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Medical Errors and the Laboratory: How Healthcare Organizations are Improving Rates and Improving Patient Care

Amanda Payton
jamesonsmommy8711@gmail.com

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By: Amanda L. Payton, MLT(ASCP)

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Abstract:

Errors in medicine have been a common occurrence since the birth of medicine, but have been brought to light more recently as more patients are becoming more active in their own care. Errors which involve the laboratory can be catastrophic for a patient, as a wrong test result can alter the entire treatment plan a physician implements. Healthcare organizations and accrediting organizations have become diligent about tracking errors and the most common sources of error, so that new policies, procedures, and technology can be implemented in order to reduce errors. The laboratory itself has made many strides in error prevention, but has encountered hurdles due to the difficulty of tracking errors that occur within the walls of the laboratory. Different steps which occur in the total testing process, or TTP, have been identified to better track sources of errors, and to better focus methods of which to prevent errors. The different steps of the total testing, the pre-analytical, analytical, and post-analytical phases of testing have drastic differences in the amount of errors that occur in each step. The step where the majority of errors occur is the pre-analytical phase, which consists of patient identification, specimen collection, and transport of specimens to the laboratory. Due to the large number of errors that occur in this phase, particularly with patient identification, healthcare organizations have begun to implement barcode technology for patient identification, medication distribution, blood transfusions, and labeling of specimens collected from the patient. Errors have been reduced greatly over the past several years, but there is still a long way to go to prevent all errors from occurring in patient care.

Introduction

Medical errors have occurred since the beginning of medical practice throughout the world, especially in primitive times when technology was practically nonexistent. From the times of tasting urine for glucose content, to using rabbit blood to determine pregnancy, errors were widespread and usually unnoticed until a person experienced adverse effects from the error. Errors in medicine are less common in present times than they were when medicine appeared in civilization, primarily because of the increase in technology utilized in the medical setting, and advanced training of personnel providing direct and indirect patient care. Errors in medicine were not of particular concern to patients seeking medical treatment, until To Err is Human, written by the Institute of Medicine, was published in 1999. According to the National Academies Institute of Medicine (IOM), medical errors lead to an estimated 44,000–98,000 deaths and perhaps as many as 1 million injuries per year in the United States (Hollensead, et. al. 2004). This publication brought to light the many instances of medical errors that occur in healthcare organizations, and how detrimental these errors could be for patients, whether miniscule or the cause of a sentinel event. A sentinel event is an occurrence in a healthcare organization which causes great harm to death to a patient. Healthcare organizations have a higher percentage of errors in comparison to other organizations, due to the complexity of patient care and quality assurance. Also, with the ever increasing number of patients who want to be advocates of their own care in a healthcare setting, potential errors are even more important to prevent. Also, errors tend to occur more frequently in organizations under pressure to increase revenue, lower costs, and operate at close to full capacity (Hawkins 2012).

Another contributing factor is the shortage of nursing staff and the ever-increasing shortage of laboratory professionals, which places a strain on current employees. Errors are more

common when staff is overworked due to staffing shortages, because less attention is paid to detail and more to "getting the job done." According to Danielle Olds and Sean Clark in the article *The effect of work hours on adverse events and errors in health care*, fatigue of healthcare workers due to overtime work contributes to increased error rates (Olds, Clarke 2010).

Even with the technology in medicine presently, errors still occur on a regular basis, and many of these errors relate to the laboratory, either directly or indirectly, and how specimens are obtained and results reported out on patients. It is estimated that sixty to seventy percent of decisions for admission, discharge, and medication are based on data retrieved from laboratory results (Da Rin, 2009), so preventing errors which pertain to the laboratory is an imperative step in maintaining patient care and the best course of action and treatment of their disease processes. While errors do occur within the walls of the laboratory, most errors which relate to the laboratory occur outside the lab, which can make testing and resulting patients difficult. In the article *Errors in the clinical laboratory or errors in laboratory medicine?*, written by Mario Plebani, it is stated that "Many mistakes in the total testing process are called 'laboratory errors', although these may be due to poor communication, action taken by others involved in the testing process (e.g., physicians, nurses and phlebotomists), or poorly designed processes, all of which are beyond the laboratory's control (Plebani 2006)." In this paper, the issues pertaining to errors in medicine, particularly those related to the laboratory, which areas of the total testing process and patient care workflow are more susceptible to errors, and steps that healthcare organizations are taking to prevent errors from occurring will be discussed at length.

The Total Testing Process

The total testing process, or TTP, contains three steps, the pre-analytical phase, the analytical phase, and the post-analytical phase. Lundberg (1981) described the nine steps in turnaround time: ordering, collection, identification, transportation, preparation, analysis, reporting, interpretation and action. Of the steps identified by Lundberg, ordering, collection, identification, transportation, and preparation, all occur in the pre-analytical phase of testing, which arguably makes these steps the most important in preventing errors in medicine, particularly in the laboratory. According to Mario Plebani in the article *Quality indicators to detect pre-analytical errors in laboratory testing,* "pre-analytical errors account for up to 70% of all mistakes made in laboratory diagnostics, most of which arise from problems in patient preparation, sample collection, transportation, and preparation for analysis and storage (Plebani 2012)."

The majority of errors relating to the laboratory occur in the pre-analytical phase of testing, which includes patient identification, ordering tests, specimen collection, specimen receipt into the laboratory, and any other procedures that must be completed before testing can begin (i.e. centrifugation, aliquoting, diluting, etc.). Most of these steps occur outside of the laboratory, so an error in any of these steps can affect the work performed in the laboratory, and the results reported on the patients. Mario Plebani stated in the article, *Errors in clinical laboratories or errors in laboratory medicine?*,

> "A mistake can occur in each of the 11 steps in this process or in any of the places where a handoff can occur, starting from test request and ending with the physician's reaction to laboratory information. According to this perspective, the proposed definition of

> laboratory error is ‘‘a defect occurring at any part of the laboratory cycle, from ordering tests to reporting results and appropriately interpreting and reacting on these (Plebani 2006).’’

As stated above, errors can occur at any point in the total testing process, especially in those areas where a handoff of information occurs, such as placing verbal orders, shift change reports in the laboratory or at the nursing stations, or communication between the laboratory to other departments. In this case, communication is key in preventing errors at all phases of the total testing process, but communication must be but one step taken to help prevent errors in the medical setting.

The Pre-Analytical Phase

In the pre-analytical phase of testing, there are many aspects which could be potential sources of error. Some of the areas more prone to errors are patient identification, order entry, improper specimen collection, and improper transport of specimens to the laboratory. Out of these steps, patient identification is arguably the single most important step in preventing an error in regards to the laboratory. The article titled *Patient safety in the clinical laboratory: a longitudinal analysis of specimen identification errors* states that “accurate specimen identification is a challenge in all hospitals, and a mislabeled specimen can lead to devastating consequences for patients. In an effort to decrease the risk of potential harm caused by labeling errors, some hospitals have implemented a zero tolerance laboratory specimen labeling process. (Bruckner, Hilborne, Tamashiro, Wagar, Yasin 2006).” Errors in patient identification may cause results to be reported out on the wrong patient, which in some cases, could cause incorrect

medical intervention, and in extreme cases, patient injury or death. The laboratory is an area in which an error in patient identification could cause significant harm to the patient (Bruckner, et. al. 2006), which is why correct identification of every patient, every time any procedure is performed, is a requirement, not an option. Patient identification has become one of the Joint Commission on Health Care Organizations, or JCHAO, list of patient safety goals in 2003 (Bruckner, et. al. 2006) because of its importance to the total care and experience of the patient.

Another source for potential errors in the pre-analytical phase is incorrect ordering, which could cause delayed testing, incorrect results, and possibly missing a critical result because the test needed was not ordered, therefore not performed. This source of error is out of the control of the laboratory, as the majority of ordering is performed by the physicians or qualified nursing staff. This step is extremely important in preventing errors, because in order for the correct results to be reported out on the correct specimens, laboratory and other healthcare personnel must have the correct orders of what testing is to be performed. If incorrect testing is ordered that does not include what the physician may be investigating, a critical result may be missed, which could cause adverse effects on the patient. Also, if the physician orders testing on the wrong patient, it could cause unnecessary procedures not relevant to the patient's treatment and diagnosis (Hammerling 2015). Correct order input is essential in maintaining patient care and preventing errors. Computerized ordering systems designed for physicians have greatly reduced the frequency of errors in order input, but they do not account for ordering on wrong patients.

An additional aspect of the pre-analytical phase of the total testing process which is susceptible to errors is improper specimen collection, which can cause a delay in testing and also cause unnecessary procedures on patients when they must be drawn again due to incorrect specimen collection. This aspect includes hemolysis of blood samples, improper collection of

tubes for the testing ordered, difficulty obtaining the specimen, improper storage of specimens, and illegible or missing collection or patient information on the label, which requires a specimen to be recollected.

