

Review

Causes, consequences, detection, and prevention of identification errors in laboratory diagnostics

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Abstract

Laboratory diagnostics, a pivotal part of clinical decision making, is no safer than other areas of healthcare, with most errors occurring in the manually intensive preanalytical process. Patient misidentification errors are potentially associated with the worst clinical outcome due to the potential for misdiagnosis and inappropriate therapy. While it is misleadingly assumed that identification errors occur at a low frequency in clinical laboratories, misidentification of general laboratory specimens is around 1% and can produce serious harm to patients, when not promptly detected. This article focuses on this challenging issue, providing an overview on the prevalence and

leading causes of identification errors, analyzing the potential adverse consequences, and providing tentative guidelines for detection and prevention based on direct-positive identification, the use of information technology for data entry, automated systems for patient identification and specimen labeling, two or more identifiers during sample collection and delta check technology to identify significant variance of results from historical values. Once misidentification is detected, rejection and recollection is the most suitable approach to manage the specimen.

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Introduction

Recent evidence attests that healthcare is no safer place than it has traditionally been assumed to be. Today, an estimated 98,000 Americans die each year as a result of medical error, and a nearly equal number succumbs to infections they acquire in hospitals (1). While those numbers have been revised by estimating the patient prognosis and probability that death could have been prevented by optimal care (2), the more closely we examine patient care, the more error we find. These error rates mirror a disappointing situation worldwide which is objectionable at the beginning of the new millennium. In fact, despite many efforts and recommendations to improve patient safety, we still lack concrete evidence that safety and quality of healthcare have reached their pinnacle. The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as "...any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer" (3). By definition, medical errors can occur at any stage in professional practice, including prescribing, order communication, product labeling, packaging, compounding, dispensing, distribution, and administration. Although there is a common perception that most medical errors arise from inappropriate or delayed clinical management, mistakes associated with diagnosis, either delayed or missed, may still occur with frequency. In the renowned publication of the IOM report on medical errors (To Err is Human) (1), the term "medication errors" is cited 70 times, while "diagnostic errors" appears only twice. This is interesting, since diagnostic errors comprised 17% of

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the adverse events in the Harvard Medical Practice Study (from which 44,000–98,000 deaths numbers of the IOM were drawn), and account for twice as many malpractice suits as medication errors (4). From literature searches of English language studies identified in the National Patient Safety Foundation bibliography database, Medline and EMBASE, diagnostic errors vary from 26% to 78% of identified medical errors in a primary care setting (5). Overall, the error rate in laboratory medicine ranges from less than 0.05% up to 10%, depending on the wide variety of definitions, the methods for identifying error frequency and nature and the type of healthcare facility (6, 7). The great majority of these errors, however, occur for individual or system design defects in extra-analytical phases of the total testing process, especially in the preanalytical setting, which is incidentally one of the most labor-intensive activities and it is largely performed in the wards, outside the control of the clinical laboratory (8). Most errors arise from inadequate procedures for collection of the specimen, including inappropriate quality (hemolysis, clotting, and contamination), insufficient volume to perform the analysis, inappropriate containers and, last but not least, misidentification (7).

Despite the existence of an internationally accepted recommendation for the area of Laboratory Medicine (9), the practical application of the concept of “Direct (positive) identification” is limited. It must be emphasized that this term indicates a situation where the identity of the patient is unequivocally linked to the sample, and the link is maintained throughout the total testing process. A procedure for the correct identification of patient and related objects in any medical procedure is also recommended by CEN – European Committee for Standardization TC 251-Health Informatics (10). Therefore, through their work on the website specimenscare.com and their cooperation with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Patient Safety, the European Preanalytical Scientific Committee realized that there was a need for a further review of patient misidentification, which is a concerning source of errors in laboratory diagnostics.

Prevalence of patient misidentification

Proper patient identification is the mainstay of patient safety in any healthcare organization, being a necessary component for providing safe (effective) clinical and diagnostic services. Misidentification occurs not only in consulting rooms, wards, and operating theatres, but also in laboratories and imaging suites, often resulting in someone receiving inappropriate treatment or getting the wrong test results. There is, however, an objective difficulty in providing a reliable estimate of this concerning phenomenon, since misidentification errors are frequently not easily detectable or, as in the case of front-line healthcare staff, no harm comes to the patient so it is not deemed to be worth the time to fill out an incident report. There also

may be the inhibition caused by fear of blame (11), or perhaps high levels of embarrassment since the errors seem so simple to be prevented.

