ROOT CAUSE ANALYSIS OF PRE-ANALYTICAL ERRORS IN LABORATORY DIAGNOSTICS

by

Zahra Bolandbala

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ProQuest LLC.
789 East Eisenhower Parkway
P.O. Box 1346
Ann Arbor, MI 48106 – 1346

The Dissertation Committee for Zahra Bolandbala certifies approval of the following dissertation:

ROOT CAUSE ANALYSIS OF PRE-ANALYTICAL ERRORS IN LABORATORY DIAGNOSTICS

Committee: Maureen Marzano, PhD, Chair

Jennifer Lapin, PhD, Committee Member

Marilyn Griffin, PhD, Committee Member

Maureen Marzano

Jennifer Lapin

Jennifer Lapin

Dr. Marilyn L. Griffin

Marilyn Griffin

William C. Beck II

William C. Beck II, PhD
Academic Dean
School of Advanced Studies
University of Phoenix

Date Approved: 07/31/2017

ABSTRACT

Laboratory diagnostics are the gate keepers of healthcare. The quality of services in all three phases of laboratory procedure, pre-analytical, analytical, and post analytical, is critical for the provider's decision making and for patient safety. Because the pre-analytical phase of the laboratory is the first step to ensure patient safety, it is essential that any errors occurring in this phase are being monitored and studied. In this study, the researcher focused on the factors that are correlation with the pre-analytical mistakes in the laboratory diagnostics. The concentration was on the experience, skills and knowledge of the phlebotomist as the human factor. Also, the relationship between job stress, workload, operations design, communication, transportation, and the errors in the pre-analytical phase of laboratory diagnostics was analyzed. For this reason, the researcher has used historical data from the years 2011, 2012, 2013, and 2014 gathered from the database of a diagnostic laboratory in the San Francisco Bay area. The correlation between the pre-analytical errors and human factors was tested using multiple linear regressions and one-way ANOVA. The results showed that five factors such as phlebotomist education or training, skill, communication, technology, and operations significantly are related to the laboratory pre-analytical errors. Stress, with the value of β=+.361, and workload, with the value of β =.719, had significant effect on pre-analytical errors. However, phlebotomist's experience and transportation had no significant correlation on pre-analytical errors in the laboratory field as individual variables. Therefore, further research is needed to fully develop a better understanding of these factors.

DEDICATION

This study is dedicated to my parents who I miss in my life, my daughter, Pardis and my son, Toohid. You wished me to become a Doctor, and here I am!

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LIST OF ABBREVIATIONS

Agency for Healthcare Research and Quality……..…..…AHRQ

American Academy of Orthopedic Surgeons ……..…….…….....AAOS

American Association for Justice…….…….…..… AAJ

American Clinical Laboratory Association…….……..ACLA

American College Health Association …….....….ACHA

Center of Disease Control and Prevention ……..……CDC

College of American Pathologists...……..…..…… CAP

Computerized Physician Order Entry.....…....CPOE

Department of Health and Human Services……. DHHS

Electronic Health Record..…….……..……..... EHR

Electronic Medical Record…….……....….EMR

Healthcare Financial Management...…….……..…HFM

Healthcare Provider……....……..... HCP

Institute of Medicine……..…..…. IOM

Joint Commission on Accreditation of Healthcare Organizations ……..……JCAHO

National Committee for Clinical Laboratory Standards.....…....NCCLS

Occupational Safety and Health Administration …….…….OSHA

Patient services center…….……..... PSC

Point of care testing ……..…..POCT

Provider stress scale……..…….PSS

Routine hematological testing..……..…..... RHT

Skilled Nursing Facilities …….……....SNF

Chapter 1

Introduction

Health care organizations rely upon consistent laboratory services (Centers for Disease Control and Prevention [CDC], 2012). Laboratory diagnostics are involved in 60–70% of medical decisions, and a critical key in the patient safety solution (Agarwal, Chaturvedi, Chhillar, Goyal, Pant, and Tripathi, 2012; American Clinical Laboratory Association, ACLA, 2009). Laboratory test processes are composed of three stages:

PRE-ANALYTIC ⇒ ANALYTIC ⇒ POST-ANALYTIC

Each part of the total testing process (TTP) can be directed separately to improve patient safety, and quality of service. Any mistakes in the laboratory field are related to patient safety. In laboratory testing, errors are defined as a rejected specimen, any blood or urine sample that cannot be successfully processed because it does not meet the acceptability criteria of the laboratory or if the sample has not been received (Jones, Calam, & Howanitzet, 1997).

Plebani (2006) described that majority of the laboratory mistakes occurred before and after the analytical phase of diagnostics. She explained that 46-68.2% of total mistakes are caused by pre-analytical sources, whereas 18.5-47% of total errors were originated in the post-analytical phase. Pre-analytical errors are defined as any process which may compromise the accuracy or reliability of the test result that occurs before a sample is analyzed, Errors in the pre-analytical stage of testing can be a serious hazard to patient safety; therefore, the phlebotomists can consider themselves as the gatekeepers of patient safety. Pre-analytical errors can take place at the time of patient registration,

patient identification, test order entry, specimen collection, specimen miss-identification, specimen transportation, or specimen delivery in the laboratory.

