

Specimen Labeling Errors in Surgical Pathology: An 18-month Experience

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Abstract and Introduction

Abstract

Elimination of medical errors is important for pathologists. Errors occurring in surgical pathology involve specimen defects, specimen labeling, processing, diagnosis, and reporting defects. Errors occur during prelaboratory, laboratory, and postlaboratory phases.

We reviewed our experience with mislabeled specimens in the laboratory for an 18-month period. The percentage of error was calculated on a per case, block, and slide basis. Errors were characterized by site and as incorrect patient or site. The study involved 75 labeling errors (0.25% of cases) that were detected. Of the 75 errors, 55 (73%) involved patient name, and 18 (24%) involved site. The majority of mislabelings (52 [69%]) occurred in the gross room. Although infrequent, labeling errors involved misidentification of patient or specimen source. Of the errors, 73% (55/75) of errors resulted in slides assigned to an incorrect patient. Most errors occurred in the gross room. Newer technologies such as bar coding and radio frequency chip methods may reduce the frequency of specimen labeling errors.

Introduction

Medical error reduction has become a major focus for organized medicine since the publication of the Institute of Medicine's report on medical errors in 1999.^[1] However, in a recent review of errors in anatomic pathology, errors involving specimen labeling were only briefly mentioned.^[2] Labeling errors can result in inappropriate therapy or the withholding of therapy in patients with unrecognized malignancies. Identification errors involving laboratory specimens may involve misidentification of a patient or the patient's specimen^[3] or the site from which the specimen was obtained. Such errors may result in significant patient inconvenience or harm. Identification errors are frequent by anecdotal evidence,^[3] but few studies have documented the frequency of such errors in the anatomic pathology laboratory. Identification errors fall into 2 categories represented by patient identification errors and specimen identification errors. In a *patient identification error*, a specimen is labeled with the incorrect patient name or identification number. In a *specimen identification error*, a specimen is misidentified as to site of origin or time of collection but the specimen is correctly associated with patient name and/or unique identification number.

Identification errors can be classified as preanalytic, analytic, and postanalytic. All 3 types are of concern to pathologists. Preanalytic, or "clinical," errors can be addressed by standardization of the specimen collection process and feedback to clinical staff. Only the analytic errors are directly addressable by laboratory professionals and surgical pathologists. A number of authors have addressed labeling errors in laboratory medicine, including Q-Probes analyses undertaken by the College of American Pathologists (CAP).^[4-6] These authors have described methods for error reduction.^[4-6] Of the Q-Probes accessioning errors, 10% were due to misidentification. The majority of routine practices for the identification of labeling and specimen identification errors probably underestimates the frequency of occurrence of such errors, and many errors may go undetected.^[3] Labeling errors may be detected by the laboratory staff, pathologists, or clinicians. Labeling errors detected before patient harm or inconvenience has occurred are frequently designated "near misses."^[3]

Few studies have addressed the frequency of labeling errors for anatomic pathology specimens. In a CAP Q-Probes program, specimen identification and accessioning deficiencies were found in 60,042 of 1,004,115 cases accessioned (6.0%).^[3,7] Errors associated with specimen misidentification accounted for 9.6% of the total errors.^[7] Labeling errors have been categorized as class 1, typographical errors with no clinical consequences; class 2, minor errors unlikely to

have clinical consequences; and class 3, errors that are significant and have the potential to detrimentally impact patient care.^[8]

Francis et al^[8] documented the frequency of preanalytic errors in a high-volume endoscopy center. In a study of 8,231 specimen containers, they documented a 0.09% rate for class 3 errors in which specimen bottles were mislabeled for patient name or unique identification number. They described a method for significantly reducing this error rate for mislabeling with significant clinical implications.^[8]

A few studies have documented error rates for specimen identification and information transmission in surgical pathology and cytopathology specimens.^[9,10] In observational studies by Raab et al^[9] and Smith and Raab,^[10] no specimen was found to be totally free of defect, although the frequency and type of defect varied considerably. Approximately 1.5% of specimen containers lacked an accurate patient name or second identifier.^[9] These near-miss errors required accessioners to spend considerable time (15–45 minutes) correcting these defects.^[9] In the study by Smith and Raab,^[10] the rate of operator-dependent near-miss events in the gross room was 0.6 events per specimen. The operator-dependent errors were subcategorized into accessioning (wrong accession number written on requisition form), set up (requisition paired with incorrect specimen container), and "grossing" (different requisition forms in grossing area at the same time). These near misses or potential errors could have had significant impact on patient care in that an incorrect diagnosis might have been rendered for a patient.