Misidentification is a major risk not only in the area of laboratory medicine but in many other critical issues concerning the patient treatment, such as prescription/administration of drugs; a proper identification of a patient should be carried out before any medical procedure, possibly in an automatic way (12). A major area of risk involves blood transfusions. As of March 2008, the Joint Commission (JC), formerly Joint Commission on Accreditation of Healthcare Organization, sentinel event database included 114 cases of transfusion errors (Sentinel Event Alert #10) from January 1995 to March 2008 (13). Patient misidentification was also cited in more than 100 individual root cause analyses by the United States Department of Veterans Affairs (VA) National Center for Patient Safety from January 2000 to March 2003 (14). Over the 12-month period of February 2006 to January 2007, the United Kingdom National Patient Safety Agency received 24,382 reports of patients being mismatched to their care (15). Retrospective and prospective data collected in an Academic Medical Center showed that registration-associated patient misidentification errors occurred from 7 to 15 times per month (16). A particularly common class of errors results from patient misidentification in Neonatal Intensive Care Units (NICU). Simpson et al. reported that 25% of the serious medication errors that were seen during a 6-month study period in a British NICU were caused by patient misidentification (17). Similarly, Suresh et al. reported that 11% and 10% of errors, submitted to a voluntary, anonymous, internet-based reporting system for medical errors over almost 2 years at the University of Vermont College of Medicine NICU, involved patient misidentification and mislabeling of samples, respectively (18).

Comprehensive statistics on identification errors are available from the field of transfusion medicine, where the prevalence is reportedly heterogeneous, but the overall chance that a patient might receive a blood product intended for another patient is rather high, approximately 1 in 20,000 (19, 20). A study using hemolytic transfusion reactions as a case-finding method reported a specimen identification error rate of 19 per million specimens (21). A further study, based on historical ABO typing to determine whether an incoming specimen was improperly identified, estimated a “wrong blood in tube” rate of 337 per million specimens (22). Data from New York State also indicate that approximately 1 of every 33,000 red cell units transfused is ABO-incompatible with the recipient. National application of these data suggests that as many as 360 ABO-incompatible whole blood and red cell transfusions might occur annually in the United States (12). Based on reports of the Serious Hazards of Transfusion (SHOT scheme) between 1996 and 2003, the risk of an error occurring during transfusion of a blood component is estimated at 1:16,500 and of receiving an ABO-incompatible transfusion at 1:100,000 (23). Phlebotomy and blood bank laboratory

errors cause some of these ABO-incompatible transfusions, but the greatest number result either partially or solely from the failure of transfusionists to properly identify either the patient or the blood component the patient receives.

With the exception of blood transfusion practice, the prevalence of patient misidentification in other healthcare settings, such as clinical laboratories, has been less extensively investigated. Unfortunately, misidentification often has complex causal pathways, takes time to be revealed and may not harm for hours (missed acute pulmonary embolism), days (missed deep vein thrombosis), or even years (missed cancer). Therefore, it does not produce the same visceral wallop as misadministration of drugs or wrong-site surgery. Moreover, diagnostic errors are difficult to detect objectively, particularly through retrospective chart review. However, although patient identification errors in transfusion medicine occur in 0.05% of specimens, the rate is much higher for general laboratory specimens, around 1% (24). In 1995, a prior Q-Probes study observed a misidentification error rate of 7.4%, with individual hospital rates generally related to hospital size, smaller hospitals having a higher error rate (25). A subsequent Q-Tracks inter-laboratory quality improvement program showed a reduction of the initial error rate of 7.4% to 3.1% following continuous monitoring and educational initiatives (26). A study of 14 Australian laboratories, where errors transcribing a patient's name from pathology requisitions to computer systems were reviewed, the median institution made transcription errors involving patient identity in 1% of cases, whereas the worst performer made identification errors in 9% of cases (27). In the College of American Pathologists (CAP) Q-Probe study, performed in 660 institutions, a total of 5514 of 114,934 outpatient requisitions (4.8%) were associated with at least one type of order entry error, including one or more discrepancies in the identity of patients or physicians (28). Reviewing more recent studies on this topic, laboratory errors due to misidentification ranged from 1% to 2% for inpatients and from 0.2% to 6% for outpatients (29). More recently, Carraro and Plebani reported that the frequency of misidentification in a stat laboratory might be as high as 8.8% (30). An additional CAP Q-Probes study of patient and specimen identification errors at 120 institutions identified an overall rate of patient identification errors of 55 per 1,000,000 billable tests. More than 50% of identification errors were reported to result from primary specimen labeling errors, and 22% were attributed to computer registration errors or order entry errors. In this study, 5731 identification errors were detected before test results were released, and 974 were found after results had been verified. Thus, 85% of reported identification errors were detected within the laboratory before result verification (31).