The tasks related to the correct phlebotomy procedures are important for obtaining blood specimens for analysis, and it is vital that the specimen used for such testing is not contaminated before testing. The lack of a conceptual framework in phlebotomy is an obvious inefficiency (Lippi et al., 2006). Building clear and consistent procedures are needed to clearly explain how to identify a patient, collect and label a sample, prepare, and then transport the specimen for analysis. To make sure that written procedures are regularly monitored, those who do pre-analytic work need to understand the proper procedures, and also recognize why these steps are significant and how failure to correctly follow instructions can cause serious errors (Plebani, 2012). Centers for Disease Control and Prevention (CDC, 2012) suggested that it is necessary to build up a structure for patient protection that will be reliable within the organization.

Chapter One of this study presents the background of the problem, problem statement, purpose of this research, significant, and nature of the study that is the quantitative multiple regression approach guided by central research questions and hypothesis, and conceptual framework.

Background of the Problem

The outcome of laboratory testing significantly is related to medical diagnoses, analyses, and treatment (Lippi et al., 2006). Various licensed healthcare providers place huge trust upon laboratory results when making decisions concerning patient diagnosis and treatment (Ernst, & Ernst, 2003; Magnarelli, Anderson, Johnson, Nadelman, & Wormser, 1994). Clinical laboratories are a complex, multilayered and highly

sophisticated segment of the healthcare industry and an essential part of the decision-making for patient health. Therefore, laboratory testing errors have considerable relation to the patient health outcomes (Shaw & Strombler, 2005). These errors can cause significant deviations in care and can potentially raise levels of patient injury and death. The majority laboratory errors (55%) do not cause damage, 8% cause temporary harm, but 0.08% of laboratory errors cause permanent harm or death to the patients Snydman, Harubin, Sanjaya, Lopez, and Salem (2012).

The Institute of Medicine (IOM, 1999) reported that the consequence of medical errors within hospitals in the United States each year is 770,000 harmed patients, and 44,000 to 98,000 deaths. The American Association for Justice (AAJ, 2005) reported that preventable medical errors are causing 98,000 deaths each year. Laboratories' contribution within health care errors was 37,532, which are 14.1% of all reported errors (Snydman et al., 2012). Out of these errors, pre-analytic laboratory mistakes accounted for 81.1% (Snydman et al., 2012).

The Congressional Budget Office (2008) reported that there were 181,000 serious injuries because of medical mistakes in 2003. Another estimate reported by the Institute for Healthcare Improvement (2008) showed 15 million incidents of medical harm each year in United State. Leape et al. (1991) reported the results of 1,133 medical record evaluations: 70% were preventable errors, 6% potentially preventable, and only 24% were not preventable. Another report by the U. S. Department of Health and Human Services (DHHS, 2008) showed that 44% of errors occurred could have been prevented with efficient patient care. Two hundred and twenty-five thousand people die each year in the United States, because of unintentional and preventable medical mistakes (World

Health Organization, WHO, 2009). Andel et al. (2012) pointed out that around 200,000 Americans die every year from avoidable medical errors. The study showed that deaths from avoidable medical error have more than doubled in the past decade.

The sixth primary cause of death in United State is medical errors (Centers for Disease Control and Prevention, CDC, 2012). The issue of medical errors is recognized as a very serious U.S. healthcare concern in terms of avoidable patient death and injury, achieving successful treatment and controlling the costs. Patient safety in relation to controlling medical errors is important to providing proficient care. The solution to improving patient safety is to recognize the primary sources of errors, learning from error details and trying to abolish circumstances that supply preventing errors (Jenkins & Lemake, 2009). Health care provider's negligence affects patient care physically, emotionally, and economically. Health care organizations experts stated that failure to advance patient safety can cause major financial and human loss for the citizens (Jenkins & Lemake, 2009).

In addition to patient injury, medical errors turn into huge costs for the health care industry. Berwick and Leape (1999) announced that the expected price of medical errors in the United States is approximately $17 billion-$29 billion each year. But in another report IOM (1999) reported that medical errors cost for the population are almost $37.6 billion yearly. Preventable medical errors related costs are about $17 billion, and nearly half of the costs for these preventable medical errors are direct cost to the health care (IOM, 1999). One year later, IOM (2000) announced that mistakes in health care are appraised to be more than $5 million per year in an outsized hospital. Five years later, Healthcare Financial Management (HFM) reported that of the $29.5 billion medical error

costs in the United States, $17 billion relates to increased medical errors and $1.1 billion relates to lost productivity due to short term disability claims (as cited in Ledue, 2010).

Shreve et al. (2010) used medical claim data to measure the cost of medical errors annually in U.S. healthcare. The result of the study shows that approximately 1.5 million medical errors occurred annually costing $19.5 billion. Poor quality in healthcare causes other indirect financial costs such as employees' injuries. The estimation of the indirect costs of poor quality is 3 to 5 times higher than the direct costs (Occupational Safety and Health Administration, 2004).

