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SPECIMEN LABELING IMPROVEMENT PROJECT: SLIP

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Table of Contents

Abstract

Blood specimens are labeled at the time of acquisition in order to identify and match the specimen, label, and order to the patient. While the labeling process is not new, it is frequently laden with errors (Brown, Smith, & Sherfy, 2011). Wrong blood in tube (WBIT) poses significant risk. Multiple factors contribute to mislabeling errors, including lax policies, limited technological solutions, decentralized labeling processes, multi-tasking, distraction from the clinician, and insufficient education and training of staff. To reduce blood specimen labeling errors, a large academic medical center implemented an innovative technological solution for specimen labeling that integrates patient identification, physician order, and laboratory specimen identification through barcode technology that interfaces with the electronic medical record at the point of care. A failure mode, effects and critical analysis (FMECA) were completed to assess for system failure points, and to design workflow prior to training staff. Four failure points were identified and eliminated through workflow adjustments with the new system. Staff training utilizing simulation highlighted system safety points. This quality improvement process applied across adult and pediatric acute and critical care units provided dramatic reductions in blood specimen labeling errors pre/post intervention.

Keywords: specimen labeling, error, failure modes, effects and critical analysis, (FMECA), simulation, wrong blood in tube (WBIT), patient safety.

Specimen Labeling Improvement Project: SLIP

Blood specimens are labeled at the time of acquisition in order to identify and match the specimen, label, and order to the patient. While the labeling process is not new, it is frequently laden with errors (Brown, Smith, & Sherfy, 2011). Multiple factors contribute to mislabeling errors, including lax policies, limited technological solutions, multi-tasking/distraction from the clinician, and insufficient education and training of staff. Technological advances to support blood specimen labeling are expensive and have not been widely implemented. The potential consequences of a mislabeled specimen include misdiagnosis, potential miss-transfusion, patient discomfort in obtaining a new specimen, delays in treatment, and poor utilization of expensive resources.

Among the most serious labeling errors is wrong blood in tube (WBIT). Mislabeling pre-blood transfusion specimens, resulting in WBIT, is an international practice issue and well documented in the literature to be the most common cause of an adverse blood transfusion reaction (Ansari & Szallasi, 2011). WBIT is usually discovered when a patient's blood sample is found to have an ABO/Rh type that does not match the ABO/Rh type in that person's historic Blood Bank file. According to the 2011 National Blood Collection and Utilization Survey Report (2011), hospitals reported 182,000 sample collection errors. Of these errors, 5,747 were WBIT errors (3.2% of sample collection errors) (2011 NBCUS Report, 2011).

In various settings, a number of process improvement measures have been implemented in an effort to reduce mislabeling errors specifically for specimens' utilized pre-blood transfusion. The most frequently reported interventions to reduce specimen-labeling error are strict policies (in clinical setting and Blood Bank), education, and two person checks. However, these interventions have not resulted in the elimination of error. The persistence of error is

attributed primarily to human factors (Rees, Stevens, Mikelsons, & Darcy, 2012). Those facilities that have automated the process of patient identification (barcoding) with label printers at the bedside, integrating physician order entry, have experienced the most significant reduction in labeling error. Brown et al. (2011) reports a "label error reduction from 103 to 8 per year ($p<.001$)" with implementation of barcode technology and bedside printers (p.13).

Consistent with reports of specimen labeling error in the literature, blood specimen labeling errors are prevalent at one large academic medical center (medical center). Efforts to reduce mislabeled specimens by means of sharing error data with management have not achieved desired results. Implementation of strict policies with accountability, education of clinicians, technology at the point of care, and systems approaches to reduce labeling error is all strategies supported in the literature (Evanovitch, 2012). A specimen labeling improvement project (SLIP) was undertaken at the medical center utilizing known strategies for reducing blood specimen mislabeling with implementation of an innovative point of care specimen collection management system (SCMS) integrated with a broader laboratory information system (LIS).

Background Knowledge

The setting for this project is a large (700+ bed), non-profit, tertiary/quaternary academic medical center located on the West Coast, adjacent to medical, nursing and dental schools. The patient population is diverse and complex. Laboratory tests approximate on average 448,000 tests per month. Blood transfusions approximate 27,000 units of blood per year and each patient must be typed and cross-matched to receive a unit of blood (Laboratory Medical Director, personal communication, August 28, 2014). In 2012, an electronic medical record (EMR) was implemented across the medical center that includes physician order entry (CPOE) and barcode technology for medication administration. At the time of the EMR rollout, the Laboratory did

not have an information system that interfaced with the EMR. Integration of laboratory information was thought to be critical, not only for access to patient laboratory values but also because all pre-analytic blood specimen processes were manual, requiring paper requisitions and generic handwritten or centrally printed labels. Subsequently, the Laboratory implemented a new Laboratory Information System (LIS) with interface to the EMR. Included in the LIS was a software system providing the ability to integrate a provider order for specimens with patient identification, as well as specimen label printing at the point of care. Prior to the LIS, Blood Bank and Laboratory medical directors would send error data to nurse managers, encouraging them to follow-up with staff on accurate specimen labeling. Initially, senior nurse leaders were not included in the specimen label error data distribution and therefore, were not aware of the issue, or the challenges experienced by staff to label specimens correctly.

According to the Federal Drug Administration (FDA) report on Fatalities Following Blood Collection and Transfusion (2012), the blood supply is safer today than at any time in history due to advances in donor screening, improved testing, automated data systems, and changes in transfusion medicine practices (FDA, 2012). Yet, a patient is more likely to have an adverse blood transfusion reaction related to a mislabeled specimen (WBIT) than a viral infection (Dzik et al., 2003; Brown, Smith, & Sherfy, 2011). In fiscal year 2012, two of the 65 total transfusion-related deaths reported to the FDA were attributed to labeling errors (FDA, 2012). Institutions that measure their WBIT rates have reported that mislabeled specimens account for their highest error rate and these errors are most commonly detected in the laboratory. Type and cross match blood specimens are compared to a patient's previous documented blood type to ascertain a match. According to Ansari and Szallasi (2011), the estimated "raw" WBIT rate published in the literature is 1:2262 samples (p. 298). The reported

rate of 1:2262 samples is a reduction based on an international study conducted in 2003 reporting that 1 in every 165 samples was mislabeled (Dzik et al., 2003). Tondon et al. (2010) conducted a prospective data analysis and found that blood sample labeling errors were due to failure to label at the bedside or labeling two or more samples at the same time by the same phlebotomist. The authors proposed a strict policy of rejecting any mislabeled specimen (Tondon, Pandey, Mickey, & Chaudhary, 2010). This approach does not account for those patients that have not been previously transfused and therefore may not have a documented blood type for lab to recognize a mislabeled specimen (WBIT). Vuk et al. (2014) report "silent WBIT cases" are unrecognized when two donors have the same blood type during cross match (p. 1201). Dzik et al. (2008) proposed a statistical process control (SPC) method as a means to reduce labeling errors through use of data control charts. A similar approach was attempted without success at the medical center.

The PROBE-TM study (2007) attempted to utilize a simple intervention in the form of a barrier-warning label on blood bags reminding staff to check the patient's wristband prior to transfusion. The investigators concluded that this approach did not improve patient identification but suggested the robust study design could be applied to investigate other interventions (Murphy et al., 2007). The most promising method for reducing blood sample labeling errors was reported by Brown et al. (2011) utilizing barcode technology, order integration and bedside printers. The authors noted a statistically significant reduction in number of labeling errors, from103 to eight per year ($p<.001$) (p. 13). Although this technology is expensive, most medical centers moving to an EMR have either implemented or plan to implement barcode technology for medication administration. Barcode technology for patient

identification and bedside printers for specimen labels could significantly reduce WBIT errors and other blood specimen label errors.

Technology and methods to reduce labeling errors has not caught up to the safety of the blood itself. Understanding and reducing human factor error in the clinical setting through the use of education, policy and technology is essential to eliminating labeling error and reducing the possibility of an ABO incompatible transfusion, which can result in significant morbidity and mortality. According to Reason (2000), "the basic premise in the system approach is that humans are fallible and errors are to be expected, even in the best organizations. Errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in 'upstream' systemic factors" (Reason, 2000, p. 768).

Local Problem

The process for labeling specimens at the medical center following implementation of an EMR, but prior to the SLIP project, was laborious and carried with it a high risk for error. Specimen labeling errors occurred with all specimen types. For the purposes of this project, the focus was specific to blood specimens. A clinician would obtain an order for a blood specimen, pick up the paper requisition from the printer (mixed in with other requisitions) at the central station, gather phlebotomy supplies (tubes, needles, tourniquet) and go to the patient room in order to obtain a blood specimen. Labels were obtained at the central desk (mixed with other labels) after the specimen was drawn. Distraction, label mix-ups, wrong requisitions, and lack of proper identification of the patient could all contribute to labeling errors. The Joint Commission's number one National Patient Safety Goal for 2014 continues to be "reliably identify the patient", "use at least two patient identifiers when collecting blood samples and other specimens", and "label containers used for blood and other specimens in the presence of the

patient" (The Joint Commission, 2014, p. 1). Additionally, in a study at University of Wisconsin, Rees et al. (2012) found that one frequently occurring specimen labeling error had to do with obtaining labels from a department printer rather than at the bedside, resulting in staff picking up labels for the wrong patient. The labeling system at the medical center seemed designed to ignore the Joint Commission standards and to replicate errors found in another large academic medical center.

Blood Bank and Laboratory have been acutely aware of specimen labeling errors. Incident report data reviewed at nurse quality meetings highlighted labeling errors. When the Chief Nursing Officer became aware of the problem she sent out several memos to all nursing staff outlining the important steps of labeling correctly. Label error criteria were categorized by Blood Bank (see Figure 1.0 – Blood Bank Error Criteria).

Figure 1.0. Blood Bank Error Criteria

Category	Errors Included
Near Miss Specimen Errors **Includes serious specimen errors, which could potentially lead to issuing a wrong unit of blood to a patient. These include the following types of errors:**	1. **Wrong Blood in Tube – Usually discovered when a patient's sample is found to have an ABO/Rh type that does not match the ABO/Rh type in that patient's historic Blood Bank file.** 2. **Discrepancy between patient information (name and MRN) on specimen and requisition.** 3. **Patient information on specimen is incorrect or missing** 4. **Patient information on requisition is incorrect or missing** 5. **Unlabeled**

Specimen Collection Problems

Includes other types of specimen problems, which prevent Blood Bank from testing a sample. These specimen problems require the patient to be drawn again and take up extra nursing and Blood Bank staff time to manage.

1. **Unsigned specimens – per AABB Standards (CA law) Blood Bank must be able to identify the individual who drew the sample. Thus Blood Bank requires all samples to have legible name/signature of phlebotomist (or 5 digit MD #).**
2. **Hemolyzed specimens**
3. **Phlebotomist signature on tube is illegible**
4. **Requisition missing**
5. **Quantity Not Sufficient (QNS)**
6. **No specimen**
7. **Wrong tube type**
8. **Empty tube**
9. **Other (i.e. date of draw missing, Draw Date/Time the same for 2nd ABO/Rh sample, diluted with saline, spillage)**

(Medical Center Transfusion Medicine, 2012).

In 2013, there were 117 near miss labeling events and 612 collection problems (see Appendices A and B-Blood Bank Specimen Labeling Errors and Collection Errors 2011-2013).

Unlike Blood Bank, Laboratory blood specimen-labeling error data is not separated into the same categories (near miss and collection). On average, 88 blood specimen-labeling errors are noted by Laboratory each month (Communication from Laboratory Medical Director, August 2014) (see Appendix C - Laboratory Specimen Labeling Errors Jan. 2013 to June 2013). Time to correct an error was estimated at a minimum of one and a half hours (30-40 minutes Laboratory personnel and one hour for Nursing personnel).

Errors in labeling specimens have never been an accepted practice but the magnitude of the problem was never fully appreciated until implementation of an EMR and LIS. With WBIT occurrences increasing, Transfusion Medicine led the way in insisting on improvement measures in specimen labeling, knowing the risk of a wrong blood transfusion and associated morbidity and mortality. Additionally, a clinical nurse specialist assigned as a category manager for the incident report system for blood transfusion alerted senior nursing leadership to the details of the mislabeling problem, prompting the nursing leadership into action.

Intended Improvement/Purpose of Change

The goal of this project was to reduce specimen-labeling error by replacing the manual specimen collection workflow, which included the necessity of printing labels and a paper requisition for each test at a central station and providing in its place a system for positive patient identification through barcoding and order matching. Plans had been in place to implement a SCMS for several years. However, due to limitations in technology, in the Laboratory and prior to an EMR, the project was placed on hold. The project was re-ignited when the increase in the medical center's WBIT errors were brought to light, as patient safety is paramount for the organization. Implementation of a SCMS is not widespread in health care due to cost and complexity but has shown impressive results in specimen labeling error reduction (Morrison et al., 2010).

In 2001, "The Institute of Medicine issued a report, *Crossing the Quality Chasm: A New Health System for the 21st Century,* which outlines six overarching "Aims for Improvement" for health care:

Safe: Avoid injuries to patients from the care that is intended to help them.

Effective: Match care to science; avoid overuse of ineffective care and underuse of effective care.

Patient-Centered: Honor the individual and respect choice.

Timely: Reduce waiting for both patients and those who give care.

Efficient: Reduce waste.

Equitable: Close racial and ethnic gaps in health status." (IHI, 2014, p. 1).

Based on the overarching aims for healthcare, the AIM statement for this project is to reduce specimen-labeling errors in blood specimens drawn in acute and critical care by 50% in nine months. The new SCMS technology and specimen labeling workflow was piloted on one acute

care adult unit and one acute care pediatric unit to determine if the technology, workflow, and education of staff was operational and effective in reducing blood specimen labeling errors.

Review of the Evidence

Prior to implementing an error reduction strategy for specimen labeling, it is important to examine the evidence nationally and internationally, asking the question "What strategies reduce blood specimen labeling errors in acute care/critical care settings?" A comprehensive literature search of PubMed, CINAHL, and EMBASE was conducted, followed by an analysis of the words contained in the titles and abstracts of the published studies, as well as the index terms used to describe the article. Reference lists of all studies were searched for additional studies not previously identified. Only English language studies from 2000 to 2014 were considered for inclusion. Of note, the literature search did not surface any randomized controlled studies (see Appendix D – Evidence Table: Specimen Labeling Error).

Cottrell et al. (2013) "conducted a systematic review addressing the issue of WBIT" (p. 197). Nine studies were eligible for inclusion and no randomized controlled trials were eligible (p. 199). The investigators found the incidence of WBIT was studied extensively, with a finding of WBIT in 1:1,500 to 1:3,000 samples. After a thorough review, all interventions to reduce WBIT were successful to some degree and multiple interventions over time were more likely to sustain a reduction in WBIT, though the duration of the reduction was unclear. Positive patient identification, "zero tolerance" policies, education, weekly feedback, second check of ID, and electronic transfusion systems were found to be effective, individually and/or in combination (Cottrell et al., 2013).

A one-year prospective study conducted by Elhence et al. (2012) in the Department of Transfusion Medicine at a large tertiary academic medical center in India tracked all near-miss

and adverse events in the transfusion process and found that of the 285 transfusion related events, 271 (95%) were near-miss events. Of those events, 53% were patient sampling errors, labeling errors, blood component handling errors, and storage errors. Nine of these errors resulted in WBIT and were associated with collection of two or more samples from the same ward (Elhence, Shenoy, Verma, & Sachan, 2012).

An extensive analysis of laboratory event reports in 30 health care organizations studied by Syndman et al. (2014) found that "pre-analytic laboratory events were the most common (81%); the top three were specimen not labeled (18.7%), specimen mislabeled (16.3%), and improper collection (13.2%)" (p. 147). The author further notes that "clinical laboratories contribute to nearly 23% of all reported errors", contributing to unnecessary patient harm and cost (p. 147).

As far back as 2003, Dzik et al. and the Biomedical Excellence for Safer Transfusion (BEST) Working Party of the International Society for Blood Transfusion were investigating mislabeled and miss collected blood samples. Eighty-two facilities located in 10 countries participated in a collaborative three-month study to identify and report mislabeled specimens, WBIT, and other collection errors. The authors report that the "rate of mislabeled and miss collected specimens was 1,000 to 10,000 fold more frequent than the risk of a viral infection" (Dzik et al., 2003, p. 40).

Valenstein et al. (2006) went on to conduct a Q-Probes Study with 120 clinical laboratories to further understand error rates, adverse patient outcomes, and factors associated with lower error rates and better detection of errors. The investigators found that identification errors were common. "Participants from 120 institutions submitted information about a total of 6,705 identification errors. Of these, 5,731 (85%) of errors were detected before results were

released by the laboratory and 974 (14.5%) were detected after results were released" (p. 1109). Grimm et al. (2010) conducted a similar study to Valenstein utilizing a Q-Probe analysis of 122 clinical laboratories but focused on mislabeling and WBIT samples. "A total of 112,112 sample labels were reviewed and 1,258 mislabeled samples were identified for an overall mislabeled sample rate of 1.12% or 1 in 89 samples" (p. 1114). "The rates of mislabeled samples and WBIT for United States participants were comparable to those reported in European countries" (p. 1108).

A prospective study by Tondon et al. (2010) conducted at a 740-bed hospital blood center from January 2007 to June 2008 found error rates similar to those reported in previously noted studies. Additionally, the Tondon study identified two key circumstances related to mislabeling; (1) multiple blood samples from same ward, and (2) failure to label at the bedside (p. 311). In examining root causes for error, the findings regarding WBIT errors occurring when multiple samples are obtained from one ward were similar to the findings in the study conducted by Elhence in India.

