SAFE PRACTICE 14: LABELING DIAGNOSTIC STUDIES

The Objective
Reduce the risk of misinterpretation of radiology, laboratory, and pathology studies due to miscommunication or inaccurate labeling.

The Problem
Mislabling or incompletely labeling radiology, laboratory, and pathology specimens can lead to misinterpretation of results and to potential harm to patients. Literature relevant to this safe practice focuses entirely on examining the process and accuracy of labeling laboratory tests and specimens. [Hunt, 2008] More than 7 billion laboratory tests are performed in the United States annually. It is estimated that these tests influence 70 percent of medical decisions. [Silverstein, 2004]

Several large studies have determined that specimen identification errors occur at a frequency of between 0.1 and 5 percent. [Ibojie, 2000; Novis, 2004; Valenstein, 2004; Howanitz, 2005; Wagar, 2006; Lippi, 2009]

The most comprehensive and recent study by Wagar et al. reviewed 3.3 million specimen labels from 147 laboratories. Labeling errors were identified in 0.92 per 1,000 specimens. [Wagar, 2006] Of these labeling errors, 29.9 percent were mislabeled; 22.7 percent were partially labeled; 21.9 percent were unlabeled; 20.7 percent were incompletely labeled; and 6.1 percent were illegibly labeled. [Wagar, 2006] A similar analysis of 21,351 surgical specimens found 4.3 per 1,000 identification errors, made up of 0.512 percent (53/10,354) identification errors for specimens originating in an outpatient clinic, and 0.346 percent (38/10,997) errors for specimens originating in the operating room. [Makary, 2007] In comparison, a multicenter (97) study in 2008 concluded that computer order entry errors for send-out tests occurred twice as frequently as order entry errors for other types of tests. [Valenstein, 2008]

The severity of iatrogenic injury resulting from laboratory specimen identification errors is wide ranging. [Levinson, 2008a; Levinson, 2008b] Errors can potentially result in delayed diagnosis, additional laboratory testing, severe transfusion reactions, and treating a patient for the wrong disease. [Wagar, 2006] Wrong-patient cancer resection cases have appeared in the news. [Fischer, 2005; CBS News, 2003] A more recent five-week study in 2006 examined the occurrence of adverse events from laboratory identification errors for 120 separate clinical laboratories. Of 345 adverse events reported (1 of 18 identification errors), 72.8 percent resulted in significant patient inconvenience with no change in treatment or outcome; 22.6 percent resulted in an unknown patient impact; and 4.6 percent resulted in a change in patient treatment, but with no known change in patient outcome. [Valenstein, 2006]

Most laboratory errors are attributable to specimen misidentification; thus, an effective labeling process will dramatically increase the preventability of such cases. [Bonini, 2002; Denham, 2005; Denham, 2008; Lippi, 2009; O’Neill, 2009] Reported error rates have improved, and the College of American Pathologists Q-Probes and Q-Tracks programs, as well as advancements in technology (e.g., barcoding), have fostered this. Radio frequency identification tags have been proven, in conjunction with a two-healthcare-provider accuracy confirmation, to decrease specimen labeling errors by 90 percent. [Francis, 2009] Also, at the Beth Israel Deaconess Medical Center in Boston, it was shown that through educational awareness...
and strict labeling techniques, blood specimen labeling errors decreased by almost 80 percent. [O’Neill, 2009]

Healthcare costs associated with laboratory specimen identification errors have not been formally studied. These specifically involve costs to re-perform tests and costs associated with adverse patient events. This may include legal claims. An analysis of 272 surgical pathology legal claims found that 5 percent involved allegations of specimens being mislabeled and mixed between patients. [IOM, 2000] Hospital costs associated with error prevention involve the investment of staff time in ensuring high-quality coordination between the clinical laboratory and interacting departments within the hospital, as well as investments in information technology to assist in labeling and reporting.

**Safe Practice Statement**

Implement standardized policies, processes, and systems to ensure accurate labeling of radiographs, laboratory specimens, or other diagnostic studies, so that the right study is labeled for the right patient at the right time. [IHI, 2004; JCR, 2010]

**Additional Specifications**

- Label laboratory specimen containers at the time of use and in the presence of the patient. [AHRQ, N.D.a]
- Take the critical steps of identifying the individual and matching the intended service or treatment, including read-back, to that individual to prevent miscommunication or inaccurate labeling. [AHRQ, N.D.b]
- Use at least two patient identifiers (neither to be the patient’s room number or physical location) when taking blood samples or other specimens for clinical testing, imaging, or providing any other treatments and procedures. [JCR, 2010]
- Label x-ray imaging studies with the correct patient information while in the darkroom or close to the imaging device.
- Mark “left” or “right” on each radiographic image to prevent misinterpretation on the light box.
- Monitor and report errors and harm related to mislabeling to the organization-wide risk-assessment activity as part of a performance improvement program that addresses mislabeling of specimens or diagnostic studies.