Causes of patient misidentification

Many factors may contribute to misidentification, including malpractice, issues related to workflow, materials used in the identification process, or the

Table 1 Prevailing causes of misidentification in laboratory diagnostics.

1.	Physician ordering laboratory tests on the wrong patient
2.	Incorrect or incomplete entry of patient's data in the Laboratory Information System
3.	Collection of specimens from the wrong patient
4.	Inappropriate labeling of the specimens
5.	Lost identification (label) on the specimens
6.	Incorrect entry of patient's results in the database of the Laboratory Information System

approach taken by the staff to confirm the identity of individual patients (Table 1). Pragmatically, all these causes arise throughout the preanalytical step of the total testing process and can be clustered into five major categories: incorrect collection of patient's data on admission, collection of specimens from the wrong patient, problems with labels on the specimens, problems emerging during specimen processing, and incorrect entry of patient's results in the Laboratory Information System (LIS) database.

A common charting error involves a physician ordering laboratory tests on the wrong patient, either because the patient gives someone else's identity or because the physician makes mistakes while completing the order. Patients with identical names present a unique challenge to acute healthcare settings, a situation particularly relevant in communities where most individual's names are not unique (32). If a patient is misidentified during admission, incorrect data are entered in the patient's profile and an incorrect armband might be generated and placed on the patient's wrist. Apparently, simple data, such as an individual's name or date of birth, might be much more complex than they first appear and may pose problems for the use of informatics tools. Mistakes might also occur as a result of language or communication barriers: names of patients coming from foreign countries might be unfamiliar to the local healthcare personnel and potentially misspelled or misinterpreted, especially when handwritten. As for public demand, a doctor's handwriting has been fodder for jokes for decades. Accordingly, handwritten entries, small font size, and poor visibility of the patient's name and number on paper order copies (often via an addressograph imprint), compounded by look-alike last names, can also result in entering orders into the incorrect profile. If the patient is unable to speak, the problem remains. Misidentification may also occur for data duplication (patient name and medical record number, MRN) in the healthcare system, when patients might be attributed with identical identification codes. Collection of specimens from the wrong patient is a common cause of misidentification. Under some circumstances, either intentionally or accidentally, the patients' armbands might have been removed and studies have indicated that many patient-identification errors occur when patients are without identification armbands. Less frequently, errors might arise as patients are wearing more than one wristband (33). The risk of sample misidentifica-

tion is likely to be higher when there is a spatial and/or temporal interval between patient identification, sample labeling, and blood drawing. Other causes are biological samples with lost identity (label), labeled with incorrect accession numbers, multiple phlebotomists using one printer, resulting in mixing one another's printed labels, specimens batched in areas with pre-printed labels from different patients, handwritten labels being applied to specimen containers, tissue cassettes, and slides, all frequently leading to misidentification (33).

Incorrect entry of patient results in the LIS database can occur, especially when a query-host system between instrument and LIS is unavailable or malfunctioning. The laboratory personnel are hence forced to enter data manually by using initials or parts of the name, digits of the National Healthcare System or laboratory code. Many facilities always encounter patients with the same name or similar identification numbers and, to our knowledge, no system of alerts has been developed when such data duplication occurs in a health system.

The NICU environment and patient population present additional challenges since the complex nature of this ward and the vulnerability of the population places young patients at extremely high risk of misidentification and so to adverse events related to these errors. Unlike many pediatric or adult wards, NICU patients are not able to participate actively in the identification process and many of the commonly used methods to identify individuals in everyday life, such as physical appearance (size, age, hair color, and gender), are not immediately apparent or distinguishable within this population. As such, NICU clinicians must rely on standardized patient wristbands for identification purposes (34). Unfortunately, however, wristbands might not be regarded as a panacea, in that reports from general hospital and NICU populations demonstrate that errors in wristband content or use might also be frequent, thus underlining the importance of quality and information contained in the wristband itself. A survey from the CAP identified 45,197 errors out of 1,757,730 (2.6%) wristbands during 2 years monitoring (1999–2000) in 217 institutions, which were attributed to missing wristbands (72%), missing ID information (9%), illegible wristband (8%), erroneous ID information (7%), conflicting wristband (4%), and incorrect wristband (1%) (26). Recent reviews of experience within the 34 NICUs of the Vermont Oxford NICU 2002 Quality Improvement Collaborative found that standard identification bands are not present on 20%–80% of NICU patients (34). Conversely, identification bands are often affixed to a patient's bedside or chart. In part, this practice is related to concerns regarding the fragility of a premature infant's skin that can lead to skin lacerations and erosions when standard plastic-coated identification bands are placed around arms or legs. In addition, the need to rotate intravenous lines frequently between limited sites often requires identification bands to be removed. Even when identification bands are present and contain the correct identifying information, these

identifiers may not be recognizably unique to busy NICU clinicians. The sequential nature by which MRNs are assigned in many hospitals means that patients who are admitted to the NICU within a relatively short timeframe are at highest risk of sharing similar medication administration records, a problem exacerbated by multiple births (34).