Dunn and Moga (2010) conducted an extensive qualitative analysis at the Veterans Health Administration of 227 root cause analysis reports, from March 2000 to March 2008, to identify vulnerabilities in specimen collection, processing, analysis, and reporting associated with patient misidentification (p. 244). Their findings prompted the following recommendations for improved safety and reduced error: Wireless barcode technology at the bedside to confirm patient identity and to label a specimen immediately with a barcode label; barcode technology for the blood transfusion process; using of unique patient identifiers; automating laboratory forms; eliminate re-labeling in laboratory; making centralized phlebotomy continuously available; and eliminating paper labels in the operating room (p. 255). When these

recommendations are linked with an updated laboratory information system, the turnaround time for reporting results is reduced. After implementation of many of this study's recommendations, the SLIP team found similar results preliminarily with regard to a reduced turnaround time for Laboratory at the medical center. Though the study was conducted from 2000 to 2008 and published in 2010, many of the recommendations are still not in place in most institutions, demonstrating an unfortunate lag between evidence of best practice and implementation.

Standard quality improvement measures have demonstrated some success in reducing specimen-labeling errors, although the error rate is not zero. A study by Wagar et al. (2006) utilized longitudinal statistical tools to analyze and trend patient safety implementation projects. The study found that 24/7 phlebotomy service, electronic event reporting, and automated processing contributed to decreased patient identification errors. The investigators also note, that "Specific elements that contribute to success are sometimes difficult to identify in a longitudinal analysis schematic"(p. 1668).

Dzik et al. (2008) found that application of a simple statistical process control (SPC) was a useful tool to monitor critical processes and could be applied to specimen collection and labeling. The SPC tool was adapted by 10 hospitals across five countries over a two-year period. A similar SPC tool is utilized at the medical center for tracking with results shared with managers. The tool is useful for process tracking but has not proven to be effective in reducing error or changing practice behavior.

Education has been noted in the literature to have a positive impact on reducing specimen labeling and collection errors. Bolenius et al. (2013) found that phlebotomists had poor adherence to blood specimen collection guidelines. In that study, phlebotomists were divided into an intervention group (n=84) (received education) and a control group (n=79). "The

educational program included three parts: guideline studies, an oral presentation, and an examination. Improvements were noted in the intervention group after education" (p. 1).

Strict policies whereby blood banks reject any mislabeled specimens or specimens with error are documented in the literature to be of some success in reducing error. One such study from O'Neill et al. (2009) supports these findings. In their retrospective study, the investigators studied the "combined effect of an educational campaign with strict enforcement of a specimen-labeling policy by all clinical laboratories on the incidence of mislabeled and WBIT specimens detected in blood bank" (p. 165). The intervention demonstrated a 73.5% (0.034% to 0.009%; p<= .0001) WBIT reduction and an 84.6% (0.026% to 0.004%; P<= .0001) reduction in mislabeled specimens (p. 164).

The emergency department at the medical center is one of the areas with the greatest number of mislabeled specimens and WBIT errors. A pre-post intervention study by Hill et al. (2010) demonstrates that pairing of an electronic physician ordering system combined with barcode patient identification and barcoded specimen labels in an emergency department does reduce labeling errors. A 74% relative and 31% absolute decrease in labeling errors was noted (p. 630). Continued error was attributed to instances where physician order entry and/or barcode identification was not used. Brown et al. (2011) noted that utilization of this same technology reduced labeling errors from 103 to 8 per year (p. 1).

A study by Morrison et al. (2010) confirmed positive outcomes with use of a barcode identification system combined with automated label printing, but found recurrent errors related to the lack of physician order integration, where paper requisitions were relied upon. Mismatch of requisitions and blood tubes were the primary errors noted. This is somewhat surprising, given that the study group encompassed only a small group of phlebotomists. Even when a

clinician has only one task, human error plays a role. Even more troubling, a study by Snyder et al. (2010) found that barcode identification systems are not foolproof. Malfunctioning and poorly maintained barcode printers can introduce error in to the system via erroneous barcode labels and/or identification wristbands. The investigators strongly recommend industry standards to address equipment functioning and quality.

Anasari and Szallasi (2011) investigated the use of a two-clinician patient identification check and a change in nursing policy regarding phlebotomy and found marginal improvement. The authors did not conduct a statistical analysis of their results. The study further highlights the need for blood bank to "exhaust all resources in preventing" error (p. 301). In 2006, the American Association of Blood Banks (AABB) began requiring two "independently drawn" specimens pre-transfusion for any patient not previously type and cross-matched by a facility (p. 300). In 2009 at their institution, the authors implemented the two-specimen intervention. Shortly thereafter, phlebotomists began altering the workflow process by drawing two specimens from a patient at the same time. We have had similar issues at the medical center.

Reduction of human error and diffusion of innovation are concepts highlighted in the evidence as critical factors in designing an error free system for specimen labeling. A combination of technology, system design, strict policies and education can reduce error. More research is needed to obtain zero error rates in blood specimen labeling.

Conceptual/Theoretical Framework

Theoretical and conceptual frameworks provide a guide for translating science into practice. According to White and Brown (2012) a systematic approach to the translation of new knowledge into practice, guided by a framework or model, will increase the chances of a successful implementation (p. 25). A conceptual framework, (*The Swiss-Cheese Model of*

Human Error by James Reason) and a theory, (*Diffusion of Innovations* by Everett Rogers) were utilized as frameworks for implementation of the innovative point of care specimen labeling system (SCMS).

In 1990, James Reason, professor of psychology at University of Manchester, proposed that human error could be approached from a person perspective or a system perspective. The person approach has historically asserted that errors arose from poor mental processes such as carelessness, negligence, forgetfulness, inattention and lack of motivation. A systems approach assumes humans are imperfect and errors will occur but are a consequence of system issues or a breakdown in "defenses" such as alarms, warning systems and poorly designed processes. The defenses are equated to layers of Swiss cheese with holes that open and close. A breakdown in one layer of cheese (hole) would not generally cause a bad outcome but if multiple layers of cheese holes aligned simultaneously, a major error is likely (Reason, 2000). Reason further categorizes these breakdowns as two distinct types of failures: active and latent. Active failures are those errors committed by front-line operators and include such things as not following policy and procedure, omitting an important step in a process, or ignoring a warning signal. Latent failures are present in a system before a recognizable error or failure and lie dormant until a combination of factors ignite their presence. All systems have a certain number of latent failure points and the goal is not to eliminate all factors but to identify and neutralize. Error can be introduced into a system at all levels and at any time. According to Reason, "Error proneness and the capacities for being stressed, failing to perceive hazards, being ignorant of the system, and having less than ideal motivation are brought by each individual to the workplace" (Reason, 1990, p. 479). Furthermore, according to Rasmussen (1983), people have three levels of performance: (1) skill-based errors (action made is not what was intended); (2) rule-based

mistakes (action intended did not achieve intended outcome); and (3) knowledge-based mistakes (actions are intended but did not achieve outcome due to knowledge deficits) (p. 259).

Understanding Reason's conceptual framework as it relates to latent failure points in a system, knowing these latent failure points contribute to the current labeling process error rate, and incorporating the science of human factors engineering provides a framework for addressing blood specimen labeling errors at the medical center. The goals of human factors in health care are to support the health care professional in their work and to promote safe, quality care (Russ et al., 2013, p. 802). Human factors science is "about designing systems that are resilient to unanticipated events and modifying the design of the system to better aid people" (Russ et al., 2013, p. 803) and to address the levels of performance noted by Rasmussen. In addition, according to Russ et al. (2013) stand-alone trainings are generally a weak intervention, but designing training programs after evaluating the workflow supports safety. The SLIP project team took a systems and human factors approach in designing the SCMS implementation. The team conducted a failure modes, effects, and critical analysis (FMECA) to understand system vulnerabilities and potential latent failure points. It developed potential strategies to mitigate identified vulnerabilities while designing simulation training and workflow processes prior to implementation of the SCMS with staff involvement. The SCMS eliminates at least four failure points from the current manual labeling process. However, error reduction will only be accomplished if the new innovative technology is adopted throughout the organization.

Once the implementation plan was developed, the SLIP project team focused on innovation adoption, best framed through Everett Roger's (1962) theory on Diffusion of Innovations. Rogers, a professor of communication studies, theorized that diffusion of an innovation (perceived as new) occurs through communication channels among members of a

social system over time. Wide adoption of an innovation must occur in order for the adoption to self-sustain and there is a point where the rate of adoption reaches a critical mass. Rogers conceived of five categories of adopters: innovators, early adopters, early majority, late majority, and laggards" (Rogers, 1962, p. 150). Further, he claimed that each individual experiences five stages of accepting an innovation: knowledge, persuasion, decision, implementation, and confirmation. During the decision stage, the individual decides whether to adopt or reject the innovation. Adoption is an individual process, whereas diffusion is a group process and social systems determine norms on diffusion. Additionally, certain specific characteristics of innovations influence adoption: relative advantage, compatibility, complexity or simplicity, trial ability, and observability (Rogers, 2004).

Implementation of SCMS technology and process were directed toward reconfiguring the value chain for patients by reducing specimen label errors. The patient is unlikely to notice the change in process but will benefit from avoiding the necessity of additional phlebotomy due to a labeling error. Error reduction also saves clinicians time through decreases in follow-up and lab re-draws, not to mention reduced turnaround time for laboratory test results. Highlighting benefits to patients and staff encourages adoption to new workflows.

Nurses in acute and critical care were introduced to and trained on SCMS. Unit-based nursing champions (early adopters) were identified and received additional training on SCMS, allowing them to support their peers with the new technology and process and to communicate any issues to the project team. This approach is a cultural norm and has been used successfully in numerous large initiatives at the medical center. Simulation training (highly regarded) and staff involvement with the FMECA and project planning contributed to effective communication

about the new process and its optimization. The sole competitor was the previous paper-based process known by all clinicians.

Methods

Ethical Issues

The goal of the SLIP project was to implement a quality improvement process and meet the University of San Francisco's (USF) definition of quality improvement (as defined by The Institute of Medicine): "a systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product" (USF DNP Department Policy, 2014, p.9). On September 23, 2013 USF determined that the project met the guidelines for an Evidence-based Change in Practice Project as outlined in the Doctor of Nursing Practice Project Checklist (see Appendix –E- Student Project Approval: Statement of Determination). There are no identifiable ethical issues or conflicts of interest noted for this project.

Setting

The SLIP project was conducted at a 700+ bed academic medical center on the West Coast. The medical center is known for providing care to patients with highly complex medical and surgical diagnoses. The academic medical center is undergoing a major transformation as evidenced by a new vision, name, and newly developed strategic plan (2014-2019) that will guide the organization in delivering on their mission. Implementation of an innovation in specimen labeling, which enhances safety and care delivery, is consistent with mission, vision and values and strategic plan of the organization. The medical center's vision is to provide innovative, high-quality, cost-competitive clinical services, and to deliver unparalleled patient

experience across the entire continuum. Strategic goals, being a leader in destination programs, promoting a high valued system, and achieving a culture of continuous process improvement all further define how the organization will live its mission. Utilizing these directional strategies provides stakeholders with their purpose and alignment.

For acute care patients, phlebotomists work with specimens obtained from a direct stick to the patient. Registered nurses (RN) obtain all blood specimens in critical care and line draws in acute care. Prior to implementation of the SCMS, acute care staff labeled their specimens after collecting the specimen and critical care staff labeled beforehand. Phlebotomy is not a core skill for RNs and has been loosely coupled with the Laboratory. Blood specimen labeling errors, primarily an issue with RN phlebotomy, had been identified by the medical director of Blood Bank and the medical director of Laboratory as a serious safety issue over several years. The director's approach of sharing data with managers proved ineffective in reducing blood specimen labeling errors. Senior nursing leaders did not fully appreciate the issue at the time. Implementation of an EMR further highlighted the problem. Potential for error abounded with mismatched specimen labels, requisitions and patients. Systemic issues could not be corrected at the local level. Subsequent implementation of a LIS for Laboratory provided the necessary software and integration of systems for utilizing technology to address the specimen labeling issue.

Planning the Intervention

Plans were developed for implementation of the SCMS to integrate order entry with patient identification and specimen labeling at the point of care (see Appendix – F – SCMS Concept). Initially, SCMS was to roll out across all inpatient settings and in the Emergency Department at the medical center. However, having identified complexities of SCMS early on,

the SLIP project team determined that a smaller scale implementation would yield a higher rate of success and that further implementation of SCMS could be accomplished at a later time. The goal of this project was to reduce specimen label errors by replacing the existing manual specimen collection workflow with an innovative, integrated technology, SCMS. Patient safety is a primary objective of the medical center and implementing a new collection management system for blood specimens addresses the need for improved workflow and reduced labeling errors.

Objectives

1. Utilize current barcode scanning equipment and EMR for SCMS;
2. Train staff on SCMS processes by utilizing a simulation training approach;
3. Implement SCMS on two pilot units, with spread to adult/pediatric acute and critical care units.

Initially, SCMS was to roll out across all inpatient settings and emergency department at the medical center. However, having identified complexities of the SCMS early on, the SLIP project team determined that a smaller scale implementation would yield a higher rate of success and further implementation of SCMS could be accomplished at a later time. Emergency Department, Mother/Baby, and Perioperative Services all have higher labeling error rates than acute and critical care and also have dissimilar and complex workflows that need further analysis prior to SCMS implementation.

Laboratory purchased 150 wireless label printers in anticipation of implementing SCMS. As part of the EMR plan the medical center had already installed barcode scanners at every inpatient bedside for medication administration along with a computer workstation. An early version of label printers had been tested on a handful of units several years prior and failed

miserably. At the time, there was no EMR with order integration and barcode scanners had not been installed. Achieving a better result required thoughtful planning. This project was multi-faceted and required a significant amount of support from IT, dedicated time to conduct a FMECA and streamline workflow, resources to educate/train staff, and time for policy revisions.

A nurse informatics project manager and Laboratory Services manager, was assigned to the SLIP project as well as an information technology (IT) project manager. These three leaders coordinated logistics and drove the project. The Associate Chief Nursing Officer (ACNO)/Doctor of Nursing Practice (DNP) student took administrative lead of the project and partnered with the Patient Safety manager. The Chief Nursing Officer (CNO)/Executive Director of Patient Care Services covered executive sponsorship. The Chief Medical Officer offered, as a resource, a GE Six Sigma/Lean consultant to assist with data management and to provide structure using six sigma and Lean tools. A staff nurse was added to the SLIP team. Staff involvement is a key to success in most of our projects, as staff brings valuable insight to workflows and processes that are not apparent to those not practicing at the bedside. An educator was assigned to develop simulation scenarios and assist with initial training. The listed roles comprised the core SLIP team. Additional stakeholders, including staff were included on an ad hoc basis (see Appendix – G – Stakeholder, Role, Responsibility and Communication Matrix).

Effective communication was essential with a project of this magnitude both with the project team as well as with external customers such as clinicians, providers, and managers. A weekly project team meeting was held to review deliverables, issues, changes, risks and decisions. Development of a SharePoint site facilitated daily updates and communication within the team. Unit-based super-users provided local staff support.

The ACNO/DNP student explored the literature for evidence-based approaches to correcting specimen labeling errors and to better understand the problem on a global level. Evidence in the literature indicates that the SCMS approach has achieved the best results in reducing specimen-labeling errors. Focus and commitment from Laboratory, Blood Bank, IT, and executive leadership provided a platform for success in moving forward with this project. Staff has embraced bedside technology and historically, when they are included in project planning/implementation, they have engaged in supporting project success.

A business case was compiled to determine the best option going forward.

Options

Option #1 Maintain Current System: The specimen labeling system was paper-based and did not interface with the EMR. Specimen labels were printed at a central station in batches. Nurses would obtain laboratory requisitions from one printer at the central station and labels from another printer. There were many opportunities for mismatching labels, requisitions and specimens. Patient identification at the point of care for obtaining specimens was inconsistent. The medical center has approximately 50-100 (88 average) specimen labeling errors per month in Laboratory and another 88/month in Blood Bank at a cost of $125.00 each. Patient safety is compromised with potential for a life-threatening event due to a mislabeled specimen or WBIT. Laboratory turnaround times are slowed down when error occurs and clinician time is increased due to the need to address an error.

Option #2 The Preferred Solution: Implement SCMS across the adult, pediatric acute and critical care areas. SCMS integrates patient identification, provider order, and laboratory specimen identification through barcode technology and interfaces with the EMR at the point of care. Nurses will use this technology as a safer process for specimen labeling.

Option #3 Alternative: Implement SCMS on a limited basis to selected inpatient areas. Training costs account for a large portion of the expense of this project. Limiting the areas where SCMS is utilized reduces training costs. However, two standards of specimen labeling would exist, potentially leading to confusion, inconsistency, and non-standard workflows for nurses, phlebotomists, and laboratory technicians processing specimens in the laboratory. Standard specimen labeling processes with integration in the EMR reduces opportunity for error. A cost/benefit analysis of the three options was completed (see Appendix–H- Cost/Benefit Analysis). Maintaining the current labeling process was the most expensive option, noting that every error could result in a potential lawsuit. Options #1 and #3 did not meet the objectives of improving safety and reducing error. Option #2 cost had an equal benefit within a year, primarily due to cost avoidance. An even greater benefit noted if multiple lawsuits were avoided.

The project team's decision, supported by the executive sponsor and Laboratory collaborative sponsors, to move forward with Option #2 in a phased approach: acute and critical care (adults and pediatrics) phase one, Emergency Department and Mother/Baby in phase two, and Perioperative Services and Respiratory Therapy in phase three. One adult and one pediatric acute care unit piloted the new SCMS for one month to assess for workflow issues, equipment issues and to optimize processes prior to further rollout. A project charter was developed by the SLIP team to further define the project scope and deliverables (see Appendix – I – Project Charter).