Another report from IOM (2006) estimated that about $ 3.5 billion is paid every year in the U.S. healthcare system because of medical defects. The estimations are not inclusive of errors occurring in nursing homes, private doctors' clinics or pharmacies (IOM, 2006). Bruna et al. 2011 reported $17.1 billion dollars as the cost of medical errors that harmed patients in 2008 (Bruna, 2011). Van Den Bos et al. (2011) reported that the cost of health care in 2008 was 2.39 trillion and 0.72% was spent on medical errors. Centers for Disease Control (2007) reported that the laboratory error rate is about $2.3% of medical errors. But in consideration of the laboratory's diagnostic role, the relation of laboratory testing on the cost and quality of health care should be much greater.

Problem Statement

Seven to ten billion laboratory tests are performed each year in the United States (Boone, 2005). Laboratory analysis constitutes 70% of the examinations used to assess a patient's health status (Ernst & Ernst, 2003). Despite the significant reduction of analytical errors in laboratory medicine, pre-analytical errors are still occurring. Most of the laboratory errors happen either before (pre-analytical) or after (post-analytical) the

test has been done (Plebani, 2012). The general problem is that the pre-analytical errors in laboratory testing have negatively related to laboratory quality, and patient safety (Plebani, 2012). The specific problem is that the pre-analytical phase of laboratory, and the procedures related to laboratory quality control has been poorly studied as the main causes of errors. Although laboratories have a major role for providers decision, but the role that the laboratory has in providing results to the healthcare providers have been poorly studied. Possible causes of this problem is increasing healthcare cost and losing patient trust in the healthcare system. Perhaps a study that investigates the root causes of the errors in a quantitative correlation method could prevent or reduce the laboratory pre-analytical errors. According to Rin (2010), redesigning the laboratory operations that reduce the difficulty and complexity for all providers can eliminate laboratory errors and patient harm.

Purpose Statement

The purpose of this quantitative correlational study was to determine whether a relationship between the theories correlates the independent variables to the dependent variable. In this study, independent variables were identified as operation or system errors, human errors, communication, technology, and transportation and the dependent variable was the pre-analytical errors in the laboratory diagnostics. Multiple regression analysis, the Pearson Correlation analysis product of Correlation Coefficient, and ANOVA, were used for hypotheses testing to determine any relationship among the independent variables and dependent variable.

The study was conducted in laboratory department of a non-profit healthcare organization, in the United States, San Francisco Bay area. The instrument used for data

collection was a survey distributed to approximately 200 phlebotomists to measure the relationship of workload and job related stress on the pre-analytical errors in the laboratory testing. Existing data from reports that captured the total errors by category made in 2011, 2012, 2013, and 2014 was analyzed using SPSS v21, to determine the phlebotomists' skill, experience, knowledge, and training (human errors), communication, technology, system design, and transportation relationship on the pre-analytical errors in the laboratory testing. Additional statistical data was collected on four different pilot projects for one month in fall 2015 to measure the correlation of the operational system, effective communication, ongoing training and advanced technology on the phlebotomists' job performance.

Significance of the Study

Seventy percent or more of examinations to assess patient's health status include laboratory analysis (Ernst & Ernst, 2003). Therefore, it is crucial that the specimen used for such testing is not altered in any way. Laboratory related errors are major contributors to avoidable illnesses and deaths, and unique environmental and system factors may increase the risk of patients facing problems with incorrect laboratory test results (Plebani, 2012). Technology improvement and automated instruments have cut down the mistakes in the analytical phase of laboratory tasks and have improved the quality of test results (Carraro & Plebani, 2007; Plebani, 2012). But errors occurring during the pre-analytical phase still exist. Pre-analytical laboratory phase is the next challenge for laboratory diagnostics. Plebani and Carraro (1997) reported that, within 40,490 test analyses, 189 mistakes were acknowledged. The majority (68.2%) happened in the pre-analytical phase, 18.5% errors are happening in the post-analytical and 13.3% occurred in

the analytical phase of the total testing processes (Plebani & Carraro, 1997). Another report by Hawkins (2012) showed the similar results. He categorized the laboratory errors as post- analytical (1.5%), analytical (9.6%), and pre-analytical (88.9%).

According to Plebani and Carraro (1997) understanding the frequency, variety, and type of errors happening in the laboratory site is a determination to control the majority serious concerns in the testing process. For several years, the medical laboratories focused on quality in analytical step and the result was considerably decreasing the problems and increasing the quality of the test results. But the larger growth of the incidence of errors in the pre and post-analytical phases and their potential correlation to patient harm has led more concerns to improving laboratory errors in other phases, too.

In this study, the researcher focused on some of the independent variables or possible causes that might be related to pre-analytical errors, which may include the following factors: job stress, workload (multiple tasks), lack of knowledge and requested skill, lack of technology, system operations errors, miscommunication, and transportation. Some of the common sources of pre-analytical errors include ordering tests on the wrong patient, ordering the wrong test, missed tests, choosing the inappropriate collection container, hemolyzed specimens, clotted specimens, and the improper labeling of containers.