Potential consequences of patient misidentification

Although harmful incidents from patient misidentification are frequently reported, there are many differences in degree and definition across the available studies, which make it rather difficult to draw definitive conclusions. Reports of fatal hemolytic transfusion reactions due to misidentification of laboratory specimens have appeared in mass media and peer-reviewed literature for decades (20, 35), accounting for the largest proportion of all adverse events. Based on reports of the Serious Hazards of Transfusion (SHOT scheme) between 1996 and 2003, the risk of death as a result of an incorrect blood component transfused is around 1:1,500,000 (23). The hemovigilance program in Quebec identified mistransfusion as the most common major adverse event occurring at a rate of 1 in 12,000 transfusions (36), and similar findings have been reported from the hemovigilance program in France (37).

It is often difficult to establish a strict causal link between laboratory errors and patient outcomes, especially outside the transfusion medicine setting. There is, however, clear evidence that laboratory errors, in general, might impact on patient care producing serious harm, with a risk of inappropriate care and adverse events ranging from 6.4% to 12% of total errors (6). Nutting et al. reported that 27% of laboratory problems discovered in their survey were judged by the physician to have an effect on patient care (38). In a study monitoring laboratory mistakes in stat exams from four different departments, Plebani and Carraro concluded that most of the laboratory mistakes (74%) did not affect patient outcomes (39). However, in 19% of the patients they were associated with further inappropriate investigations and unjustifiable increases in costs, whereas in 6.4% of the patients they were associated with inappropriate care or inappropriate modification of therapy (2.2% inappropriate transfusion, 2.2% inappropriate modification of heparin infusion, 1.0% inappropriate infusion of electrolyte solution, and 1.0% inappropriate modification of digoxin therapy) (39). Hofgärtner and Tait also reported the average level of actual harm resulting from errors during clinical genetic testing; moderate or high levels of harm occurred in only 0.008% of total cases (40). When relating patient harm to the specific problem of misidentification, the CAP Q-Probes study reported that approximately 1 in 18 identification errors resulted in an adverse event. More than 70% of the adverse events resulted in significant patient inconvenience with no known change in treatment or outcome. Extrapolating the adverse event rate observed in this study to all United States hospital-based laboratories suggests that more than 160,000

adverse events per year result from misidentification of patients' laboratory specimens (31). In February 2006, a project completed at the VA New York Harbor Healthcare System identified several adverse consequences associated with misidentification of patient samples, including unnecessary prostatectomies, delay in treatment of tumors or infections, medical treatment for the incorrect patients, unnecessary diagnostic procedures, and unnecessary hospitalizations (33). Suresh et al. also highlighted that identification errors in the NICU might produce serious harm in 2% of the cases, and minor harm in 25% of the cases, respectively (18). These events are particularly concerning, as a significant number could be easily prevented by an obsessive attention to clerical details (41).

Detection and prevention of patient misidentification

Patient identification has represented for a long time a dogma for many operating within the healthcare system. Despite some progress, however, correct patient identification is still a goal that must be achieved to obtain the best possible standard of care. As such, improving the accuracy of patient identification has been the most important among the JC National Patient Safety Goals from 2003 throughout 2008, which includes the specific issue "Improve the accuracy of patient identification" in the "Ambulatory Care Program" (42). Awareness of a problem does not mean, however, that there is always an easy solution and the many efforts placed to overcome this challenge have been somehow less productive than expected. According to Leape and Berwick, the need to reduce medical errors is obvious and the mandate is clear (43). Nevertheless, there are no "quick fixes", nor are there ready-to-use universal solutions and so the necessary changes are implemented as a variety of cultural and technical changes. First and foremost, like any industrial process, a system that measures quality and safety must be created and implemented within the daily practice. Regardless of the specific target, two approaches for improving quality in healthcare are commonly suggested. The first, called "quality by inspection", is a system based on the belief that quality is best achieved by removing "bad apples." The second, based on the theory of continuous improvement, calls for understanding and revision of the production process rather than placing blame on the individual (44). While the problem of medical error is not fundamental due to lack of knowledge (45), laboratory errors represent a distinctive entity, since "malpractice" can result from educational drawbacks other than environmental or attitudinal pitfalls. Typically, healthcare workers, similar to employees in many other industries, tend to work around problems when these are encountered, meeting patients' immediate needs but not resolving the root causes of the problems, so that they are faced with the same problems every day for years. These