The SLIP team (plus ad hoc group) conducted a FMECA from January to March 2014 prior to finalizing education and simulation training as a proactive risk assessment to determine failure modes in the specimen labeling process using SCMS as a new system. Identified

vulnerabilities would be mitigated, if possible, prior to implementation. The FMECA was presented to Patient Safety Committee and approved. An education plan was developed that included training unit-based super-users for local support of staff and trouble shooting issues, as well as training pilot unit staff in SCMS. Initially, the plan for education had been a one-hour classroom training. However, that quickly evolved (after FMECA results) to a two-hour simulation training, including a module on specimen labeling errors and a video showcasing the path of a specimen through the Laboratory (See Appendix –J- Training Module). In addition, further investigation of safe practices by a staff member of the SLIP team uncovered a process called Final Check that verbalizes a final check of the last three digits of the medical record number. All involved in the FMECA supported incorporating Final Check into the SCMS process.

> "In May of 2011, Palmetto Health Richland Hospital in Columbia, South Carolina and the South Carolina Hospital Association partnered with Outcome Engenuity in a project to demonstrate a rapid reduction in the number of mislabeled blood specimens. The goal was to achieve a 90% drop in mislabeled specimens (the wrong patient's label on a blood specimen) in a 90-day time frame. The project was intended to be a broader demonstration of the power of Just Culture concepts to dramatically reduce the rate of adverse patient safety events. The project was met with immediate success at Palmetto Health. As a second phase, the South Carolina Hospital Association recruited five additional hospitals to implement The Final Check in an attempt to validate its universality. As with Palmetto Health Richland, five additional hospitals showed a 90% reduction in mislabeled specimens in the first month after implementation, improving to a

93% reduction after three months. The success has been sustained for five months thus far, as of June 2012" (Final Check, n.d., p. 1).

Implementation of the Project

Back-end IT infrastructure to support implementation of SCMS was performed in 2012 and was part of a separate capital budget project. Barcode scanners were installed with EMR implementation in 2012. Equipment installation for SCMS began in January of 2014 by Facilities and IT. This entailed installation of brackets to hold label printers, mobile carts, and testing of wireless connectivity with the label printers. Connectivity issues were immediately identified; IT attempted to remedy, but without success. The Informatics nurse determined that an adaptive approach was needed. Cables were purchased to wire the wireless label printers to in-room computers. Acute care units have fewer laboratory orders requiring nurse phlebotomy; therefore, each acute care unit has three or four portable label printers to use with specimen collection. The SLIP project training for super-users and staff (pilot units) began in March, conducted by an educator and project managers from Informatics and Laboratory. Education was well received. Staff commented that they felt prepared to use SCMS on their units and had a better understanding of specimen management and the importance of labeling correctly. Process compliance monitoring began immediately, with data collected by Laboratory and observation from nurse managers. The SLIP team was interested in whether staff were using the new system or continuing to use the old paper-based system. Observations revealed staff was using the new Final Check process in addition to the labeling system. Over the course of the pilot month, compliance rose to 90% as more staff was trained on pilot units. Workflows were adjusted based on staff feedback and new discoveries with the SCMS functionality. After a successful pilot series, further training and rollout of SCMS occurred across all of the acute care units,

following the same optimized model. A workflow assessment of critical care was conducted and simulation training adjusted accordingly. Critical care staff was trained and SCMS implemented. Compliance monitoring was incorporated. A draft specimen labeling policy/procedure was written with input from SLIP team members, Laboratory medical director, and reviewed by staff to ensure the document reflected practice (See Appendix –K- Specimen Labeling Policy).

Feedback from staff and Laboratory was evaluated to determine if there were further training needs and/or equipment and workflow issues had surfaced. Super-users provided onsite unit support to staff and were able to answer numerous questions. IT intervened on equipment issues. The staff nurse working with the SLIP team provided training for staff returning from leave of absence and those new to the organization. Training for new hires will be incorporated into new hire orientation.

Planning the Study of the Intervention

Regular debriefing on project implementation was essential to assessing a successful implementation and to inform improvements for phases two and three. An overall approach of Plan, Do, Study, Act (PDSA) drove the project through to completion in phase one and will be used for subsequent phases. The project began in October 2013 with an initial meeting of key stakeholders from the project team, Laboratory, Blood Bank, IT, Facilities, Performance Improvement, and Nursing Education. In November 2013, the design was completed and later enhanced after the FMECA was completed. Training began in March with the pilot units utilizing SCMS by April 2014. (See Appendices L and M- Gantt Chart and Training and Implementation on SCMS). Numerous improvements were made on the pilot units prior to broader rollout. As an example, labeled specimen tubes began arriving in the Laboratory with labels that were offline. Laboratory personnel were convinced the nursing staff was mislabeling.

However, on investigation, the team discovered that the labels were not properly inserted in the label printers. Loading labels into printers was incorporated into training.

Staff was asked to complete a Survey Monkey to provide feedback on satisfaction with the new system and training, as well as to report any challenges. One comment nicely sums up the system "when all the technical aspects are functioning properly, it is a highly efficient process. The workflow does take some getting used to, however, once settled, it's safe and quick and I can use my time for other patient concerns" (See Appendix –N- Survey Monkey Tool). Laboratory and Blood Bank continued to send specimen labeling error data. The SLIP team extracted the units using SCMS to determine improvements/error reduction. The Laboratory manager involved in the project provided feedback from the Laboratory's perspective. The FMECA process informed educational planning for simulation training (workflows and potential failure points) and identified equipment adjustments required prior to implementation. Steps in the FMECA process included:

- Steps in the process of using SCMS (bedside procedure or handheld portable Dolphin)
- Potential failure modes
- Potential causes of failure
- Effects of the failure
- Ranking severity, probability of failure effect and detection
- Calculating criticality to rank order potential failure modes and prioritize remedial efforts
- Potential solutions and outcome measures

(See Appendices – O and P– Failure Mode, Effects and Critical Analysis (FMECA) Summary and Workflow Analysis).

Project details were carried out by the IT project manager, Informatics nurse and Laboratory manager, all with strong project management skills. Installation of brackets, ordering additional label printers, cables and labels, and assisting the educator with staff training comprised some of their project duties. Facilities, Clinical Engineering, and IT ensured equipment was ready for use across 15 units. Once the equipment was in place, training and follow-up were key items going forward, with approximately 1800 nurses to be trained. Nurse managers were accountable for staff following the new labeling process. The ACNO/DNP student granted approval for financial resources to order equipment and find rooms for training when the simulation lab was unavailable. The Patient Safety Manager and ACNO/DNP student co-presented the project to the Patient Safety Committee and other interdisciplinary forums to communicate the change process.

Primary objectives were achieved and the organization gained valuable insights about the risks associated with specimen collection and labeling. Timeline challenges were ongoing. Labor disputes and competing priorities necessitated adjusting schedules. Discussions of risks/benefits of delaying training and/or implementation were frequent and acknowledged that the primary desired outcome was a robust, accurate labeling process. Baseline data demonstrated the need for improvement (See Appendices – A, B and C - Blood Bank Specimen Labeling Errors and Laboratory Specimen Labeling Errors 2011-2013).

Methods of Evaluation

Instruments used for evaluation were multifactorial. Laboratory specimen labeling error data collection was in place prior to SCMS implementation and continued after implementation. The GE consultant collaborated with Performance Improvement to extract from the data set those units using SCMS to measure improvement. The LIS vendor-developed Survey Monkey

to staff, collected information on satisfaction and challenges with the training and process (See Appendix –N - Survey Monkey). An observation tool developed by the SLIP staff nurse representative provided a mechanism for observing practice and measuring process (See Appendix – Q-Observation Tool). Measurement of staff compliance with using SCMS is tracked through a manual process in the Laboratory and provided to the GE consultant for analysis. Other metrics and data analysis for specimen labeling are still in development. Patient days were used for a denominator to determine labeling error rates. In September, new software installed in Laboratory will enable counting of samples (denominator). Further discussion with Performance Improvement is necessary in order to determine ongoing process measures, frequency of measurement, and reporting structures. Only labeling error measurements were provided by Laboratory prior to SCMS.

A strengths, weaknesses, opportunities and threats analysis (SWOT) was used to determine risk and feasibility of this project (see Appendix – R – SWOT Analysis). Resources are stretched for IT-related projects, which must compete with EMR updates, optimization, report requests, and the ongoing construction of a new facility at a new campus location. However, laboratory orders touch every patient and any error poses significant risk for adverse outcomes.

Project expenses and return on investment (ROI) were determined in a financial analysis compiled by the ACNO/DNP student. Budget for SCMS implementation consisted primarily of training expense, with an estimated 3,644 hours (2 hours/nurse x 1,527 nurses). Staff backfill time was unnecessary, as other staff on duty could provide care delivery during training. Staff direct-labor expense was calculated at $65.00/hour and indirect labor expense at 30%, totaling $85.50/hour. Licensing and acquisition of SCMS software occurred through Laboratory and was

integrated into the EMR by IT through a separate capital expenditure. Additional expenses incurred included funds for printers, cables, power strips, and wiring. Project managers, GE consultant, and educator were included in budget projections. The nurse's home unit absorbed staff nurse participation time on the SLIP team. Project sponsors were not included as expenses, given that this type of project is a portion of their daily work. ROI occurs after 48 months based on an assumption that labeling errors are eliminated and cost avoidance produces a savings. SCMS does not generate revenue. Further cost avoidance from lawsuits are possible but not captured in budget projections (see Appendix – S – Budgetary Return on Investment Plan (ROI)).

SCMS implementation in critical care surfaced workflow issues not apparent in acute care. Volume of laboratory orders, physician practices in critical care and EMR design imposed unexpected challenges. A critical care focus group of staff, IT, and Laboratory was designated to meet weekly and work through and resolve issues. Avoiding development of a workflow breakdown was paramount to quickly resolving workflow problems.

Analysis

Both quantitative and qualitative data were collected from participants to evaluate process, satisfaction, error rates, and problems with the new system. Survey Monkey software was used for an online survey and Laboratory information system was used to note labeling errors and Laboratory turnaround time. Patient days were used as a proxy denominator for number of specimen samples. Data analysis is a work in progress with the SLIP project. More time is needed to trend data and hardwire new processes and workflows, continually monitoring for unintended latent failure points.

Results

Program Evaluation/Outcomes

The medical center is a complex, somewhat chaotic organization, that despite environmental and system challenges, delivers extraordinary care. Standardization of processes has not been emphasized historically. Leadership realizes the lack of standardization creates a vulnerability. The evidence in the literature is clear: standardization enhances patient safety. In addition, once the medical center as a whole is aware of a safety issue, there is an impetus to correct the problem. Therefore, over the past several years, the focus has been on setting in place standard processes and workflows. Reason's work makes it apparent that any system will have latent failure points that need to be recognized and monitored. Lack of standard workflows creates difficulty in tracking failure points.

Staff response to SCMS has, for the most part, been positive. Equipment and EMR workflows are continually under revision and are the greatest sources of complaint. As a result of feedback on inconsistent equipment and supply availability, the Unit Coordinators were enlisted to conduct daily checks of necessary items (See Appendix – T –Unit Coordinator Checklist). The Laboratory Medical Director and Blood Bank Medical Director are both pleased and anxious for SCMS to be implemented across the organization. Senior leadership is impatient with project length, had to be reminded of previous decisions that slowed progress. Quality leaders desire full implementation as soon as possible.

As with many projects, no one had any idea the magnitude this project would entail in terms of length, required resources, and impact prior to the FMECA and phase one implementation. Initially, the idea was to use existing technology (barcode scanners and bedside computers), then add label printers at the bedside to improve patient identification and specimen labeling. During the course of the project, questions arose regarding EMR workflow and

Laboratory interface in general, but those were not within the scope of this project. The initial improvement plan evolved over time, as previously noted, driven by several factors, including new knowledge (FMECA), labor disputes (slowed timeline), IT connectivity (slowed timeline), adjustment in required equipment (wireless label printers an adaptive model), competing priorities for project managers, and competition for training space. The SLIP team and medical center leadership mitigated all of these challenges for phase one. The enthusiasm of all participants was of great help in moving the project forward, as was team communications to others in the organization. The simulation training provided a positive and informative approach, not only regarding SCMS but also in regard to human factors error. Development of a process audit plan with a schedule for all units and managers is still needed and is under consideration.

Despite numerous challenges, implementation of SCMS has been dramatically successful in reducing blood specimen labeling errors, although compliance with using the system is currently at approximately 50%. Once fully implemented across the medical center, it will represent a significant step toward ensuring patient safety. Early results are positive. As noted, more data collection and analysis is needed (See Appendices U, V, W, X and Y – Training Compliance, Efficacy of SCMS with Blood Bank, Efficacy of SCMS with Lab, Laboratory Labeling Errors After SCMS, and Laboratory Reported Labeling Errors). Laboratory turnaround time data is not presented due to the need for further analysis. Pressure is mounting to complete phases two and three of SLIP, which will include Emergency Department, Mother-Baby and Perioperative areas. However, the medical center is preparing for a new campus and facility; resources are stretched. The SLIP team recommended to senior leadership of Laboratory and Nursing to wait on phase two and three until the campus transition is complete. Risks of waiting

include ongoing safety issues with specimen labeling in high-risk areas and the possibility that the project will not reinvigorate for phase two and three. The benefits of waiting include an opportunity to re-focus, ability to study workflows in complex settings before implementing, and time to install equipment with testing prior to implementation. Leadership made the final decision to wait until the new campus transition was complete. In the meantime, the medical director of Laboratory and members of the SLIP team will contact other organizations that have implemented SCMS and use the same EMR, to exchange information. The team hopes to glean insight for those issues identified in phase one and to better prepare for phase two and three implementation.

Discussion

Summary

Implementation of SCMS was successful for several reasons: (1) the system and process reduced RN time for specimen collection; (2) it provided a streamlined workflow; (3) it improved safety for patients; (4) it led to a reduction in both labeling error and Laboratory turn-around time (preliminary data). Two factors contributing to the success of implementation were: (1) conducting a FMECA to understand workflows and failure points prior to education programming, and (2) incorporating staff on the SLIP team and in workgroups. Role-play simulation training was somewhat new for the medical center. It has proven to be a powerful tool in demonstrating to staff the full scope of a process, highlighting potential failure points and providing feedback to staff after return demonstrations. Role-play simulation training was utilized with barcode medication administration; data analysis shows a 95% barcode compliance rate for patient identification and medication identification. Translating medication administration processes to blood specimen collection processes may have contributed to early

success. Unit-based super-users have been, and continue to be with this project, successful models for the medical center, supporting staff when they need it. Ongoing leadership will be necessary to sustain error-labeling reductions, including regular review of data at quality meetings. Holding staff accountable to use SCMS is another critical factor. In an emergency, paper requisitions may be used for blood specimens. Unfortunately, some staff has continued to use paper requisitions in non-emergent situations. Laboratory is considering increased restrictions and will not accept paper requisitions for non-emergent specimens. Development of a process audit plan with a schedule for all units and managers is necessary and will be developed in the next month.

Advanced practice nurses prepared in systems thinking, integrated with quality and performance, are essential for projects such as SLIP. The gap between evidence and practice continues, but as more nurses are prepared in advanced roles, that gap should narrow. It is unclear whether the project managers would have facilitated a FMECA or enhanced simulation training without influence of the ACNO/DNP student and Patient Safety Manager. Further, this project highlights the need for flexibility from the micro to macro levels.

Relation to Other Evidence

The SLIP project results appear to be similar to findings from other organizations that implemented a SCMS type system. Results are not directly comparable; the sample denominator is needed from Laboratory. However, internal pre/post improvement is evident and comparable. Other organizations report strict processes and policies, but also note potential breakdown in workflow processes. Observation and direct feedback to staff after implementation are interventions known to improve processes and outcomes. The SLIP team is committed to

conducting periodic observations and following up with managers to ensure hardwiring of the new system.

Barrier to Implementation/Limitations

Studying the SCMS process uncovered issues with connectivity and equipment, physician orders, workflow and integration with Laboratory processes. A few issues were anticipated and a few were not anticipated. Some of these workflow issues have impact on RNs, particularly in critical care, and are under investigation for improvement solutions. Equipment functionality has been the biggest concern for acute care, specifically regarding wireless printers that did not have adequate and consistent connectivity. An adaptive model was implemented. RNs obtained a label printer from a central unit location and then plugged the printer into the computer in the patient room. Ports have become worn and damaged with plugging and unplugging. Further investigation of alternatives for an adaptive model is underway.

Sometimes when an organization has a heavy focus on outcome data, the process to achieve those outcomes may cover other issues that might thwart safety. An example is the expectation to use barcode medication administration. The SLIP team found that the nurse determination to use a barcode scanner potentially introduces error. If the barcode scanner is not functioning properly at the patient bedside and troubleshooting does not result in a functioning scanner, the nurse is likely to go to another room to use that scanner. When identification and labeling do not occur at the point of care, safety is compromised. Greater focus on equipment maintenance was an outcome of this project.

The greatest challenge for the SLIP project team has been resources to train (including space limitations), progression to implementation, data analysis, and full evaluation. Although this project was a collaborative effort between Nursing and Laboratory, most of the project has

been led by Nursing. This makes sense for training and unit implementation, but not necessarily in terms of accountability for data analysis and accountability for ongoing resources to disseminate SCMS across the medical center. Unforeseen labor disputes and IT issues disrupted original timelines and these changes had a consequence to the project, as resources were pulled to other planned implementations. Competing priorities are a known operational balancing act. Phase two and three will be implemented at a later date.

Interpretation

Units that have implemented SCMS have reduced levels of specimen labeling errors. Standardizing workflow, identifying patients, integrating physician orders electronically through the EMR, and labeling specimens at the point of care all contributed to reducing errors in specimen labeling. While eliminating breakdowns in system processes and maintaining strict adherence to policies is difficult, both are essential to sustaining improvement. Regular measurement and data presentation, holding leaders accountable for outcomes, and gathering feedback from nurses regarding barriers to improvement will all support sustaining the gain. Until there is accurate sample data (denominator), comparable data to outside organizations is forthcoming. Pre/post results are dramatic but trending is needed. The SLIP team expected significant improvement but knew that until all staff had been trained on SCMS and was using the system, data would not reflect the full impact of SCMS. Discontinuation of paper requisitions is needed to force function staff to use SCMS.

