

Mislabeled Cases, Specimens, Blocks, and Slides

A College of American Pathologists Study of 136 Institutions

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• **Context.**—Accurate specimen labeling is a major patient-safety initiative by the Joint Commission and the College of American Pathologists. Inadequate specimen labels have led to patient injury from wrong patient diagnosis, wrong side treatment, and delay in diagnosis.

Objectives.—To quantify the rates of mislabeled cases, specimens, blocks, and slides and to identify the sources of error and the ways in which errors are detected.

Design.—In this voluntary-subscription Q-Probes study, participants prospectively reviewed surgical pathology cases for 8 weeks or until 30 errors (mislabeled cases, specimens, blocks, and slides) were identified. Information collected on each labeling error included the work location where the defect occurred, what was mislabeled, the number of items affected, the point of detection, and the consequences of the mislabeling error, along with institutional demographics and practice. The rates of mislabeled cases, specimens, blocks, and slides were tested for association with institutional demographics and practice variables.

Results.—Of the 136 institutions providing information on a total of 1811 mislabeling occurrences, the overall mislabeling rates per 1000 were 1.1 cases, 1.0 specimen, 1.7 blocks, and 1.1 slides. Of all mislabeling events, 27.1% were cases, 19.8% specimens, 25.5% blocks, and 27.7%

slides. The work locations at which the errors occurred were 20.9% before accessioning, 12.4% at accessioning, 21.7% at block labeling, 10.2% during gross pathology, and 30.4% at tissue cutting. Errors were typically detected in the first or second steps immediately following the error. Lower mislabeled slide rates were associated with continuous individual case accessioning and use of formal checks at accessioning. Routinely including a statement in the gross description that the specimen is labeled with the patient's name and is properly identified was also associated with lower rates of specimen mislabeling. The errors were corrected before reports were issued 96.7% of the time; for 3.2% of errors, a corrected report was issued. In 1.3% of error occurrences, participants gauged that patient care was affected.

Conclusions.—This study quantified mislabeling rates across 136 institutions of cases (0.11%), specimens (0.1%), blocks (0.17%), and slides (0.11%). Errors in labeling appear nearly equally throughout the system of accessioning, gross pathology processing, and tissue cutting. Errors are typically detected in the immediate steps after the errors occurred, reinforcing the need for quality checks throughout the system.

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Patient and specimen identification are critical elements to patient safety in surgical pathology. Goal 1 of the Joint Commission's patient safety goals (National Patient Safety Goal 01.01.01) emphasizes improved patient identification.¹ This encourages proper identification of specimens by instructing laboratories to "[u]se at least two patient identifiers when providing laboratory services."^{2(p2)} Despite the care and effort devoted to specimen management in surgical pathology, many opportunities for mishaps remain. Recognizing multiple levels of tissue

handling during which errors can enter the testing process, the Laboratory Accreditation Program of the College of American Pathologists emphasizes the importance of specimen identification with 5 checklist items (Anatomic Pathology [ANP].11800, ANP.21050, ANP.21100, and ANP.21150 [September 27, 2007] and Laboratory General [GEN].40491 [October 31, 2006]).^{3,4} These checklist questions focus on specimen, block, and slide labeling.

In the preanalytic phase of surgical pathology, as tissue specimens are collected, transported, accessioned, dissected, embedded, cut, and placed on slides, there are multiple points where patients' tissues are transferred or handed to another person. Specimen identification must be maintained across these hand offs. This study documents the rates of misidentification of cases, specimens, blocks, and slides. It also records how identification errors are detected and identifies practices that are associated with better performance.

MATERIALS AND METHODS

The basic mechanism of this Q-Probes study has been previously described.⁵ Briefly, Q-Probes studies are subscrip-

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tion-based quality assurance studies. They are conducted for a defined period by many laboratories using the same protocol. This design captures the advantages of peer group comparison for determining quantitative levels of performance.