Makary et al^[11] reviewed a total of 21,351 surgical specimens and detected 91 errors in specimen labeling. Of these errors, 11 (12%) involved specimens associated with an incorrect patient assignment. In their study, specimens most commonly mislabeled were breast, skin, and colon.^[11] The majority of labeling errors occurred in biopsy specimens.

Specimen labeling errors within the laboratory can occur at several points of specimen processing. Within the gross room, specimen containers can be paired with cassettes labeled with an incorrect case number (wrong patient) or an incorrect part number (wrong site). In the histology laboratory, cassettes at the cutting station can be paired with incorrectly pencil-labeled slides (wrong patient or site), or a correctly pencil-labeled slide can have the wrong paper label applied (wrong patient or site). A surgical pathologist may pick up an incorrect slide and dictate a report with an incorrect diagnosis for the patient's laboratory data being reviewed. Errors may also occur during transcription when dictations are transcribed to the wrong report number and patient. Examples of most of these have been described in the literature. Meyer et al^[12] reported a 0.59% error rate in placing paper labels on correctly pencil-labeled glass slides.

We investigated the frequency of labeling errors in an anatomic pathology practice processing more than 29,000 specimens in an 18-month period. We analyzed the types of specimens involved, laboratory location where the error occurred, the training level of the person making the error, the potential impact on the patient, and the person detecting the error. Herein, we report the results of that study.

Materials and Methods

The University of Utah Department of Pathology and ARUP Laboratories (Salt Lake City) maintain extensive quality assurance (QA) and quality control (QC) records documenting all labeling errors in the preanalytic, analytic, and postanalytic phases of anatomic pathology specimen analysis and reporting. In addition, the QA records include data on all federal and CAP mandates concerning data required on requisition forms and anatomic pathology reports. We reviewed the QA/QC records for an 18-month period. Only labeling errors occurring in the laboratory phase were analyzed. During this period, 29,479 cases were accessioned, and the QA/QC data concerning these cases were reviewed. Errors were characterized as mislabeled cassettes/blocks (gross room errors), mislabeled slides (histology laboratory), and mislabeled reports. Errors were characterized as incorrect patient or correct patient but incorrect specimen site or location designation. Finally, the type of specimen (biopsy vs resection) and tissue site were recorded along with the training level of the staff making and detecting the errors.

Results

The 29,479 cases accessioned were associated with 109,354 blocks and 248,013 slides. Characteristics

of the errors are shown in [Table 1](#). The percentage of error was calculated on a per case, per block, and per slide basis. The study included 75 labeling errors that were detected (0.25% of cases, 0.068% of blocks, and 0.030% of slides). The majority of mislabeling (52 [69%]) occurred within the gross room owing to incorrect labeling of the cassette submitted to the histology laboratory. These errors were detected in the histology laboratory, by a surgical pathologist or the referring clinician on reading the patient's surgical pathology report. Errors occurring within the histology laboratory were most commonly detected by the sign-out surgical pathologist.

The majority of labeling errors occurred in biopsies of the skin, esophagus, kidney, and colon. The distribution of labeling errors by tissue and specimen type reflected the distribution of case types received in surgical pathology. Hence, most errors occurred with small biopsy specimens from the endoscopy and dermatology clinics, which supplied the majority of specimens examined in the surgical pathology laboratory.

Discussion

Since the Institute of Medicine's report on medical errors in 1999,^[1] increased attention has been given to potential sources of error in medical practice. The CAP has performed Q-Probes studies investigating labeling errors in anatomic and clinical pathology.^[6,7] Labeling errors may occur in the preanalytic or analytic phases of specimen processing in surgical pathology, as well as during the reporting process. Labeling errors involving the accurate linkage of the patient with the surgical specimen may result in delay of diagnosis or institution of inappropriate therapy.^[2,3] Labeling errors resulting in inappropriate identification of a specimen as to tissue type, site, or time of specimen acquisition may result in less harm but still seriously poor outcomes for a patient. Errors in correct lateralization (right vs left) can result in serious complications such as treatment of the wrong organ or limb.

We investigated the percentage of mislabeled specimens in a surgical practice during a period of 18 months. We found that approximately 0.25% of cases were associated with a labeling error in the laboratory phase of analysis. In a study by Makary et al^[11] evaluating 21,351 surgical specimens, 11 (0.05% of specimens) mislabelings were detected in which labeling errors resulted in assignment of the specimen to an incorrect patient. In their study, the errors were not specifically assigned to the preanalytic or analytic phase of specimen analysis. In our study, we investigated only labeling errors occurring during the analytic or laboratory phase of analysis. The preanalytic phase of specimen labeling was specifically studied in a large endoscopy center.^[8] Francis et al^[8] studied more than 8,000 specimen containers and demonstrated a 0.09% rate for incorrect specimen labeling. A few other studies had addressed labeling issues in the anatomic pathology laboratory,^[7] and the findings are comparable.

