

# Specimen mislabeling: A significant and costly cause of potentially serious medical errors

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Preanalytical errors are a significant source of medical errors that can jeopardize patient safety. Proper specimen labeling practices are critical components of effective and accurate patient identification.

These variables are now considered part of the preexamination process in the newest CLSI quality system management guideline, GP26-A3, as well as the newest relevant ISO guideline, ISO-IEC Standard 15189: Medical laboratories – Particular requirements for quality and competence.

Major types of specimen labeling errors are associated with a small number of common causes. Specimen labeling errors have significant consequences for patient care, for healthcare management and for increasing costs that are often unaccounted for.

Specimen labeling errors may be prevented by adhering to appropriate policies as well as unique educational programs, marketing strategies and other techniques.

Recently, a multidisciplinary work group at a U.S. clinical institution suggested that the average hypothetical additional incurred total charges per specimen mislabeling occurrence would have been of USD 712.

## Introduction

Laboratory professionals worldwide currently face a great challenge to achieve complete quality management of the total testing process to ensure the accuracy and reliability of test results.

In 1999, the U.S. Institute of Medicine's (IOM) report, *To Err is Human*, claimed that the number of individuals

who annually die in the U.S. due to medical errors was between 44,000 and 98,000 [1].

In 2001, the IOM report, *Crossing the Quality Chasm*, called attention to the gap between a desired optimal state of healthcare quality and where it currently was [2].

In 2003, another IOM report, *Patient Safety*, now a part of IOM's *Quality Chasm* series, demanded a new paradigm in healthcare aimed towards achieving the highest levels of patient safety while significantly reducing the incidence of medical errors [3].

The repercussions of these IOM reports have led to reinvigorated efforts to improve the quality of patient care, increase patient safety and reduce medical errors in healthcare, both in the U.S. and worldwide.

Achieving desired quality goals requires the establishment of standards of performance and development of process measuring techniques for integration into a continuous cycle of quality improvement (CQI).

Whether in a clinical laboratory, respiratory therapy or any other critical care setting, the total laboratory specimen testing process provides an unlimited number of opportunities for CQI.

According to GP26-A3, the newest quality management system guideline from the Clinical Laboratory Standards Institute (CLSI, formerly the National Committee for Clinical Laboratory Standards or NCCLS), key components of the laboratory's path of workflow are the preexamination, examination and postexamination processes [4].

This change in terminology (from preanalytical, analytical and postanalytical phases) is intended to include the same concepts and align the laboratory-specific requirements in CLSI GP26-A3 with those contained in ISO 15189 [5].

Of course, it is well known that the largest component of variability or potential for error lies in the preanalytical phase or preexamination process with estimates

suggesting that 60-75 % of the total error may occur at this stage (unpublished data).

## Specimen labeling errors: common types and their causes

A critical preexamination-process step is the accurate and timely labeling of specimens. CLSI GP26-A3 defines all the key components of the preexamination process as examination ordering, sample collection, sample transport and sample receipt/processing.

Many continuous quality improvement (CQI) opportunities exist with these components of the total testing process since the final goal is to ensure that the appropriate specimen type is collected in the appropriate specimen container at the right time from the correct patient. Accurate patient identification is thus fundamental and cannot be taken for granted.

In 2004, and now again in 2005, the U.S. Joint Commission on Accreditation of Healthcare Organizations (JCAHO) regards improving the accuracy of patient identification so important that it is listed as the #1 JCAHO National Patient Safety Goal [6].

But accurate and timely labeling of specimens is an integral part of patient identification and cannot be taken for granted as a "given" in the total examination process.

Ensuring accurate specimen labeling is critical because errors resulting from a failure in this step can, at best, provide results of no clinical value and, at worst, lead to the most adverse of patient outcomes [7].

The majority of errors in specimen labeling typically occur as failures in workflow or process rather than as failures to have delineated specimen labeling policies or procedures.

During initial training, in-services and routine patient encounters, healthcare professionals can be expected to perform work properly. But when limited resources become an issue, even the best-trained, experienced

staff member may deviate from proper and generally accepted practices.

Common examples of general specimen labeling errors and their causes include:

- Failure of responsible staff to correctly match patient identification criteria to the order (the U.S. JCAHO requires a minimum of two identifiers to be used for both inpatients and outpatients)
- Failure of responsible staff to affix proper specimen labels to the collection tube immediately after specimen collection (e.g., placing drawn tubes in a cup or emesis basin and proceeding to another task before affixing labels)
- Practice of drawing blood prior to receipt of a test order, e.g., drawing multiple tubes of blood (sometimes done in Emergency Department settings) on a patient so that the specimens are immediately ready for transport to the laboratory once the orders are finalized and the labels generated
- Practice of having one staff member draw a sample with another staff member labeling the sample (sometimes occurring in Operating Room or critical care settings with arterial blood gas, or ABG, measurements)
- Practice of collecting multiple patients' specimens prior to affixing the proper specimen label(s) to each patient's specimen collection tube(s)
- Practice of collecting specimens (again can be associated with ABG draws in a critical care setting) with hand-written backup requisitions and labels to be properly labeled before analysis by another staff member (secondary labeling)
- Practice of using a temporary label initially with the permanent specimen label to be affixed at a later point in the preexamination process (secondary labeling)

While all of these problems can also occur with mixed venous blood gas specimens, improperly labeled ABG specimens present additional issues. At my institution, a recent random monthly audit indicated that roughly 5 % of specimen labeling errors occurred with ABG specimens. Often the ABG specimen is irreplaceable, leading to

relabeling by an acute care worker who drew the specimen and must come to the testing area. But there may also be times when the specimen must be discarded. Neither practice is recommended and does not meet the highest standard for patient care.