In this particular Q-Probes study, subscribers prospectively reviewed surgical pathology cases in the fall of 2009 until an 8-week period had elapsed or until 30 error incidents related to mislabeled cases, specimens, blocks, or slides had been identified. In categorizing the defects, participants used the following definitions:

- **Mislabeled Case.**—Wrong accession number was applied to the entire case (eg, S07-0001 versus S08-0001; S08-00101 versus S08-00110).
- **Mislabeled Specimen.**—Wrong specimen labeling was due to mix-up of specimens within a case (eg, right versus left specimens in a bilateral biopsy from the same patient).
- **Mislabeled Block.**—Histologic block was labeled with the wrong patient/case identification or wrong sequence number or letter. This could be due to the wrong label being applied to the block or to tissue being placed in the wrong block. Undetected mislabeling of cases, mixed-up cases, or mislabeled specimens also lead to mislabeled blocks.
- **Mislabeled Slide.**—Histologic slide was labeled with the wrong specimen/patient identification, sequence number, or letter. This may be due to an error in labeling at the time of slide preparation or to wrong sections being placed on the slide. This error may also be caused by undetected mislabeling of blocks, specimens, or cases.

To produce denominators for rates of labeling errors during the study, participants counted the total numbers of cases, specimens, blocks, and slides reviewed. When participants discovered instances of mislabeling, they recorded (1) the station in the surgical pathology process at which the error occurred (eg, before or at accessioning, block labeling), (2) which elements in the process were mislabeled (ie, case, specimens, blocks, slides), (3) the number of specimens, blocks, and slides affected, (4) the point in the surgical pathology process when the errors were detected, and (5) the outcome (consequence) of the error (ie, mislabeling corrected, corrected report issued, and/or patient care affected).

Excluded from the study were surgical pathology cases that were processed before the study period but were subsequently identified as mislabeled during the study period. Also excluded were prepared slides received from another institution and blocks or slides cut in other laboratories. Finally, participants also completed a questionnaire that summarized institutional and laboratory demographic and practice variables that could be compared with the mislabeling rates in the surgical pathology process.

Statistical Analyses

The case, specimen, block, and slide mislabeling rates per 1000 were calculated. All four rates were skewed so a log transformation for regression-based analyses was used.

Individual associations between the rates and the demographic and practice variables were investigated using Kruskal-Wallis tests for discrete-valued independent variables and regression analyses for the continuous independent variables. Variables with significant associations ($P < .10$) were introduced into a multivariate regression model. All variables remaining were significantly associated at the $P < .05$ significance level.

RESULTS

One hundred thirty-six laboratories collected and submitted data. The institutional demographic characteristics are shown in Table 1. Most of participating institutions (93.4%; $n = 127$) were located in the United States, with the remaining located in Saudi Arabia (4.4%; $n = 6$), Canada (1.5%; $n = 2$), and Lebanon (0.7%; $n = 1$).

Table 1. Institution Demographics

Characteristics	Institutions, No. (%)
Institution type	
Voluntary, nonprofit hospital	68 (53.1)
Private, independent laboratory	21 (16.4)
Proprietary hospital	6 (4.7)
County hospital	6 (4.7)
Group practice	5 (3.9)
Veterans hospital	5 (3.9)
Governmental, nonfederal university hospital	4 (3.1)
Nongovernmental, university hospital	3 (2.3)
System/integrated delivery network	3 (2.3)
Independent blood bank	1 (0.8)
Children's hospital	1 (0.8)
Other, nongovernmental	1 (0.8)
State acute hospital	1 (0.8)
City hospital	1 (0.8)
Other, governmental, nonfederal	1 (0.8)
Indian health service	1 (0.8)
Occupied bed size	
0–150	36 (33.3)
151–300	35 (32.4)
301–450	17 (15.7)
451–600	11 (10.2)
>600	9 (8.3)
Institution location	
City	72 (55.8)
Suburban	34 (26.4)
Rural	21 (16.3)
Other	2 (1.6)
Governmental affiliation	
Nongovernmental	109 (85.2)
Governmental, nonfederal	13 (10.2)
Governmental, federal	6 (4.7)

Of the participating institutions ($n = 136$), 40.7% ($n = 55$) were teaching hospitals, and 24.4% ($n = 33$) had a pathology residency program. Within the past 2 years, the Laboratory Accreditation Program had inspected 89.3% ($n = 121$) of the laboratories. Laboratory inspections were also conducted by the Joint Commission at 28.2% ($n = 38$) of institutions within the past 2 years. Table 1 displays additional practice characteristics of participating institutions.