persistent difficulties manifest themselves as regular inefficiencies within the system, and they occasionally lead to catastrophic mistakes. Basically, the chance of misidentification may develop at any stage in the total testing process and increases exponentially with the number of steps through which it must pass. As originally depicted by "Reason using the traditional Swiss cheese model", an error (misidentification) is the consequence of an accident trajectory (unpredictable event) penetrating the defensive layers of a particular process (laboratory diagnostics). Each defensive layer (slice of cheese) has a number of vulnerabilities (holes) that are continually opening, shutting, and shifting their location, leaving the opportunity for a trajectory of accident opportunity that may irreversibly penetrate the barrier (46). Therefore, the most suitable solution for such a concerning vulnerability is to re-examine processes and redesign all the steps to make them less vulnerable to human or technical errors, i.e., "Root Cause Analysis" (RCA). RCA is designed as a process to describe in chronological and precise detail what happened during a close call or an adverse event, identify the root causes of that event and, most importantly, recommend corrective actions. To successfully prevent laboratory errors, a process and risk analysis, i.e., the detection of the most critical and at risk steps in the laboratory process, is very important. In this respect, the use of the ISO risk curve, representing the most critical processes as a result of the cognitive analysis, hazard and operability study and absolute probability judgment can be very helpful (47, 48). Although it is theoretically possible to find all identification errors (e.g., by performing molecular identity testing on every specimen) (31), this is impractical to achieve in practice and several, alternative "defensive layers" should be set (Figure 1).

Monitor identification errors

Although RCA is prerogative of total quality systems in both industry and healthcare, it needs to be linked to a reliable error monitoring system to work properly (29). Laboratory service errors are detected in many ways, including caregiver complaints, incident reports from inside or outside the laboratory, error checking protocols within the laboratory, and a variety of laboratory management reports. Basically, the number of errors found at a particular institution depends to some degree on how methodically laboratory staff and clinical caregivers look for errors. This fact sometimes produces a paradox, in that facilities that are more focused on detecting and correcting errors may appear to have error rates higher than rates at institutions that do not pay as much attention to discovering errors (31). Nevertheless, a continuous monitoring process based on reliable performance indicators adapted to the local environment would help detect vulnerabilities, allowing redesign or reorganization of processes according to a safer model, possibly with decreased complexity and hence less error-prone activities. The opportunity to relate identification errors to economical and clinical outcomes

Paper orders



- Implement computerized physician order entry
- Avoid hand-written entries and small font size
- System of alerts about potential duplication of patient's data (name and code)

Order entry



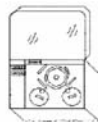
- Use computerized data entry
- Produce automatic systems for patient identification (bar coding, radiofrequency)

Sample collection



- Use automated systems for patient identification
- Use two identifiers
- Collect samples from one patients at a time
- Label correctly the specimen
- Introduction of RFID-based test tube systems

Sample analysis



- Predispose an adequate environment
- Increase automation
- Work in "query-host", with automated data entry in the laboratory repository

Results reporting



- Introduce computer-based medical records
- Apply Delta Check technology to evaluate laboratory results
- Introduce a systematic policy for errors detection and reporting

Figure 1 Prevention of identification errors throughout the total testing process.

would also provide the ideal basis for an efficient audit and feedback with clinical departments and decentralized ambulatory facilities, improving the entire healthcare process. Powerfully supported by innovative information technology, this approach would not entail extraordinary expenditures, which is an important consideration for healthcare managers (29). Preliminary experiences demonstrate that ongoing monitoring is worthwhile, as it is associated with a lower rate of misidentification (31). Obviously, this system will only work if preventive and corrective actions are taken to eliminate the root cause of a detected non-conformity.

Accurate data entry

As most identification errors arise during order entry or patient admission, handwritten entries and small font sizes should be avoided. Moreover, patient data should be carefully checked for potential duplication (patient name and codes). If feasible, computerized physician order entry should be preferred and system of alerts should be made available to warn about

potential duplication of data (patient name and/or codes).