### Consequences of these errors (patient, hospital, financial)

Unquestionably, the most serious consequence of specimen labeling errors on the direct care of patients is of one of the following types:

1. Failure to provide proper and immediate care to a patient based on the lack of accurate test results associated with the proper patient
2. Provision of inappropriate care to a patient based on a test result that is actually not from that patient

Any other consequence, adverse outcome, cost or additional charge identified is secondary to these two critically important consequences. For these other consequences, the best-case scenario is no further jeopardy or harm caused to the patient, while the worst-case scenario could be the most serious and adverse of clinical outcomes.

Even an outcome of no immediate impact on patient care or safety can still result in delays in treatment as well as increased anxiety for patients, family members and friends as well as the caregivers. So there will always be consequences or costs of specimen mislabeling that are immeasurable and that might be considerable. Other immeasurable costs include further patient discomfort as well as risk of an additional collection of a previously mislabeled specimen.

Typical examples of the measurable financial costs occurring as a result of improper specimen mislabeling are listed in **TABLE I**. Note that the actual direct costs associated with redrawing a laboratory specimen such as the direct phlebotomy labor as well as the consumables and supplies for the blood draw may often only be the "*tip of the iceberg*" when it comes to costs. Other measurable costs that are not considered in **TABLE I** are the liability costs of medicolegal decisions.

### Costs for redrawing specimen

- Phlebotomy labor
- Consumables
- Phlebotomy supplies

### Costs for reanalyzing specimen

- Mislabeled specimens may not be recognized until after testing

### Additional facilities costs

- Additional patient appointment to draw another specimen
- Increased length of stay (e.g., one inpatient day or increased LOD in e.g., ED)
- Potential for additional physician time
- Potential for additional home health and/or hospice visit

### Additional non-phlebotomy labor costs

- Nursing services
- Physician services
- Laboratory supervisor/manager/other staff to investigate mislabeling problem and arrange for redraw

TABLE I: Significant measurable costs associated with improper specimen labeling practices

For those individuals responsible for evaluating the financial impact of specimen mislabeling in their institution, one approach is to work with a multidisciplinary group (particularly including non-laboratory staff involved with the preexamination process) to identify ALL costs associated with a selected number of specimen mislabeling cases.

The purpose of this would be to arrive at a consensus that, excluding outlier cases, the cases are sufficiently representative that a mean cost per specimen mislabeling incident can be calculated as depicted in **FIG. I**.

For this calculation, assume Hospital X has a specimen labeling defect rate per million opportunities of 3000 (99.7 % accuracy or a 4.25 process sigma defect rate). Hospital X has an average specimen mislabeling 250 times per month. Through specimen mislabeling case audits, key staff in Hospital X determined that the average total cost per mislabeling incident is USD 500.

The annual cost of specimen mislabeling incidents for Hospital X is:

$$3000 \cdot \text{USD } 500 = \text{USD } 1.5 \text{ million}$$

This calculation excludes any "downstream" medicolegal or liability costs.

FIG. I: Sample calculation illustrating the total annual costs potentially associated with improper specimen labeling

## Prevention of these errors

The first step in reducing specimen labeling errors is to ensure that appropriate specimen collection policies and procedures are developed, implemented and followed. Ongoing staff in-service training and competency assessment are important aspects of reducing specimen labeling errors.

A measuring process must be put into place that provides accurate tracking and quantitation of specimen labeling errors. In order to establish higher standard quality metrics, one might choose to employ Six Sigma methodology, CQI tools and techniques to improve quality [8, 9, 10].

After critically examining the complexity of process and workflow, certain steps in the preexamination process might also be consolidated or eliminated using a process simplification method such as LEAN [10].

In order to optimize patient safety, the IOM reports underscored that error identification, quantitation and reduction must be accomplished in an environment in which full disclosure of errors can be accomplished, i.e., in a blameless environment.

Of course, this does not imply a lack of accountability for those involved in making, or creating an opportunity for making, a medical error such as specimen mislabeling. Once the involved areas and/or individuals are identified, there needs to be in-service and additional training to ensure that their performance improves to ensure patient safety.

Other important characteristics of an environment in which the necessary process improvements can occur are the strong promotion of awareness and effective communication between stakeholders.

Creative approaches to reducing the incidence of specimen mislabeling errors may also include educational methods or techniques as well as institution-wide marketing campaigns to raise awareness about the problem.

