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What is This?
Developing and Pilot Testing Practical Measures of Preanalytic Surgical Specimen Identification Defects

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Abstract

Accurate patient identification is a National Patient Safety Goal. Misidentification of surgical specimens is associated with increased morbidity, mortality, and costs of care.1,3 Surgical specimen identification defects are errors that occur with regard to the identification of the patient associated with a surgical specimen or the characteristics of the specimen itself. Correction of such identification defects consumes valuable resources; each may take an average of 3.5 hours to correct.2 These defects are common, occurring in an estimated 6% of operative cases.4 Moreover, these defects may lead to incorrect therapy5 and are estimated to cause up to 160,000 adverse events annually in the United States.1

To address the surgical specimen identification problem, The Joint Commission has made accurate identification of laboratory specimens a National Patient Safety Goal, requiring at least 2 patient identifiers on specimen labels.5 The College of American Pathologists also requires 2 or more patient identifiers on specimen labels plus other labeling requirements as part of their Laboratory Accreditation Program for anatomical pathology.7 They also have measured specimen identification defects through their Q-Probes program1,4,8 and have developed and pilot tested practical measures of preanalytic surgical specimen identification defects during the preanalytic phase of pathology testing (from the operating room to the surgical pathology laboratory) that could be used to quantify the occurrence of these defects. The measures (6 container and 6 requisition identification defects) were developed by a panel of physicians, pathologists, nurses, and quality experts. Overall, there were identification defects in 2.9% of cases (1780/60 501; 95% confidence interval [CI] = 2.0%-4.4%), 1.2% of containers (1018/81 656; 95% CI = 0.8%-2.0%), and 2.3% of requisitions (1417/61 245; 95% CI = 1.2%-4.6%). Future research is needed to evaluate if hospitals are able to use these measures to assess interventions meant to reduce the frequency of specimen identification defects and improve patient safety.

Keywords

surgical specimens, identification errors, labeling errors, quality measures, surgical pathology

Misidentification of surgical specimens is associated with increased morbidity, mortality, and costs of care.1,3 Surgical specimen identification defects are errors that occur with regard to the identification of the patient associated with a surgical specimen or the characteristics of the specimen itself. Correction of such identification defects consumes valuable resources; each may take an average of 3.5 hours to correct.2 These defects are common, occurring in an estimated 6% of operative cases.4 Moreover, these defects may lead to incorrect therapy5 and are estimated to cause up to 160,000 adverse events annually in the United States.1

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tried to reduce these errors through their Q-Tracks pro-
gram. These accreditation processes help ensure that safe protocols are in place in surgical pathology labor-
atories of accredited hospitals.

Surgical pathology errors have traditionally been
categorized into 3 phases of the testing process: a preana-
lytic phase (from the operating room to the path-
ology laboratory), an analytic phase (from speci-
men receipt in the pathology laboratory to analytic
test results), and a postanalytic phase (involving the
reporting of the pathology test results). Although there
are national standards pertaining to this process (eg,
as part of the accreditation and inspection practices of
the College of American Pathologists), they pertain
almost exclusively to the analytic phase.7 There is still
no standardized surveillance or valid measures to
assess adherence to these regulatory standards in the
preanalytic phase and to allow frontline providers
from both surgery and pathology to jointly evaluate
and improve their performance with regard to preana-
lytic surgical specimen identification.11 Preanalytic
surgical specimen identification defects also have
been the least well studied and represent a potential
source of significant patient harm, despite the fact that
these defects are preventable and unambiguous.10

The goal of this research was to develop a measure-
ment tool of practical, process-based, standardized
measures with explicit definitions to give frontline
providers a shared framework that they could use to
evaluate the quality of surgical specimen identifica-
tion in the transition from the operating room to the
surgical pathology laboratory. In this article, the
authors describe the development of these quality
measures and pilot test them in evaluating surgical
specimen identification defects in a large cohort of
Midwestern hospitals.

Methods

Developing the Set
of Quality Measures

The model previously published by Rubin et al13 was
used to help design this project. The steps of this
model include defining the audience and use for mea-
surement, choosing the clinical area to evaluate, organ-
izing an assessment team, selecting the processes or
aspects of care to measure, writing the measure speci-
fications, performing preliminary tests, and establish-
ing scoring and analytic specifications.

An interdisciplinary panel convened and used the
model13 to develop a specific set of surgical specimen
quality measures that frontline providers could use to
evaluate and improve their performance in surgical
specimen identification. The panel included physi-
cians, nurses, students, and administrators with expert-
tise in surgical care, quality improvement, and/or
pathology. Panel members represented the Johns
Hopkins Medical Institutions, the Henry Ford Health
System, and the Michigan Health and Hospital
Association (MHA) Keystone Center for Patient Safety
and Quality.

