth discussion of common pitfalls than can occur within pathology operations, as well as the interpretative errors that may influence both therapy and prognosis. However, it is important to note that despite comprising a relatively small fraction of health care-related errors, adverse errors in both anatomic and clinical pathology continue to occur with unacceptable consequences, including mortality [14, 20]. Such errors have the potential to consume patient and provider time, increasing costs, while diminishing trust in the health care system. Experts in the field of pathology are only beginning to understand the implications of the 1999 IOM report on their specialty, with particular emphasis on a need for collaboration with other specialties, including surgery [10].

5.1. Clinical vignette #1: discussion of "lessons learned"

Case vignette #1 (CV1) includes several key points that highlight the problem of "latent errors," both during the pre- and post-analytical phases. The crux of this case is that

somewhere during the process of securing specimen(s) for the initial biopsy sample and review, an error occurred resulting in patient-specimen mismatch. Labeling error is not a phenomenon unique to pathology, but can occur in any process leading up to a report generation for therapy or prognosis. Labeling errors may occur when specimens are labeled with incorrect patient name/identification, or accession number, but may also be related to the sample's origin (e.g., lower versus upper extremity); time (e.g., two procedures by two different surgical teams); or location (e.g., endoscopy suite versus operating room). The possibility of labeling errors also exists within the analytical framework whether in regard to the pathologist(s) or in the context of report retrieval/delivery [21, 22]. About 0.25% of cases are subject to a labeling error during the pre-analytical phase, with a majority of errors (73%) being associated with patient name [21]. Implementation of safety measures such as open communication with the patient and formalized checklists incorporated in transfer of information/specimens from the operating room to the laboratory and vice versa have shown significant efficacy in reducing labeling errors (as in aviation) [23]. Root cause analysis performed in CV1 ultimately determined that the error occurred during the initial specimen processing stage due to a clerical mistake [16].

Due to the potential for substantial downstream impact of erroneous labeling and thus the generation of incorrect pathology/laboratory reports, these events warrant an expanded discussion (**Figure 1**). It has been reported that specimen labeling errors tend to be evenly distributed among the processes of accessioning, gross pathology processing, and tissue cutting, with some additional errors being identified in subsequent steps of processing [24]. Approximately 1.3% of these errors affect patient care [24]. The many "moving parts" within the pathology/specimen processing workflow may be subject to significant risk of errors and "near misses" [25]. The emergence of adverse or "never events" in patient care typically involves multiple breakdowns in both systemic and individual processes (the phenomenon known as the "Swiss cheese model") [17, 26, 27]. Failure to recognize errors in multiple successive steps of specimen preparation and interpretation can result in significant errors and resultant patient harm, as demonstrated in CV1. A proactive and critical review of processes may aid in reducing the incidence of such events [28].

The inherent complexity of multi-step processes is implicated in the genesis of pathology errors. Lack of adequate coordination and/or communication is often cited in this context. Lapses in communication are among the most common sources of medical error, with over 20% of cases identifying communication errors as directly contributing to wrong site, wrong procedure, and wrong patient surgical procedures [29], and there are numerous calls for improvements in this area throughout all specialties [8, 17–19, 30]. CV1 highlights a breakdown in communication, and the importance of cross checks and verifications used for initial error rectification. Every critical communication carries a risk of error, but at the same time, it presents an opportunity for detection of error. For example, preoperative checklists and surgical "time-outs" have been shown to make operative care safer [31, 32]. A similar framework for preventing "never events" may also be effective in reducing pathology labeling errors [33]. Moreover, the initial errors that may have occurred during initial specimen processing in CV1 may have been compounded by other errors, including potential oversight issues from downstream employees who were under time constraints/heavy workloads thereby failing to

institute proper quality and verification procedures. There was also a degree of confusion following the second biopsy, generating unnecessary work and consuming additional resources. Finally, appropriate disclosure of errors should be provided to the patient in order to help foster mutual trust and understanding [10].

Despite the relative commonality of labeling errors, research on their prevalence and consequences is sparse [10]. To elucidate the nature of error in specimen/patient labeling, large Q-PROBES studies have been conducted, with one study noting an error rate of 6% involving specimen identification and accession defects, with specimen misidentification constituting nearly 10% of the errors [34, 35]. Issues involving labeling have been classified as follows:

- **Class 1**—Typographical errors that do not result in clinical consequences.
- **Class 2**—Errors which are unlikely to result in clinical consequences.
- **Class 3**—Errors which may be detrimental to patient care.

One study in particular documented a 0.09% rate of Class 3 errors among 8231 specimens [36]. This underscores the need for better preventative measures, with the aviation industry as one of the prime examples of error reduction [37]. Moreover, current studies underestimate the true error frequency, as many are undetected [35].