Hemolysis, which is defined as the destruction of red blood cells, can affect certain tests if present. Hemolysis generally occurs during the venipuncture process, as a result of several different factors which occur in vitro, or outside of the body. Some of the factors that cause increased levels of hemolysis include the bevel of the needle resting on the vein wall, smaller gauge needles, vein collapse or hematoma formation, choice of draw site and equipment, and pressure exerted onto the vein during venipuncture. According to the article *Identification of the types of preanalytical errors in the clinical chemistry laboratory: 1-year study at G.B. Pant Hospital, "*Hemolysis leads to the extravasation of intracellular contents into the plasma, leading to false high values of potassium and intracellular enzymes such as SGOT and LDH. It also leads to a prolonged turnaround time (TAT) due to the need for fresh samples for processing the request (Chawla, R., Goswami, B., Tayal, D., Mallika, V.)." If hemolysis is present, many of the patient's chemistry analytes may appear to be elevated. If a specimen is found to be hemolyzed once centrifuged in the laboratory, it should be rejected immediately and redrawn to ensure that the most acceptable specimen is analyzed. Hemolysis may result in spuriously elevated serum potassium and bilirubin, as well as acid phosphatase, zinc, magnesium, albumin, and creatine kinase (Burns, Yoshikawa 2002). Hemolysis is also greatly increased in specimens collected by non-laboratory personnel. An analysis of blood draws in the emergency department versus laboratory collection found that a possible cause of higher hemolysis rates among emergency department personnel is the type of needle used for collection. Plastic cannulas used for IV insertion seemed to display a higher hemolysis rate than those draws performed with a metal

cannula (Burns, Yoshikawa 2002). Proper training of non-laboratory personnel in obtaining blood samples from patients is essential to preventing this type of error from occurring. Hemolysis affects patient care by subjecting them to unnecessary repeat blood draws, as hemolyzed blood cannot be analyzed due to erroneous results. It can also delay patient results, and possibly the reporting of critical results because of the increased time it takes to obtain a repeat specimen for testing.

Another error which occurs in the pre-analytical phase of testing that could cause a patient to be redrawn unnecessarily is obtaining the incorrect tubes for the tests ordered. Venipuncture tubes have different additives in them, indicated by the color of the stopper on the top of the tube. Some tests require certain anticoagulants or a certain ratio of blood to anticoagulant in order to analyze the patient's blood in the laboratory. Certain anticoagulants will alter chemistry results, so care must be taken when performing venipuncture, whether the nursing staff or laboratory staff are obtaining the specimen, to correctly fill tubes which correlate with which tests are ordered and ensure that proper collection procedures are followed to prevent carryover of one anticoagulant to the other tubes does not occur. Performing testing on a sample which has been mixed with the incorrect anticoagulant can alter chemistry analytes in a patient's blood sample, which may cause unnecessary treatment or medication distribution. Personnel must know what tubes are drawn for each test to be collected, and must be trained in the proper collection of blood in order to properly collect specimens from the patient to prevent rejection and recollection of specimens. Laboratory personnel must also be highly trained to identify results not consistent with the patient's previous results, or results not conducive to life, so that incorrect results are not reported out, causing unnecessary treatment for the patient.

The pre-analytical phase, according to Mario Plebani, can further be divided into another phase, the pre-pre-analytical phase. This phase contains the steps that happen in the total testing process which do not include the laboratory directly, which means that they are entirely out of the control of laboratory staff. This section includes the initial identification of the patient upon admission, the ordering of tests, either by nursing staff or the physician, collection of specimens by non-laboratory personnel, and transportation of the specimen to the laboratory. These steps in the total testing process must be extensively examined for error prevention by the healthcare organization itself, as these steps are out of the control of the laboratory. According to the article *Exploring the iceberg of errors in laboratory medicine*, Mario Plebani states that up to twelve percent of total reported errors in the total testing process occur in the pre-pre-analytical phase (Plebani 2009). That number varies, depending on the source cited, and what each source considers to be included in the pre-pre-analytical phase, but the sentiment is always the same; that the majority of errors occur before testing is even performed on a sample in the laboratory, and that errors made in this step are the most detrimental to the patient, as an incorrect test result on the incorrect patient could cause serious problems for the patients. Incorrect diagnoses, medication dosages or prescriptions, and wrong courses of treatment could all be implemented based on one incorrect laboratory result, which is why preventing errors before the specimen is even received into the laboratory is of utmost importance to everyone, but most importantly, the patients. The pre-pre-analytical phase of testing is difficult to track errors within, because of the vague area between the laboratory and the clinical staff, and lack of responsibility for this area. Non-laboratory personnel will blame the laboratory, and laboratory staff will blame the other department, therefore either department feels like the pre-pre-analytical phase is not under their umbrella of responsibility. Healthcare organizations are trying to hone in on procedures that can

reduce errors in the pre-pre-analytical phase, as well as all areas of the total testing process. The pre-pre-analytical phase contains the steps of specimen identification and collection, which are common causes of errors, and have become the focus of many initiatives regarding the prevention of errors in entire organizations, not just the laboratory.

Overall, the pre-analytical phase of testing is arguably the most important phase in preventing medical errors which affect the laboratory. From the ordering process, to patient identification, to specimen collection and preparation, this phase has the most room for potential errors, as communication is an essential part of this phase. Healthcare organizations are working continuously to develop quality assurance and quality control procedures, as well as implementation of new procedures and policies and new equipment to help prevent errors overall, but especially those which occur in the pre-analytical phase of testing. Ways that laboratories are working to prevent errors in this phase will be discussed at length later in this paper.

The Analytical Phase

The analytical phase of testing includes the testing performed on the specimens once they are received into the laboratory. This can include placing specimens onto an automated analyzer, or performing manual testing. Errors are rare in this phase, because of the increase in technology used to obtain results from specimens, and highly trained personnel. The analytical phase makes up an estimated 7-13% of total reported errors (Plebani 2006). In recent decades, standardization, automation and technological advances have significantly improved the analytical reliability of laboratory results and decreased the error rates (Plebani 2006). Quality control and calibration procedures are standardized by accrediting agencies for laboratories, which prevents errors from

occurring in this phase. Errors do still occur in this phase, and even though they are infrequent, they can be detrimental to a patient. *Errors in clinical laboratories or errors in laboratory medicine?* states that," the real number of mistakes made in laboratory testing is not fully recognized, because no widespread process is in place to either determine how often mistakes occur or to systematically eliminate sources of errors (Plebani 2006)." Most errors occur in the analytical phase because of calibration or quality control errors, human error, and running testing on the incorrect patient. Errors in this phase are especially difficult to track, as stated in *The detection and prevention of errors in laboratory medicine*, written by Mario Plebani:

> "Laboratory professionals are reluctant to divulge data on the frequency and types of errors observed in their own setting for fear of a sense of blame, individual failure and culpability associated with these events. This, in turn, makes it difficult to evaluate the entire testing process and set quality specifications for each step in order to identify weakness in policies and procedures to provide opportunities for quality improvement through the formulation and prioritization of corrective actions. Finally, laboratory testing is no longer performed only in the clinical laboratory setting: point-of-care testing, the fastest growing segment of current clinical laboratory testing market, near-patient testing and self-monitoring are widely used alternative or complementary testing options (Plebani, 2010)."

Preventing errors in the analytical phase of the total testing process is especially important, since the testing of specimens is performed in this phase. Healthcare organizations must create policies and procedures specific to the analytical phase of the total testing phase, because tracking errors in this phase is difficult to accomplish. In addition, accrediting agencies for medical laboratories are creating and implementing policies designed to prevent errors in the

analytical phase, as well as creating a means of tracking these errors, analyzing the data, and creating new procedures and policies to further prevent errors in the analytical phase of the total testing process. Some errors that occur in the analytical phase begin at the pre-analytical phase, so creating new technology and procedures, along with quality assurance plans and quality control procedures in the pre-analytical phase of testing, will reduce the error rate in the analytical phase even further.

The Post-Analytical Phase

The post-analytical phase of the total testing process consists of the posting of results to the patient's chart, relaying critical results to the physician in a timely manner, and the treatment plan implemented by the clinician after test results are examined. Errors in this phase are generally out of the laboratory's control, with the exception of relaying critical test results to the physician in a timely manner. Accrediting agencies have focused in on the timely relay of critical results as a quality indicator in patient care. In *Exploring the iceberg of errors in laboratory medicine*, written by Mario Plebani, it is stated that:

> The Joint Commission's National Patient Safety Goal 2, which calls for hospitals to "improve the effectiveness of communication among caregivers", specifically includes the communication of critical laboratory test results as a part of this goal. "Readback" protocols (asking the recipient to repeat the information just communicated) are a user-friendly tool that can prevent such errors. However, information technology should and must support efforts to improve these communications (Plebani, 2009).