In selecting a process of care, the authors first consid-
ered the 3 stages in which surgical specimen defects are
typically stratified: stage 1, the preanalytic phase (from
the operating room to the pathology laboratory); stage 2,
the analytic phase (from specimen receipt in the pathology
laboratory to analytic test results); and stage 3, the postana-
lytic phase (the reporting of pathology test results). The pre-
analytic phase was chosen because specimen identification
defects in this stage are completely preventable and unam-
biguous, yet their prevention requires the coordination of
frontline staff from both pathology and surgery.10

The process of writing measure specifications
began in the fall of 2008. A literature review was con-
ducted to identify previously published measures of
surgical specimen defects. The authors’ work built
mainly on the validated error taxonomy developed by
Zarbo et al,11 work previously done at the Henry Ford
Health System in Detroit2,14 and the Johns Hopkins
Medical Institutions in Baltimore10 and on the
Association of periOperative Registered Nurses’
Perioperative Standards and Recommended Practices
for “specimens in the perioperative environment.”15

The panel of experts used an iterative process to achieve
group consensus on a preliminary set of surgical specimen
identification quality measures. Conference calls were
conducted every 2 to 4 weeks to evaluate progress and
discuss barriers. With each iteration, each panelist consid-
ered the validity and feasibility of data collection based on their
clinical experience and perceptions. The goal of the inter-
disciplinary panel was to develop explicit specifications
for each of the candidate measures in order to standardize
data collection and reduce the potential for bias. The speci-
fications described who should collect the data, what to
measure, how to measure it, and when to measure it.

Pilot Testing of Surgical
Specimen Quality Measures

In the fall of 2009, the preliminary set of candidate mea-
sures, measure specifications, and a preliminary data col-
collection tool were ready for pilot testing. All hospitals in
the MHA were invited by the MHA Keystone Center to
voluntarily participate in what was called the “Keystone
Surgical Specimen Project.” The preliminary materials
were distributed to all participating hospitals to determine
their face validity. The measures and data collection tool
were revised based on feedback from each hospital. In the end, the panel agreed on 12 candidate measures: 6 container identification defects and 6 requisition identification defects. They also developed 3 composite measures to calculate defect rates: (1) case defect rate: number of operative cases productive of a tissue specimen submitted to surgical pathology with 1 or more defects divided by the total number of cases; (2) container defect rate: number of containers with 1 or more defects divided by the total number of containers accessioned; and (3) requisition defect rate: number of requisitions with 1 or more defects divided by the total number of requisitions accessioned (Table 1).

Initially, an “other” category also was included for both container and requisition defects to allow teams to record additional defects that they identified.

A final Microsoft Excel–based “Specimen Error Toolkit” was assembled with the measure definitions, the daily data collection forms known as “Surgical Specimen Defect Log Sheets” for printing (available from the authors on request), a data collection workbook for monthly tabulation, and the instructions for data collection. This toolkit was distributed to all participating institutions. A multidisciplinary improvement team also was assembled at each participating hospital. This team consisted of a project coordinator, frontline medical and nursing staff from the surgical operating room, and surgical pathology laboratory staff. One team member at each site was trained via a webinar on how to educate his or her team to correctly use the measure definitions to identify defects and to collect data using the toolkit.

### Data Collection

Data were collected prospectively on each candidate measure from January to March 2010 to evaluate baseline performance. Teams used the paper-based standardized log sheets to record at the case level the frequency of container or requisition surgical specimen defects. The defects were classified according to the 12 candidate measures (Table 1). At the end of each month, teams used the Excel-based data collection workbook to total the number of defects recorded from each case and submitted the monthly report forms to the MHA Keystone Center via e-mail.

At the end of 3 months, the panel of experts reviewed the data collected and identified that defects entered in the “other” category varied across sites and within sites over time. Some teams were erroneously recording container or requisition defects that belonged in 1 of the 6 specific defect categories into the “other” category. As a result, it was not possible to accurately interpret the frequency of “other” defects, and as such, the “other” category was removed from...
the toolkit. Only container and requisition defects are reported for the 12 candidate measures. For inclusivity, however, all defects were included in the calculation of composite defect rate measures.

### Hospital Characteristics

Hospital characteristics (critical access, bed size, number of operating rooms, and total surgical operations per year) were obtained from the 2009 American Hospital Association annual survey data. All hospitals were in Michigan except for 1 in Iowa. Urban hospital status was defined using the core-based statistical area (CBSA) type of “Division” or “Metro” (defined as a population of at least 50 000). All other hospitals were defined as rural. The CBSAs are defined yearly by the Office of Management and Budget (http://www.whitehouse.gov/sites/default/files/omb/fedreg/metroareas122700.pdf).