Both gross and histological laboratories need to continue to strive for error correction in regard to sample/patient labeling. With the former, specimen containers may be paired with cassettes that involve incorrect case numbers (e.g., incorrect patient specimen) or incorrect part identification (e.g., incorrect anatomic site), while the latter tends to involve pairing cassettes with erroneous slides (e.g., incorrect patient and/or site) or incorrectly applying a digital/paper label to a pencil-labeled slide. To highlight this problem, one 18-month review of errors in the laboratory setting noted a 0.25% class 3 mislabeling rate [36]. Of note, stratification of error based on specimen type/procedure may prove useful in patient safety optimization.

While CV1 does not delve into specific root cause(s) of error, it serves as an excellent platform for further discussion. One study noted a 0.25% error rate was recorded across 29,479 cases, with a significant proportion of errors (69%) occurring in the gross specimen processing room [36]. Most errors were associated with incorrect patient (73%) or specimen site (24%); and further demonstrated that a significant proportion of labeling errors (88%) were made by laboratory assistants [36]. However, these near misses were largely recognized in subsequent steps by histology technologists or surgical pathologists signing out casework. Improved training programs, as well as initiatives to improve error reduction, may involve optimizing work load and alleviating time constraints [10].

A smaller, but still significant proportion of labeling errors occur in histology laboratories (25%). Errors in the histology laboratory tend to be limited largely to two event types [38]:

- Block specimens that were matched with pre-labeled (penciled) slides (63%).
- Placement of the incorrect pre-printed label on pencil-labeled slides (37%).

Some institutions have developed alternative methods including placing labels opposite to pencil labels on glass slides to reduce such errors [38]. Samples that were often small and relatively uniform in appearance were associated with higher rates of labeling error (e.g., renal and skin biopsies). In addition, processing difficult and similar samples in batches may also carry a higher risk of error [21]. For high-throughput laboratories, incorporation of inking practices to patient biopsies as a means of secondary identification has reduced errors without affecting sample integrity during subsequent steps. However, such methods have also resulted in a 20% increase in grossing time [39]. Large-scale reviews of labeling errors also suggest that laboratories with built-in quality assurance protocols have statistically significant reductions in identification errors [40].

Beyond any process-related lapses concerning patient/specimen identification, the complexity of the clinical picture surrounding the sample is often cited as a potential source of error for the interpreting pathologist(s) [8]. Access to complete information regarding the clinical picture, including clinical discussions prior to analysis or during intraoperative consultation, can better equip pathologist(s) to assess and relay accurate information. Advances in computer and information technology (i.e., electronic medical record) have yielded anecdotal improvements [8], but efficacy in this regard is not compelling.

Specimen integrity verification and standardization of variables during clinical analysis is of key importance. Specimen defects are typically classified as errors that may include inadequate sample size/volume, inappropriate representativeness, or failure to invoke ancillary testing, all of which may result in misdiagnoses [15]. For example, the variability in discerning and recognizing clinical landmarks within resected tissue specimens may depend on the type of tissue marking dye used [41]. Currently, sample criteria standardization (e.g., tissue, blood, plasma, molecular, etc.) and general laboratory workflow continue to be areas of opportunity for improvement [42, 43]. Contribution of specimen defects toward errors in patient safety is small, but important. Furthermore, the relationship between false-negative (and false-positive) diagnoses and the associated medico-legal implications needs to be addressed [14].

For errors that manage to "evade" redundant safety measures, there are two significant considerations relevant to patient safety. The first aspect is the completeness of report and the second regards the presence of any critical values [8]. The pathology report remains a mainstay and foundation for communication between the pathologists and clinicians involved in patient care, whether it concerns diagnosis, treatment, or prognosis. Studies of physician satisfaction with pathology reports highlight the importance of timeliness of reporting, emphasis on significant results, and general communication of relevant details [44, 45]. While there is currently no universal methodology regarding composing pathology reports, the four following tenets have been identified as useful in improving communication between physicians [46]:

- ***Use headlines to emphasize key elements***—Highlighting the main diagnosis apart from additional case details. These tend to predominate amongst "patient-centered" reports as opposed to "specimen-centered" reports.
- ***Maintain layout continuity***—Providing a redundant layout for reports so health care professionals within an institution may become familiarized with interpretation of the report.

- ***Optimize information density***—Grouping information within a report into familiar units for optimal reader retention
- ***Reduce clutter***—Exclusion of nonessential information, or grouping of additional, yet insignificant details into report addenda so that it does not detract/confuse the reader.