Improvement projects such as SLIP are equivalent to peeling an onion with many layers. The project team acknowledges that until a workflow analysis is completed for any given area, it is nearly impossible to anticipate failure points. Phase two and three units have high volume Laboratory orders and complex workflows. The experience of completing phase one SCMS,

informed the decision to study workflows in phase two and phase three areas prior to implementation. Other opportunities for improvement with Laboratory specimen ordering and collection have surfaced. Though they were not within scope for this project, they have been brought to the attention of and key leaders. As mentioned previously, SLIP team members and Laboratory medical director will be contacting other organizations for their expertise.

Conclusions

Systems approaches and technology, combined with human factor science, are absolutely necessary for error reduction and patient safety. Unfortunately, equipment manufacturers and organizations often do not incorporate these strategies to reduce error and the burden is left to those directly delivering care to patients. In addition, a change in one system impacts other systems and produces unanticipated consequences. Thoughtful plans, resources, implementation, and evaluation are necessary for success. If appropriate quality measures are not instituted on the front end of a project, the time to course correct after implementation is large. Specifically, more research is needed regarding what, on the surface; seem to be straightforward processes, such as labeling a specimen. Implementation of SCMS has reduced specimen-labeling errors and will be more broadly installed in coming months. Even with the new system and technology, error is not eliminated nor does it approximate six-sigma. The medical center is moving toward technology as a strategy to improve systems, reduce redundancy, improve safety and improve efficiency. A systematic review of each service interface would likely highlight those processes needing improvement, which is preferable to waiting for an untoward event to surface the problem.

Other Information

Funding

Funding for the SLIP project occurred over several years (implementation of EMR, barcode scanners, LIS), under capital funding. One hundred fifty wireless label printers were purchased by Laboratory. Additional equipment, installation needs, and staff time to participate and be trained in the project was absorbed into Nursing Administration cost center. Nursing maintains project and discretionary funds for projects that are not fully funded or need support.

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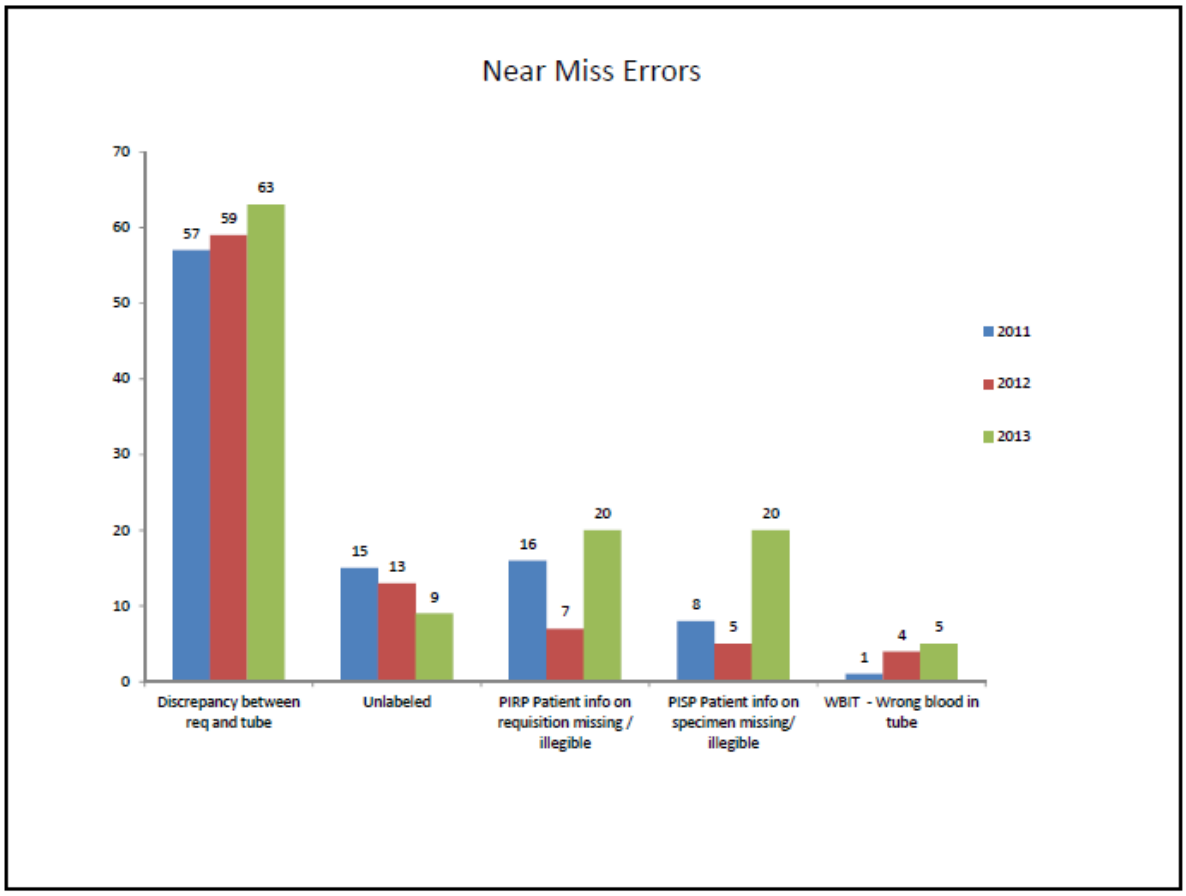
White, K. M., & Dudley-Brown, S. (2012). *Translation of evidence into nursing and health care practice*. New York: Springer Publishing Company.

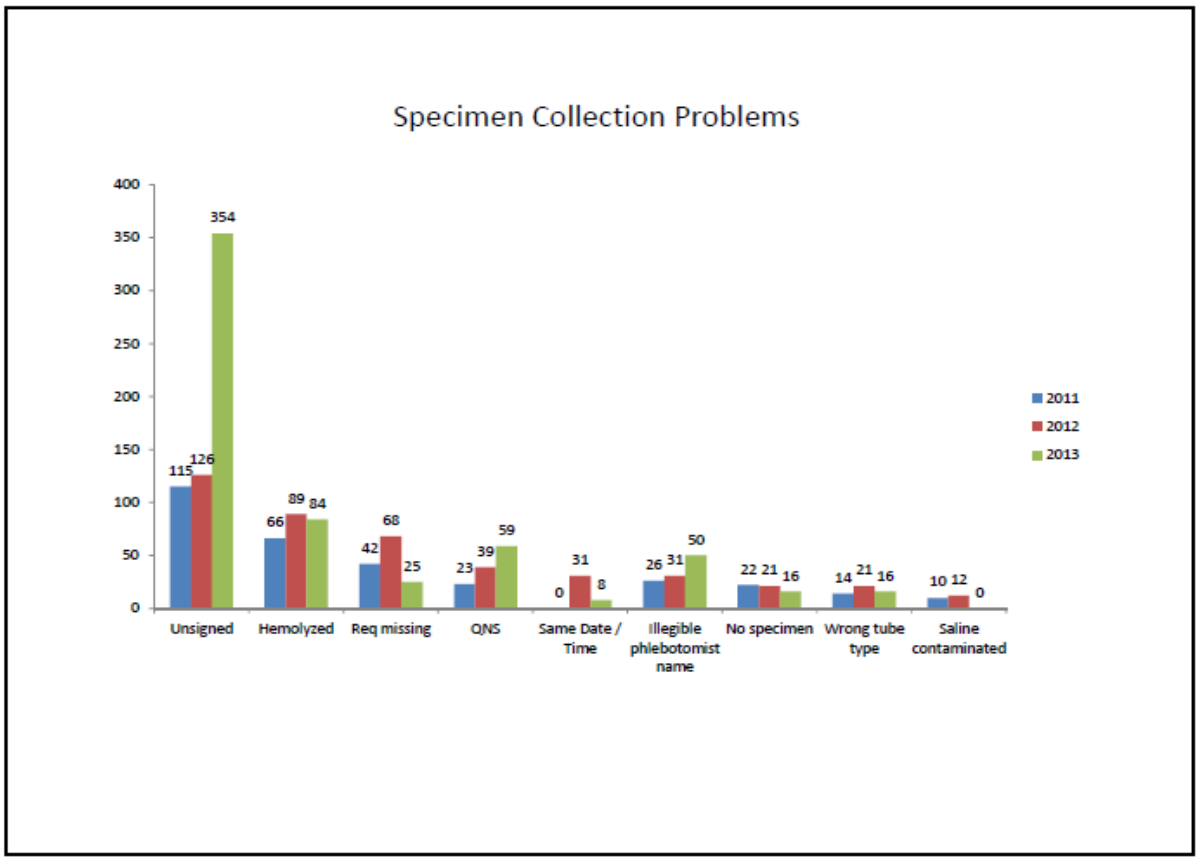
Appendix A

Blood Bank Specimen Labeling Errors 2011 to 2013



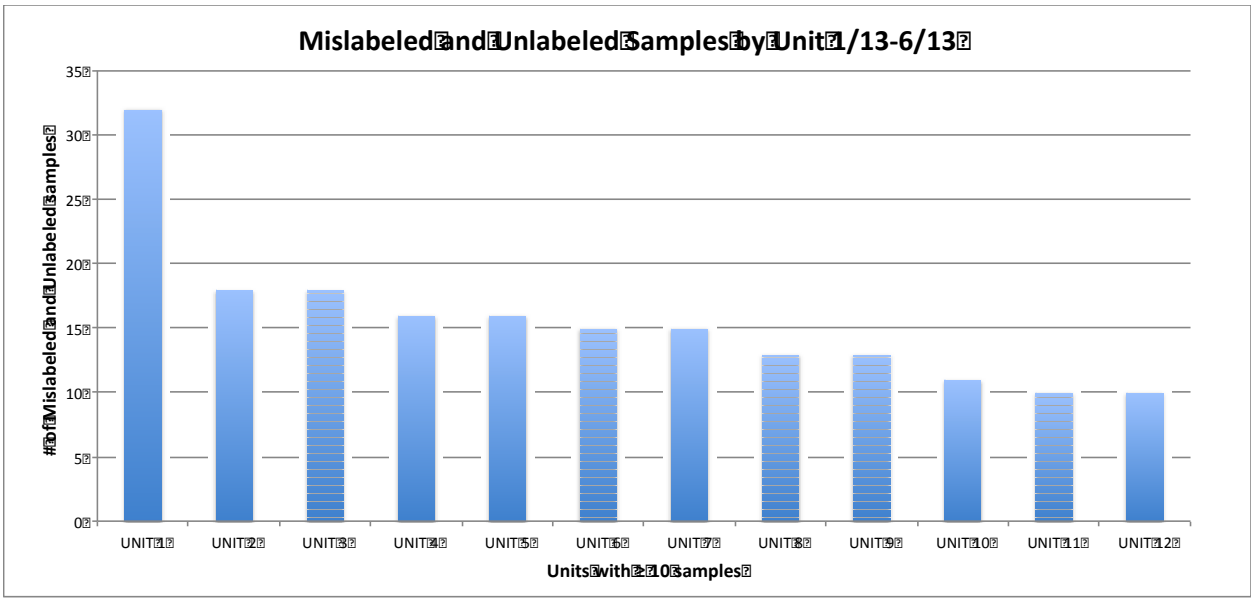
Appendix B

Blood Bank Specimen Collection Errors 2011 to 2013



Appendix C

Laboratory Specimen Labeling Errors January 2013 to June 2013



Appendix D
Evidence Table: Specimen Labeling Error

STUDY	METHOD	SAMPLE	INTERVENTION	OUTCOMES / RECOMMENDATIONS	STRENGTH OF EVIDENCE I-V	QUALITY OF EVIDENCE A-C
Anasari & Szallasi 2011	Retrospective qualitative study	N=59,373 (26 WBIT)	Incidence of wrong blood in tube (WBIT) over 4 years	(WBIT) represents leading cause of potential mis-transfusions. Two specimens and policy impact some labeling errors but more safety measures needed	III	C
Bolenius et al. 2013	Quasi-experimental study	N=84 N=79	Pre/post questionnaire after education	Some improvement but not significant	II	B
Brown et al. 2011	Pre/post intervention study	N=103 errors/yr	Implementation of specimen collection/labeling system with barcode technology and label printers	Decrease from 103 labeling errors to 8/year (p<.001)	III	B
Dunn & Moga 2010	Qualitative study	N=227 root cause analysis reports	Qualitative analysis of 227 root cause analysis reports from Veterans Health Admin.	Pre-analytic phase errors accounted for 182 out of 253 patient misidentification errors	III	B
Dzik et al. 2003	Qualitative study	N=71 hospitals completed questionnaires N=62 hospitals submitted data N=690,000 samples	Hospitals in 10 countries reported mislabeled and mis-collected sample data	Study concludes mislabeled and mis-collected samples rate is 1000-10,000 (1 in 165 samples) more frequent than risk of viral infection from blood	III	B
Dzik et al. 2008	Non-experimental longitudinal study	10 hospitals in 5 countries	Applied statistical process control charts tabulating the frequency of mislabeled and mis-collected blood samples over 2 years	Participating hospitals found the SPC tool helpful in monitoring specimen labeling error reduction progress	III	B
Elhence et al. 2012	Non-experimental longitudinal study	N=285 transfusion related events from 2009 to 2010	Prospective study in India to record, classify and analyze near miss and adverse events	53% were near miss events that occurred at bedside	III	B
Grimm et al. 2010	Prospective study	N=122 institutions	Each institution reviewed inpt and outpt ABO samples for labeling errors	All institutions combined had a mislabeled sample rate of 1.12%	III	B
Henneman et al. 2010	Prospective observational study	N=28 nurses, 16 techs, 17 ED assoc.	Simulated patient scenarios with eye-tracking device	Wide variation among health care workers in verifying patient id	III	B
Hill et al. 2010	Pre/post intervention study	Pre N=724,465 Post N=334,039	Physician order entry and barcode id	Combination of Physician order entry and barcode reduce Emergency Dept. specimen labeling errors (31%) with 95% confidence	III	A
Kim et al. 2012	Retrospective analysis study	N=9072	Standardized process-driven id and specimen labeling protocol	Decrease of 5.79 events/1000 to 3.53/1000	III	C
Morrison et al. 2010	Pre/post intervention study	Pre N=181,758 Post N=184,043 specimens	Barcode patient identification and label printers, training	43% reduction in mislabeled samples 38% reduction in unlabeled samples	III	A
O'Neill et al. 2009	Pre/post intervention study	Pre N=106,174 Post N=104,860 specimens	Education and strict policy adherence	73.5% reduction in WBIT errors (0.034% to 0.009%; p<.0001)	III	B

STUDY	METHOD	SAMPLE	INTERVENTION	OUTCOMES / RECOMMENDATIONS	STRENGTH OF EVIDENCE I-V	QUALITY OF EVIDENCE A-C
Rees et al. 2012	Pre/post intervention	N=197 specimen identification events	Four areas of focus; establishing clear expectations of staff, education, process (system) review and feedback	Post interventions an 85% error reduction in specimen label errors	III	C
Snyder et al. 2010	Quasi-experimental study	N=10 defective barcodes N=225 scans/barcode	Re-scans conducted by 3 operators, 15 times each, using 5 different scanner models	As many as 3 incorrect patient identifiers generated from single defective barcode	II	B
Snydman et al. 2012	Qualitative study	N=37,532 laboratory event reports from 30 health care orgs	Cross-sectional analysis of 30 organizations of reported laboratory events in US	Pre-analytic laboratory events were the most common (81.1%)	III	B
Tondon et al. 2010	Prospective study	N=32,189 recipient samples N=22,794 donor samples	Prospective study to report distribution, type and frequency of errors through blood bank	Total of 342 errors (6.2/1000 samples) with 87.1% clerical and 86.5% outside of blood bank	III	B
Valenstein et al. 2006	Q-probes analysis study	N=120 institutions	Compilation of lab patient id errors over 120 institutions	Most errors are detected before results released (85%)	III	B
Vuk et al. 2014	Non-experimental longitudinal study	N=955,218 blood donations collected over 12 year study period (2002-2013)	Longitudinal study of WBIT frequency in donor samples in Croatia	WBIT error rate was 34 (0.0018%). Potential causes multifactorial and controllable	III	B
Wagar et al. 2006	Non-experimental longitudinal study	N=16,632 total specimen errors 2003-2005	24/7 phlebotomy service, electronic event recording, automated processing	Implementation of patient safety measures reduces specimen-labeling errors. 1230 total errors/month reduced to 555/month	III	B

Level 1 = Experimental study/randomized controlled trial (RCT) or meta-analysis of RCT
Level II = Quasi-experimental study
Level III = Non-experimental study, qualitative study, or meta-synthesis
Level IV = Opinion of nationally recognized experts based on research evidence or expert consensus panel (systematic review, clinical practice guidelines)
Level V = Opinion of individual expert based on non-research evidence. (Includes case studies; literature review; organizational experience eg. Quality improvement and financial data; clinical expertise, or personal experience)

A = High Research—consistent results with sufficient sample size
Summative Reviews—well-defined, reproducible search strategies
Organizational—well-defined methods using a rigorous approach
Expert Opinion—Expertise has been clearly evident

B = Good Research—reasonably consistent results, sufficient sample size
Summative Reviews—reasonably thorough and appropriate search
Organizational—well-defined methods
Expert Opinion—expertise has been clearly evident

C = Low Quality or Major Flaws Research—little evidence with inconsistent results, insufficient sample
Summative Reviews—undefined, or poorly defined methods
Organizational—adequate reliability or validity
Expert Opinion—expertise has not been discernable

Newhouse, R., Dearholt, S., Poe, S., Pugh, LC., White, K., *Johns Hopkins Evidence-Based Practice Appraisal.*

Appendix E

Student Project Approval: Statement of Determination

University of San Francisco
School of Nursing and Health Professions

Student Project Approval:
Statement of Determination

Title of Project: Develop a strategy to reduce pre-transfusion blood specimen labeling errors at the point of care in a hospital setting.