### Statistical Analysis

The defect-related data were aggregated to report rates for the overall cohort (definition of calculations in Table 1). Medians with ranges and means with standard deviations were used to summarize the data. A quasi-likelihood model using the Poisson distribution, with scaling using the Pearson $\chi^2$ statistic to accommodate for overdispersion, was used to generate confidence intervals (CIs) for the defect rates. All analyses were conducted using Stata version 10.1 (Stata Corp, College Station, TX). This research was approved by The Johns Hopkins University Institutional Review Board.

### Results

In all, 69 hospitals submitted data during the 3-month study period. Table 2 summarizes participating hospital characteristics. The total number of surgical operations per year performed in each hospital ranged from 163 to 61 161, with a median of 4650. The total number of beds (median = 96; range = 20-1089) and the total number of operating rooms (median = 4; range = 1-73) also were widely distributed.

It was found that 87% of hospitals reported data over all 3 months, and reporting compliance for each of the 3 months was greater than 90%; 63 hospitals reported container and requisition defects in month one, 66 in month two, and 68 in month three. A total of 196 data-months were reported for both containers and requisitions and 197 data-months for case defects (1 hospital reported only requisition defects in month 2 and only container defects in month 3). In 28 of 196 (14.3%) data-months, hospitals reported “other” container defects, whereas in 38 of 196 (19.4%) data-months, hospitals reported “other” requisition defects.

The median number of surgical pathology cases accessioned per hospital over the 3-month period was 523 (range = 15-4370). The median number of containers accessioned per hospital over the 3-month period was 654 (range = 15-6600). The median number of requisitions accessioned per hospital over the 3-month period was 457 (range = 15-6600).

The overall defect rates for the cohort are displayed in Table 3. A summary of container and requisition defects is displayed in Table 4. The most common container defects were omitted or incorrect specimen source or type, and the most common requisition defects were omitted or incorrect specimen source or type, and the most common requisition defects were omitted or incorrect date/time defects. The category of requisition defects occurring at the highest percentage of hospitals was specimen source/type defects.

### Discussion

In this study, the authors developed a set of practical, process-based, standardized measures with explicit definitions to evaluate the quality of surgical specimen identification in the transition from the operating room to the surgical pathology laboratory. They pilot tested the definitions and measures in a cohort of 69 diverse hospitals in Michigan (1 in Iowa) and found an average case identification defect rate of nearly 3%. They also found an overall container identification defect rate of about 1% and a requisition identification defect rate of more than 2%.
The rates of surgical specimen misidentifications reported here are unique, in that they derive strictly from operating rooms and are solely from specimen requisitions and specimen containers in the preanalytic phase of surgical tissue specimen processing. Therefore, there are no direct comparisons with pathology misidentification rates reported previously in the literature. However, a few similar studies have been conducted by various methodologies to estimate broader types of specimen misidentification, including identification defects in clinical pathology (eg, blood, urine, and body fluid specimens) in addition to those in surgical pathology. It should be noted that the number of clinical pathology specimens most often far exceeds the number of surgical pathology specimens in any individual laboratory.

For example, Valenstein et al.¹ examined identification defects for released test results at 120 institutions throughout all 3 phases of specimen processing (preanalytic, analytic, and postanalytic). The defects reported were predominantly from clinical pathology tests (general chemistry, hematology, microbiology, and transfusion medicine) and therefore were expressed in rates per 1 million billable tests. The numbers of tests corresponding to specific laboratory domains or to surgical (anatomic) pathology were not stated. The use of a denominator of billable tests contrasts with most other studies,²,⁴,⁵,¹⁰ including ours, that assess defects using total number of operative cases productive of tissue specimens submitted to surgical pathology as the denominator. Nonetheless, Valenstein et al.¹ calculated an overall laboratory misidentification rate for released results of 55 defects per million billable tests. They found that “primary specimen label errors” were the most common, accounting for 55.5% of defects. However, additional information about the type of labeling deficiency was not reported. Therefore, it is not known if these defects resulted from mislabeling of patient name or ID and/or specimen type, source, or laterality.