Elimination of secondary labeling practices as well as protocols that call for any other than the single right approach to labeling a specimen for which a test is ordered immediately after the specimen is collected will also prove beneficial.

Recently, the use of a bedside barcode labeling system, in combination with institution-wide marketing techniques, was reported to reduce specimen labeling errors by 41 % [11].

## Personal experience with specimen labeling errors

Within the Loyola University Health System (LUHS), the frequency of specimen labeling errors is a quality metric that our Department of Pathology and Clinical Laboratories has routinely tracked and tried to improve, by unit and/or health system location, for well over a decade.

Although our institution is currently implementing computerized physician order entry (full CPOE project completion expected by 2006), many critical care areas such as the OR have provided specimens with manual requisitions and, also rarely, used questionable specimen labeling practices.

Recently, the total number of mislabeled specimen errors identified by our department (from all laboratory sections including blood bank) was occurring at a defect rate of roughly 4.4 Sigma (that is, ~ 99.8 % of all specimens received were labeled correctly upon receipt).

This was still determined a significant area of opportunity for improvement. Our institution appointed a Specimen Labeling Steering Committee with senior faculty, director or manager representatives from Pathology, Clinical Laboratories, Hospital Administration, Nursing, Risk Management and our key clinical quality assurance/patient safety department (the Center for Clinical Effectiveness).

Under the auspices of this steering committee, task forces were created to focus on inpatient units,

ambulatory care areas and the emergency department. Efforts are currently under way to reduce the incidence of specimen mislabeling errors.

Recently, I participated in a new program at LUHS, Innovations in Leadership (INL), bringing a multidisciplinary group together to foster professionalism among all stakeholders in medical education. As a small team of clinical faculty, resident physicians, medical students and nursing staff, our group's project focused on assessing the impact of specimen mislabeling on process quality, resource utilization and patient safety.

Through the experiences of this group, selected ideas, concepts and opportunities for process improvement in specimen labeling practices at LUHS, some of which are described in this article, were identified. Using an approach similar to that in **FIG. 1**, but looking at hypothetical additionally incurred charges rather than costs, our INL workgroup compiled total charge data for a randomly selected group of 10 mislabeling cases.

After elimination of outliers (2), the average hypothetical additional charges incurred per case were USD 712 with cases from all major service areas. While no additional charges were billed, all providers have an understanding of the ratio of their costs to charges.

Clearly, the additional financial burden to an institution for specimen mislabeling errors is, in fact, the extra cost per case. Our INL workgroup recommended increasing the combined use of educational techniques, marketing strategies and use of a bedside barcode labeling system.

Both the group of recommendations from our INL workgroup as well as other solutions described above are in the process of being implemented. The results from some of these efforts will be presented at the 2<sup>nd</sup> Conference of the Institute for Quality in Laboratory Medicine in Atlanta, Georgia, USA in April, 2005 [12].

## References

1. Kohn LT, Corrigan JM, Donaldson MS. *To Err is Human: Building a Safer Health System*. Washington, D.C.: National Academy Press, 1999.
2. Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health Care System for the 21st Century*. Washington, D.C.: National Academy Press, 2001.
3. Aspden P, Corrigan JM, Wolcott J and Erick SM (ed.). *Patient Safety - Achieving a New Standard of Care. From the Quality Chasm Series*. Washington, D.C.: National Academy Press, 2003.
4. Berte LM, Boone DJ, Cooper G *et al*. Application of a Quality System Model for Laboratory Services; Approved Guideline - Third Edition. NCCLS Publication GP26-A3. Wayne, Pa.: NCCLS (now CLSI), 2004; 24, 36.
5. Technical Committee of the ISO/TC212 Clinical Laboratory Tests and In Vitro Diagnostic Test Systems. ISO-IEC Standard 15189: Medical laboratories – Particular requirements for quality and competence. International Organization of Standardization. Geneva, Switzerland, 2003.
6. JCAHO 2005 National Patient Safety Goals from the website of the Joint Commission on Accreditation of Healthcare Organizations. <http://www.jcaho.org>.
7. Centers for Disease Control 2004 Top 2004 Healthcare Safety Challenges from the website of the Centers for Disease Control. <http://www.cdc.gov>.
8. Westgard JO. *Six Sigma Quality Design & Control*. Westgard QC, Inc. Madison, WI, 2001.
9. George ML. *Lean Six Sigma for Service - How to Use Lean Speed & Six Sigma Quality to Improve Services and Transactions*. McGraw-Hill, New York, 2003.
10. From the website of the Six Sigma Quality Resource for Achieving Quality Results. <http://www.isixsigma.com>.
11. Simpson JB. A unique approach for reducing specimen labeling errors: combining marketing techniques with performance improvement. *Clin Lead & Mgt Rev* 2001; 15(6), 401-05.
12. Institute for Quality in Laboratory Medicine at the website for the IQLM. <http://www.phppo.cdc.gov/dls/iqlm/default.asp>.