Brief Description of Project: Pre-transfusion blood sample labeling errors increase the risk of transfusion-associated patient morbidity and mortality and continue to be a significant risk in hospital settings in the US and internationally. According to the literature, pre-transfusion blood specimen labeling errors present a greater risk than the safety of the blood and error reduction may be reduced through education, policies, and barcode technology.

Baseline error data will be collected including blood transfusion specimen label errors and wrong blood in tube errors (WBIT) across all inpatient units. Utilizing process mapping to understand current process, review of current policies, and thorough literature review for evidence based practices, and introduction of barcode technology as an improvement strategy. Lean methodologies will be utilized to reduce process waste and engage staff in process improvement solutions.

Post improvement data will be collected on a unit-by-unit basis and a root cause review of each error as a means to further understand and improve the process.

To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used: (http://answers.hhs.gov/ohrp/categories/1569)

X☐ This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). Student may proceed with implementation.

☐ This project involves research with human subjects and must be submitted for IRB approval before project activity can commence.

Comments:

Signature of Supervising Faculty_____ (date)

Signature of Student _____ (date)

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

STUDENT NAME: Traci Hoiting DATE: September 23, 2013 .

SUPERVISING FACULTY: K T Waxman.

Instructions: Answer YES or NO to each of the following statements:

Project Title:	**YES**	**NO**
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	**X**	
The specific aim is to improve performance on a specific service or program and **is a part of usual care**. ALL participants will receive standard of care.	**X**	
The project is **NOT** designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does **NOT** follow a protocol that overrides clinical decision-making.		**X**
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	**X**	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	**X**	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	**X**	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	**X**	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., **not** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	**X**	
If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: *"This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board."*	**X**	

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

THIS TABLE PROVIDES AN OVERVIEW OF THE DIFFERENCE BETWEEN RESEARCH AND QUALITY OR PROCESS IMPROVEMENT

	RESEARCH	QI/PROCESS IMPROVEMENT
DEFINITION	"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities." http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102	Assess or improve a process, program or system to improve performance as judged by the evidence, i.e., established/ accepted standards
PURPOSE	Answer a question or test a hypothesis	Improve performance/ process or systems
BENEFITS	May or may not benefit current patients, but may benefit future patients	Directly benefits a process, program or system and may or may not directly benefit patients
RISKS	May put subjects at risk	Does not increase risk to patients with exception of possible privacy/ confidentiality concerns
DATA COLLECTION	Systematic data collection	Systematic data collection
DATA ANALYSIS	Statistically prove or disprove hypothesis	Compare a program/ process/ system to an established set of standards

Appendix F

SCMS Concept

SCMS

Design Points

State of the Art Technology

- Portable Equipment
- Interfaces with Electronic Medical Record
- Barcode Technology
- Interfaces with Laboratory System
- Point of Care Technology
- Reduces Errors

Product Concept

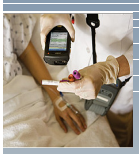
Target Customer(s)

Nursing Staff

Use Cases

Safety: Patient, lab order, specimen identification
Regulatory: Label at point of care
Efficiency: No paper requisitions

Product



Point of care specimen labeling technology

Problems To Be Solved

Labeling errors due to mislabeled specimens and misidentified patients
Decentralized specimen collection process
Multiple steps to assemble supplies

Customer Benefits

Functional: Equipment, specimen tubes, laboratory order, labels, and patient identification all in one place

Emotional: The organization cares about my patients and me

Social: Safety for Patient-Centered Care

Appendix G

Stakeholder, Role, Responsibility and Communication Matrix

Stakeholder	Role	Responsibilities	Communication
CNO	Executive Sponsor	Approves budget, resources, point of escalation for issues that can't be resolved within SLIP team	Communication to senior executives on project progression/issues
Medical Directors, Laboratory and Transfusion Medicine	Collaborative Oversight of SLIP Project	Removing barriers during project implementation	Communication to Medical Staff Quality Committees
ACNO/DNP Student	Project Sponsor-Nursing	Approves scope, FMEA co-lead, training time, budget for training, escalation of issues	Communication to Nursing Directors/Managers
Patient Safety Manager	Project Sponsor-Patient Safety	FMEA co-lead, chairs SLIP project team, represents Quality Management Team	Liaison to Quality Management and Patient Safety
Informatics Nurse	Project Lead-Nursing	Purchase of equipment, coordinator of project, and training, super-user competency sign-off	Project Update Communication
Laboratory Services Manager	Project Lead-Laboratory Services	Laboratory Services configuration, training, SCMS expert	Liaison to Laboratory Management Leadership
Information Technology Project Manager	IT Systems Management	Coordinate all IT interfaces, SCMS vendor interface and wiring	Liaison to IT Leadership
GE Consultant	GE Six Sigma/Lean Consultant	Incorporating Lean and Six Sigma concepts into project, data analysis	Liaison to Performance Improvement
Staff Nurse	Project Assistance	Policy review, workflow review, training, observation survey development, general troubleshooting	Liaison to Staff and within SLIP Team
Educator	Simulation Educator	Development of simulation scenarios and training	Liaison with Nursing Excellence

Appendix H

Cost/Benefit Analysis

Cost/Benefit Analysis

Category	Details	Cost in First Year
Option # 1 No change	Cost of error correction: Personnel time=$125/error x 729 errors (1 year, 2013) Cost of potential lawsuit: $500,000 (history of 1 lawsuit related to mislabeled specimen)	$91,125 cost of errors: BB & Lab $500,000 cost of one lawsuit
Total		**$591,125**
Option # 2 Phased approach	Phase 1 equipment and training acute care/CC care (adults and peds) Phase 2 and 3 ED, Mother-Baby, Periop	$354,563 $ 100,000
Total		**$454,563**
Option # 3 Only complete Phase 1	Only do Phase 1	$354,563
Total		**$354,563**

Benefits

Benefit	Benefit Within 12 Months
Avoid potential lawsuit related to specimen labeling	$500,000 x 1 ($500,000 x 729 actual errors = $364,500,000) potential expense from lawsuits
50% reduction in specimen labeling errors in 9 months (personnel time)	$45,563.00
Patient satisfaction	$50,000
Total	**$595,563**
Potential Expense if Each Error Resulted in a Lawsuit	**($364,595,562)**

Appendix I

Specimen Labeling Improvement Project Charter

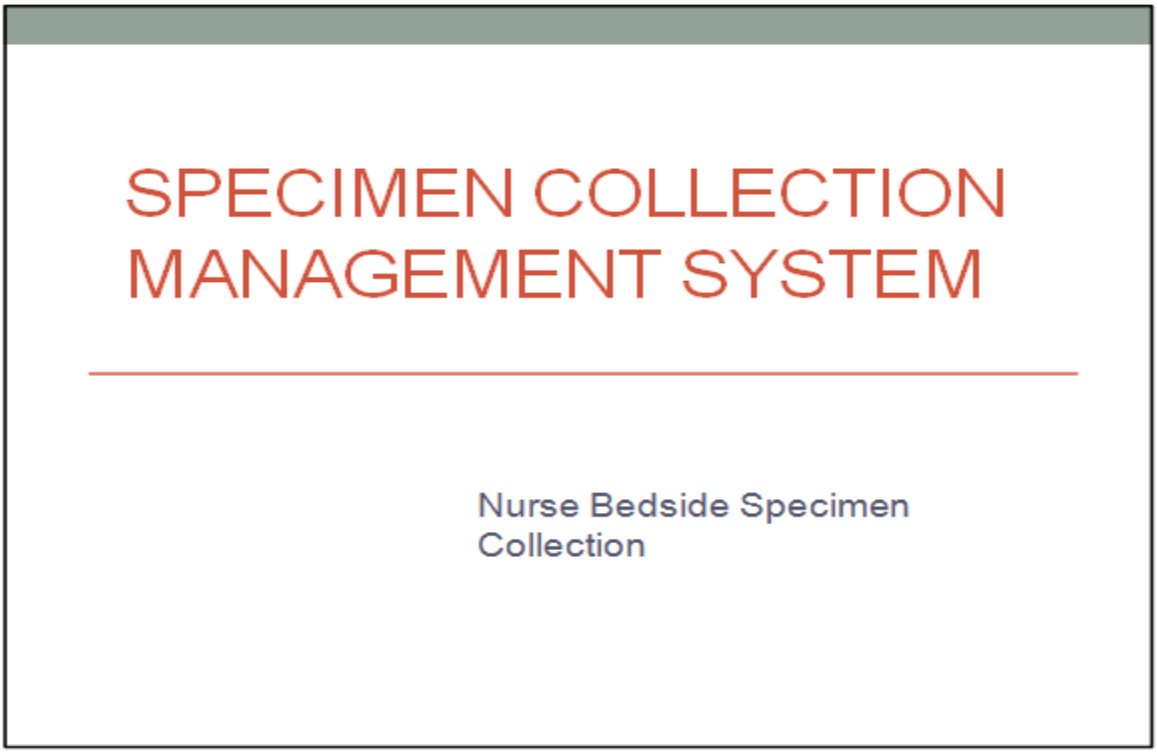
<table>
<tr><th>Project Objective</th><th>Scope</th></tr>
<tr><td>• Reduce specimen labeling error by replacing current manual specimen collection workflow including the necessity to print a paper requisition for each test and labels at a central station and to provide positive patient identification with barcoded patient identification and order matching to enhance specimen collection processes.</td><td>In Scope:
• Phase 1: Inpatient Nursing Units (adults/pediatrics)
• Phase 2: ED and Mother/Baby
• Phase 3: Perioperative areas, Respiratory Therapy collected specimens,
• Lab Tests: All order types, blood specimens for clinical lab/Blood Bank

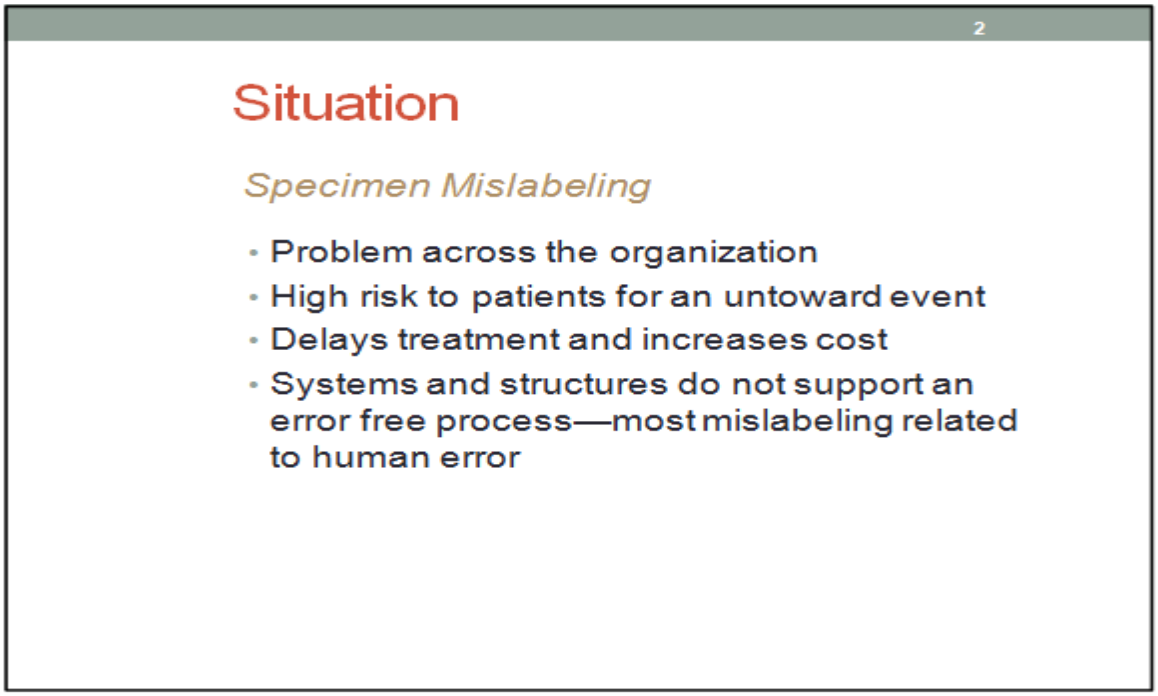
Out of Scope:
• Special procedural areas, Outpatient locations, non-blood specimens</td></tr>
<tr><th>Deliverables</th><th>Information Technology</th></tr>
<tr><td>• Technical go-live for pilot unit: 03/01/14
• Pilot go-live for 2 nursing units: 03/31/14
• FMEA: January to March 2014
• Additional unit go-live: TBD

• Training materials reflect continuity from Computer Provider Order Entry (CPOE) order entry to SCMS Registered Nurse (RN) workflow using computers, scanning devices, and specimen label printers
• Completion of training is mandatory for inpatient RN staff</td><td>• Procurement/deployment of wireless and wired label specimen printers to patient care areas
• Customer Service Support provided by IT
• Backend infrastructure built and supported by IT
• SCMS application deployed to all patient care computers</td></tr>
<tr><th></th><th>Success Criteria</th></tr>
<tr><td></td><td>• Utilization by end-users 70% after one month
• Patient identification with barcoding and order matching >90% after one month
• Mislabel reduction by 50% after nine months for acute/critical care</td></tr>
</table>

Appendix J

SLIP Training Module

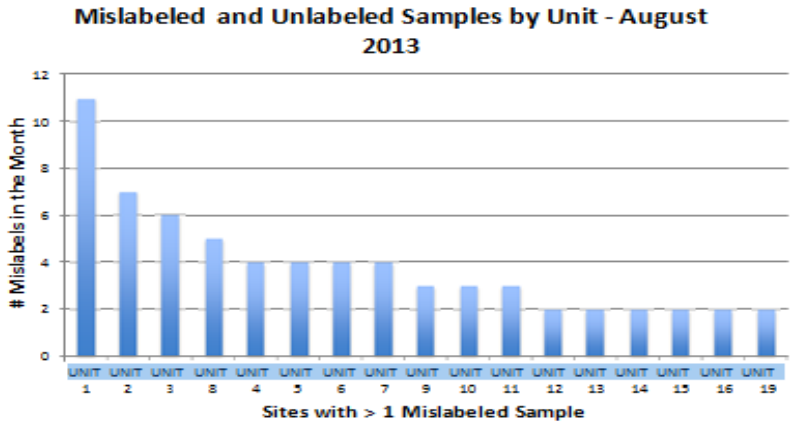




3

Mislabeled & Unlabeled Data

Does not include Blood Bank



4

Lab Specimen Error Types

Type	Errors
Near Miss Specimen Errors Serious errors, which could lead to issuing wrong unit of blood.	1. Wrong Blood in Tube (WBIT)– sample has ABO/Rh type mismatch with ABO/Rh type on file. 2. Discrepancy (name & MRN) btw specimen and requisition. 3. Incorrect/missing pt info on specimen 4. Incorrect/missing pt info on requisition 5. Unlabeled
Specimen Collection Problems Problems preventing Blood Bank from testing sample requiring specimen redrawn.	1. Unsigned specimens* 2. Hemolyzed specimens 3. Phlebotomist signature on tube is illegible 4. Requisition missing 5. Quantity Not Sufficient (QNS) 6. No specimen 7. Wrong tube type 8. Empty tube 9. Other (i.e. missing draw date, same draw date/time for 2nd ABO/Rh sample, diluted with saline, spillage)

*AABB Standards (CA law): Blood Bank must be able to identify the individual who drew the sample. Blood Bank requires legible name/signature of phlebotomist (or 5 digit MD #).

5

Hospital Clinical Lab Data

January 2014, total of 85 error out of 6,363

LOCATION	# OF ERRORS	TOTAL
UNIT 8	1	395
UNIT 7	2	291
UNIT 12	1	94
UNIT 2	6	671
UNIT 4	3	389
UNIT 5	3	105
UNIT 6	2	67
UNT 33	3	176
UNIT 14	1	119
UNIT 28	3	300
UNIT 15	12	621
UNIT 29	5	159
UNIT 32	5	114
UNIT 9	3	361
UNIT 34	2	115
UNIT 35	2	161
UNIT 3	5	624
UNIT 1	16	434
UNIT 36	10	1167

That is equivalent to 13,358 failures per one million specimen collection

Compare

6

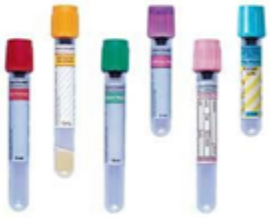
Evidence

Specimen Mislabeling

- Nationally a widespread problem.
- In FY2012, two fatalities, of the 65 total transfusion-related deaths reported to the FDA, were attributed to labeling errors (FDA, 2012).
- Hospital RN stories:
  - Mismatched labels and requisitions result in:
    - Delay in Labs/Second Stick
    - Toxic Vancomycin Level
    - Rapidly deteriorating patient

7

What is Specimen Collection Management System?