Study variables. The relationship between independent and dependent variables change study outcome. A dependent variable is an outcome or result of independent variable that the researcher desires to calculate or give details. “Changes in the dependent variable are presumed to be caused by the independent variable” (Burns & Grove, 2007,

p. 537, 542). In the current study, the researcher investigated the correlation between the independent variables: phlebotomists' skill, experience, knowledge, and training identified as human errors, phlebotomist work load, job related stress, communication, technology, system design, transportation, and the dependable variable: defects in pre-analytical phase of the laboratory testing. Focus was on laboratory pre-analytical errors in an effort to verify the compliance and control of medical laboratory errors through effective operations management, processes, practices and planning. Poor quality, patient safety, health care organization operations, technology, and health care costs are all other concerns that were considered during this study. These problems are recognized as a serious U.S. healthcare concern in terms of preventable patient death and injury, achieving efficient treatment and controlling the costs.

The lack of study on pre-analytical errors in the laboratory field to prevent or reduce errors and to improve patient safety has confirmed a need for continue studying this phase of the laboratories. This study's results might help in the progress of preventing or eliminating errors in the first phase of the laboratory's testing, and promoting quality of care. This study's results can aid others in understanding the complexity and range of pre-analytical errors causing and contributing to laboratories errors and their relation to the patient safety and health care costs.

Nature of the Study

This study utilized a quantitative study method using a correlational design to determine the relationship between the criterion variable and predictor variables. The data were gathered by surveying 200 phlebotomists working in the outpatient laboratory services centers (PSC), inpatient laboratory, and skilled nursing facilities (SNF). These

phlebotomy groups are employed in a non-for-profit hospital in San Francisco Bay area laboratory department. The aim was to obtain data about the phlebotomists' perspective of workload and job stress in the pre-analytical phase of the laboratory setting.

The quantitative method provides the researcher the accessibility to gather the data in the statistical design, to implement objective result, and reach a high stage of accuracy and dependability. Using the quantitative method permits the investigator to describe the research problem definable with specifics information (Frankfort-Nachmias & Nachmias, 1992). The researcher is able to specify the independent and the dependent variables clearly, to test the study hypotheses, to reach the best neutral assumptions by decreasing bias of result, and to accomplish the highest level of dependability of collected data due to mass surveying (Balsley, 1970).

The researcher in this study explored numerous study design choices and data analysis considerations. The appropriateness of the qualitative option research was compared with quantitative method with correlation design and the value of the approaches. In this study, the utilization of quantitative research method with correlational design is considered to achieve the projected rationale of this study: to complement the choices for examining the relationship between the operation, or system errors, job stress, work load, human errors, communication, technology, and transportation (independent-variables) to pre-analytical phase laboratory errors (dependent variable). To test the hypothesis in this study, multiple regression analysis, the Pearson correlational product of correlation coefficient and ANOVA were used.

The purpose of using multiple regressions in this study was to determine the relationship between independent or predictor variables and a dependent variable.

Multiple regressions was an appropriate choice because more than one independent variable was present in this study (McDonald, 2014). The Pearson Correlation product was used to measure the strength and direction of linear correlation between pairs of continuous variables. The Pearson Correlation calculates if a statistical validation is present for a linear relationship between the same sets of variables in the population (Mukaka, 2012). Selection of ANOVA in this study was to measure the relation size of variance between groups compare to the average variance within groups. According to Kim (2014) the one-way analysis of variance (ANOVA) is a proper technique to evaluate the means between more than one group. Although ANOVA is appropriate for comparing means in measured studies, if the samples are not independent a repeated measures test must be used.

This research study adopted a quantitative approach using the survey design to evaluate the phlebotomists' workload and their job stress level for the study. The purpose of the survey was to capture the phlebotomists' perspective of their work environments where they feel comfortable to express their insights. The survey was implemented at two departmental in-service meetings. The provider perspective survey (PPS) instrument incorporated a quantitative, non-experimental design for gathering statistics on the phlebotomists' comments concerning job stress, workload causes, and pre-analytical errors. Utilizing a survey arrangement employs set of questions or a mixture of survay to bring together information from a sample group with the objective of generalizing the results to a larger group (Sprinthall, 2006).

To obtain the data about other independent variables, phlebotomists' skill, experience, knowledge, and training (human errors), communication, technology, system

design, and transportation; the researcher analyzed the existing data from the hospital laboratory database that captured the total and type of the errors in years of 2011, 2012, 2013, and 2014. The software used in this study for analyzing data was SPSS version 21.

Research Questions and Hypotheses

From the phlebotomist's point of view, the relevant factors that may cause pre-analytical errors during a test total process can be all of the following: lack of knowledge, deficient performances, poor system designs, poor computer systems and technology and lack of communication among the various other health care providers and the laboratory department, or poor communication among the different departments inside the laboratory (e.g. poor communication between phlebotomists and clinical laboratory scientists, or the processing department, and phlebotomists). The relationship between all the factors mentioned, and errors happening in the pre-analytical phase require further investigation. In this study, the researcher aim was to address this relationship by addressing the following questions and the hypotheses. Hypotheses tested in this study are listed below to achieve a comprehensive investigation by using a multiple regression study to evaluate the control of all the independent variables on laboratory pre-analytical errors.