Mislabeled Cases, Specimens, Blocks, and Slides

From a total of 427 255 reviewed cases, 1811 cases (0.4%) had some type of mislabeling. In 490 instances (27%; 1.1 cases per 1000), the entire case was mislabeled. In 358 cases (20%), 796 specimens (1 per 1000) of a total 774 373 specimens were mislabeled. In 461 cases (25%), 2172 blocks (1.7 per 1000) of a total of 1 304 650 blocks were mislabeled. In 502 cases (28%), 2509 slides (1.1 per 1000) were mislabeled from a total of 2 261 811.

Table 2 shows the distribution of errors types and the location in the process at which those errors occurred. Misidentification errors of cases and specimens occurred most often before accessioning (at collection) or at accessioning. Block-labeling errors occurred most frequently during block labeling. Slide-labeling errors occurred most often when tissues were cut and when slides were mounted. Table 3 shows where errors occurred in the process and at what location in the process those errors were later detected. Errors were typically detected in the 1 or 2 steps after the point at which the

Table 2. Error Incidents by the Location at Which the Error Occurred

Location	Cases, No. (n = 490)	Specimens, No. (n = 358 cases)	Blocks, No. (n = 461 cases)	Slides, No. (n = 502 cases)
Before accessioning	155	382 ^a	64 ^a	139 ^a
Accessioning	131	207	300 ^a	206 ^a
Block labeling	83	56	1331	249 ^a
Gross dissection and sectioning	41	48	345	219 ^a
Embedding	1	4	39	46 ^a
Tissue cutting and slide mounting	63	58	75	1546
At microscopy	8	31	11	104
Transcription	8	10	7	0
Total	490	796	2172	2509

^a Some of the error incidents at this point were due to a cascading effect (eg, 1 mislabeled case leads to 3 mislabeled specimens, 5 mislabeled blocks, and 10 mislabeled slides).

errors occurred. In 96.7% of cases (n = 1751), the mislabeling was corrected without any additional consequences. In 3.25% of cases (n = 59), a corrected report was issued, and in 1.3% of cases (n = 24), participants assessed that patient care was affected in some way.

Practice Variables

Table 4 demonstrates the distribution of surgical pathology cases and personnel at participating laboratories. The median participant laboratory had accessioned approximately 13 500 cases in 2008, had 5 pathologists, 1 pathologist assistant, 5 histology technicians, 2 clerks, and 2 "other" workers. Table 5 lists a number of laboratory practice characteristics related to accessioning and processing in the laboratory. Gross examination and section preparation of surgical pathology cases were reported to have been performed 48.1% of the time by a pathologist assistant, 24% by the pathologist, 13.4% by the histology technician, 8.5% by a resident, and 6.1% by another worker.

Table 6 contains practice characteristics related to block labeling. Table 7 contains practice characteristics related to slide labeling. Table 8 demonstrates other laboratory practice characteristics.

Table 9 lists statistically significant correlations between mislabeling rates and various practice variables. The median rate at which slides were mislabeled was lower in laboratories with continuous individual-case (one by one) accessioning. Slide mislabeling rates were also lower in laboratories that had a formal, documented quality check at accessioning. Finally, the median rate of specimen mislabeling was lower at laboratories in which the gross description report specifically included a statement indicating that each specimen was labeled with

the patient's name and properly identified. The remaining practice characteristics listed in Tables 5 through 8 and other demographic data do not correlate at significant levels with the rates of mislabeled cases, specimens, blocks, or slides.

COMMENT

In this study, we met our primary objective of establishing a 0.11% multi-institutional rate for misidentification or mislabeling, with a rate of 0.1% for specimens, 0.17% for blocks, and 0.11% for slides. Errors were detected relatively evenly throughout the entire tissue processing system. One concern that the study addressed was whether a cascade of errors would follow from early case or specimen identification errors, which would be amplified in blocks and slides. Although this occurred for some cases, the cascade effect was dampened because early case and specimen identification errors were usually corrected in the immediate, subsequent steps. Thus, quick recognition led to few cases in which the misidentification error continued throughout the entire process. This demonstrates that those staff members in closest proximity to the specimen are usually able to identify upstream errors. Rather than cascading, identification errors occurred at 3 major, roughly equally, transition points: (1) before and at accessioning, (2) at block labeling and gross processing, and (3) at tissue cutting and slide mounting. Quality-assurance checks were effective when they focused on mislabeling immediately after each of these events, leading to detection of most errors.