In the post-analytical phase, conveying critical results to the physician can mean the difference between life and death for some patients, as laboratory results may catch a disease

process before symptoms appear. The reporting of critical laboratory results relies heavily on assurance that the specimen was drawn or collected from the correct patient, at the correct time, which is another important reason for prevention of patient identification errors and errors in specimen collection. Healthcare organizations are focusing more on prevention of errors in the pre-analytical phase, but many quality assurance programs implemented by healthcare organizations which are dedicated to preventing errors and protecting patients are focusing more on the post-analytical phase.

Errors which occur in the post-analytical phase are just as, or more important, to prevent in the healthcare setting, because treatment plans, medication dosages and timing, and even surgical procedures or discharge dates, are determined largely from laboratory results. Errors in this phase are miniscule compared to the amount of errors that occur in the pre-analytical phase, and particularly in areas which communication is an integral part of patient care, however, errors which occur in the post-analytical phase of the total testing process are important to prevent as well. Hospital accreditation agencies focus largely on this area of the total testing process, as previously mentioned with the Joint Commission. Core measures, which are areas of patient care which can be tracked and are proven to be the most susceptible to errors are established to ensure that errors are prevented. These core measures focus heavily on the post-analytical phase of the total testing process, with measures such as the aforementioned "Readback" policy of repeating results back to the person reporting the results, to turnaround times of stat and timed testing, to ensuring that medication levels are drawn at the appropriate time to ensure proper dosages of medication.

The post-analytical phase of testing and prevention of errors lies heavily on the laboratory, as well as with the clinical staff, but errors in this phase can directly affect the

laboratory, even after results are reported. Communication is key in the post-analytical phase, and any break down of the communication between the laboratory staff and the clinical staff could be detrimental to the patient. The article, *The potential for improved teamwork to reduce medical errors in the emergency department,* written by Daniel Risser, Matthew Rice, Mary Salisbury, Robert Simon, Gregory Jay, and Scott Berns, explores examples of actual closed malpractice suits to exhibit how important communication is in health care, especially in the emergency department, and offers team building skills to implement for healthcare staff to better improve communication among not only caregivers, but for everyone involved in the care of the patient. Laboratory staff must also be trained in communication to other departments within their healthcare organization, to ensure that critical laboratory test results are delivered in a timely manner to the clinician. Most healthcare organizations currently have policies in place that address the amount of time it should take from results being reported to the clinician being notified, but mistakes still happen, and critical values still get missed or even misread by the laboratory and clinical staff. Increased technology has reduced the incorrect reporting of results, however, computer downtime and keyboard errors still happen, and can lead to errors in reporting results. It is extremely important to keep in mind the turnaround times of specimens as well, because in some cases, time is of the essence in reporting out results, especially medication levels and those results which come back as critical values. Physicians use results to determine treatment plans, therefore, reporting the correct results in as little time as possible is essential in preventing errors in the post-analytical phase. In the post-analytic phase there is the possibility of inappropriate response to the receipt, interpretation and utilization of laboratory information (Plebani 2010). An Incorrect response to the results reported out by the laboratory is out of the laboratory's control, however, the implications of such may affect the laboratory as well as

patient care. Patients are a healthcare organization's highest priority, which means that all departments within the organization, especially the laboratory, should keep patient care at its highest concern.

Point of Care Testing Errors

Another aspect that must be addressed for errors is point of care testing. Point of care testing is testing performed at the patient's bedside, with results posted to the chart immediately after performing the test. The most common of these tests is a finger stick glucose reading performed with a glucometer. As stated in the article *Preventing medical errors in point-of-care testing: Security, validation, performance, safeguards, and connectivity,* written by Gerald Kost, MD, "As more testing shifts to the bedside, and is performed by increasing numbers of physicians, nurses, and nurse practitioners, there must be adequate safeguards to prevent medical errors and reduce risk." Point of care testing is increasing at a rapid rate, which requires error prevention focused on this type of testing. While testing is not directly performed in the laboratory, most healthcare organizations place responsibility of maintaining point of care testing equipment, quality control, and result review with the laboratory. While this type of testing is more convenient for care takers, because of the short time it takes to obtain a result, it is important to note that:

> "Point-of-care testing may be prone to serious disadvantages, such as (a) insufficient validation of trained and certified operators, (b) little or no security of patient test results and quality control data, and (c) limited connectivity (bidirectional communication) with the electronic medical record. Instruments lack algorithms to assess the competency of operators. The use of unauthorized point-of care test results in diagnosis and treatment

> does not comply with practice standards; accreditation requirements; or the security, confidentiality, authentication, integrity, and auditing requirements of the Health Insurance Portability and Accountability Act (Kost 2001)."

Point of care testing was developed as a way to eliminate the sources of error that occur with the collection, transport, and analysis of specimens in the laboratory. This new technology, however, has created its own set of errors, therefore, an analysis of the process of point of care testing to prevent errors in result reporting is essential to providing optimum patient care (Plebani 2009). Portable point of care instruments, such as glucometers, arterial blood gas analyzers, and urinometers, could increase nosocomial infections due to cross contamination between patients, but proper decontamination procedures could reduce this risk. Point of care instruments, while more convenient for clinicians and those who are directly caring for the patients, can compromise patient safety and quality of the healthcare the patients receive. Kost created a model that healthcare organizations, as well as manufacturers of testing equipment, can follow to ensure that errors in testing are prevented, which was necessary with the ever increasing number of healthcare organizations performing a variety of tests at the patient's bedside instead of sending specimens to the laboratory.

Error rates for point of care testing are higher than with other laboratory results, because of the lack of proper training of personnel performing testing, and the instant posting of results to the patient's chart. If a patient is identified incorrectly, there is less room for error prevention before the result posts to the chart, which could cause unnecessary treatment for the patient. Kost's model for error prevention utilizes the pre-, intra-, and post-analytical phases of the total testing process to better organize prevention, but it leaves out an imperative step: test indication and frequency (Plebani 2009). One particular source of error is arterial blood gas analysis that

includes a potassium level. When sending a specimen to the laboratory for analysis, the specimen would be discarded if it was found to be hemolyzed. In a point of care testing setting, whole blood is analyzed, which means that a hemolysis factor is not accounted for. This could lead to inaccurate results, which could lead to incorrect treatment due to erroneous laboratory results. If questionable results are obtained using point of care equipment, a specimen should also be sent to the laboratory for confirmation.

There are several sources of error when it comes to point of care testing. Some of these sources are operator incompetence, not adhering to procedures, and the use of uncontrolled reagents or equipment (Plebani 2009). A large percentage of operators indicated that they had not been formally trained on how to use the point of care equipment, and an even larger percent of them could not locate the procedure manual when prompted. Operators also frequently do not calibrate or analyze quality control on the instruments to ensure proper working function, and do not follow the manufacturer's instructions for use, which could lead to incorrect results due to a non-calibrated instrument. Operators also reported using reagents and test strips beyond the expiration date, which may not provide accurate results due to the degradation of the reagents due to humidity, heat, and light (Plebani 2009). All of these factors have a significant impact on the quality of the results reported from point of care testing, and must be addressed and corrected in order to provide the most accurate results for clinicians.

Gerald Kost created a model in 2001 outlining the procedures needed in order to prevent errors involving point of care testing. This model includes the following steps to secure integrity and operations of instruments used at the bedside:

A. Protect instrument operations, match clinical goals, and avoid repudiation

1. Establish a security level that matches clinical goals

2. Correlate acceptable risk with the protection level

3. Define clinical sites where validated operators can use instruments

4. Avoid security repudiation

B. Ensure the integrity of test data and confidential information

1. Protect patient results, monitor access, and track use

2. Download test results and performance data to computerized systems

3. Encrypt data as necessary for electronic, telephone, or wireless transmissions

4. Prevent network security breaches and guard time and date functions

C. Provide practical, intelligent, user-friendly, and user-definable software features

1. Expedite first clearance when the operator starts using the instrument

2. Automate recognition of operator or use short personal identification number (PINs) and/or passwords

3. Streamline subsequent access but maintain user accountability

4. Build in a date registry so that user cannot bypass times functions

D. Discourage fraudulent use, tampering, and theft

1. Disable if term of calibration or other protocols expires

2. Lock down if user repeatedly enters invalid access codes

3. Shut down if detect tampering and investigate violations

4. Sound alarm and/or lock out if transported outside approved clinical site. (Kost 2001)

The basis of Kost's model as shown above is to make point of care instrumentation as user friendly as possible, while also ensuring the accuracy and reproducibility of results. It also sets guidelines for the equipment itself, to protect it from theft or destruction. This protects the users, as well as the healthcare organization by ensuring that the equipment is well cared for so that replacements will be scarce and only ordered if necessary. It also proposes security measures to prevent the unauthorized access of protected health information. Kost also proposed steps to ensure the competency of operators performing the testing, as well as measures to improve the performance of point of care testing. Kost's model for ensuring the competency of operators is as follows:

A. Lock out operators not approved to use instruments

1. Assign users appropriate levels based on competency and responsibility

2. Time out access after instrument is idle for defined interval

3. Include a special entry code for instrument set-up

4. Monitor rate of invalid operator use for performance improvement

B. Make exceptions during medical emergencies

1. Include an option to override operator lockout during emergencies

2. Provide emergency access with a special code

3. Assure testing does not shut down during emergencies

4. Flag and track test results and operators for follow-up

C. Integrate competency requirements for accreditation

1. Fulfill accreditation requirements for operator credentials, certification, and documentation

2. Lock out user after expiration of certification or too few tests performed in time interval

3. Prevent operators who are not retrained or not recertified from using instrument

4. Notify operator of why locked out, corrective action, and contact person

D. Balance validation requirements versus rapid response and user friendliness

1. Tailor validation requirement to instrument format (e.g., handheld, portable, or transportable)

2. Maintain appropriate therapeutic turnaround time for critical care and other clinical needs

3. Focus on ease of use, flexibility, and cost-effectiveness through user-defined options

4. Discourage inadvertent use outside hospital (e.g., by children at home) (Kost 2001).

These steps ensure that personnel responsible for performing point of care testing are properly trained in how to handle the equipment, as well as sets goals for turnaround time. It also covers how to prevent unauthorized users from accessing the equipment, and how users get certified and trained to perform the testing before ever using it on the patient population. Kost has outlined a concrete plan, not only for healthcare organizations, but also for manufacturers, to use as a guideline for policies and procedures involving point of care testing. His article entitled *Preventing medical errors in point-of-care testing: Security, validation, performance, safeguards, and connectivity* was one of the first articles to divulge details on how healthcare organizations can implement point of care testing, and prevent errors that come along with that implementation. Preventing errors related to point of care testing is extremely important currently, as many tests are now being performed at the bedside, and the expansion of these tests is likely to continue in the healthcare climate of present times. Patients want fast but accurate care, and point of care testing provides fast test results for faster treatment.

Accrediting Agencies Involved with Improvement of Errors

There are several accrediting agencies worldwide, which focus on quality improvement and patient safety. Several are focused on the laboratory, while others are focused on healthcare organizations as a whole. These agencies are responsible for creating quality assurance programs for healthcare organizations to implement which are aimed at improving the patient experience, as well as reducing errors in all areas of patient care. These accrediting organizations are also

responsible for deeming healthcare organizations properly certified in order to receive reimbursement from Medicare and Medicaid. According to the article *A review of medical errors in laboratory diagnostics and where we are today,* written by Julie Hammerling,

> "In order for a health care organization to participate in and receive payment from Medicare or Medicaid programs, it must be certified as complying with the Conditions of Participation (CoP), or standards, set forth in federal regulations. This certification is based on a survey conducted by a state agency on behalf of CMS. However, if a national accrediting organization, such as The Joint Commission (TJC), formerly known as the Joint Commission on Accreditation of Health Care Organizations, has and enforces standards meeting the federal CoP, CMS may grant the accrediting organization "deeming" authority and "deem" each accredited health care organization as meeting the Medicare and Medicaid certification requirements. The health care organization is then considered to have "deemed status" and is not subject to the Medicare survey and certification process. Laboratories can also be accredited by the College of American Pathologists (CAP) and the Commission on Office Laboratory Accreditation (COLA), both of which also have deemed status with CMS (Hammerling 2015)."

Organizations which focus on healthcare organizations as a whole include, the Joint Commission on Healthcare Organizations and the Federal Drug Administration. Accrediting organizations which focus on the laboratory itself include the College of American Pathologists (CAP) and American Association of Blood Banking (AABB). Of these accrediting organizations, the two that are most involved in creating policies and procedures and quality assurance tracking and planning, are the Joint Commission and CAP. These organizations focus on improving the patient experience and overall care while in a healthcare setting by setting

certain goals that healthcare organizations must follow in order to become or remain certified, as well as creating workflow procedures which can be tracked to help identify areas where errors typically occur, so that they can be identified and researched to form a solution for reducing errors.

The Joint Commission enforces certain Patient Safety Goals, which are drafted to ensure that patients are receiving the best possible care, every time, with as little room for error as possible. Some of the Patient Safety Goals for 2017 are: Identify patients correctly using two identifiers at every interaction; Improve staff communication, which includes getting the right test results to the right staff member at the right time. These are the goals which directly relate to improving patient care by reducing errors. The Joint Commission also compiled a list of "do not use" abbreviations to reduce medication errors and errors in test ordering. This accrediting organization is committed to raising the bar of healthcare organizations and challenging them to provide the best care, from the most qualified personnel, every time. They do inspections of healthcare organizations every three years to ensure that all protocols are being followed, as well as examining new organizations to certify them.

The College of American Pathologists, or CAP, is an accrediting organization dedicated to the laboratory and ensuring that laboratory professionals are performing testing correctly and reporting out correct results on patients with minimal errors.

> "The College of American Pathologists (CAP) Laboratory Accreditation Program is an international program designed to improve patient safety by advancing the quality of pathology and laboratory services through education, standard setting, and ensuring

> laboratories meet or exceed regulatory requirements. More than 6,000 laboratories worldwide are CAP accredited (Hawkins 2012)."

They establish proficiency testing for laboratory employees to ensure that personnel and equipment are performing at optimal levels, they establish guidelines for laboratories to follow which include procedures to help reduce errors within the laboratory, and inspect laboratories to certify them and recertify them if already CAP certified. CAP also has established quality assurance and management techniques to reduce laboratory associated errors, as well as errors in patient identification. Together, the Joint Commission and CAP ensure that healthcare organizations perform the highest quality patient care by implementing strategies for all healthcare workers to adhere to so that patients receive the most appropriate care possible and by holding all healthcare organizations to the same high standard of patient care and satisfaction.

Technological Advances to Improve and Reduce Errors

Technology has played a major role in the reduction of medical errors, particularly in the last ten years. Electronic medical records, computerized ordering of tests, and state of the art equipment all have reduced errors in all of healthcare, but especially within the walls of the laboratory. Implementation of electronic medical records systems streamlines communication between the laboratory and other members of the healthcare team, by allowing each department to see the results in real time and allowing for proper documentation of critical values, patient identification, and delta checks on patient results. Many of the electronic medical records systems on the market currently have incorporated barcoded armbands, medications, blood products, etc., in order to reduce errors in patient identification. Many healthcare organizations have implemented barcoding systems in order to properly identify the patients, and the

computerized records systems link the barcoded patient armband to every test performed on that patient, and the system will also flag the user if the patient armband scanned does not match the record open on the computer system. According to the article *Effectiveness of barcoding for reducing patient specimen and laboratory testing identification errors: A laboratory medicine best practices systematic review and meta-analysis*, written by Susan R Snyder, Alessandra M Favoretto, James H Derzon, Robert H Christenson, Stephen E Kahn, Colleen S Shaw, Rich Ann Baetz, Diana Mass, Corinne R Fantz, Stephen S Raab, Milenko J Tanasijevic, and Edward B Liebow:

> "Electronic barcoding for identification of patients, specimens and laboratory testing is used to positively establish identification and link specimens and tests to a patient throughout the entire testing process including test ordering, specimen collection, analysis and test result reporting. Barcode scanners are used to confirm patient identity. Other options include barcoded patient wristbands, portable printers to generate labels at the bedside, and use of an interface with a computerized physician order entry (CPOE) system (Snyder, Favoretto, Derzon, Christenson, Kahn, Shaw… 2012)."

There have been many studies performed over the years tracing barcoding systems for patient identification, and every study performed has concluded that barcodes for patient identification reduce patient identification to almost a zero percent occurrence. However, this technology is not fool proof, and can still lead to errors. In the article *Patient misidentifications caused by errors in standard bar code technology*, written by Marion L. Snyder, Alexis Carter, Karen Jenkins, and Corinne R. Fantz, a study was conducted using barcoded patient armbands, and as many as three incorrect patient identifiers were generated from a single bar code. Some of the sources of errors were

identified as minor bar code imperfections, failure to control for bar code scanner resolution requirements, and less than optimal printed bar code orientation. Scanners that do not scan the barcode correctly on patient armbands could possibly transmit results to the wrong patient's medical record. The study the authors performed was mainly used with point of care testing, which is a huge source of error with severe implications if an error does occur, as the results transmit to the patient's medical record almost instantaneously after performing testing. While a barcode system for patient identification has greatly reduced the incidence of patient misidentification, healthcare workers should not become reliant completely on this technology to prevent errors in identification of patients. Common sense and communication are still the biggest steps in preventing patient misidentification in the health care setting.