RQ1. What is the relationship between laboratory pre-analytical errors and the phlebotomist's (human factors) skills, experience, training, knowledge, communication, and transportation?

Hypothesis 1a (null). Laboratory pre-analytical errors are not related to the phlebotomist's skills, experience, training, knowledge, communication, and transportation as, human factors.

Hypothesis 1a (alt). Laboratory pre-analytical errors are related to the phlebotomist's skills, experience, training, knowledge, comunication, and transpotation as, human factors .

RQ2. What is the relationship between the laboratory pre-analytical errors and the operations system?

Hypothesis 2a (null). Laboratory pre-analytical errors are not related to the operations system.

Hypothesis 2a (alt). The key to reducing pre- analytical errors is related to the operations systems in the laboratory.

RQ3. What is the relationship between technology and laboratory pre-analytical error rates.

Hypothesis 3a (null). Pre-analytical errors are not related to the technology system.

Hypothesis 3a (alt). Pre-analytical errors can be reduced by advance technology.

RQ4. What is the relationship between the phlebotomists workload and job stress and the errors in the pre-analytical phase in laboratory testing?

Hypothesis 4a (null). Phlebotomist workload and job stress is not related to the erors in the pre-analytical phase.

Hypothesis 4a (alt). Phlebotomist workload and job stress is related to the errors in the pre-analytical phase.

Hypothesis elaboration. Human error in health care could be perceived by two unlike approaches, "the person approach and the system approach"; each model has own perspectives (Reason, 2000). The person approach in laboratory field stresses the careless

acts and procedural deviations of phlebotomist, lab assistants, CLSs, and pathologists. Studies have shown that these potentially dangerous acts are coming mainly from different mental tasks such as lack of memory and focus, poor enthusiasm, inaccuracy, carelessness, and irresponsibility (Reason, 2000). The related protective measures are anticipated primarily at reducing risky variation in human performance (Reason, 2000). Wording human errors as concerns rather than reasons places the error occurrence as a failure of organizational system (Reason, 2000). The goal of this study was to measure the relationship of the phlebotomists' skill, experience, knowledge, communication, and sample transportations under category of the human errors with the pre-analytical errors in laboratory testing to examine the theory of human error.

Poor phlebotomy skills and experience will compromise the specimens in different way; as the literature reviews in this study shows. Guimaraes, Wolfart, Brisolara, and Dani (2012) reported that blood clots were the major cause of sample rejection (43.8%), and 24% of rejected samples had insufficient sample volume. However, Brunori et al. (2011) reported that, hemolysis is the most common cause of blood sample inadequacy. Another study by Salvagno, Lippi, Bassi, Poli, and Guidi (2008) showed the percentage of sample rejections by category; not received in the laboratory (49.3%) hemolysis (19.5%), clotting (14.2%), and insufficient volume (13.7%) (Salvagno et al., 2008). An efficient educational plan can be considered in reducing the number of inaccuracies caused by human error, improved safety, and quality control (Keller, 2008).

The human mind tends to over-generalize, which means that people have been over-confident in their ability to remember things. This thought increases the probability

of error because it is not possible to be perfect all the time. Sufficient and efficient training of employees all through the organization should be required to increase proficiency in following processes and procedures (Boone at el., 1995). In this study, the researcher designed a training system to answer this hypothesis.

Human have to agree organizations relating human communication and selections are disposed to fault. Communication issues characterize the most common source of medical errors. Communication is a most important process in providing safe patient care (Evanoff et al., 2005; IOM, 2004a; Leonard, Graham, & Bonacum, 2004; Lingard et al., 2004; Sutcliffe, Lawton, & Rosenthal, 2004). Miscommunication can cause varieties of medical errors and can involve all members of a health care group (Agency for Healthcare Research & Quality, 2012).

Sample transportation is known as a most important element contributing to delays in high quality clinical laboratory results to both in-patients and outpatients (Plebani, 2012). Important result variations have been observed due to transportation time (Zaninotto et al., 2012). Transportation time, or speed of vehicle that transporting the specimen, or number of times that the specimen was transported can cause the opportunities for various types of error (Bates et al., 1995). Another study has shown no clinically major effect of transporting systems on hematology and coagulation results (Miller, Nelson, & Spurlock, 2001). The data to test hypothesis 1 were used from the hospital database that captured the total and type of errors in the years 2011, 2012, 2013, 2014.

Hypothesis 2a (null). Laboratory pre-analytical errors are not related to the operations system.

Hypothesis 2a (alt). The key to reducing pre-analytical errors is related to the operations systems in the laboratory.

Healthcare needs to move from a culture of human blame to an organizational approach that maintains and promotes preventing errors (Barach, 2003; Institute of Medicine, 2000, 2004). Since the implementation of electronic physician ordering systems in the medical laboratory, many errors associated with paper test requisitions have been eliminated, but human errors still occur. For example, the computer system and the electronic medical record (EMR) chosen in this research have not prevented all errors. The EMR system used by the healthcare providers and the selected laboratory were Cerner, ADM and Web outreach.