It seems that the incidence of specimen mislabeling in the preanalytic phase is relatively similar to our experience of errors in the laboratory phase of specimen analysis. The major or class 3 labeling error rate of 0.09% described by Francis et al^[8] is lower than our 0.25% incidence of major mislabeling in the analytic phase. Differences in study design may explain our higher rate of error. In the study by Francis et al,^[8] the error rate was based on a per specimen bottle rate, whereas our rate was calculated on a per case basis. Because several specimen bottles may be present for a given case, the 2 rates are not directly comparable. For gastrointestinal (GI) biopsy specimens, the number of specimen bottles usually closely approximates the block number. Hence, a better comparison between our study and that by Francis et al^[8] is equating our rate of labeling errors per block with their rate of major labeling errors per specimen bottle. In this case, our mislabeling rate per block of 0.068% is similar to the 0.09% reported by Francis et al.^[8] This rate is also similar to the 0.05% rate of error for incorrect patient labeling reported by Makary et al.^[11]

Anatomic pathology labeling errors can occur at a number of points in specimen preparation and analysis. During the "grossing in" procedure, tissues can be placed in an incorrectly labeled cassette, resulting in assignment to the wrong patient or the wrong site in the correct patient. In the former instance, the patient can receive an incorrect diagnosis resulting in an inappropriate therapy or follow-up. In the latter case, therapy may be directed at the wrong site or stage may be incorrectly assigned.

In our study, 73% of errors resulted in incorrect linkage of a specimen with a patient. Of these "wrong patient" errors, 69% occurred in the gross room ([Table 1](#)). In the majority of cases, the labeled cassettes were switched between 2 patients whose specimens were sequentially "grossed in." In all cases, these switched cases were small biopsy specimens in which the prelabeled cassettes had been placed with the incorrect paperwork and specimen containers. The staff members working in the gross room include pathology residents, certified pathology assistants, and laboratory assistants. The laboratory assistants had at least 2 years of college and received on-the-job training but were not certified. Of the specimen labeling errors, 46 (88%) of 52 were made by laboratory assistants. While laboratory assistants prepare the majority of small cases, they seem to be overrepresented in cases involving mismatching of specimen with labeled cassette. "Wrong site" mislabelings were less frequent and were due to incorrect assignment of a subset number or letter to a cassette. The majority of these errors were made by laboratory assistants (11/18 [61%]), with most of the other wrong site errors being made by pathology residents.

Raab et al^[9] in a direct observation of specimen accessioning and grossing documented that 1.7% of specimen containers lacked an accurate patient name or second identifier, 3.4% lacked a date of collection, and 7.3% lacked a physician name. In that study, the frequency of specimen defect types varied considerably by preanalytic collection site, and patient name defects occurred only in some clinics. They considered the root cause of the majority of defects to be the result of lack of standardized preanalytic processes and lack of redundant checks.^[9] Smith and Raab^[10] in a similar observational study demonstrated that near-miss events were 0.6 events per specimen. These errors were subcategorized into accessioning, set-up, and grossing errors. Errors in these areas occurred at a rate of 5.5 events per specimen. The most important of these errors were assignment of a wrong accession number to a requisition form, the requisition paired with an incorrect specimen container, and 2 or more requisition forms in the grossing area at the same time. They concluded that traditional batch flow design in surgical pathology grossing facilities led to unacceptably high rates of process and operator-dependent near misses.

Our experience with mislabeled specimens is similar in that the majority of errors (69%) occurred in the gross room and involved the mislabeling of cassettes with subsequent block and slide being associated with an incorrect patient or incorrect site. These near-miss errors were usually recognized in the histopathology laboratory by histotechnologists or subsequently by surgical pathologists signing out the cases.

Of the mislabelings, 19 (25%) occurred in the histology laboratory. All mislabelings occurred during 1 of 2 procedures. The first procedure was performed by certified histotechnologists and involved blocks being matched with slides pre-labeled by pencil on the frosted glass end of the slide. These pencil-labeled slides were matched with the blocks at the time of tissue sectioning and the sections transferred to the glass slides. In 12 cases (63% of histology errors), a certified histotechnologist mislabeled a glass slide before cutting the section or transferred the cut section onto the incorrectly pencil-labeled slide. In 7 cases (37% of histology labeling errors), a laboratory assistant placed an incorrect preprinted label on the pencil-labeled glass slide. This error represented 9% of all labeling errors and occurred in 0.003% of all slides prepared. Meyer et al,^[12] in a retrospective review of slide labeling in Papanicolaou testing, found incorrect attachment of a paper label to a previously pencil-labeled slide to occur in 0.59% of slides. They developed an alternative technique in which the paper label was placed at the opposite end from the pencil labeling of the slide. This method seemed to substantially reduce labeling errors to nearly zero.