Electronic medical records systems are becoming the norm in healthcare organizations in current times. These systems streamline patient care by making pertinent medical information easy to access by many healthcare providers. Most healthcare organizations have some sort of electronic medical records system in place, but organizations which operate for-profit or small, critical access hospitals may not have the extra funds needed to acquire and maintain these updated systems. These systems, while expensive at implementation, have proven to have financial benefits in the long term for the organizations that implement them. This is accomplished by streamlining the ordering of testing to reduce duplicate orders or ordering on incorrect patient charts, reducing the time spent charting which improves patient care and revenue by reforming the way patients are seen and how much time is spent with the patients.

These systems allow patients more access to their medical records, which allows them to become more proactive in their health care. These systems help to prevent errors by incorporating the aforementioned barcoding system for identification, medication dispensing, blood product transfusions, and other tests and procedures. These systems also frequently include a photo of the patient attached to the chart, which can help with identifying that the correct patient is receiving the correct care every time. Electronic medical records systems are not immune to errors though, as errors still do occur even with the implementation of these systems. Nursing staff and physicians could order testing on the incorrect patient's chart, especially if more than one record is opened at one time. Identification errors may still occur, as barcoding and electronics are not always the most reliable form of preventing errors. As technology becomes more advanced, these systems must be upgraded to keep up with the ever-changing updates, which could be discouraging to smaller organizations who do not want to allocate the funds needed to update these systems.

Considering the vast number of electronic records systems on the market presently, healthcare organizations must do thorough research to determine which one will be the best fit for their organization, which one will perform the way it needs to within the organization, and provide the most error prevention at the lowest possible cost. In the article titled *Reducing the frequency of errors in medicine using information technology,* written by David W. Bates, MD, MSC, Michael Cohen, MS, RPH, Lucian L. Leape, MD, J. Marc Overhage, MD, PHD, M. Michael Shabot, MD, and Thomas Sheridan, SCD,

> "The health care industry spends less on information technology than do most other information-intensive industries; in part as a result, the dream of system integration been realized in few organizations. For example, laboratory systems do not communicate directly with pharmacy systems. Even within medication systems, electronic links between parts of the system—prescribing, dispensing, and administering—typically do not exist today. Nonetheless, real and difficult issues are present in the implementation of information technology in health care, and simply writing a large check does not mean that an organization will necessarily get an outstanding information system, as many organizations have learned to their chagrin (Bates, et. al. 2001)"

Electronic medical records systems provide help to healthcare organizations in reducing errors, but as mentioned previously, they are not perfect, and all members of the healthcare team must be diligent in the prevention of medical errors by taking responsibility for their actions, communication between members of the healthcare staff, and meticulous detail to ensure that errors do not occur.

Integrated Workstations to reduce Errors in the Pre-Analytical Phase

Healthcare organizations have recognized the need for improvement of error prevention, particularly in the pre-analytical phase of the total testing process, therefore, new technology has been invented to target the pre-analytical phase. Pre-analytical robotic workstations, and automated phlebotomy tray systems have greatly reduced errors in the pre-analytical phase when implemented in healthcare organizations. One of the devices that some institutions have implemented is called an automatic tube labeler. The article titled *Pre-analytical workstations as*

a tool for reducing laboratory errors, written by Georgio da Rin, describes the tube labeler system:

> "The tube labeler is a device that:
>
> • Based on the test order from the LIS/HIS, automatically selects appropriate tubes from several hoppers,
>
> • Prints separate bar-coded labels for each tube,
>
> • Precisely applies the label to avoid difficulty in reading the bar code,
>
> • Places patient tubes into an appropriate container for each patient.
>
> The drudgery and danger involved in the manual blood tube preparation are thus being obviated (da Rin 2010)."

These systems also utilize the barcoded armband system for patient identification, as they are set up to ensure the scanning of the patient barcode, as well as the barcode for the tube set, much like medication distribution. The barcodes are connected via the interface, to ensure that the correct patient is being drawn for the correct testing. These systems must also duplicate the steps that humans would follow to accomplish the same outcome, as stated by da Rin:

> "Pre-analytical workstations must be able to duplicate actions carried out by people. The system must be able to identify the patient to whom a specimen belongs and which tests have been requested on that sample (da Rin 2010)."

Pre-analytical workstations are increasingly being utilized in healthcare organizations to further reduce errors in the pre-analytical phase of the total testing process. These systems

automate the steps taken in this phase to prepare the specimen for analysis. These systems utilize barcoded labels, which then separate the tubes based on which tests are to be performed, and delivers them to the appropriate department via a conveyor belt system. They also include centrifugation, specimen quality checks, and storage of specimens once testing has been completed. The different components of a pre-analytical workstation are as follows:

1. Sample specimen input area: This part of the system is where samples are loaded into the system. This part of the system can separate stat from routine, centrifuged from unspun, and different types of testing to make transport to the appropriate department more streamlined and accurate.

2. Sample identification: This part of the system utilizes barcoded labels to identify and scan each tube to determine which patient the testing is to be performed on, and what tests are to be performed on each tube. Some systems have multiple barcode readers placed throughout the system to ensure proper specimen tracking.

3. Tube types: These systems have racks that can handle all types of tube sizes and colors, but some tubes and stoppers require manual decapping and centrifugation.

4. Transport system: This part of the system contains conveyor belts which carry racks of tubes to the department that will be responsible for performing the testing on each tube.

5. Sorting or routing device: This part of the system scans each tube, and then sorts the tubes depending on tube size, department, test, etc., and places it in the appropriate rack. This part of the system works closely with the transport system.

6. Automated centrifuge: This part of the system contains an on-board centrifuge, where the system places tubes into the centrifuge for preparation to perform testing. Some systems require multiple centrifuges, as coagulation testing requires longer centrifugation at a higher RPM, and some tubes may need to be manually placed to ensure proper balancing of the centrifuge.

7. Level detection and evaluation of specimen adequacy (specimen integrity): This is a part of the automated system which checks each specimen for clots, hemolysis, icterus, lipemia and other interfering substances. Many chemistry analyzers measure hemolysis, icterus, and lipemia on board, but automatic transport systems have the capability to perform this testing as well. This section also detects the volume of each tube and can determine if the volume is appropriate for testing.

8. Decapping station: This is the section of the system which removes caps from the tubes in preparation for placement on the appropriate analyzer. There are some caps that require manual removal, however, including rubber stoppers and screw-on tops.

9. Aliquoter: This section removes the appropriate volume of specimen needed for an aliquot and places it in a labeled tube for testing. This section can also detect volume and notify the technologist whether there is adequate volume of specimen to perform add-on testing.

10. Interface to automated analyzer: This section connects to an automated analyzer, which performs testing on the appropriate specimens.

11. Specimen Delivery/Sorting: This section sorts tubes by size, test, etc., and places each tube into the appropriate storage rack after testing is completed.

12. Recapping station: This section recaps specimens after testing is completed, by either using heat-sealed plastic film, or foil. This is performed to prepare the specimens for storage.

13. Take-out stations: This section holds specimens while testing is being performed, and allows for technologists to remove specimens, either for repeat analysis or to prepare the tube to be sent to a reference lab if necessary. (Da Rin 2010)

These automated systems are becoming increasingly utilized in healthcare organizations, but are still not in use regularly due to the immense cost of installation and upkeep of such systems. Smaller organizations, and not-for-profit healthcare organizations may not be able to afford these types of automated systems. They also decrease the need for physical labor, and may decrease the demand for qualified technologists. Malfunctions in the system could cause errors to be made, as technology is not error-proof and machines are not invincible.

Communication Between Departments

When reviewing methods to decrease the occurrence of medical errors in a healthcare organization, it is important to review policies and procedures, as well as the technology used to identify patients and specimens, but one critically important step in reducing errors is communication between members of the healthcare team. A breakdown of communication in any stage of the total testing process could prove to be catastrophic to a patient's overall outcome. One way that healthcare organizations can improve communication is by following every step of the total testing process and determining those areas which rely the most on communication between both members of the laboratory and to the other departments responsible for the care of the patient. In the article *Reducing diagnostic errors through effective communication: Harnessing the power of information technology*, written by Hardeep Singh,

MD, MPH, Aanand Dinkar Naik, MD, Raghuram Rao, BA, and Laura Ann Petersen, MD, MPH, there are two forms of communication that must be focused on to improve communication among healthcare workers, interpersonal and informational communication. "Interpersonal communication is the verbal exchange of information between 2 individuals (e.g., physicians, patients, nurses, etc.). Informational communication, conversely, entails the processing and management of data such as notes in a chart, written instructions, laboratory values, imaging reports, or any aspect of data retrieved with an electronic chart system (Singh, Naik, Rao, Peterson 2008)." Both of these types of communication are vulnerable to communication breakdown, particularly in data gathering and the verification of a diagnosis.