Return On Investment

Improved lab workflow

Better Turnaround Time

Improved quality of care and patient safety

Improved collection workflow

Better tracking of samples

Reduced costs

Better Specimen Management

8

New Workflow

- **S**can - **V**erify - **C**ollect - **L**abel - **F**inal **C**heck

9

When to use Specimen Collection Management System

Specimen collections to be used with Specimen Collection Management System:

- Blood Bank (i.e. cross match)
- Hematology (i.e. cbc)
- Chemistry (i.e. metabolic panel)
- NCPL (i.e. ABG) – *include Epic paper req.*
- Microbiology (i.e. blood cultures) - *include Epic paper req.*
- Immunology (i.e. Hep A)
- Cytogenetics - *include Epic paper req.*
- Bone Marrow Transplant Lab
- Immuno Transplant Lab
- Research lab collections

Specimen Collection Management System is NOT to be used to collect:

- Pathology (i.e. cytology)

10

Accessing Specimen Collection Management System

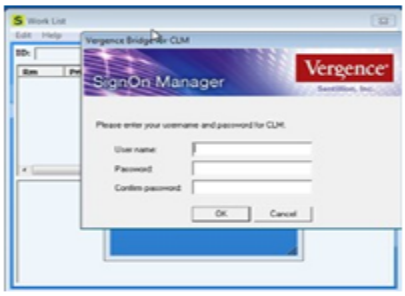
Log-on to Bedside Computer

- **"LabColl" icon within Sentillion toolbar**

11

First Time Login

Bedside Computer

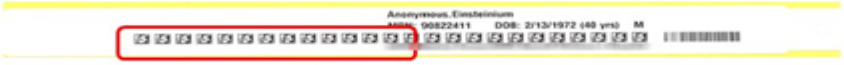


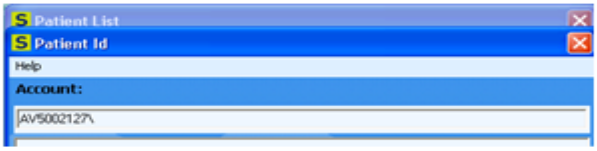
- First-time login will require username and password
- Single sign-on thereafter

12

Scanning the Patient

- **Scan the patients armband 2D bar codes**



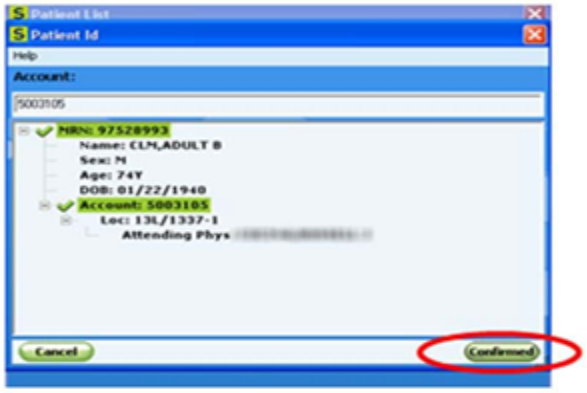


- **Select "Tab" or "Enter" key on keyboard**

13

Positive Patient Identification

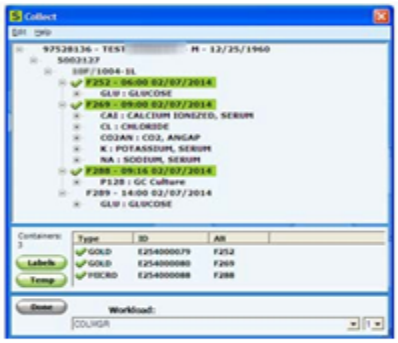
- **VERIFY patient you intend to draw by comparing patient name on screen to armband name.**
- **Click the "Confirmed" button when you have completed the positive patient ID.**



14

Collect Screen

- **Accession number (Oldest at top of list) will automatically be selected.**
- **Click desired accession numbers to collect.**
- **As you select accessions, the containers will appear in draw order in the middle of the screen.**



Important! Patient account is locked when on "Collect" screen; make sure to navigate off of screen when finished by closing screen with X

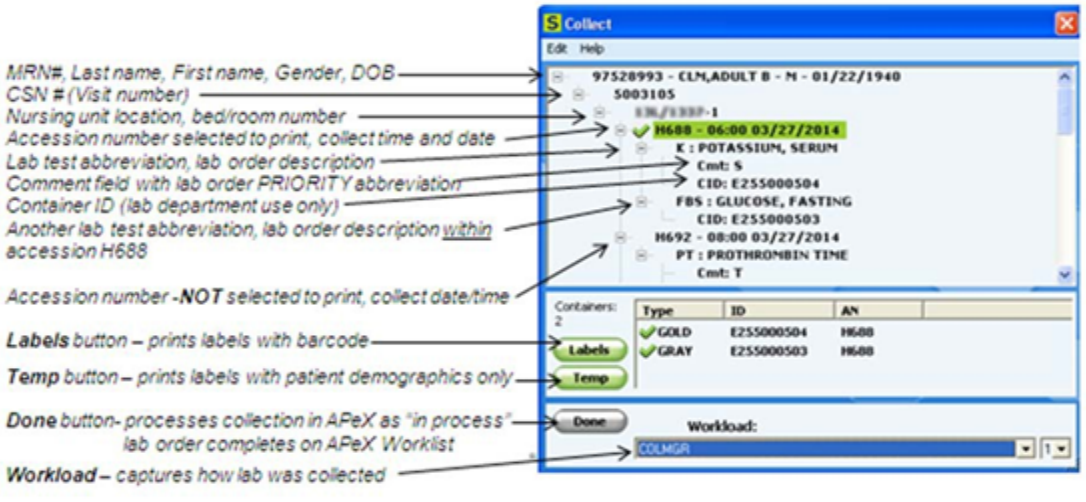
15

Accessions

- Grouping of labs based on time ordered
  - 3 hours in past, 1 hour in future
- Designed to reduce:
  - Nosocomial Anemia
  - CLABSI
  - Peripheral Sticks
- Which labs?
  - Routine (one time order, not timed)
  - Scheduled (e.g. q 4, q 12, daily)
- Timed and Stat *will not* be grouped
  - Unless other labs are within 5 minutes

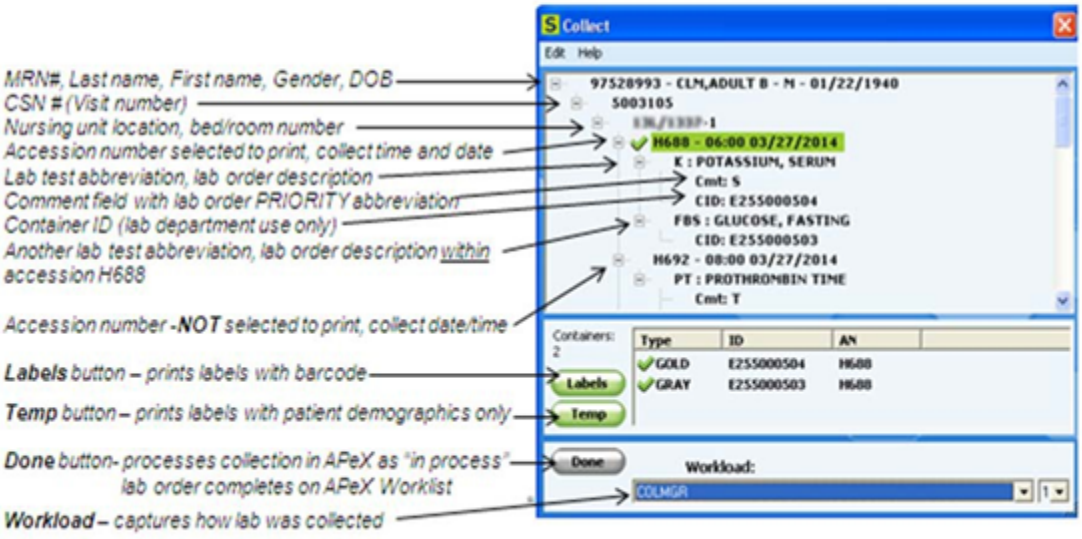
16

Details of Collect Screen



16

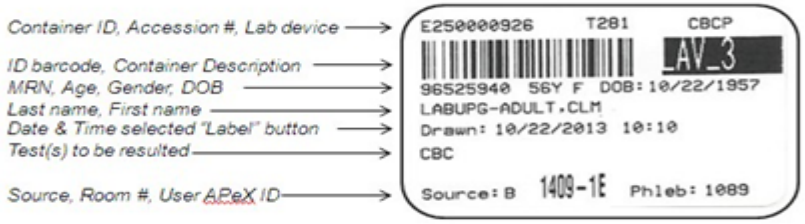
Details of Collect Screen



17

Next Steps

- **Collect specimen(s) or Draw blood sample**
- **Click the Labels button.**
- **Labels print**



- **Affix labels to appropriate colored containers (tubes)**
- **Label Check -** *"Color to the other"*

18

Miscellaneous Labels:

- Multiple lab tests EXCEEDS the labels character limit
- ++++++++++++++++++++++

- When you see this label, **PROBLEM** - call the lab. The container has not been defined.

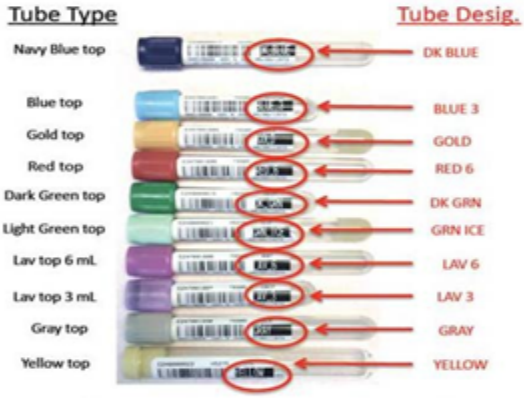
- When you see label, **CALL lab** - call the lab. The container can only be obtained in the lab.

19

Using Collection Manager Labels

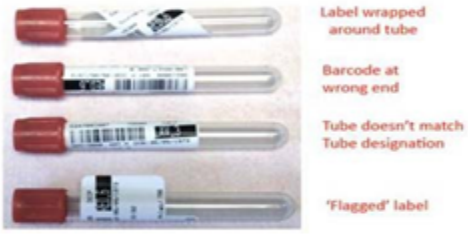
Collection Manager Label

Correctly Labeled Tube



Tubes are shown in correct draw order

Incorrectly labeled tubes



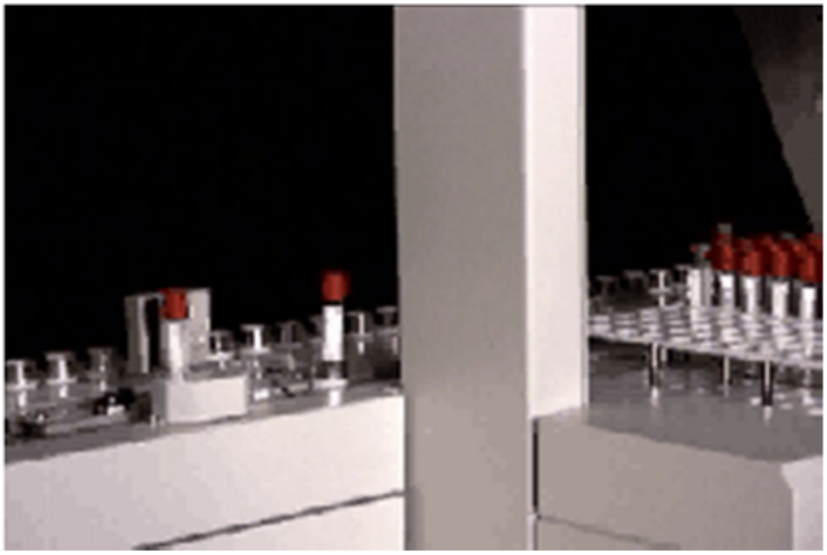
Questions? Call the lab at [redacted]

20

New Specimen Labels - Affixing

21

Impact to Lab Department



22

The Final Check

1. **Compare tube top color to the color on the label**
2. **Compare ALL tubes to patient armband**
3. **Read the last 3 numbers of the MRN on the armband *OUT LOUD!***
4. **Read the last 3 numbers of the MRN on each label *OUT LOUD!***

For reference: http://www.thefinalcheck.org/

23

Done

- Select "Done" button after Final Check
- "Done" impacts the following:
  - ✓ Epic lab order status -"in process"
  - ✓ Epic Chart Review displays collected date/time
  - ✓ Epic Work list displays lab task as completed
  - ✓ Epic lab order – Provider cannot update
  - ✓ User cannot reprint this lab order label

24

Change Management

Same process

- **Review lab orders in Epic**
- **Release orders as needed (i.e. PRNs)**

Changes

- **Shared Zebra LP2824 label printer**
- **Printer at bedside**
- **Scan armband**
- **Print & affix labels bedside**
- **The Final Check**

25

Change Management

Big Win! Changes

- **Label replaces Epic paper requisition**
- **Use SCMS label and send paper requisition for:**
  - ✓ *Microbiology & Cytogenetics (i.e. cultures, genetic studies)*
  - ✓ *NCPL Unit 28 (Blood gases)*
- **User ID on label – print username only for updates**
- **DRAW DATE/TIME already on label - only need to update if it is 30 minutes or more from actual draw time**
- **NOTE: For SCMS downtime, use Epic req *and* ADT label**

Appendix K

Specimen Labeling Policy

Office of Origin: Department of Patient Safety

I. PURPOSE

To enhance patient safety by providing a consistent method for correct identification of inpatient and outpatient specimens.

II. REFERENCES

The Joint Commission National Patient Safety Goals

The Joint Commission Laboratory Accreditation Manual, Standard

QC.2.20 Laboratory Manual for MEDICAL CENTER Clinical

Laboratories

Administrative policy 2.1.1 Patient Identification

Department of Pathology Specimen Receipt, Identification, and Rejection Policy

III. DEFINITIONS

Not applicable.

IV. POLICY

For all specimens taken from patients for clinical testing or received in a laboratory setting from within or outside of Medical Center, the person collecting or receiving the specimen must verify the correct specimen and correct patient by comparing two unique identifiers to one or more source documents, such as the order for the lab test, or other appropriate paperwork, and labels for the specimen.

The two identifiers are the patient's name and medical record number. If for some reason the specimen must be/has been collected before a patient has been registered or if the specimen is from a source outside of Medical Center, the patient's name and birth date may be used as the patient identifiers.

This policy applies whether a specimen is sent to the laboratory for processing or is used for a point-of-care laboratory test.

V. PROCEDURES

A. Collecting specimens

1. Refer to the MEDICAL CENTER and MEDICAL CENTER SATELLITE Clinical Laboratories Manual, the MEDICAL CENTER Pont- of-Care Testing Manual, and department-specific procedures for test-specific information related to how to collect and send a specimen.
2. Prior to obtaining the specimen, assure proper patient identification by comparing two patient identifiers provided by the patient or from the patient ID wristband (inpatient) per Patient Identification Administrative Policy 2.1.1 to the order(s) or paper requisition(s). If using a manual process (e.g. a system other than Specimen Collection Management System) assure printed specimen labels match two patient identifiers and the patient information on the requisition. For specimens, such as urine, stool, sputum, collected by the patient, apply an addressograph/Epic patient label to the specimen container prior to giving it to the patient. Departments using Specimen Collection Management System will attach a Specimen Collection Management System generated label to the container after the specimen has been obtained.
3. If the order or paperwork (labels and paper requisition) and one or more of the identifiers do not match, do not collect the specimen. Obtain correct patient or correct paperwork and repeat patient verification process. If unable to verify, notify the appropriate provider who ordered the test.

B. Labeling Specimens

1. For specimens being sent to the main Clinical Laboratory using a requisition it must include, at a minimum, the following:

ii. patient's first and last name

iii. patient's sex and date of birth

iv. Medical Record number

v. patient location

vi. ordering physician name and identification number (ambulatory patients)

vii. applicable ICD-9 code(s) (ambulatory patients)

viii. tests to be performed

2. For specimens being sent to Pathology, the requisition must contain:

ii. Patient's first and last name

iii. Medical record number and/or birth date

iv. Location (hospital, clinic, private office)

v. Date specimen obtained from patient

vi. Attending/referring physician name

vii. Specimen source/site

viii. Pre-op diagnosis, ICD-code, or relevant history

3. Specimen label:

i. For Clinical Laboratory specimens labeled using Specimen Collection Management System labels are generated after collection of specimens and include patient first and last name, medical record number, date of birth, date collected, time collected and phlebotomist code and test to be run.

ii. Specimens collected without Specimen Collection Management System MUST at a minimum include patient first and last name, medical record number or date of birth and date collected.

1) For Clinical Laboratory samples, when preprinted labels from the Clinical Labs or Specimen Collection Management System are not available, use an addressograph/Epic label, or legibly print the patient's first and last name, MEDICAL CENTER medical record number or date of birth and date and time of collection.

2) For Clinical Laboratory specimens collected for Blood Bank tests, including blood typing, and/or cross match, the addressograph/Epic label must include patient's full name, medical record number, date of birth, date/time drawn and person collecting sample information (written legibly) name (first and last) or code or if collected by a physician, physician ID number and name (first and last). Initials are NOT accepted.

3) For Pathology specimens, the site/source must be included if multiple sites are involved, in addition to name, medical record number and/or date of birth.

4. Label every specimen obtained in the room or at the bedside of the patient except when the specimen is collected by the patient himself, such as urine or stool. In this case, label the container with an addressograph/Epic patient ID label prior to giving it to the patient. Departments using Specimen Collection Management System will attach a Specimen Collection Management System generated label to the container after the specimen has been obtained.

5. Place only specimen(s) and any paperwork from only ONE patient in a bag for transport to the laboratory. Ensure that specimen(s) and paperwork in the bag are from the same patient.

C. Labeling Specimens Removed During A Surgical Procedure

1. The specimen label includes the patient identification information, the specimen source identification, and any other information required by laboratory policy.

2. Specimens are properly labeled in the room where they are collected; such sites include operating rooms, examination and treatment rooms in ambulatory practices, and any other area where specimens are obtained.

3. For pathology specimens, the patient identification label should be affixed to the side of the specimen container, and not on the lid if at all possible.

D. Receipt of Mislabeled and Unlabeled Specimens

1. When the identification of a specimen submitted for analysis is in any way questionable, the laboratory will recommend that, if feasible, a new specimen should be obtained.