Nakhleh and Zarbo⁴ collected data from more than 1 million surgical pathology cases from 417 institutions worldwide and found that defects in specimen identification and accessioning occurred in 6.0% of cases. By their methodology, only 9.6% of those defects were “specimen identification deficiencies.” Although not presented formally in that publication, one can calculate that these surgical specimen identification deficiencies occurred in 0.58% of that large number of surgical pathology cases. However, another 77% of those defects were classified as “deficiencies related to incorrect or missing information,” some of which, by the authors’ methodology and that of others,²,⁴,¹⁰,¹¹,¹⁴ also would be considered surgical specimen identification defects. These included defects in tissue source/type or date of procedure. In general, this lack of standardized definitions, measures, and methodology has made it difficult to accurately estimate and compare the incidence of these defects at different institutions and to identify the types of defects that are most prevalent.

D’Angelo and Zarbo,² by prospective study, documented a misidentification rate of 1.67% of all surgical pathology cases occurring throughout all 3 test phases (preanalytic, analytic, and postanalytic) of the complete surgical pathology process. Uniquely, this study measured the hours of labor required to correct each defect and found that the average was 3.5 hours per defect. In another study of theirs,¹⁰ tracking

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### Table 3. Overall Defect Rates for Cohort.

<table>
<thead>
<tr>
<th>Composite Defect Measure</th>
<th>Overall Rate (Fraction)</th>
<th>95% CI †</th>
<th>Median (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total case defects</td>
<td>2.9% (1780/60 501)</td>
<td>2.0%-4.4%</td>
<td>1.0% (0%-31.2%)</td>
</tr>
<tr>
<td>Container defects</td>
<td>1.2% (1018/81 656)</td>
<td>0.8%-2.0%</td>
<td>0.3% (0%-15.2%)</td>
</tr>
<tr>
<td>Requisition defects</td>
<td>2.3% (1417/61 245)</td>
<td>1.2%-4.6%</td>
<td>0.6% (0%-36.4%)</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval. †Estimated by Poisson regression with Pearson χ² statistic scaling for overdispersion.

### Table 4. Summary of Container and Requisition Defects.

<table>
<thead>
<tr>
<th>Type of Defect</th>
<th>Number of Defects in Cohort</th>
<th>Number of Hospitals with Defect, n = 69</th>
</tr>
</thead>
<tbody>
<tr>
<td>Container defects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>348 (100.0%)</td>
<td>50 (72%)</td>
</tr>
<tr>
<td>Source/type</td>
<td>128 (36.8%)</td>
<td>31 (45%)</td>
</tr>
<tr>
<td>Laterality</td>
<td>83 (23.8%)</td>
<td>15 (22%)</td>
</tr>
<tr>
<td>Label</td>
<td>68 (19.5%)</td>
<td>27 (39%)</td>
</tr>
<tr>
<td>Patient identification</td>
<td>33 (9.5%)</td>
<td>17 (25%)</td>
</tr>
<tr>
<td>Numeric identifier</td>
<td>21 (6.0%)</td>
<td>11 (16%)</td>
</tr>
<tr>
<td>Missing specimen</td>
<td>15 (4.3%)</td>
<td>8 (12%)</td>
</tr>
<tr>
<td>Requisition defects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>859 (100.0%)</td>
<td>48 (70%)</td>
</tr>
<tr>
<td>Date/Time</td>
<td>514 (59.8%)</td>
<td>29 (42%)</td>
</tr>
<tr>
<td>Specimen source/type</td>
<td>130 (15.1%)</td>
<td>34 (49%)</td>
</tr>
<tr>
<td>Laterality</td>
<td>80 (9.3%)</td>
<td>16 (23%)</td>
</tr>
<tr>
<td>Missing requisition</td>
<td>70 (8.1%)</td>
<td>14 (20%)</td>
</tr>
<tr>
<td>Patient name</td>
<td>49 (5.7%)</td>
<td>25 (36%)</td>
</tr>
<tr>
<td>Numeric identifier</td>
<td>16 (1.9%)</td>
<td>10 (14%)</td>
</tr>
</tbody>
</table>
in-process defects, again throughout all 3 test phases, defects resulted in rework of some kind in nearly 1 in 3 surgical pathology cases. Clearly, surgical specimen identification defects, especially misidentifications that may require molecular DNA profiling to correct, are extremely costly in terms of manpower and unnecessary health care expense.

Within the preanalytic phase specifically, there have been fewer studies. One single-center, prospective analysis of preanalytic surgical specimen defects by Makary et al10 found that defects occurred in 4.3 of 1000 or 0.43% of cases. However, this study only looked at container defects. In comparison, the current study’s container defect rate, from 69 centers, was 1.2% (95% CI = 0.8%-2.0%) of containers. Francis et al,17 meanwhile, prospectively analyzed endoscopy specimen labeling defects specifically before and after the implementation of a radiofrequency identification system. Their 3-month baseline defect rate was 9.3% for containers only.