Healthcare organizations have implemented procedures and information technology systems which alleviate the breakdown of communication based on the Institute of Medicine's recommendation to redesign and error-proof the healthcare delivery system (Singh 2008). One way to reduce errors in communication is by the use of electronic medical records, which has been discussed previously. These systems standardize result reporting for the entire healthcare organization, which allows for more seamless communication between departments. Another way that organizations are alleviating communication breakdown is by standardizing communication throughout the organization so that everyone is on the same page, so to speak, about what is happening with the patient. Another idea previously discussed is the implementation of a "Read-back" system, which means that any time an order, or abnormal laboratory results are relayed to a physician or nurse via phone, the recipient must read back the value or order so that it can be verified by the caller.

Some ways that communication may be alleviated in the data gathering step of formulating a diagnosis include the use of electronic medical records to fill in gaps of medical

information which could be missed by using paper charting, involving the patients in their own by allowing them to access their records and print off their medical history so that physicians have a full medical picture of the patient to aid in diagnosis, utilizing reminders in the system for certain diagnostic tests or orders to alleviate the problem of missed testing, communication between physicians via progress notes, and by linking the records of patients to many other organizations so that their records may be accessed by consulting physicians with ease. One issue with relying on electronic medical records, however, lies in the reminder section, which alerts physicians of abnormal lab values. In a system that does not filter out critical results, physicians may not acknowledge the values or acknowledge them without viewing them because of the volume of notifications they receive about every patient under their care. Therefore, a useful tool in improving this communication breakdown would be to allow users to filter the reminders, showing only those which are critical and require immediate attention. This leads into the ways that communication in the diagnosis verification process can be improved. Other ways which can improve communication of test results include: reporting results directly to the patient, although most physicians only prefer this method when test results are normal with no need of an immediate follow-up; several different ways of reporting results, including calling abnormal results directly to the physician, paging, and electronic delivery via the electronic medical record; and tracking consultations to identify patients who either never received a follow up consultation, or never showed up for scheduled appointments with the consulting physician (Singh 2008).

One area of the healthcare setting particularly reliant on accurate communication is the emergency department. This department is prone to errors, partly because of the lack of

communication between caregivers, and partly because of the need of quick and efficient care, which could lead to errors. The article titled *The potential for improved teamwork to reduce medical errors in the emergency department* states that, "a willingness to squarely face this problem of inherent human error and seek systematic solutions has been missing in the health care community (Risser 1999)." This quote inherently means that, as a healthcare community, healthcare workers are held to a higher standard of perfection, not only by the public, but by themselves. Errors are viewed as "mistakes", instead of simply accepting the fact that errors are bound to happen, because humans are not perfect.

The emergency department is of particular focus for communication breakdown, because any misstep in this department could be fatal for some patients, while just an inconvenience to others. By improving overall teamwork and communication among the emergency department, other departmental communication will improve as well. Most patients who are admitted into an inpatient hospital are seen through the emergency department first, so this is where the initial diagnosis and laboratory testing is performed to determine an appropriate treatment plan throughout their admittance and after discharge from the hospital. In a healthcare setting, particularly in the emergency department, there are many communication aspects which must be attained in order to provide the best care for the patient: a team structure, task prioritization, cross-monitoring (which is, in a nutshell, coworkers checking each other's work), and assertiveness (Risser 1999). Without these aspects of communication, a breakdown occurs and patient care suffers.

Team building exercises and training for all emergency department staff improves communication between coworkers, and improves patient care by providing each caregiver with

a safety net of support so that errors are less likely to occur. When more than one person is responsible for a patient, and orders, results, and diagnoses are double checked and sometimes triple-checked by members of the team, things are less likely to "slip through the cracks", which improves overall patient care. Risser's article compares the teamwork needed in the emergency department to that of an air traffic control team, in that everyone must be in sync and on the same page regarding each patient they treat, or else the patients begin to receive subpar medical care and may suffer from misdiagnoses, or poor treatment. Risser's article identifies the three types of errors that all healthcare workers are prone to making, in an effort to introduce them into the team work model to better educate healthcare workers on how to prevent errors by improving communication. These three types of errors are:

> "1. Slips-failures to properly adjust well-practiced tasks that require little conscious attention to the characteristics of a new situation (e.g., without thinking, ordering the adult dose of a medication for a pediatric patient). The slip is the common failure of the seasoned expert.
>
> 2. Lapses-failures of memory that cause tasks not to be done (e.g., forgetting which ankle is to be radiographed after leaving the bedside). The lapse is a common error for caregivers facing task overload or distraction.
>
> 3. Mistakes-the selection of incorrect actions caused by misclassifying a situation or failing to take into account all relevant factors in a decision (e.g., evaluating a patient for nausea, vomiting, and dehydration but failing to recognize new-onset diabetes as a likely cause). A mistake can occur whenever any caregiver's analytic processing activities are disturbed, disrupted, or missing key information; mistakes can be triggered by many

> factors, including personal stress, fatigue, task overload, environmental distractions, as well as a lack of clinical knowledge. Perfect execution of poor or inaccurate care plans distinguish mistakes from slips and lapses (Risser 1999)."

Communication is a commonly overlooked, but extremely important aspect of patient care and preventing medical errors. Healthcare organizations are increasingly recognizing the importance of communication skills in exemplary patient care, therefore they are introducing more procedures and continuing education programs dedicated to improving communication. Some organizations hold disaster drills for first responders and emergency department staff, as well as for staff of the ancillary departments (laboratory and radiology), to recognize breakdowns in communication which can be corrected in a controlled setting. These exercises also serve as team building exercises, to help coworkers work better together, both under pressure and in every day patient care settings.

Quality Indicators Used to Track and Improve Error Rates

Recently, some of the accrediting agencies for hospitals and laboratories have created quality indicators for tracking errors and implementing policies to prevent them from occurring. Specifically, the College of American Pathologists, or CAP, have been instrumental in quality indicators for laboratory operations. The Q-Tracks initiative was adopted in 1999 and is a voluntary quality initiative program designed to track, identify, and reduce errors which occur in relation to the laboratory. Specifically, the Q-Tracks program focuses on patient identification. The initiative relies heavily on phlebotomists and other laboratory personnel tracking and keeping records of any discrepancy in patient identification over a certain period of time, usually

between three months and one year. According to the article *Laboratory medicine quality indicators: A review of the literature,* written by Shahram Shahanigan and Susan Snyder,

> "A quality indicator is a tool that enables the user to quantify the quality of a selected aspect of care by comparing it with a criterion. A quality indicator may be defined as an objective measure that evaluates critical health care domains as defined by the IOM (patient safety, effectiveness, equity, patient-centeredness, timeliness, and efficiency), is based on evidence associated with those domains, and can be implemented in a consistent and comparable manner across settings and over time."

By definition, quality indicators are certain measureable criteria which can be tracked in order to create better policies and procedures to improve patient care. CAP's Q-tracks program is specific to laboratory medicine, and any quality indicator relating to the laboratory can be tied to any step of the total testing process, as long as the measure is reproducible, and as long as the measure is linked to one of the Institute of Medicine's health care domains (Shahanigan 2009).

The Institute of Medicine has implemented certain health care domains to determine the importance of quality indicators. These are grouped into three areas: importance, scientific soundness, and feasibility. In the importance category, there are several criteria, including the relevance to stakeholders, importance to health, equitable distribution, improvement potential, and health care system development. In the scientific soundness category, there are more criteria, which include clinical logic, and measure properties, which include reproducibility. In the final category, which is feasibility, the categories include explicit specification and data availability (Shahanigan 2009). Indicators involving the laboratory focus more on testing itself, however, there are indicators in place to track patient identification, appropriateness of testing ordered,

patient satisfaction with phlebotomy procedures, specimen rejection and rationale behind the rejection, blood culture contamination, specimen container informational errors, proficiency testing performance, inpatient laboratory result availability, corrected reports, critical value reporting, turnaround time, and physician satisfaction with laboratory services (Shahanigan 2009).

The indicators involved with the pre-analytical phase of testing include patient identification, appropriateness of testing ordered, specimen rejection, blood culture contamination, and specimen container informational errors. The first indicator discussed will be patient identification, which monitors patients who are missing an armband, or have the incorrect band on their arm, illegible, or conflicting armbands. The reason behind this indicator is simple: to ensure that laboratory professionals are performing the correct testing on the correct patient, every time.

The next indicator is the appropriateness of the testing ordered on each patient. The purpose behind this indicator is to ensure that the correct testing is performed on patients based on what disease processes they may already have, or what their physicians want to screen for based on risk factors, family history, etc. This indicator is also useful in reducing unnecessary, duplicate, or wasteful testing. Preventing unnecessary testing not only saves the hospital's resources, but also saves the patient money.