According to Mello, Studdert, Thomas, Yoon, and Brenna (2007) improvement in the organization can decrease the error rates, promote patient safety, and improve the health care quality. The emphasis is on procedure structures and process to make the organization responsible instead of the individual's decisions and actions (Bucknall, 2010). In this study, the researcher attempted to identify why the error happened not who made it. Hypothesis 2 takes the position that errors are preventable with proper system redesign and new technologies. Hypothesis 2 was tested using the hospital database that captured the total and type of errors in the years 2011, 2012, 2013, and 2014.

Hypothesis 3a (null). Pre-analytical errors are not related to the technology system.

Hypothesis 3a (alt). Pre-analytical errors can be reduced by advance technology.

Proper patient and specimen identification is the most important subject. Effective technology and strategies to reduce identification-related errors include use of wristbands

for inpatients, barcoded labels for containers and tubes, and computerized practitioner order entry (CPOE). The utilization of CPOE and consistent order entry will help to eliminate missed tests, wrong test order entry due to abbreviations, and illegible handwriting errors. Implementing CPOE will reduce illegible signatures or missing ordering provider's information. CPOE will avoid the time that the phlebotomist or other laboratory staff spend contacting the physician for clarification. Advanced technology will provide electronic patient registration, physician order entry, lab results, billing and financial information. Hypothesis 3 takes the position that errors are preventable with advanced technology, and was tested with the data that captured the total and type of errors in the years 2011, 2012, 2013, 2014.

Hypothesis 4a (null). Phlebotomist workload and job stress is not related to the errors in the pre-analytical phase.

Hypothesis 4a (alt). Phlebotomist workload and job stress is related to the errors in the pre-analytical phase.

According to WHO (2010) poor lighting, fatigue, noisy environment, and an extreme workload may contribute to medical errors. Staff become exhausted or take private problems to work. These issues disturb their performance and their focus on the job. In health care, inpatient and outpatient services should review and observe situational factors to make sure that interruptions are kept to a lowest amount. The American Academy of Orthopedic Surgeons (2008) advised that in health care patient protection should be the main concern. The evaluation and preservation of a harmless work setting is the best cost-effective instrument for reaching this standard. Phlebotomists who fall behind in their tasks may hurry through their patients to catch up, and these kinds of

actions can promote errors. In this study, hypothesis 4 was measured using Provider Stress Scale (PSS) and Quantitative Workload Inventory (QWI) survey to investigate the correlation between phlebotomist job stress and workload and errors.

Hypotheses Key Points

- Human error refers to the provider's skill, knowledge, years of experience, and type of provider.
- Job stress was measured by survey
- Workload refers to multiple tasks of the providers and was measured by survey
- System error refers to lack of effective computer system, deficiency of ongoing training regarding the job competencies or procedures, and ineffective operational system.

Theoretical Framework

The laboratory theoretical framework is defined in Figure 1. This framework supports the strategic relationship between total testing process in the laboratory testing and patient safety. This procedure indicates when a health care provider starts testing practices to recognize, to identify, and to make a decision on a patient's health condition or treatment. The physician orders the laboratory tests, the phlebotomists or nurses identify the patient, collect the sample, prepare and transport the specimens to the lab for testing. Then the sample evaluated or analyzed, results are documented, and reported to the physician or person who requested the tests. Treatments or follow ups will be started based on the clinical laboratory scientists', or pathologists' description, and the ordering physician interpretation of the test results. In practice, the laboratory's contribution in the

steps in the total testing process differs based on the setting, type of test, and type of laboratory.

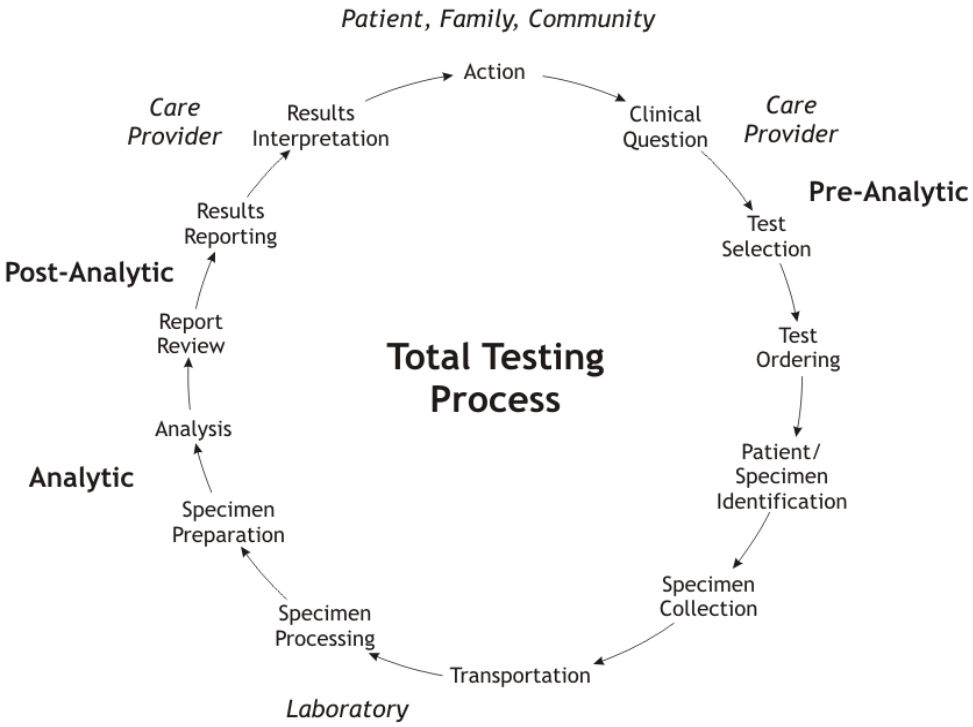

Figure 1. Three phases of laboratory's total testing processes. Adapted from "Presentation at the Institute on Critical Issues in Health Laboratory Practice: Managing for Better Health," by J. Boone, September 23-26, 2007. Copyright 2007 by Centers for Disease Control and Prevention.