The quality checks in place varied among study participants: 68% of laboratories (n = 92) had a documented quality check at accessioning, but only 27% (n = 37) have a quality check at transcription. Most laboratories

Table 3. Frequency of Error Incidents and Detection by Location^a

Location	Error Location, No. (%) (n = 1810)	Location of Error Detection, No. (%) (n = 1804)
Before accessioning	378 (20.9)	
During accessioning	225 (12.4)	337 (18.7)
Block labeling	393 (21.7)	
Gross dissecting and sectioning	184 (10.2)	267 (14.8)
Embedding	19 (1.0)	159 (8.8)
Tissue cutting and slide mounting	551 (30.4)	135 (7.5)
Before releasing slides to pathologist		428 (23.7)
During microscopy	44 (2.4)	376 (20.8)
During transcription	16 (0.9)	37 (2.1)
After releasing case		65 (3.6)

^a Numbers refer to the number of cases affected (not specimens, blocks, or slides), even if the error occurred during labeling of specimens, blocks, or slides.

Table 4. Distributions of Surgical Pathology Laboratory Characteristics

Characteristic (No. of Laboratories Responding), N = 136	All-Institution Percentiles		
	10th	50th (Median)	90th
No. of surgical pathology cases signed out in 2008 (N = 128)	4150	13 543	68 558
No. of laboratory personnel involved in providing surgical pathology services			
Pathologists (N = 131)	2	5	16
Fellows (N = 79)	0	0	2
Residents (N = 84)	0	0	16
Pathologist assistants (N = 107)	0	1	6
Histology technicians (N = 127)	2	5	15
Clerks (N = 107)	0	2	9
Other (N = 86)	0	2	12

maintained checkpoints at accessioning, gross examining, embedding, slide cutting, and slide labeling, and at case examination (Table 8). Decreased error rates, however, were associated significantly with only one of these checkpoints: accessioning.

Error prevention is, of course, preferable to error detection. The introduction of technology and the adoption of lean-process methods may improve laboratory efficiency and reduce errors.^{6,7} However, in this study, we failed to demonstrate a detectable benefit from computer technology (eg, barcodes) or from the introduction of lean processes in decreasing identification errors. The lack of evidence for the prevention of identification errors from computer technology and lean technologies may actually be due to the varied nature of the introduction of technical devices and lean method as well as to the inconsistency of their application.

Specifically inquiring about the use of block and slide labelers, the study documented a varied picture: 57% of laboratories (n = 74) use automatic block labelers, and 13.5% of these labelers (n = 10) incorporated barcodes in

Table 6. Practice Characteristics Related to Block Labeling

Characteristic (No. of Laboratories Responding), N = 136	Institutions, No. (%)
Is an automated block labeler used? (n = 130)	
Yes	74 (56.9)
No	56 (43.1)
If you use an automated block labeler, does it incorporate a barcode? (n = 74)	
No	64 (86.5)
Yes	10 (13.5)
If you use an automated block labeler, is the labeling information generated automatically from the accessioning software? (n = 73)	
No	47 (64.4)
Yes	26 (35.6)
If you use an automated block labeler, which best describes your process? (n = 74)	
Label blocks in small batches including multiple cases	37 (50.0)
Label blocks for one case at a time before gross examination	29 (39.2)
Only label blocks for an individual case during gross examination of the specimen	5 (6.8)
Label all blocks as one batch	3 (4.1)
Are blocks labeled with a second identifier as well as the accession number? (n = 131)	
No	102 (77.9)
Yes	29 (22.1)
If blocks are labeled with a second identifier, which secondary identifier is used? (n = 29)	
Patient name	25 (86.2)
Medical record number	4 (13.8)
When labeling blocks in a batch, how are blocks kept with their respective case before sectioning? (n = 119)	
Blocks are simply placed on the specimen container	65 (54.6)
Blocks are placed adjacent to the specimen container	22 (18.5)
Blocks are placed in a unique holder and attached to the specimen container	12 (10.1)
Blocks are physically attached to the specimen container by tape	1 (0.8)
Other (bin/divided compartment, cassette, numeric order)	19 (16.0)