**Applicable Clinical Care Settings**

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

**Example Implementation Approaches**

- Acceptable person-specific identifiers that may be used are the individual’s name, an assigned identification number, a telephone number, a photograph, or another person-specific identifier. [JCR, 2010] Technologies such as the use of barcoding that include two or more person-specific identifiers (not including room number) should be considered as acceptable identifiers. [Francis, 2009; JCR, 2010]
- Didactic elements of training on the mislabeling of studies or specimens may be delivered through multimedia or distance learning strategies that can be updated with the latest evidence. Documentation
of participation can be kept to verify compliance, ensure that new and temporary staff receive such training, and provide continuing education credits.

In pathological studies, sequentially inking specimens with different colors is an effective method for decreasing labeling errors. [Raff, 2009]

**Strategies of Progressive Organizations**

Machine-readable patient identification systems are replacing conventional wristbands in some organizations to reduce patient identification errors. [Da Rin, 2009; Zarbo, 2009] Monitoring of pre- and postimplementation phases provides information on risk reduction opportunities and near misses. Numerous technologies are being studied to reduce the risk of human error involved in the labeling of studies.

**Opportunities for Patient and Family Involvement**

Include patient and/or family members during the care team planning of appropriate communication of labeling studies.

Inform patients and family about the identification protocols so they are aware and know what to expect.

**Outcome, Process, Structure, and Patient-Centered Measures**

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily all address external reporting needs.

**Outcome Measures** include reduction in direct harm associated with adverse drug events and procedural treatment; misadventures, including death, disability (permanent or temporary), or preventable harm requiring further treatment; missed diagnoses; unnecessary, inappropriate, and/or delayed treatment associated with incomplete information; repeated testing; cost of unnecessary treatment; and malpractice liability.

**Process Measures** include assessing initial performance gaps and the impact of performance improvement, such as frequency of repeat laboratory or imaging studies resulting from mislabeling errors and frequency of adherence to policies and procedures.

- NQF-endorsed® process measure:
  1. #0511: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy [Other]: Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT) that were performed.

**Structure Measures** include verification of the existence of a performance improvement program and explicit organizational policies and procedures addressing the appropriate labeling of specimens, and diagnostic and imaging studies; the verification of educational programs; and the existence of formal reporting structures for accountability across governance, administrative leadership, and frontline caregivers.
Patient-Centered Measures include patient involvement as part of the care team and perception of the quality of communication during the identification process.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Children’s Healthcare Settings:** All requirements of the practice are applicable to children’s healthcare settings.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

Research continues to advance the use of technologies that consistently and accurately complete patient identification as a vital component of the labeling process. Applied human factors training workflow design is being researched and will likely provide insights about the design of best practices. [Hunt, 2008; Zarbo, 2009]

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Other relevant practices include Safe Practice 12: Patient Care Information; Safe Practice 15: Discharge Systems; and Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry.

Notes


June 1, 2010

Dear Healthcare Leader:

We are delighted to announce that the National Quality Forum has graciously given us permission to distribute copies of the *NQF Safe Practices for Better Healthcare – 2010 Update*. This section has been provided to you in the interest of helping you implement, and/or educate others to adopt the suggestions and implementation examples into your safe practices.

The National Quality Forum is dedicated to providing evidence-based practices as ready-to-use tools to improve safety. The practices in the *NQF Safe Practices for Better Healthcare – 2010 Update* have been evaluated, assessed and endorsed to guide large and small healthcare systems in providing the safest care in every area of patient safety. We give our highest recommendation for them as a valuable resource toward patient safety from hospital bedside to boardroom. It is in the fulfillment of this mission that NQF makes the gift of this to you in your pursuit of your quality journey.

We hope that you will recommend that others purchase the report from NQF. The home page of the National Quality Forum can be accessed at the following link: [http://www.qualityforum.org/](http://www.qualityforum.org/) and an abridged report of the *NQF Safe Practices for Better Healthcare—2010 Update* can be downloaded free online at: [http://www.qualityforum.org/Publications/2010/04/Safe_Practices_for_Better_Healthcare_--_2010_Update.aspx](http://www.qualityforum.org/Publications/2010/04/Safe_Practices_for_Better_Healthcare--2010_Update.aspx). To obtain the full report for a cost of $29.99, please contact NQF by phone during business hours at 202-783-1300 or via e-mail at info@qualityforum.org and their staff will contact you for payment details.

If you want to have a free copy of the entire set of practices, you may receive one if you fill out a web-based survey that may be filled out at [http://www.safetyleaders.org/2010nqfResearchStudy/index.jsp](http://www.safetyleaders.org/2010nqfResearchStudy/index.jsp).

We want to acknowledge you and your institution for your current efforts in patient safety. We hope you enjoy this important information and find it useful in your future work.

Sincerely,

Charles R. Denham, M.D.
Chairman