2. If the laboratory is unable to determine from whom a specimen has been collected with a reasonable degree of certainty, a new specimen must be obtained.

3. When there is a mismatch between the name on any paperwork and on the specimen (Mislabel) the specimen should in virtually all circumstances be recollected. In cases where a mislabeled specimen is irretrievable or where re- collection would jeopardize patient care (e.g. invasively collected samples, intra- operative samples, timed samples, etc.) AND the specimen itself can be identified with reasonable certainly, exceptions to the above policy may be made. These decisions will be the responsibility of the Laboratory Medicine resident on duty or a Laboratory Director. In cases where the mislabeled specimen is approved for testing, the patient's physician must accept responsibility in writing for the specimen being processed. The test result in the patient's chart will carry the notation the sample was "REC'D MIS(UN)LABELED-RUN AT MD'S REQUEST and under some circumstances an entry may be made in the progress notes by laboratory staff further describing the relevant circumstances.

4. The pathology department will make every effort to obtain the information needed to process the specimen; however, if they prove unsuccessful, the specimen will not be processed.

VI. RESPONSIBILITY

Questions about the implementation of this policy under routine circumstances should be directed to Patient Safety Department 555-1212.

VII. HISTORY OF POLICY

Separated from Patient Identification policy, April

2002 Approved April 2002 by CEO

Revised July 2005 by Director, Regulatory Affairs Reviewed

September 2005 by Policy Steering Committee

Reviewed by Patient Care Director, Ambulatory Care Services

Approved November 2005 by Executive Medical Board, Governance Advisory Committee

Reviewed by Lab Standards Committee, January

2010 Reviewed by Patient Safety Committee,

February 2010 Reviewed by Policy Steering

Committee, March 2010 Reviewed by Senior

Leadership Group, March 2010 Reviewed by

Patient Safety Committee May 2010

Revised by Patient Safety Manager July 2014

Reviewed by Patient Safety Committee July 2014

Reviewed and approved by Policy Steering Committee September 2014

Appendix L

Gantt Chart

Milestones	2013			2014								
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept
Initial Meeting	10/1											
Design		11/10										
FMECA				1/6								
Training						3/1 Pilot Units	Acute Care Units			CC Unit		
Implement						3/30 Pilot Units	Acute Care Units			CC Unit		
Evaluation							4/1					
Phases 2 & 3 TBD												

Appendix M

Training and Implementation Schedule on SCMS

Training and implementation of SCMS

3/01-3/31	5/13-6/5	6/17-6/30	7/17-7/17	7/21-8/6
Unit 5	Unit 7	Unit 39	Unit 43	Unit 8
Unit 32	Unit 27	Unit 40	Unit 22	Unit 12
	Unit 13	Unit 41		Unit 28
	Unit 14			Unit 42
	Unit 6			Unit 29
	Unit 38			Unit 34
	Unit 10			Unit 35
	Unit 18			Unit 19
	Unit 3			
	Unit 44			

Appendix N

Survey Monkey Tool

Initial Report

Last Modified: 06/17/2014

1. Shift primarily work

#	Answer	Bar	Response	%
1	AM Shift		43	55%
2	PM Shift		35	45%
	Total		78	

Statistic	Value
Min Value	1
Max Value	2
Mean	1.45
Variance	0.25
Standard Deviation	0.50
Total Responses	78

2. Please rate the following

#	Question	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Total Responses	Mean
1	I use the Specimen Collection Management System application & printer every time I have a lab/test specimen collection due.	15	35	11	13	4	78	2.44
2	All lab/test orders that I need to collect display in Specimen Collection Management System.	17	33	8	15	5	78	2.46
3	All lab/test orders are displaying appropriately within Specimen Collection Management System	18	36	11	9	4	78	2.29
4	Specimen Collection Management System work flow increases patient safety with the use of barcode scanning and bedside labeling.	27	36	12	3	0	78	1.88
5	Printer is readily available when I need it.	33	27	7	6	5	78	2.01
6	Specimen Collection Management System is readily available when I need it.	23	34	9	7	5	78	2.19
7	Printer is simple to use (including changing labels)	19	34	16	6	3	78	2.23
8	Specimen Collection Management System is simple to use.	17	32	16	10	3	78	2.36
9	I check the tube color every time I collect labs and say the color out loud.	21	47	5	4	1	78	1.94
10	I use The Final Check every time I collect labs and say the MRN out loud.	21	38	13	6	0	78	2.05
11	SIM training and support provided was sufficient for the Specimen Collection Management System and printer roll out.	20	41	9	5	2	77	2.06
12	I feel confident in my abilities to use Specimen Collection Management System and printer hardware based upon my SIM training.	17	45	11	2	3	78	2.09
13	My understanding of Specimen Collection Management System was enhanced by training in the SIM lab.	23	42	9	1	3	78	1.96
14	The Specimen Collection Management System & printer workflow impede (or obstruct) my patient care.	11	19	14	22	12	78	3.06

3. What do you like best about the new specimen collection process?

Text Response
patient safety in identification
Save paper, not printouts!
patient safety
Increase to patient safety
So easy and safe, my work is much faster.
It Limits the possible mistakes that could be made.
scanning
printed labels, the process increases patient safety, ease of use.
It ensures accurate patient labeling. I have not been called for issues from the lab.
Ease of use. Workflow is much easier
I like that I know exactly what tubes are necessary for lab collection (before I would wonder if one or two tubes were appropriate).
Very simple to use and very safe for patient. Will not have wrong label on tubes.
When all the technological aspects are functioning properly, it is a highly efficient process. the workflow does take some getting used to, however, once settled, it's safe and quick and I can use my time for other patient concerns
clear labels for labs.
it's easy
using Specimen Collection Management System to print specimen labels might eventually eliminate the need to print lab requisitions and patient labels for specimens which would theoretically improve patient safety and increase workflow efficiency.
Easier labeling: not having to sign
I have less of a chance of drawing up the wrong specimens and less of a chance of mislabeling. It very accessible when available for AM lab draws of transplant patients.
less paper waste
The double checks that make it safe.
labels are printed in room
no more lab reqs
A fine system when it works
its easy to use
When there are no technical issues its usually fine
Very efficient.
It is very easy.
Labels, not having to sign/date/time labels.
Scanning the patient allows for less mislabeling occurrences.
Pretty easy to use.
no req need
Not wasting all the paper for requisitions
It is thorough.
when working properly it is an easy, safe and efficient system.
It reduces error of mislabeling the wrong patient, reduces error of using the wrong tube also.
when all equipment is available and working it is good.
efficiency, accuracy, pt. safety increased
Can be a much more efficient workflow and is safer. I also enjoy not having to print a requisition or get a label.
Safer for patient
tube specific labels seem more clear and safer
accurate labels
Streamlines workflow and printing labels in the room with the patient is much safer for the patient.
It does not impede work flow it slows it down.
When it works the way it should, it is simple, fast and safe for patients. Also neat, I like neat. Seems
like a good system but I don't get to use it enough to make a valid commend.
Difficult to evaluate because I have only used it twice. The first time went very well-but I needed another RN to walk me through because it had been a while since the training. The second time it did not go well and other RNs attempted to assist me but were unable to troubleshoot the problem. So I used the requisition instead.
quick and easier not to always have to print out pt lab requisitions.

4. What do you like least about the new specimen collection process?

Text Response
selecting desired test from tree a little unintuitive as is quitting the program
The printer is not always working
it takes longer.
Dual processes for some labs. Gas lab and micro need to adapt their workflows to the new technology. It makes it less safe to have 2 processes at the bedside
not enough resources available to trouble shoot, not all tests in CM. still have to print reqs
There were moments when the paper labels kept on coming out from the printer. That was very frustrating to me. We just found out last week that the labels weren't the right one. But it's ok now. No more complaints.
It's time consuming. When the system was not working, we have to go back to the nurses' station to get the requisitions to complete this task in an old fashion way.
the process
the printed labels/label paper is sometimes out of alignment.
I have had an error message after i open the tab and scan the patient. I believe it was an error with the link of the scanner, or a disconnect with the patient's identification not being recognized in the system. The patient was switched to another room and the issue was resolved by using a different computer. It is tedious to triage issues with each system that is introduced to the staff.
Sometimes the Specimen Collection Management System application does not pull up. It also would be convenient if all lab orders (including those going to micro) could go through the Specimen Collection Management System application.
Sometimes the scanner in the room would not work.
Technical difficulties make the process twice as long. The computers in Unit 7 have been a hit and miss scenario for me
nothing
The hardware does NOT work and it is EXTREMELY annoying to waste valuable time in my shift dealing with: equipment that does not work, searching the unit for some little marking pen to clean printers when changing label rolls, bringing equipmnt into a patient room only to find that no USB cable has been installed on the computer and then having to go back and get different equipment or go back to the old patient label system, dealing with labels that don't work in the printers and cause them to malfunction, having software interfaces on two different types of devices (desktop vs dolphin) that do not function the same way, trying to use wireless equipment in patient rooms where no hard-wired equipment exists and wireless signals are unreliable, having to log in and out of one more device when trying to complete multiple patient care tasks at the same time.
The way that the info displays on the computer screen is hard to read if multiple tests are ordered/due. Rather than indentation of numerous lines, please consider different colors/bold to separate labs due at different times, patient info, etc.
The WOWs in the hallway still unable to print from them. There are still some rooms in our floor that the printer doesn't work.
not enough printers, messy display
still learning to use it as I don't do very many labs on AM shift.
must rely on technology
Some cords for our printers are ridiculously short, one room the printer "hangs" and can't sit on the work shelf. The collection screen is not user friendly to see the "big picture".
The printers are unreliable. There are a lot of printers out there that don't work and on a busy morning i am more inclined to just print up reqs and check arm bands than bother trying to find a working printer...
Some the computers in the patient rooms don't have the Lab Specimen Collection Management System. IT was not helpful at troubleshooting this.
sometimes it does not have all the test listed
Problems such as broken usb connector cables in room, difficulty in wireless connecting the dolphins to the lab printer, network issues not able to connect to printer straight to room computers, some lab orders not showing up on the lab collection screen. These issues really make the process of lab collection that much harder and time consuming.
It doesn't seem to be increasing the speed of my lab results at all. It also seems to be very difficult when there is more of an urgent situsation happening. Often MDs are using computers at that time and we have to scramble to find one to use to use Specimen Collection Management System.
DOES not always work. I literally spent 45 one morning trying to find a computer that would print labels. It's a shame that we just could not wait until EPIC had something to use for labels.
The prn lab orders don't show up on the collection list unless I have released the order in Epic. Prn orders should automatically show on my Specimen Collection Management System list.
Sometimes spits out labels without stopping when you have the MAR or other patient info windows open.
sometimes is hard to fine the exact one you are drawing when you have mutilple orders to do
reseearch labs ae not included
Learning curve/ I only use it once a week and forget in between. Maybe more initial practice would be good.

I have had trouble sometimes when I scan the patients wrist band the ID does not populate in the Specimen Collection Management System screen. I tried switching to COW's when this happened and still the same result. I guess there a some patients MRN's or possibly a glitch in the system for some patients. I use it with the majority of patients with no problem, this has only been an issue 2 or 3 times.
It is too early to tell, but for now, I find it confusing that there are some lab tests that we still need to print the request from EPIC
Not all computers/rooms have the adapters and often there is no computer avialable with the proper attachment-cord. specimens from different fluid types need to be VERY clearly separated. patients interrupt nursing more than phlebotomists--screen goes blank, our collections can be interrupted mid collection.
still some computer buginess in connecting to printer, etc...
My main problem with Specimen Collection Management System is a lack of functioning cords to plug the printers into in the room. Either I can't find the cord on the computer, it's in an awkward place near the floor, or the cord is broken. This makes me hesitant to trust that I can use the printer and actually adds a step when it doesn't work and I have to go back to the old method. So if I have extra time I'll grab the printer, anticipating that I won't find the plug for it to work, and if it does work then I'm plesantly surprised. If I'm short on time I rely on the old method because I trust that it will work and I won't be adding time to my workflow.
Access to printers and cords connected to computers- sometime available. Often missing.
The necessary equipment is not available on all computers or rooms. When it is there most of time not working properly. Training took place too far in advance of implementation on unit. There should be some on unit training available with real patients/situations. Also there should be IT rounding to ensure equipment present and in working order.
1) the software--selecting the labs I want is not intuitive and seems prone to error. 2) The workflow around cultures and blood gasses is now two steps and I'm prone to forgetting to print the recs 3) not all computers have the USB cord for the printer, so its an extra step to track down a wow.
sometimes it doesn't say what color tube to put lab in.
its not pedi friendly, and Unit 38 floor does aa lot of research labs not seen on Specimen Collection Management System; lab color on label is not helpful for pediatrics
Need to release a lab order (ex PTT) from kardex before it shows on machine otherwise it gets missed.
The fact that we still have to print the reqs for certain labs. I thought the whole point is that there is no more reqs (along with patient safety of course). Also I don't like that our printers are not hardwired in the rooms. A lot of times you pick up the printer int he meds room, take it to your room only to realize that the USB is missing, or the printer is dead,,,, or there is some other issue. Also sometimes it's too many things to carry into the room (frequently). And people frequently leave the printers in the oom and forget baout them, the printers die and then there is not enough for everyone. We do enough RN draws on Unit 14 to warrant hardwired printers. I really think that this will help this practice become a success, because currently people are frustrated with the wireless printers and default to the old way frequently.
I have not use it after the training.
Change in workflow which is difficult to use efficiently when it seems there hasn't been alot of opportunity to use on floors I have floated to.
not all floors have printers
printer sometimes jams the paper or printing the same labels repeatedly thus wasting the paper
Multiple problems with printing form WOWs, which nobody seemed to pay attention to. prn PTT orders for q6hr heparin drip patients seem to be getting missed; it is not an easy process and should be more automatic. More than once I have not found the lab I am looking for then, while playing around trying to get things to print, it magically appears.
I am frustrated that several times I go to the trouble to use the printer and it malfunctions. Sometimes completely unresponsive, once it printed about 7 empty labels between each correct label using up much of the spool of labels, another time it printed the correct information but it was partially on one label and partially on another label and then I went and got another printer which did the same thing. Needless to say that we are very busy on the floor and by that time I gave up and did it the old-fashioned way.
not all due labs are on the workflow
I would say that more than 50% of the time the printers do not work. Either no cable in the room, The printer prints out wrong/printing half on one label and half on other, the printer will not print when hitting print. I have tried many trouble shoots and still have issues. It is very time consuming because it does not work a lot of the time, then after troubleshooting and having to leave the room to go and get the papers the old way also adds risk to mistake. Then having to fill out a request for service and notifing management adds up the time spent.
Not all computers have the setup for the printer. Also, many times I can't get the label to print on the printer.
Not all computers have cables for printer.
the cables are not readily available in each room nor are they long enough to place the printer safely down to free up your hands so you can work.
more time spent on our end with set up and use of Specimen Collection Management System and printer and sometimes printer doesn't work
troubleshooting, it does not always work as it is supposed to. When the priner is turned on sometimes the papr starts to rool out on its on. How do you stop that? the label does not always print when it is supposed to
sometimes q6hr ptt do no show up for patients on heparin drips
not sure
Not all room has the cable for the printer. Sometimes, the printer is connected to the computer in room, but doesn't print out labels. Emails were sent out to help us address this. However, the problem is when I am collecting lab samples, I don't have a lot of free time. Having to bring the device into the room, getting ready to draw labs, just to find out that either the cable is not there or that it doesn't print and I need to trouble shoot really discourages me to use it again. I usually don't have time to follow up on this matter right away, so I would forget later. When this happened, it really impeded my care because I had to go out to the nursing station to get the patient's labels and bring them back to the room to draw. Things happen in between. It also made me feel frustrated and therefore interferes with my workflow. This has happened at least more than 3 times, and I start to feel like it'd better off just doing it the old way because I know it will work rather than trying this and figure out things don't work out again when I'm ready for it.

Statistic	Value
Total Responses	60

Appendix O

Failure Mode, Effect, and Criticality Analysis (FMECA) Summary

Failure Mode, Effect, and Criticality Analysis (FMECA) – 2014
Specimen Labeling Improvement Project Summary Report

Aim: During the process of blood specimen collection, errors in ordering, collection and labeling might occur that could potentially have adverse patient consequences. This FMECA was done as a proactive risk assessment prior to initiation of SCMS, a new process for specimen labeling and requisitioning of a specimen order, to determine failure modes in the specimen labeling process using SCMS identify potential solutions.

Team Lead: ACNO/DNP Student and Patient Safety Manager

Team: SLIP and Ad Hoc

Process: The team met from January 2014 – March 2014 to complete the FMECA prior to initiation of training for SCMS. SCMS is a LIS application that is used to identify patients and print labels, which serve the dual purpose of label and requisition, at the patient's bedside to eliminate the risk of specimen mislabeling and streamline specimen collection workflow. The process used to complete the FMECA was to identify:

- Steps in the process of using SCMS (bedside procedure or dolphin)
- Potential failure modes
- Potential causes of failure
- Effects of the failure
- Ranking severity, probability of failure effect and detection
- Calculating criticality to rank order potential failure modes and effects importance
- Potential solutions and outcome measures

The FMECA was completed prior to initiation of training of super users and pilot unit staff that began the end of March.