The current study’s estimate of preanalytic surgical specimen identification defects, based on examination of container and requisition defects, is 29 defects per 1000 cases or 2.9%. The authors believe that their findings are strengthened by the use of standardized measures with explicit definitions that were thoroughly vetted by physicians, frontline providers, and quality experts to identify defects in a large diverse cohort of hospitals. In this cohort, specimen source/type defects were the most common container defects, followed by laterality defects. This finding contrasts with that of Makary et al10 where missing container label (19.8%) was the most common type of preanalytic container identification defect. This suggests empirically that the most prominent type of defect may be dependent on processes unique to individual hospitals and that additional research to attempt to reduce these defects, such as that of Francis et al,17 should be hospital centered.

The authors’ findings have important implications for surgical care. In the short 3-month period of this study, defects were identified involving 1780 patients across 69 hospitals. The consequences of these defects may represent a significant patient safety risk. An estimated 17% of identification defects result in incorrect therapy,5 and nearly 6% cause adverse events.1 Hospitals cannot afford to maintain these levels of patient safety risk, particularly when it is feasible to measure the incidence of these defects, they are unambiguous, and they are preventable.10

To the authors’ knowledge this is only the third large multi-institutional study of specimen identification defects7,4 and the first study to collect data strictly from operating rooms from a large cohort of hospitals in a given state. The authors convened an expert panel, used a group consensus process to establish a standardized set of measures and definitions, and then pilot tested them to estimate defect rates by surgical specimen case, container, and requisition and to identify 12 specific container and requisition identification defects. This work offers a feasible strategy that health systems can use to quantify surgical specimen identification defects in the perioperative setting and sets the stage for additional statewide efforts to reduce the occurrence of these defects.

Successful efforts to improve surgical specimen identification defects likely will require a multifaceted approach that includes both technical and adaptive change.15 Technical change involves solutions to problems for which we know the answers (eg, handwashing to prevent infection) and often focuses on the systems of care rather than individual performance. For example, technical changes such as standardization of the defect identification process16,17 and use of color-coded sticker notification and computerized software programs16 or of radio frequency identification technology together with a paperless requisition process17 have been associated with reductions in specimen identification defects.

Adaptive change is often more challenging than technical change and requires changing people’s values, attitudes, beliefs, and behaviors.18 Many improvement projects focus the majority of their time on the technical work, yet projects fail most often because of adaptive challenges, such as clinicians who do not support the project.15 Multifaceted approaches that address both technical and adaptive change have been associated with large-scale significant and sustained reductions in health care–associated infections.19,20 It remains unclear if a similar approach could be applied successfully to achieve reductions in the frequency of specimen identification defects as well.

There are several limitations to this study. First, the content or construct validity of the measures was not rigorously evaluated. Additional research is needed before these measures can be broadly implemented. Nevertheless, teams routinely used the measures and submitted data, suggesting that these measures are feasible and have face validity among providers. Second, all data were submitted voluntarily without independent validation. Voluntary reporting may introduce bias and underestimate the magnitude of defects, particularly if hospitals with high error rates elected not to submit data. Third, the measures focus on 1 type of preanalytic surgical pathology defect—specimen identification. There are other areas of preanalytic defects, such as poor or improper sample collection and preservation, specimens “lost” in transit, and analytic and postanalytic defects that were not addressed here.11 Fourth, the initial inclusion of an “other” category prevented the authors from classifying all reported defects according to their 12 specific container or requisition defect candidate measures. Finally, with the exception of 1 hospital in Iowa, all the data come from hospitals in 1 state. Nonetheless, the authors believe that these results are generalizable, given the number and diversity of the hospitals in the cohort.

In conclusion, surgical specimen identification defects are common, yet preventable, and pose significant risks to
patients. The authors developed a set of standardized measures for the preanalytic phase and used them to detect specimen container and requisition defects and quantify performance across a large and diverse cohort of hospitals. Future research is needed to evaluate whether hospitals can use these measures to assess interventions meant to reduce the frequency of surgical specimen identification defects and improve patient safety.

Declaration of Conflicting Interests
The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Ms Holzmueller reports receiving an honorarium from MCIC Vermont, Inc, for leading a workshop on organizing and writing content of a manuscript describing quality improvement and patient safety research, and Dr Berenholtz has received support from Michigan Health and Hospital Association, the National Institutes of Health, Agency for Healthcare Research and Quality, and the Robert Wood Johnson Foundation for unrelated research; has equity ownership in Docusys; and receives honoraria and travel expenses from various hospitals and hospital associations for consulting. The remaining authors disclosed no conflicts of interest.

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