Appropriate patient identification during sample collection – direct (positive) identification

For a fail-safe patient sample identification system, as mentioned above, the identity of the patient must be unequivocally linked to the sample container at the sample collection phase, this link being maintained throughout the total testing process. To concretize this recommendation, a patient sample identification system is needed, where safety does not depend on the good will of operators, but on necessary requirements in all relevant operations. This means that if any step of the procedure is not correctly followed, the system should stop operations automatically. If such a procedure is not technically feasible, an acceptable level of safety must be an integral component of the system in which it is always possible to check if all the operations have been correctly performed. This means that, at any point in the link to the patient, sample collection, sample processing and

result reporting, or other service where identification is at risk, the system should ensure its integral security. Security at the collection phase would also imply labels to be automatically generated as a result of a request, printed by a device located near the patient, just before venipuncture, obligatorily activated by an identification worn by the patient (e.g., a wrist-bracelet with patient data) or strictly linked to the patient's body. Alternatively, if labeled blood collection tubes are prepared in advance, patient identification reported on patient sample containers should be automatically matched, at the time of venipuncture, with patient data reported on a wrist-bracelet or other device attached to the patient's body. This transaction must be automatically recorded (9). The JC National Patient Safety Goal 1A clearly mandates to "use at least two patient identifiers (neither to be the patient room number) when providing care, treatment or services, including taking blood samples and other specimens for clinical testing" (42). Therefore, patient verification using two identifiers should be required for all critical processes, especially medication use and diagnostic/monitoring activities. Of course, hospitals would have to make it a priority to ensure that two identifiers (e.g., name, birth date, identification number) are readily available and clearly legible to staff for verification. Moreover, standardization of phlebotomy around a new process ("single piece flow") in which only one patient with one set of patient labels is handled at a time, and a second patient is not phlebotomized until the first patient's specimens are submitted to the laboratory is recommended (49).

Automated systems for patient identification

Positive patient identification provides the foundation for error prevention and improvements in numerous patient-care applications. The pressure to use barcodes, especially for improving medication administration safety, has come from many organizations, including professional societies, hospital networks, industry consortiums, and patient safety groups. The JC also suggests considering, where feasible, implementation of automated systems (e.g., electronic order entry, barcoding, radiofrequency identification, biometrics) to decrease the potential for identification errors (50). Barcode data entry can be used for recording patient's data on admission, for safe collection and labeling of the specimens and for entering results in the LIS. Since their invention in the 20th century, barcodes – especially the Universal Product Code (UPC) – have become an essential part of modern civilization. Their use is widespread, and the technology behind barcodes is constantly improving. Originally, barcodes stored data in the widths and spacing of printed parallel lines, but now they also come in patterns of dots, concentric circles, and text codes hidden within images. Barcodes can be read by optical scanners called barcode readers or scanned from an image by special software. Barcodes are widely used to implement Automatic Identification and Data Capture (AIDC) systems that automatically identify

objects, collect data about them, and enter that data directly into computer systems. Technologies typically considered as part of AIDC include barcodes, radio frequency identification (RFID), biometrics, magnetic stripes, optical character recognition, smart cards, and voice recognition (35). In a valuable effort toward standardization of the design of patient wristbands, information on them and processes used to produce and check them in the healthcare setting, from 18 July 2008 all national healthcare system (NHS) organizations in England and Wales that use patient wristbands should: 1) only use patient wristbands that meet the National Patient Safety Agency's design requirements; 2) only include core patient identifiers (last name, first name, date of birth, NHS number, first line of address); 3) develop clear and consistent processes, specifying which staff can produce, apply, and check patient wristbands; and 4) only use a white wristband with black text (15). It is important to mention, however, that a patient can have multiple medical record numbers, each issued by the organization that provided them care, and such numbers uniquely identify the patient only within the issuing organization. A patient identifier that is unique only within one organization or enterprise does not address the issues of matching patients and their data among different healthcare organizations. Therefore, the Food and Drug Administration (FDA) is currently exploring implementation of a unique device identifier for medical devices, which will unequivocally contribute to further improve patient safety, reduce medical errors, facilitate device recalls, improve device adverse event reporting and, last but not least, easing patient access throughout a variety of healthcare services.