Advancements in information technology and the electronic medical record have allowed prompt delivery of reports, incorporated synoptic checklists, improved physician satisfaction, and increased completeness of reporting by 28.4% [47–49]. The field of oncology provides a strong example of standardized report elements designated by the Commission on Cancer of the American College of Surgeons [50, 51]. However, information technology improvements in report composition and delivery are not without flaws [52]. Reports to physicians/surgeons must incorporate clear and concise information whether it is at the time of specimen collection or in relaying diagnostic and therapeutic information. Face-to-face is still the preferred modality for communication [31], primarily because flaws in communication continue to prevail as serious barriers to patient safety [10].

There remain several areas of concern regarding sample handling and final reporting as it relates to clinical communication. Sample labeling and transport continue to persist as major sources of error and are compounded by subsequent failure to adhere to standard protocols, whether it involves secondary review or quality verification. One method of cross-checking and verification involves the inclusion of molecular testing prior to acting on pathology reports; however, this has been hindered by both time constraints and costs [22, 53]. In CV1 diagnostic reporting yielded highly unlikely results, which through high clinical suspicion led to further confirmatory testing. Despite ultimately receiving the correct treatment, the patient had to commit to additional time, molecular testing, and potential exposure to iatrogenic harm.

5.2. Clinical vignette #2: opportunities for improvement

Let us turn our attention to the topic of interpretive error, which is generally more localized within the overall pathology laboratory workflow. Interpretative contributions to error tend to be more insidious and have proven difficult to research, and classify [10]. Clinical vignette #2 (CV2) outlines the challenge and the importance of interpretive errors in patient management. While root cause analysis of this vignette determined that the error in question most likely involved sampling issues rather than lack of interpretive prowess, this case nonetheless prompts discussion of how providers may classify, discuss, and develop methods to reduce any associated potential harm to patients [54]. The consequences of interpretative error are legitimate causes of concern and continue to be a source of confusion (and harm) to patients [14, 20].

Case review predominates as the fundamental preventative modality for interpretive error and continues to be utilized as the primary source for research into such errors [55, 56]. In the case review discussion, it is important to first address the various applications of review, whether it is pre- (i.e., prospective) or post-sign out (i.e., retrospective), internal, external, focused, or unfocused examination. Internal reviews are often performed within a single

Specimen Type/Diagnostic Modality	N	%
General report review		
Random review	1523	2.2
Organ-specific malignancies		
Lymphomas	1291	6–7
Urological	213	10
Gastrointestinal and liver	194	12.4
Breast	610	16–20
Pediatric neoplasms	705	25.1
Soft tissue carcinomas	34	47
Historically difficult diagnoses		
Liver transplant biopsies	30	43
Thyroid aspirates	50, 113	52, 34
Vulvular dysplasia	60	23
Gestational trophoblastic disease	1851	26
Cytological:histological comparison		
Bronchoscopy biopsies	231	2.3
Cervical specimens	5159	6
Female genital tract tumors	279	6.8
Fine-needle aspiration, non-cervical specimens	898	9–12
Bladder cancer biopsies	508	41
Fine-needle aspiration, breast lesions	90	46
Cytological:cytological comparison		
Cervical specimens	13,745	45
Histological:histological comparison		
Skin biopsies	589, 478	6.5, 35
Pigmented skin lesions	392	14
Primary versus review diagnoses	354	56
Taxonomic variability (Gleason grading)		
Prostate biopsy	278	42

Discrepancy rates in interpretative outcomes of specimen types as well as varying diagnostic modalities including cytologic:histologic comparison, cytologic:cytologic, histologic:histologic, taxonomic grading (e.g., Gleason grading of prostate biopsies). Adapted from Meier, FA [12].

Table 2. Discrepancies in pathologic interpretation.

practice, allowing the opportunity for discussion of difficult diagnostic scenarios prior to clinical action while also offering the ability to develop diagnostic thresholds and taxonomies relevant to the disease process. A large study (n = 18,032 cases) regarding pre-sign out diagnostic reports indicated that at least one additional pathologist reviewed each case for ~78% of cases, thereby adding a layer of safety [57]. Despite the benefits of an internal review, it often becomes impractical because of costs and time, especially in small practices [12]. External reviews reduce diagnostic uncertainty [58], but are plagued by similar issues, especially for large practices. For this reason, conferences, which utilize a panel of experts and non-experts of various clinical backgrounds, minimize the need for external review.

Expert review for various disease processes allows for reviewers within a practice to define diagnostic thresholds and criteria of which general pathologists may not be privy. Furthermore, skillful and trained reviewers can provide specialized reports and quickly parse through highly relevant information. Such expertise is routinely utilized in oncological settings [59]. Expert reviewers help create a robust system within a practice that provides a "knowledge trickle down" effect in the practice. Nonetheless, expert review may skew agendas when reviewers encourage criteria set forth by one dominant pathologist (e.g., senior or most experienced partner) [60].