Of the labeling errors, 4 (5% of total errors) occurred in the pathology office where office staff placed an incorrect case number (wrong patient) on outside slides submitted for internal review. All 4 cases were identified by the sign-out pathologist because the tissue on the slide did not match the tissue described in the outside pathology report and the outside slide number did not match the accession number on the report.

GI tract biopsy specimens were the most frequent type of specimen associated with mislabeling. Mislabeled GI biopsy specimens represented 16 (21%) of 75 mislabeled specimens. This parallels the

frequency of GI biopsies in the case workload of approximately 20%. All errors in the labeling of GI biopsy specimens involved assigning the material to the wrong patient. This clustering of labeling errors in GI biopsy specimens may have resulted from GI biopsy specimens arriving in batches from the endoscopy clinic and processed in the pathology gross room as a group. Because all were grossly similar, the chances for error in matching cassettes with paperwork and specimens were relatively high.

Other specimens with a relatively high incidence of labeling errors were renal and skin biopsy specimens. Similar factors of small specimen, similar appearance, and batch processing may have increased the likelihood of specimen mislabeling (cassette mislabeling). Smith and Raab,^[10] in an observational study of gross room practices, concluded that batch flow processing led to unacceptably high rates of near-miss errors.

Training level appeared to influence the likelihood that a person would make a labeling error. While the majority of labeling errors in the gross room were made by laboratory assistants (88%), the laboratory assistants also grossed in the majority of specimen cassettes (68%). Thus, their relatively high rate of labeling error is in part explained by grossing in a relatively high percentage of total cassettes/tissue specimens. Similarly, differences in the number of errors between certified histotechnologists and histology laboratory assistants could not be explained by training level. Of 19 errors occurring in the histology laboratory, 12 (63%) were made by certified histotechnologists and only 7 (37%) by laboratory assistants.

The potential for adverse impact due to a labeling error varied considerably in this series. Of 75 labeling errors, 62 (83%) would not have had a significant impact on patient care if they had not been identified in the surgical pathology laboratory or sign-out process. Reasons for a lack of impact were discordance between patient sex and reported specimen source (prostate gland in a female patient), diagnosis without subsequent impact on patient care (cholelithiasis in a patient known not to have had a cholecystectomy), and incorrect diagnosis identical to the actual patient diagnosis (eg, normal vs normal or adenomatous polyp vs adenomatous polyp). Also, diagnoses in which the site was incorrect but did not affect stage, margin status, or need for additional surgery did not have an impact on patient outcome. Of the 75 errors, 13 (17%) could have had a significantly negative impact on a patient. The most common of these errors occurred when 2 specimens from different patients but from the same site were switched and mislabeled. Such errors occurred most commonly in batched specimens and included gastrointestinal and renal biopsy specimens. An example of such a clinically significant labeling error with patient impact was the switching of 2 colonic biopsy specimens from different patients. One biopsy showed an adenocarcinoma, and the other contained only a hyperplastic polyp. Clearly, patient follow-up and therapy would have been significantly different for these 2 patients.

The use of the Lean method has been shown to reduce errors in anatomic pathology.^[13,14] The Lean method, when coupled with automated systems, can substantially reduce errors in histology laboratories^[13] and in other components of anatomic pathology specimen tracking, processing, and reporting.^[14]

Mislabeled specimens in surgical pathology represent an infrequent but important source of medical error. In the analytic component of specimen processing, most errors occur in the gross room. This clustering of labeling errors may be due to batch processing in which similar specimens may be confused, or it may be a function of staff training level. Avoidance of batch processing and the use of newer technologies such as bar codes on specimen containers, requisition forms, cassettes, and slides or the use of radio frequency chip technology may significantly reduce the incidence of specimen mislabeling.

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Table 1. Characteristics of 75 Laboratory Labeling Errors

Characteristic	No. of Errors
Type of error	
Wrong patient	55
Wrong site	18
Incorrect label number but same patient and site	2
Where error occurred	
Gross room	52
Histology laboratory	19
Pathology office	4
Level of training or position of person making error	
Certified histology technologist	12
Laboratory assistant, gross room	46
Certified pathology assistant	2
Resident pathologist	4
Transcriptionist	4
Laboratory assistant, histology	7
Level of training or position of person recognizing error	
Pathologist	33
Certified histotechnologist	39
Transcriptionist	1
Clinician	1
Not recorded	1
Potential impact on patient if error not identified	
None	62
Wrong therapy	13

Authors and Disclosures

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