Table 5. Participant Characteristics Related to Accessioning and Laboratory Processing

Characteristic (No. of Laboratories Responding), N = 136	Institutions, No. (%)
How many gross pathology stations are routinely used? (n = 130)	
1 station	61 (46.9)
2–5 stations	54 (41.5)
6–10 stations	11 (8.5)
11–15 stations	4 (3.1)
How are surgical pathology cases typically accessioned? (n = 129)	
Continuous individual case accessioning	73 (56.6)
Multiple small batches	47 (36.4)
Multiple large batches	6 (4.7)
One batch	3 (2.3)
Is a computer system used to generate accession numbers? (n = 130)	
Yes	109 (83.8)
No	21 (16.2)
How are barcode readers used? (n = 115) ^a	
Scan requisition slips and accession cases	24 (54.5)
Scan requisition slips or specimen labels at the gross table	23 (52.3)
Access cases at microscopy	22 (50.0)
Access cases at transcription	14 (31.8)
Generate labeled blocks	12 (27.3)
Generate slide paper labels that are attached to slides	12 (27.3)
Generate labeled slides	8 (18.2)

^a Multiple answers allowed.

Characteristic (No. of Laboratories Responding), N = 136	Institutions, No. (%)
Which process best describes your method of slide labeling? (n = 128)	
Accession numbers are handwritten on the slides at the time of cutting, then batch-printed labels are attached after staining	49 (38.3)
Slides are etched using an automatic labeler doing a batch of cases at a time	30 (23.4)
Accession numbers are handwritten on the slides at the time of cutting	19 (14.8)
Accession numbers are handwritten on slides at the time of cutting, then labels are printed and attached after staining	13 (10.2)
Batch-printed labels are attached to slides at the time of cutting and survive staining	6 (4.8)
Slides are etched using an automatic labeler one case at a time at the time of cutting	6 (4.8)
Labels are printed and attached to slides at the time of cutting, one case at a time	5 (3.9)
Is an automatic slide labeler (etcher) used? (n = 130)	
No	93 (71.5)
Yes	37 (28.5)
If you use an automatic slide labeler (etcher), does it incorporate a barcode in the label? (n = 37)	
No	27 (73.0)
Yes	10 (27.0)
Do you use an automatic label maker that attaches labels to slides? (n = 125)	
No	113 (90.4)
Yes	12 (9.6)
If an automatic label maker that attaches labels to slides is used, does it incorporate a barcode in the label? (n = 11)	
No	8 (72.7)
Yes	3 (27.3)

the labels. Among these labelers, for nearly 36% of the devices (n = 26), the identification information was generated from the accessioning software. Automatic slide labelers were used by 28.5% of laboratories (n = 37). Slides with labels automatically produced and attached by a label maker were used in about 10% of processing systems (n = 12). Barcodes were incorporated in 27% of laboratories (n = 12) that used automatic labelers of either type (n = 49). Using labelers that lack integration with accessioning systems can be problematic. Although the automatic labelers reduce the risk of handwriting errors, the lack of their integration with accessioning means that identifying information must be reentered into the automatic labeler. This rework introduces another point at which errors can be introduced.

The pattern of errors in the participant laboratories suggests that there are 3 points in this process that must be tightly controlled: (1) accessioning, (2) transferring tissue into blocks, and (3) tissue cutting and slide mounting. An additional desirable feature that is essential for safety is the ability to track specimens, blocks, and slides from start to finish. To our knowledge, tracking systems that are integrated with all other available technologies, such as the accessioning system, block and slide labelers, barcode readers, and transcription systems, are quite rare but are