The next indicator used that directly involves the pre-analytical phase of the total testing process, is specimen rejection. Accurate laboratory results rely on ensuring the specimens are drawn correctly, in the correct tubes, with absence of hemolysis. This indicator allows healthcare organizations to track the reasons that specimens are rejected, figure out which departments have

the highest rejection rates, and implement continuing education and in-service programs if needed. Another indicator which goes hand in hand with specimen rejection is specimen collection informational errors. This indicator covers specimens that are rejected based on incorrect, inadequate, or illegible information on the label of the specimen.

The final quality indicator discussed which involves the pre-analytical phase of testing is blood culture contamination. This indicator monitors the number of blood cultures that come back positive for bacteria considered a contaminant and not a pathogen. Blood culture contamination is harmful for patients, not only because of unnecessary use of potent antibiotics, but also because it prolongs hospital stays, courses of treatment, and forces unnecessary additional testing. It also puts physicians in a difficult place, forcing them to choose between conservative treatment or ignoring a diagnosis that could possibly be life-threatening for the patients. Use of this indicator can lead the laboratory to what departments, or specific person, has the highest contamination rate, and re-train them on the proper procedure to draw blood cultures (Shahanigan 2009).

Quality indicators involving the analytical phase of testing is not quite as all-encompassing as it is for the pre-analytical and post-analytical phases of the total testing process, as this phase is more difficult to track and also has the smallest percentage of errors involving the laboratory. The main quality indicator for this phase is proficiency testing performance. Proficiency testing is shipped to laboratories from accrediting agencies (CAP, API, etc.), and the purpose of these tests is to compare results to the results that the accrediting agency has reached for certain tests. These tests are to be performed as if they are patients in the healthcare organization. By monitoring these proficiency tests, the competency of the laboratory, as well as the reproducibility of results by the laboratory equipment is checked (Shahanigan 2009).

Quality indicators that involve the post-analytic phase of the total testing process include the availability of laboratory inpatient results, corrected laboratory reports, the reporting of critical alert values, turnaround time, and clinician satisfaction with laboratory services. The first indicator, the availability of inpatient results, measures the percentage of results that are available for morning rounds. This indicator is organization-specific, as all hospitals have different policies on when morning labs are drawn and when doctors perform rounds. This indicator is important because if results are not available for the physicians when they are doing their morning rounds, the length of stay for some patients could be extended unnecessarily.

Another factor that is measured by quality indicators in the post-analytical phase of testing is corrected laboratory reports. This measure is used to determine the frequency of corrected reports, and to determine the rationale in each one and how it could have been prevented. Corrected reports in the laboratory consist of results that have been posted to the chart, but for one reason or another, must be altered or corrected to enter the correct results. Usually, corrected reports occur because of a few different reasons. The first, and probably most common, is the releasing of results by mistake, either before all testing is completed, or releasing a result that must be diluted to get an accurate results. The next common reason for corrected reports is incorrect results being posted to the chart because of patient misidentification. Whichever reason is given for a corrected laboratory report, it is considered an error in the post-analytical phase of the total testing process, therefore they must be tracked to determine ways to prevent the errors from happening again (Shahanigan 2009).

Another indicator used in the post-analytical phase of testing involves the reporting of critical laboratory results to the physician. Critical values are those laboratory tests that could cause harm to the patient if not addressed immediately. While

there is no uniform list of critical values, as it varies because of different instrumentation and by organization, the time in which it takes to report those values deemed to be critical alerts is, for the most part, uniform across all healthcare organizations. CLIA, which is the Clinical Laboratory Improvement Amendments, and the Joint Commission both have regulations regarding the reporting of critical values. Reporting these values in a timely manner is extremely important because the majority of these results would result in a change in the patient's course of treatment, and could be detrimental to the patient if the physicians were not made aware of them in a manner that ensures they understand and acknowledge the results being reported (Shahanigan 2009). According to the article *Reducing the frequency of errors in medicine using information technology,* written by David W. Bates, MD, MSc Michael Cohen, MS, RPh Lucian L. Leape, MD, J. Marc Overhage, MD, PhD, M. Michael Shabot, MD, and Thomas Sheridan, ScD, physician responses to critical laboratory values were improved greatly by initiating a wireless paging system for reporting the values, either by a pager or another wireless device.

Another quality indicator used to measure the processes of the post-analytical phase of the total testing process is turnaround time, or TAT. Turnaround time is defined as the time it takes from specimen receipt into the laboratory until results are reported to the patient's chart. Timely access to laboratory results can allow for shorter lengths of stay for people being seen in the emergency department, and may also affect patients admitted as inpatients, although there is not much correlation between shorter turnaround times and better patient care (Shahanigan 2009). According to the article, *Errors in Pathology and Laboratory Medicine: Consequences and Prevention,* written by Sandra Hollensead, William Lockwood, and Ronald Elin, "TAT of results becomes an important

> factor in patient care, when the effect of delayed test results is studied. According to JCAHO in a Sentinel Event Alert delayed test results is the second most common reason for treatment delay (Hollensead, et. al. 2004)."

Another quality indicator which correlates to the post-analytical phase is clinician satisfaction with laboratory services. While this may not seem like an important indicator of quality, the article *Laboratory medicine quality indicators: A review of the literature,* explains that: "The lowest satisfaction scores have been related to poor communication, including timely reporting, communication of relevant information, and notification of significant abnormal results (Shahanigan 2009)." When clinicians are satisfied with the services that the laboratory provides, it is an indicator that there is adequate communication regarding laboratory results between the laboratory and the clinicians. As mentioned previously, adequate communication is one of the biggest hurdles to preventing medical errors, especially when it relates to laboratory results and, especially, with reporting critical laboratory values to the clinicians.

While there are many indicators of quality which pertain to the laboratory, there are still gaps in determining quality indicators for some of the most common sources of error. Shahanigan explains:

> "Because there are so many processes involved in laboratory testing, there is considerable challenge in identifying, defining, and, ultimately, implementing indicators that cover the various stages of the total laboratory testing process, in general and specific to different diseases and conditions, that address the IOM domains, various testing environments, and multiple relevant stakeholders. We did not present any review of quality indicators for some steps in the laboratory testing process such as specimen receipt, log in, and

> processing, even though they are frequent sources of errors, because metrics for assessing these steps have not been well defined and standardized, and published laboratory literature has not evaluated these steps in multi-institutional settings (Shahanigan 2009)."

Workflows in the laboratory are more easily tracked presently than in the past, partly because of the increase in technology used to track information, but the process of pinpointing processes in the laboratory which are prone to errors and also developing procedures and policies and improved workflow techniques is the most difficult aspect of error prevention in the laboratory. With the many steps involved in obtaining test results, and the variety of personnel involved in the direct and indirect care of patients, laboratory errors are historically more difficult to trace. CAP has greatly improved the amount of quality indicators used to trace laboratory processes, to better ensure that errors are prevented.

One of the main Q-Tracks initiatives implemented by CAP is tracing patient identification processes by tracing patient wristband errors. Q-Tracks were implemented in 1999, about ten years after the Q-Probes initiative was implemented. Q-Probes was a one-time assessment of laboratory practices, while Q-Tracks is an ongoing investigation over a period of time to determine error frequency (Howanitz 2002). The purpose of the Q-Tracks program is not only to identify and track errors in the laboratory, but to identify the top performers in error prevention and allow them to offer input to other facilities on how to further improve their error rates.

Conclusion

As discussed, medical errors are a major concern for all healthcare organizations, especially in present times when patients are becoming more educated and involved in their care.

Errors have been greatly reduced with increased technology, quality indicators, policies, and procedures directed at tracking and preventing errors. There is still room to improve, however, and as technology advances even further, more unforeseen issues will inevitably arise to be corrected.

As mentioned previously, most errors involving the laboratory occur in the pre-analytical phase, and more specifically, the pre-pre-analytical phase of the total testing process. This area of the total testing process has been the primary focus for quality indicators, policies, and procedures, as this phase includes patient identification, ordering of tests, and collections of tests, which are all the most significant sources of errors. Through these initiatives, errors have been reduced in this phase to almost zero percent, but because of the human error factor, errors in the medical field will never be completely eliminated. Through increased technology, such as phlebotomy automated systems, which generate tubes and labels corresponding with each patient's orders, complete with barcode systems to ensure proper identification, this phase has seen the most improvement in reduction of errors. Other systems that assist in error reduction are fully automated specimen processing and analysis systems, which assist with all phases of the total testing process, and electronic medical records systems to integrate all areas of patient care to streamline the process. These systems utilize barcoded armbands, medications, specimen labels, etc. to confirm patient identity and to track each specimen from collection until results are posted to the patient's medical record.