Barcoding and RFID solutions are at the heart of many patient safety initiatives in healthcare facilities. The obvious advantage of these technologies is that they enable nurses, pharmacists, laboratory technicians, therapists, and other healthcare professionals to record and verify information more quickly and accurately than by handwriting or keyboard data entry. Similarly, RFID systems, which do not require line-of-sight access to patient identification bands (digital data encoded in an RFID tag or "smart label" captured by a reader using radio waves), may prove valuable and even more practical. On admission, patient data are encoded in a barcode or RFID tag in the wristband when it is printed (strict standards should be adopted to record comprehensive patient information, including first name, last name, middle initials, date of birth, gender, healthcare code, medical record number). Data are read and recorded by scanning with a barcode or RFID reader, instead of manually reading the wristband to verify the patient's identity. Readers are integrated with a computer that looks up the scan data in a database and displays the patient information for the nurse or other caregiver. A barcoded wristband can provide two forms of identification in one easy-to-access place by encoding the patient name and identification number. Including two forms of patient ID on the wristband aids Health Insurance Portability and Accountability Act (HIPAA)

compliance, because information encoded in a barcode instead of being expressed in text satisfies privacy requirements. Before taking a biological sample, phlebotomists or nurses scan the patient's barcoded wristband and check a mobile computer to verify the correct patient, the specifications of the order, and that the sample has not already been taken. While the sample is being drawn, a mobile printer automatically produces a barcoded label to accurately identify the sample. The staff member then immediately applies the label to the sample container. In the laboratory, incorporating barcode labels on test tubes, slides, and sample containers enable technicians to track specimens throughout the testing process all the way through the reporting of results. The required tests can even be encoded on the sample label in a two-dimensional (2-D) barcode or RFID tag to eliminate any chance of confusion as to what tests should be performed. At the same time, this barcoding aids test result recording and improves patient record accuracy, it provides measurable process improvements and time savings for laboratory staff. Finally, when manual entry of test results into the LIS is required, the laboratory technician can double check the patient code by reading the barcode on the specimen and compare it to that on the database of the LIS. Last but not least, wristbands can be incorporated into physical security systems. RFID chips can be embedded within barcoded wristbands to provide an invisible, unobtrusive form of protection that can be read through bed linen, so patients do not have to be disturbed when sleeping. They can be used with fixed readers in doorways and corridors, to help staff keep track of ambulatory patients. The chip on the wristband can also be read when the patient attempts to leave the ward, which may sound an alarm, trigger a notification at the nurses' station, or even lock the door. In healthcare settings, RFID wristbands are typically used to protect infants, Alzheimer's patients, and others deemed a high risk. Despite the potential benefits of these auto-identification technologies, clinicians must ensure that such technologies are tested adequately in the unique environment of the healthcare system and that they are implemented in a manner that avoids disruption of workflow. Nevertheless, automatic identification systems would end at least 50% of preventable medical errors, according to the US FDA (51). Accordingly, Killeen et al. reported that the introduction of barcodes in an emergency department reduced identification error rates from 2.56 to 0.49 per 1000 specimens (52), a remarkable improvement which was also confirmed in separate studies by Murphy and Kay (53), Nichols et al. (54) and Askeland et al. (55). As in the adult wards, a barcode-based electronic positive patient and specimen identification system was effective in reducing identification errors in a pediatric hospital's clinical laboratory (56). The automatic identification of samples is also recommended; each supply or disposable item used for patients should be automatically identified by the same procedure using new strategies of information system management (57).

Appropriate labeling of the specimens

Phlebotomists and nurses should be educated regarding the proper policy and procedure for blood collection. Whoever draws the blood must label the tube at the patient's bedside without taking the tube away from the patient's bedside. As already mentioned, automated labeling is preferable (the application of handwritten labels should be limited to exceptional cases) and relabeling should be minimized (33). New flexible polymer tubes containing lab-on-a-chip integrated with physical and biochemical sensor modules mounted on a flexible spiral structure for measuring physiological (temperature/flow rate) and metabolic data (glucose concentration) in a catheter application have recently been designed and fabricated (58). Expansion of this technology with RFID chips, containing a variety of patient data embedded in the primary tubes (the only data contained in barcode labels is a serial number) and equipped with signal communication modules, would be helpful not only for ensuring high quality specimens but also for tracking laboratory specimens more efficiently than using other technologies, such as barcodes. The use of RFID-based test tube systems would finally decrease the chance of read errors, improving retrieval, management, and security (both reading and writing of data to/from the RFID chip is more accurate and might be secured via a keycode) of high-value samples outside and within the laboratory environment. It is important to mention, however, that the potential for harmful electromagnetic interference (EMI) by electronic antitheft surveillance systems and RFID on implantable pacemakers and defibrillators has already been recognized (59), and it has also been recently reported that RFID technology is capable of inducing potentially hazardous incidents in medical devices, primarily due to malfunctioning of infusion/syringe pumps, external pacemakers, mechanical ventilators, and dialysis devices (60). Therefore, implementation of RFID in the intensive care unit and other similar healthcare environments should require on-site EMI tests in addition to updated international standards.