Characteristic (No. of Laboratories Responding), N = 136	Institutions, No. (%)
Do you use any type of device that physically attaches the slides and blocks together before cutting? (n = 126)	
No	125 (99.2)
Yes	1 (0.8)
Before distribution of slides, are blocks visually checked with the slides for accuracy of cut sections? (n = 125)	
Yes	66 (52.8)
No	59 (47.2)
Before distribution of slides, are blocks checked against the gross description? (n = 128)	
No	92 (71.9)
Yes	36 (28.1)
Is there a system in place to detect and track accessioning and labeling errors? (n = 131)	
Yes	98 (74.8)
No	33 (25.2)
Which of the following is routinely included in the gross description of each specimen? (n = 130) ^a	
Specimen's source and laterality	123 (94.6)
Accession number	111 (85.4)
Patient's full name	96 (73.8)
Statement indicating only that the specimen is labeled with the patient's name and properly identified	76 (58.5)
At which steps are there formal (documented) checks for catching accessioning/labeling errors? (n = 101) ^a	
At accessioning	69 (68.3)
When blocks are prepared	40 (39.6)
During gross examination	67 (66.3)
During embedding	58 (57.4)
During cutting	60 (59.4)
During slide labeling	54 (53.5)
Block check before the slides are given to pathologist	44 (43.6)
While the pathologist reads the case	58 (57.4)
During case transcription	27 (26.7)
Has a competency review of all personnel involved in accessioning and slide and block labeling been performed within the past 12 mo? (n = 130)	
Yes	105 (80.8)
No	25 (19.2)
Has the laboratory undergone a systematic improvement (lean) redesign? (n = 130)	
No	76 (58.5)
Yes, within the past 1–2 y	31 (23.8)
Yes, within the past 3–5 y	16 (12.3)
Yes, >5 y ago	7 (5.4)

^a Multiple answers allowed.

critically needed to dramatically reduce errors in specimen processing.

Other problems that have been shown to lead to errors include batch work and the ability of laboratories to sufficiently segregate cases, specimen, blocks, and slides, so they are not mixed up at the points of tissue transfer. A substantial percentage of laboratories in this study still process cases for accession (43.4%; n = 56), block (54.1%; n = 40), and slide (66.4%; n = 85) labels as batches. A pull system, as incorporated in lean production methods that

Table 9. Statistically Significant Correlations Between Mislabeling Rates and Various Practice Variables

Characteristic (No. of Laboratories Responding), N = 136	Institutions, No.	Median Mislabeling Rate (per 1000)
A. Relationship between <i>slide</i> mislabeling rate and practice variable		
Surgical pathology cases are typically processed by		
Batch accessioning	55	2.1
Continuous individual case accessioning	72	0.5
Institutions have a formal (documented) check for accessioning/labeling errors at accessioning		
Yes	67	0.6
No	32	2.3
B. Relationship between <i>specimen</i> mislabeling rate and practice variables		
The gross description routinely includes a statement indicating that the specimen is labeled with the patient's name and is properly identified		
Yes	75	0.6
No	53	1.3
C. Relationship between <i>block</i> mislabeling rate and practice variables		
Institution has a committee specifically designated for patient safety/quality assurance		
Yes	92	1.2
No	38	0.5

process specimens and blocks one-by-one, prompts for identification by scanning barcodes at the gross pathology station for only one specimen at a time. In the same way, slides should also be labeled one-by-one at the cutting station, from a barcode on the block from which the tissue is derived.

This study did confirm the value of lean processing techniques in one specific setting. The mislabeling slide rate was lower in institutions that had continuous (one-by-one), individual-case accessioning and in laboratories that emphasized a formal, documented check that probes for accessioning/labeling errors at the accessioning station. Readers should note that these 2 practices during accessioning were associated with fewer slide-labeling errors; the association speaks to a more-disciplined approach to processing at all stages and to avoidance of batch work.

In summary, this study documents that across 136 institutions mislabeling rates of cases (0.11%; 490 of 427 255), specimens (0.1%; 796 of 774 373), blocks (0.17%; 2172 of 1 304 650), and slides (0.11%; 2509 of 2 261 811) were similar. Errors in labeling appeared equally at each of the stages in the system of accessioning, gross examining, and tissue cutting. Errors were typically detected immediately

after the errors occurred. The study reinforced the value of quality checks throughout the system.

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