The analytical phase has always been the phase with the least amount of errors, but it has also been more difficult to track this phase, as it relies heavily on the pre-analytical phase to ensure proper analysis of each specimen. It is difficult to determine whether an error is directly analytical, or if it stems from the pre-analytical phase. Increased technology, strict quality control

and calibration procedures, and highly trained personnel are all factors that have contributed to the analytical phase remaining almost error free. Errors that occur in this phase are generally due to instrument malfunctions, such as quality control failure, calibration errors, or maintenance errors. Generally, errors in this phase are difficult to pinpoint because if results correlate with the patient's previous values or disease process, personnel will most likely not recognize that an error has occurred. More policies and procedures have been implemented, mainly by the College of American Pathologists, or CAP, to target this phase of the total testing process and ensure that every specimen analyzed is done so correctly.

The post analytical phase of testing involves the reporting of results to the patient's chart, reporting critical laboratory values directly to the clinicians, and the course of treatment that is determined from results received. For the most part, this phase of the total testing process is out of the laboratory's hands, once results are released to the chart, it is up to the clinicians to determine a course of treatment for the patient. Errors that occur in this phase include corrected reports in the case that incorrect results are reported, the calling of critical alert values to the physician, and the turnaround time of specimens. Corrected reports occur when incorrect results, either by analyzing the wrong patient, results entered incorrectly, or results released before all testing is completed. Quality indicators have tracked corrected reports to determine the root cause of them, and how to prevent them from happening, because if incorrect results are posted to the chart, the patient could be treated for an incorrect diagnosis, which could cause harm to the patient. The calling of critical values is also a main contributor to errors in this phase, not because of lack of the laboratory contacted the clinicians, but because of delayed treatment due to physicians not receiving the results or misinterpreting the results when they are called with them. Critical laboratory values vary somewhat depending on the organization, but the principle

of calling them in a timely manner is regulated by the Joint Commission and the organizations themselves. New technology has been implemented to assist in assuring the results reach the physicians in a timely manner, including messaging systems within the electronic medical record, and paging the physician with the value so that they are guaranteed to receive it. Turnaround time is another indicator of the post-analytical phase of the total testing process, which is the time it takes for a laboratory to process and analyze a specimen once it is received into the laboratory. This indicator is another that varies by organization, but the timely analysis and release of laboratory results so that clinicians may make decisions on a patient's treatment is universal throughout every healthcare organization.

A section of laboratory medicine that is fairly new, but becoming more popular, is point of care testing. Point of care testing is the testing of a patient's blood or other body fluid at or near the patient's bedside. It came to fruition as a way to eliminate errors that can occur from the time the patient is identified, until the specimen is received into the laboratory. Another reason for its popularity is the instant posting of results to the patient's chart, to allow for more expedited treatment plans. The main downfall of point of care testing, however, is the margin of error involved. There is less room for discovering errors before the results are charted, therefore the amount of errors is greatly increased when utilizing point of care testing. Also, there are some analytes that cannot be analyzed with point of care testing or are not as accurate when using point of care equipment. This can lead to incorrect diagnosis and treatment, and possibly injury for the patient as well. Gerald Kost created a model for reducing errors in point of care testing in 2002, and it was intended to be utilized by healthcare organizations, as well as the manufacturers of the equipment. It covered everything from personnel training, quality control and calibration, equipment malfunction, patient identification, and emergency situations. He was

the pioneer, so to speak, on error reduction in this new but rapidly evolving form of patient testing and diagnosis.

In order to help eliminate the errors involving patient identification, technology has evolved to utilize barcoded armbands, medications, blood products, and specimen labels to ensure that the right testing is performed on the correct patient every time. Barcode technology is becoming norm in healthcare organizations, and they have greatly reduced the amount of errors that occur with patient identification, but even the barcode technology has its flaws. Barcodes can read incorrectly with the scanner, which can cause results to report to the incorrect patient in the medical records system. Even with barcoded technology, personnel collecting specimens from patients for laboratory analysis must be properly trained on patient identification procedures and be diligent about checking armbands and asking patients to confirm their identity to ensure that errors do not occur.

Automated systems designed to streamline the workflows of specimen collection, analysis, and result reporting have been developed over the past few years. Automated phlebotomy systems create labels, assemble tubes, and barcode bags to ensure that every test is drawn in the correct tube, from the correct patient. These systems pull tubes for each test ordered and separate them by patient, which is designed to ensure that patient identification, collection, and transport are all performed in the correct manner to eliminate errors. Automated systems in the laboratory consisting of barcode scanners, track systems to transport specimens to the intended department, centrifuges, specimen examiners, and sorting have been implemented in larger healthcare organizations to streamline the pre-analytical, analytical, and post-analytical phases of the total testing process. These systems are convenient, but not perfect, and still may involve personnel intervention. These technological advances have reduced errors in the

laboratory, but have not eliminated them completely. These technologies are also inaccessible for smaller organizations because of the cost of implementation, which makes them a sort of luxury instead of necessity.

Another aspect to be considered when examining the prevention of errors is communication among each department involved in the direct care of every patient. Errors occur most often in steps that involve communication, including identification, ordering of tests, and calling critical alert values to the clinician. Healthcare organizations have acknowledged communication breakdown as a major contributor to medical errors, and have thereby introduced team building exercises, courses on improving communication, and policies involving acknowledging critical alert values. The emergency department is one of the main departments of a hospital where a communication breakdown could mean the difference in life or death for a patient. This area of the hospital is the point that the majority of patients have initial contact with the healthcare organization, so the prevention of errors in the emergency department is of extreme importance.

Many organizations responsible for accrediting healthcare organizations have become directly involved with error prevention. The Joint Commission has established patient safety goals, which include proper patient identification and communication between departments, more specifically, the “read back” system for taking verbal orders or for communicating critical laboratory values to the physician. The College of American Pathologists, or CAP, is specific to the laboratory and has implemented quality indicators and programs to ensure error prevention in the laboratory. Q-Probes and Q-Tracks are two initiatives created to track and improve error rates in the laboratory by tracking certain aspects of the total testing process to determine where errors occur, and to create procedures to reduce these errors. Q-Probes are a one-time

investigation, while Q-tracks are a long term investigation designed to identify the top performers in areas where errors are common, and allow them to provide input to other organizations to assist them in improving their workflows to ensure patient safety and elimination of errors. There are other accrediting organizations, such as the FDA and AABB, but the Joint Commission and CAP are the two main agencies directly involved with the reduction of medical errors.

Errors in medicine will forever be an issue, but steps have been taken to reduce the error rate enough to make patients feel safe seeking medical care. Patients are a healthcare organization's number one priority, so ensuring that every patient is receiving the most optimum care possible is of utmost importance. Examining every step of the total testing process is essential in providing the most accurate information possible to identify and prevent errors from occurring. With patients becoming more involved in their care and more diligent on their treatment plans, it is more important than ever to reduce errors in medicine and, more specifically, in the laboratory. Laboratory results account for sixty to seventy percent of medical decisions made regarding medication, diagnosis of disease, and treatment plans up to and after discharge from the hospital, so the focus on laboratory processes and procedures is of utmost importance to ensuring that patients receive the care they need for their diagnosis. Healthcare organizations must take an all-encompassing approach to error prevention, by integrating technological advances, electronic medical records systems, communication among departments regarding specimen collection and laboratory results, and ensuring that their policies and procedures correlate with the accrediting agencies' definitions of patient safety and error prevention. Focus should be placed on the pre- and post-analytical phases of the total testing process, as these phases encompass the majority of errors involving the laboratory. The pre-

analytical phase is arguably the most important phase for preventing errors, as it includes patient identification. Every step of the process is thrown off if a patient is identified incorrectly, and an incorrect identification could cause serious injury or even death if not prevented. The pre-analytical phase also includes specimen collection and transport, which are imperative to obtaining the correct results, as an incorrect collection or problem in transportation of specimens to the laboratory can cause patients to endure unnecessary procedures, such as repeat venipuncture or specimen collection, and can also delay results being reported to the clinician. If a patient is critical, time is of the essence in saving their life, and any delay in testing could prove to be detrimental to the outcome of the patient. Errors in medicine will never be eliminated completely, because of human error as well as mechanical error, but healthcare organizations are making significant strides to reduce these errors as much as possible to ensure optimum patient care. With reimbursement rates reliant on patient satisfaction, error prevention is of utmost importance, not only to the outcome of the patient, but to the success of a healthcare organization. Considering the obstacles of determining methods to prevent errors, these organizations and the accrediting organizations responsible for assuring their reimbursement status, strides have been made over the past ten years. As long as healthcare organizations continue to track all aspects of patient care, and more specifically the total testing process, error prevention will continue to be at the forefront of the success of healthcare organizations around the world.

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