On a related note, research comparing diagnostic discrepancies between random case reviews and focused review of certain difficult diagnoses has shown that the latter intuitively tends to produce higher rates of interpretative divergence (2.7% and 13.2% discrepancy rates, respectively) [61, 62]. Perhaps what is most interesting is that cases subjected to focused reviews (3.2%) generated a 10-fold increase in the likelihood of serious error/threat to patient safety as compared to random review (0.36%). Points of focused review include specimens such as premalignant breast lesions, melanocytic skin lesions, as well as taxonomic classification including Gleason grading of prostate biopsies, etc. [63–68].

Much research has been conducted to assess discrepancy rates in pathology practice, placing attention on some of the more arduous specimen types and clinical scenarios. **Table 2** outlines some of this research to display the spectrum of challenges in stratifying specimen interpretation [12]. Of significance is the general reported discrepancy rate of 2.2%. While there is variability in discrepancy rates, some diagnostic circumstances tend to result in higher discrepancy rates (when assessing case reports). Historically troublesome specimens involve organ systems that tend to encompass "linked" diagnoses (e.g., soft tissue carcinomas). Furthermore, comparison of different diagnostic modalities suggests that certain specimens are more difficult in terms of reaching consensus between the use of cytology and histology or within the same processing mechanism (e.g., histological comparison of dermatopathological specimens).

Case reviews are needed for assessing/stratifying interpretative errors in pathology, but can be flawed. Nakhleh et al. indicated that while only 8% of casework falls under case review, a typical practice expends significant time and costs in such case review [57]. Considering discrepancy rates, an argument can be made for shifting toward focused reviews. With significant variance in interpretative aptitude and experience, complete prevention of diagnostic error will be difficult. Nonetheless, pathologists should continue to work toward

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standardizing/stratifying diagnostic criteria, taxonomy, and improving ancillary tests to achieve diagnostic precision. The following five *recommendations* have been made to help reduce interpretive error [69]. Anatomic pathologists should consider:

1. Developing procedures for the review of selected cases to detect disagreements and interpretive errors.
2. Performing case reviews in a timely manner to avoid impact on patient care.
3. Documenting case review procedures relevant to their practice setting.
4. Continuously monitoring and documenting the results of case reviews.
5. Taking steps to improve agreement if case reviews show poor agreement within a specific case type.

There are three mandates within the patient safety framework for institutional accreditation designed by the Joint Commission, which include the use of pre-operative checklists, surgical time-outs, and surgical site marking [31]. These mandates provided by the Joint Commission have improved communication within teams in the operating room [70], including potential identification of discrepant results and/or potential errors. While some studies have suggested that surgical teams are the most significant determinants of patient safety in the operative setting [71], others have focused on structuring preventative protocols and safety measures as the apex of patient safety [26, 72]. While these mandates have undergone significant structural changes to maximize patient safety, adherence and noncompliance continue to negatively impact patients [73]. Increased personal accountability to reduce noncompliance is needed [74], as is the development of a diagnostic, clinical and legal environment that increases accountability, communication, and prevents adverse events [10].

CV2 presents a challenging dilemma by introducing a number of subtle "diagnostic clues" that may evade even the most experienced diagnostician or may be missed due to sampling error [14, 20]. Prolonged or extensive case reviews may prove costly for a practice and impractical for clinical situations that require both timeliness and accuracy to avoid potentially dangerous management delays. Consideration of the entire clinical picture beyond pathology testing is mandatory for the interpreting pathologist. Conversely, clinicians such as surgeons must also consider the overall "clinical picture" while reviewing the pathology report and intervening as appropriate. Lastly, this vignette poses the question as to "if, when and how" pathologists should be involved in disclosing error to patients. Research suggests that pathologists are seldom involved in error disclosure, and a significant proportion has never been involved in such processes [75]. Moreover, focused research often cites pathologists as not having the training and experience to be part of such discussions and that pathologists tend to be somewhat apprehensive regarding having discussions with clinical colleagues who may not fully grasp the intricacies of laboratory work [76]. Pathologists must make a concerted effort to not only help prevent patient harm, but also openly discuss it, especially with medical colleagues involved in the case [10].

6. Conclusion

While patient safety events, including the so-called "never events" can occur within the realm of pathology practice, the research and implications involving pathology remain limited and in early stages [10]. Errors that result in missed diagnoses, wrong site procedures, or false-positive interpretations continue to cause profound physical injury and psychological trauma for the patients, and deeply affect involved providers, teams, and institutions. Consequently, pathologists must engage in a concerted effort to build and embrace mechanisms for high reliability specimen and data processing, verification and cross checks involving diagnostic interpretations, efficient event reporting, outstanding communication, and excellent coordination involving both internal and external interactions. This, in turn, will lead to better and safer pathology systems of the future.

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