Conceptual Framework

The conceptual framework for this study is shown in Figure 2. The independent variables are made with straight lines to the dependent variable. The arrows show the relationship between the independent variables and the dependent variable. Each arrow represents one hypothesis and the relation of independent variables selected for this study on the laboratory pre- analytical errors (dependent variable).

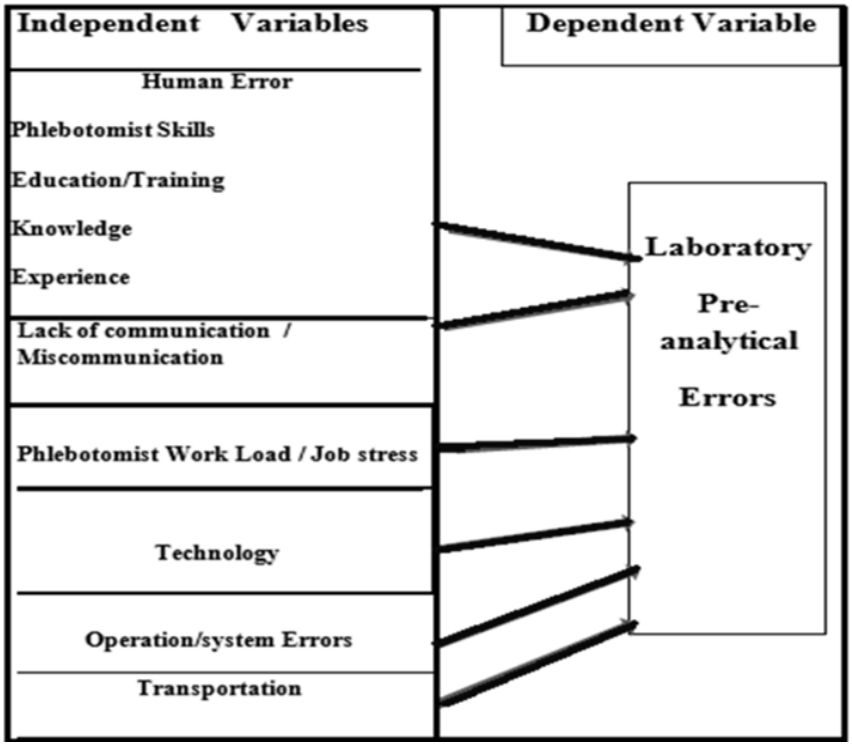

Figure 2. Relationship of variables.

Definitions of Terms

Adverse event. Unintentional errors in care that may result in challenging outcomes and may require extra care efforts (American Society for Clinical Laboratory Science, 2001).

Centrifugation. An instrument with a quickly spinning container that relates centrifugal power to its subjects, normally to separate fluids of different substance in the laboratory, separates plasma or serum from the cell (National Committee on Clinical Laboratory Standards, NCCLS, 2003).

Clotted sample. Blood samples that shows visible clots.

Electronic lab test order. Computerized lab test order available for laboratory accession. The ordering provider orders the test in the office. Paper copy may give to the patient as well.

Healthcare provider (HCP). Term used to describe persons licensed to practice medicine or perform independent patient care activities. For example, physicians, nurse practitioners and physician's assistants are healthcare providers.

***Hemolyzed sample*.** Broken blood cell, or the existence of hemoglobin in serum or plasma >100 mg/L. (Lippi et al., 2006).

Inverting. Tubes contains additives must be filled to their specified capacities and be mixed carefully. The procedure for mixing all tubes is: tubes with a clot activator 5 times, Sodium citrate tubes for coagulation testing should be inverted 3-4, the other anticoagulant tubes should be mixed 8-10 times (NCCLS, 1998).

***Inpatients (wristband*).** The in-patients must wear an ID bracelet that contains a unique hospital number, their information (first name, last name, and date of birth).

***Job stress*.** Outcome from a difference among the demands of the workstation and people's capability to manage (Isikhan, Comez, & Danis, 2004).

Laboratory test order error. Any wrong test ordered in the computer, missed test, a test ordered for different patient, or an incorrect ordering provider.

Labeling the specimen. To make sure that the collected specimens are related with the right patient, any specimen must be labeled with three pieces of patient's identification (first name, last name, date of birth), and the date and time of service must be written on the specimens.

Laboratory pre-analytical phase. The process period when the test is place in the computer until the specimen come to the lab (Hawkins, 2012).