Failure Modes/Potential Vulnerabilities:

Staff may not understand significance of proper technique, potential for error, risk of harm
Solutions:

a) Include pictures of specimens with improperly positioned labels
b) Show how labels are read by machine
c) Include stories from bedside about impact of mislabeled specimens
d) Include discussion of cognitive bias as potential source of error

There are a variety of references used by staff to determine what specimen container to use and the volume of specimen needed
Solutions:

a) Get rid of all reference material
b) Add specimen container and volume criteria to EMR work list
c) Encourage use of lab manual for infrequently obtained specimens
d) Pediatric units will need reference sheets as lab criteria defaults to adult references

Hunting and gathering of supplies adds distractions and time to specimen collection process
Solutions:

a) Standardize caddies
b) Develop checklist for managers on assuring equipment is available

There is a potential for equipment to not be available when needed which may result in staff defaulting to manual process
Solutions:

a) Establish standard work on maintenance of equipment and supplies
b) Develop TIP sheets and FAQs about maintenance of printers and cables
c) Encourage use of dedicated WOW for acute care units
d) Encourage dedicated location for equipment/supplies on all units

Equipment may not work properly
Solutions:

a) Develop troubleshooting guide
b) Encourage managers to develop process for maintaining equipment and supplies

There is a potential for staff to default to process steps that increase the risk for labeling error
Solutions:

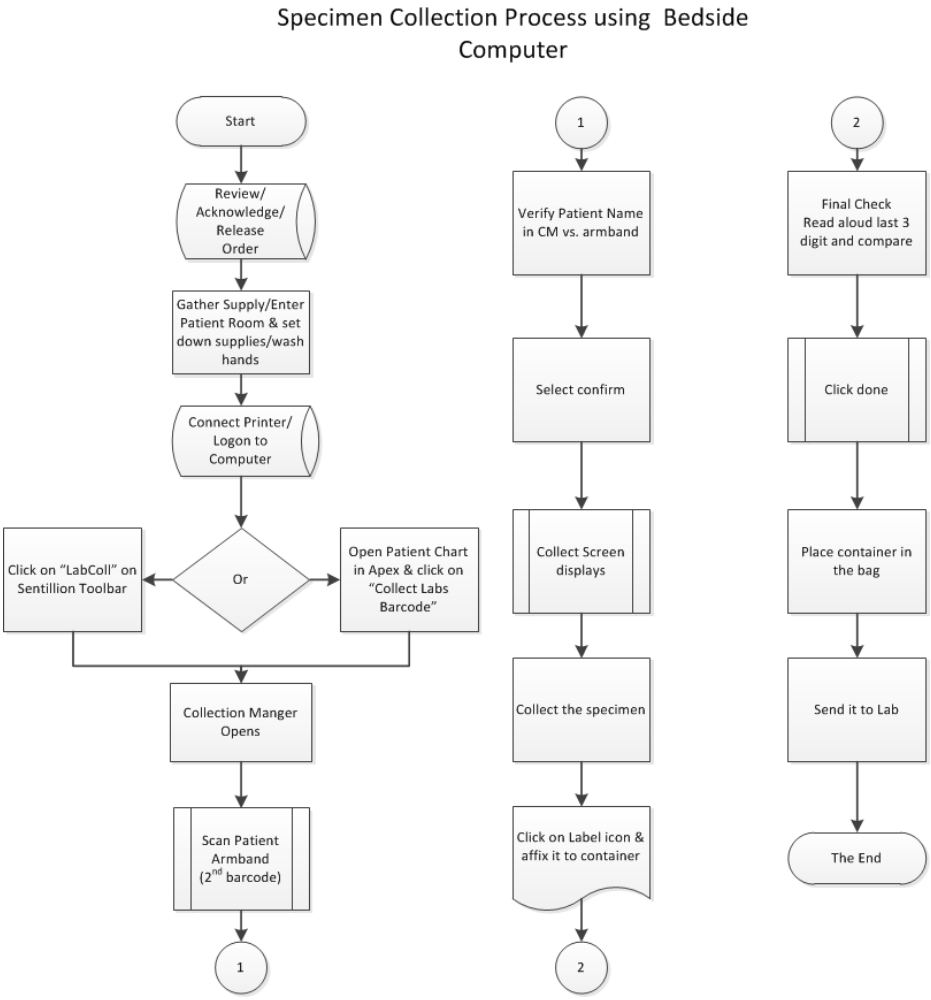
a) Establish standard work to include
    1. Drawing specimen then labeling
    2. The person obtaining specimen is the person who creates label, or if not possible the person who obtains specimen prints name on label
    3. Final check of last 3 digits of MRN said out loud
    4. Limit the number of labels at the bedside
    5. Develop SCMS Procedure
    6. Develop RN blood draw policy

Adoption of SCMS may be slow because it is a new workflow
Solutions:

a) Develop tip sheet for process, have accessible
b) Develop reports on compliance with using SCMS vs. opting out for unit managers

Appendix P

Workflow Analysis



- **The collection process was mapped in entirely and details**
- **Too manual and paper work driven and dependent**
- **Printing one place and use the labels in another place**
- **Loose labels are floating around**
- **Human Errors**

Appendix Q

Specimen Labeling Improvement Observation Tool

Medical Center

Specimen Collection Management System

Specimen Collection Observation Form

Location:_____ Date:_____

Name of Person Conducting Observation:_____

	Action
1	Requisition Printed (where, when, by whom?):
2	Label Obtained (where, when, by whom?):
3	Supplies Gathered (where, when?):
4	Hand Hygiene: (where, when?, should be more than once):
5	Identifies pt* (should compare name and MRN on armband to req):
6	Assesses venipuncture site (tourniquet applied):
7	Site preparation (cleansing technique):
8	Aseptic technique during venipuncture:

9	Needle entry angle (between 15-30^{o}):
10	Draw Order (note order in which tube colors/types are drawn):
11	Tubes filled and mixed (how full?, how mixed?):
12	Needle care (safety device used, straight to sharps container?):
13	Bandage applied (how, what):
14	Labels applied:
15	Second Pt ID*:
16	Specimen Handling (which bag, how sent to lab?)

Additional

Notes:_____

_____

_____

***Tip for patient identification**: the current practice does not promote verbalizing this step. Therefore it is sometimes difficult to ascertain compliance while observing. It is often helpful after the observation to ask how and what the RN checked for patient ID. With medication observations, the answer is often name and birthdate, not MRN.

Appendix R

SWOT Analysis

Strengths	Weaknesses
• Excellent compliance with barcode scanning technology used for patient identification with medication administration • EMR with CPOE since 2012-integrates with SCMS • Evidenced-based technology for specimen label error reduction • Supports and in alignment with medical center's strategic plan to improve patient safety	• Medical center wireless capacity • Workflow change, requiring large scale educational support • Competing medical center priorities • Clinician recognition of error impact • Additional equipment to maintain, clean and track
Opportunities	**Threats**
• Improve patient safety by reducing blood specimen label error rates • Improve patient value chain • Reduce Laboratory turn-around time • Improve clinician satisfaction • Reduce waste and inefficiencies, leaving more time for care delivery	• IT system downtime • Clinician/phlebotomist adoption • Training expense • Equipment failure, tracking and cleaning • New technology may introduce new latent failures • Failure of previous label printers

Appendix S

Budget Return on Investment Plan (ROI)

COLLECTION MANAGER BUDGET					
FISCAL YEAR	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	**TOTAL**
PROJECT YEAR	**YEAR 1**	**YEAR 2**	**YEAR 3**	**YEAR 4**	
Expenses Categories					
End User Training Salaries	**$258,063**	**$6,500**	**$6,500**	**$6,500**	**$277,563**
Simulation Educator Training Salaries	**$25,500**	**$3,200**	**$3,200**	**$3,200**	**$35,100**
Project Managers Salaries	**$70,720**				**$70,720**
Equipment (Printers, Power Strips)	**$113,600**	**$1,250**	**$1,250**	**$1,250**	**$117,350**
IT Wiring	**$13,680**	**0**	**0**	**0**	**$13,680**
GE Consultant	**$5,000**	**0**	**0**	**0**	**$5,000**
TOTAL COST	**$486,563**	**$10,950**	**$10,950**	**$10,950**	**$519,413**
REVENUE	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0**
RETURN ON INVESTMENT: $125/spec X 88/month= $11,000	**$132,000.00**	**$132,000.00**	**$132,000.00**	**$132,000.00**	**$528,000.00**
NET COST:	**$354,563**	**($121,050)**	**($121,050)**	**($121,050)**	**($8,587)**

Assumptions

Staff salary $84.50 direct and indirect (30%) x 3,644 hrs

Educator salary $110.50 direct and indirect (30%) x 230.80 hrs

Project Managers salaries $110.50 x 2 direct and indirect (30%) x 320 hrs

Printers $300.00 each x 284 and power strips $100 x 284

IT wiring for printers

GE consultant flat fee of $5000.00 for 6 months work (48 hrs total work)

ROI after 4th year based 88 specimen labeling errors/month at $125/hr. Cost avoidance of potential lawsuits not factored in ROI.

Appendix T

Unit Coordinator Checklist

Unit Coordinator SCMS rounding list:

In Patient Rooms:
- Cables present
- Cable works (plug printer in; if power = then cable intact)
- Check that Lab Coll is active (simple icon check)

In Med/Supply Room:
- Labels stocked
- Label levels in printer adequate
- Clean printers, inside and out
- Power cables present and working

Monitor open tickets

Place tickets for IT issues found during rounds

General IT fix-its:

- Dead Wow: plug in wow; open back door on bottom; flip black switch; wait 30 seconds; flip switch back)
- Broken Scanner: check that bottom of scanner is tight

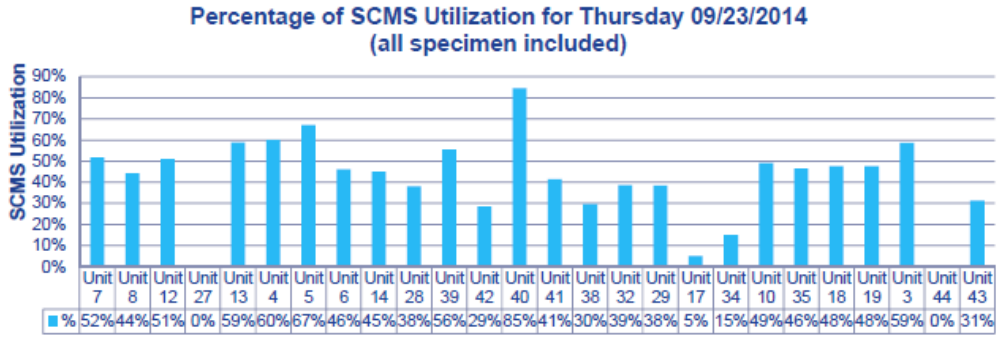
White USB cable missing: look for black USB cable!

Appendix U

Compliance and Utilization Analysis of SCMS

Compliance and Utilization Analysis of SCMS

Usage	Unit 7	Unit 8	Unit 12	Unit 27	Unit 13	Unit 4	Unit 5	Unit 6	Unit 14	Unit 28	Unit 39	Unit 42	Unit 40	Unit 41	Unit 38	Unit 32	Unit 29	Unit 17	Unit 34	Unit 10	Unit 35	Unit 18	Unit 19	Unit 3	Unit 44	Unit 43
SCMS	46	43	26	0	23	90	41	29	27	30	5	2	11	17	8	12	20	1	3	25	13	10	48	58	0	5
Not SCMS	43	54	25	23	16	60	20	34	33	49	4	5	2	24	19	19	32	19	17	26	15	11	53	41	7	11
Total	89	97	51	23	39	150	61	63	60	79	9	7	13	41	27	31	52	20	20	51	28	21	101	99	7	16
%	52%	44%	51%	0%	59%	60%	67%	46%	45%	38%	56%	29%	85%	41%	30%	39%	38%	5%	15%	49%	46%	48%	48%	59%	0%	31%



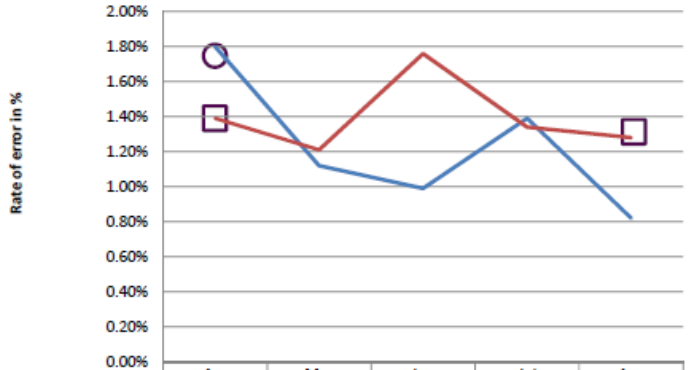
Utilization at or around 50%
New technology takes time to catch on

Appendix V

Efficacy of New Process in Blood Bank

Efficacy of New Process in BB

Blood Bank reported rate of errors with comparison between units using SCMS vs. those not using it

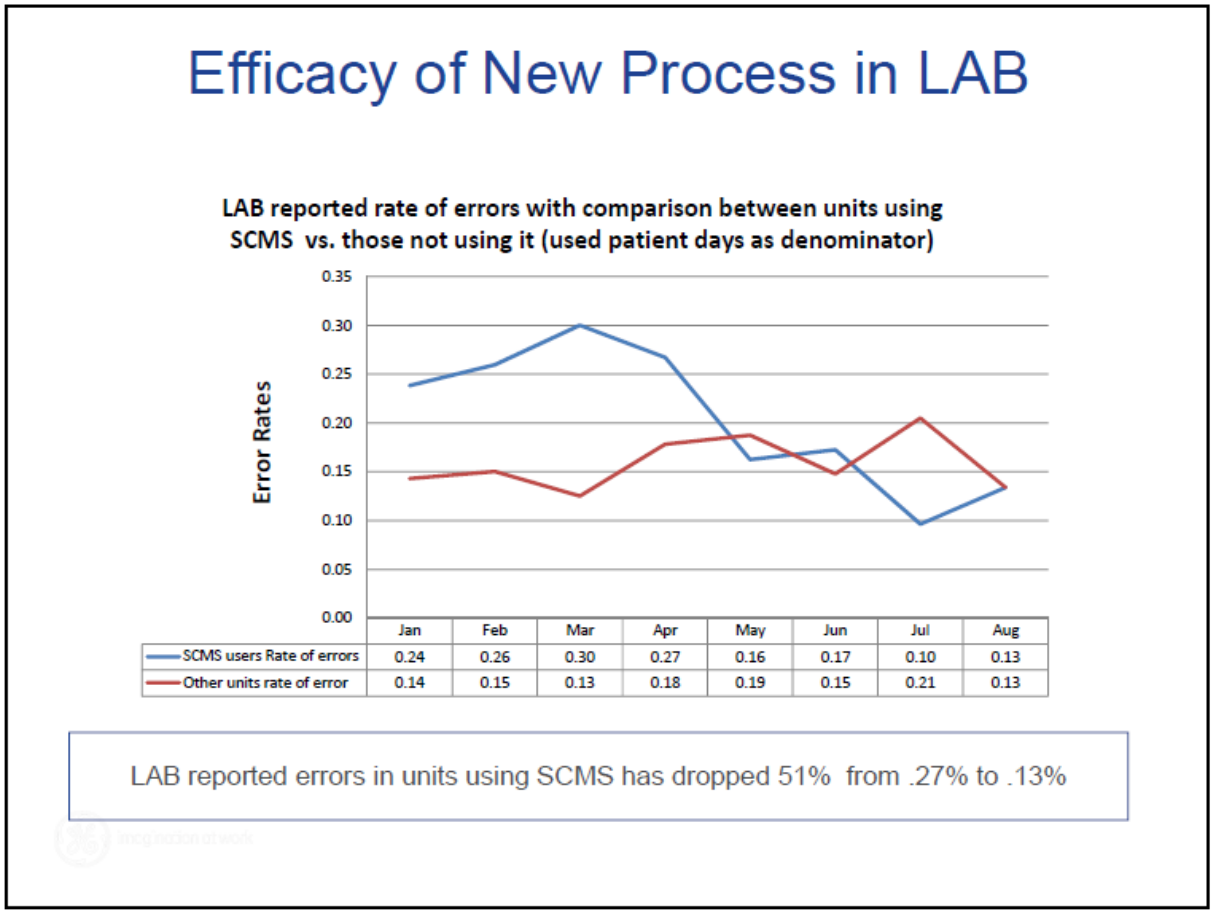


	Apr	May	Jun	Jul	Aug
BB error rate (SCMS using units)	1.80%	1.12%	0.99%	1.39%	0.82%
BB error rate (Non SCMS using units)	1.39%	1.21%	1.76%	1.34%	1.28%

BB reported errors in units using SCMS has dropped 56% from 1.8% to .82% while in departments not utilizing the new system and process we do not see that much change

Appendix W

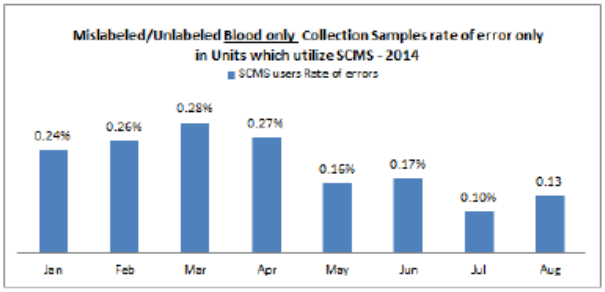
Efficacy of New Process in Laboratory

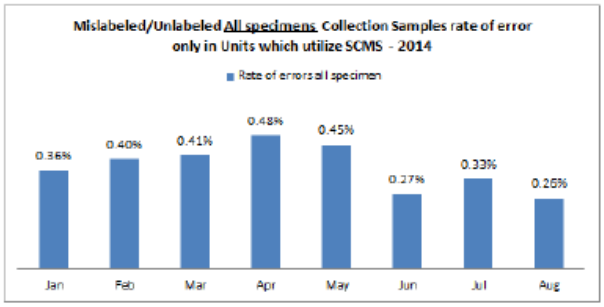


Appendix X

Laboratory Label Errors After SCMS

LAB reported errors steady decline after SCMS utilization (rate)





Appendix Y

Laboratory Reported Label Errors After SCMS

LAB reported errors steady decline after SCMS utilization (number of errors)