Adequate environment

An adequate environment is mandatory to prevent any type of error in daily laboratory practice. The work area should follow human factor principles for laboratory personnel who apply accession numbers to incoming specimens and should be re-engineered accordingly. Afterwards, automation of both the pre-analytical and analytical processes should be promoted whenever possible by (i) introduction of preanalytical processors that eliminate a variety of manual steps (lower chance of mislabeling of aliquots and losing labels from the tube), (ii) implementation of front-end automation and analyzers with direct sampling from the primary tube (lower chance of erroneous patient's data entry when manually programming the instrument), and (iii) consolidating tests on less analytical platforms (smaller number of

tubes and lower chance of errors while performing aliquots from the primary sample). While workspace around isolettes is often insufficient in the NICU, hospitals should use whatever means possible to discretely separate the work areas available for each infant to prevent mix-ups with medication administration records, flow sheets, medications, specimens, and equipment.

Result reporting

Delta check technology is an automated comparison of the patient's current and previous laboratory test value, which is designed to draw attention to laboratory results at significant variance from historical values. If the values are significantly different from historical values, the result is flagged and consideration might be given to the possibility that the specimen may have been obtained from a different patient. Delta checking procedures vary but usually involve repeating the test and investigating for misidentification. There is little doubt that this approach would be suitable, as confirmed by Oosterhuis et al. who reported that an expert system that validated test results on the basis of a multianalyte delta check detected 78% of intentionally altered test results (61). A system of alerts should also be made available in the LIS to warn about data duplication (patient name and codes) in the same health system.

Conclusions

In recent times, medical errors have been the focus of attention in the patient safety field, the healthcare facility being held accountable for creating safer systems by implementing incident reporting systems, patient safety officers, RCA, teamwork training, and more. However, healthcare systems are increasingly dependent on reliable clinical laboratory services, which, as part of the overall healthcare system, are prone to errors. But if diagnostic errors are seen as a minor (rare) phenomenon, the healthcare facility is unlikely to contribute to their solution, or even focus much attention to them. However, we have clear evidence that diagnostic errors occur with frequency, and that some of them can be caused by misidentification. Sometimes patients end up with someone else's diagnosis, incorrect medications and surgery, or having their blood collected with the next door neighbor's tubes or infants are discharged to the incorrect families (16). As quality and safety movements gallop along, the need to fix misidentification errors grows more pressing. First and foremost, any safety and quality practice put into practice to prevent this unfavorable event should prove effective and, preferably, affordable before promoting or mandating widespread implementation. There is, in fact, a serious concern in vigorously promoting or mandating safety practices with weak evidence, due to the inherent risk that squandering scarce resources diverts them from better strategies, and subjects the safety field to the whims of opinions and biases. Definitely,

rigorous studies are needed to look at what works and what does not work towards increasing patient safety. However, we have to start somewhere. As currently recommended by the JC, positive identification is the foundation of patient safety, and the use of at least two patient identifiers when providing care, treatment or services (including two identifiers to label sample collection containers in the presence of the patient) are recommended to maintain sample identity throughout the total testing process. Process-supporting information technology has also been heralded as an important building block in attempts to improve the quality and safety of healthcare. Two areas in particular have drawn both attention and funding. The first is clinical decision support, i.e., information systems designed to improve clinicians' decision making. The second involves automatic patient identification and computerized physician order entry (62, 63). Such technologies, combined with web-based electronic medical records and wireless computing, offer significant opportunities to reduce diagnostic and drug administration errors, which represented more than one-third of all medical errors and are easily preventable (64). Information technology, however, is not a safety critical object by itself, but it must be included in the generic process of safety (35). Despite the improvements, error rates with automatic identification systems, especially barcodes, still did not achieve zero errors. As with any new technology, protection against mistakes is not perfect, and new problems (resistance to change, confusion regarding the best technology, uncertainty regarding the return-on-investment) (65) and types of errors (missing or the incorrect data on the wristband, system malfunctioning, use of manual data entry when the barcode scan is unsuccessful or unavailable) may be introduced (66). However, remarkable improvement due to ongoing training and education has decreased the rate of wristband error from 5.5% in 1993 (25) to 0.1–1% in 2005 (67).

It is currently being emphasized that optimizing decisions on corrective actions and moving from a subjective individual criterion to systematic and comparative management for strategic and support processes in laboratory medicine is necessary to improve quality of laboratory services (68). While strict adherence to available guidelines and recommendations for specimen collection, the use of information technology for data entry, automated systems for patient identification and specimen labeling, two or more identifiers during sample collection and delta check technology might be effective in preventing and identifying identification errors, rejection and recollection is the most suitable approach to manage the specimen once misidentification has been ascertained.

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