Laboratory analytical phase. Define the process through the testing the sample in the laboratory (Hawkins, 2010).

Laboratory post-analytical phase. Define the process that take place after the tests are resulted and released and includes how and when the result was reported to the provide (Hawkins, 2012).

***Patient preparation*.** Before any specimen collection, review the correct test requirements such as specimen type to be collected, supplies needed and follow the procedure and the handling guidelines (Plebani, 2012).

***Patient registration*.** The patient must present a hard copy requisition, or electronic version must be available in the electronic ordering system for ordering the test. The patient fasting status and medication taken should be checked, to make sure that the specimens will not compromise the test (Plebani, 2012).

***Patient identification*.** The person collecting the specimens must check to make sure the specimens have been collected from the patient who the test was ordered for (Plebani, 2012).

***Near miss*.** Actions in which undesirable outcomes were stopped (American Society for Clinical Laboratory Science, ASCLS, 2001).

***Order of draw*.** When collecting the blood, the tubes should be collected in a particular order to avoid contamination of additives between tubes. According to the NCCLS (2003), the order of draw is as follows:

- Blood culture bottle or tube (yellow or yellow-black top)
- Red top/non-additive tube
- Coagulation tube (light blue top).
- Sodium citrate

- SST (red-gray or gold top): Contains a gel separator and a clot activator.
- Sodium heparin (dark green top): Contains Sodium heparin
- Sodium Latium [PST] (light green top): Contains lithium heparin anticoagulant and a gel separator.
- EDTA (lavender top or Pink top): Contains potassium EDTA.
- ACDA or ACDB (pale yellow top): Contains acid citrate dextrose.
- Oxalate/fluoride (light gray top)

Outpatients. Draw stations giving service to non-admitted patient in the hospital. Patient identification should be done with asking the patient to spell the first and last name and tell the phlebotomist the date of birth. All the patient information should be checked with patient again, once patient label is printed.

Phlebotomy. Phlebotomy is the act of drawing blood from the vascular system through puncture to obtain a sample for analysis and diagnosis (WHO, 2010).

Quality indicator. Is a neutral measure that appraises all acute care areas as explained by the IOM (patient safety, efficiency, patient-centeredness, suitability, and effectiveness). In a patient-centered setting, quality pointers must be monitored to protect all paces of the pre-analytical level, from test ordering to sample storage (Shahangian & Snyder, 2009)

Specimen collection procedures. The specimen requirement should be follow; collect the right container, mix well with the right additive. The phlebotomists who collect specimens should obtain training on how to collect samples for each type of test (WHO, 2010).

Specimen identification and labeling. All specimens sent to the laboratory for analytical testing should be properly labeled to guarantee proof of identity, and best reliability of patient sample from the time of collection until testing is completed and the result reported (WHO, 2010).

Sentinel event. Incident that caused death or serious harm to a patient (ASCLS, 2001).

Test requested (requisition). The test requisition includes: the patient's name, the unit, or clinic location, or source facility, and address of ordering physician if not part of the network. The requisition also includes the name(s) and signature of the provider requesting the test(s), the test being ordered, and diagnosis code, ICD9 code, or narrative description.

Requisition completed. Provided by phlebotomist or any other health care provider, name or initials of person collecting specimen, and specimen collection time and date must be on all requisitions.

Test order error rate. The total number of laboratory test order errors divided by the total number of laboratory test orders for the same entity (provider, clinic, hospital, etc.) for the same time period (one day, month, year, etc.), multiplied by 100 to yield a percent.

Test ordering process. The phlebotomist is required to order the correct test by test name or code in the computer system.

Process and transport the sample to the lab. Some specimens are time sensitive; some need to be protected from light; some need to be kept cold. So careful processing

and handling and rapid transportation are vital mechanisms to specimen reliability (Livesey, Ellis, & Evans, 2008).

Total testing process (TTP). The procedure that consists of pre-analytic, analytical and post-analytic steps to result a test. TTP provides a systems-based framework for monitoring all potential actions that can change the quality of laboratory tests (Hawkins, 2012).

Type of specimen. Blood, serum, plasma, and whole blood, urine, sputum, stool, body fluid and body tissue (NCCLS, 2003)

Venipuncture. Is the collection of blood from a vein for laboratory testing (NCCLS, 2003; Zieve & Eltz, 2011). As part of a medical technique, the puncture of a vein to draw a blood sample.

Workload. The portion of a person's capacity to perform a particular job, (Kiekkas, Sakellaropoulos, & Brokalaki, 2008).

Assumptions

The most errors in laboratory testing happen in the pre-analytical phase of the total testing process (Plebani, 2006). Improvements in the primary phases of the TTP can be accomplished with the additional hard work to reach an operational standard working procedure in the first steps of laboratory testing (Carraro, Zago, & Plebani, 2012). Most of errors in the laboratory that are related to the phlebotomist's errors are preventable. Many different efficient strategies are available for error prevention, especially for the clerical errors in pre-analytical phase of the laboratory. Examples are electronic ordering system and an effective operational system. Maintaining a strong communication method between the physicians and laboratory and an effective team work within the laboratory

departments can be a key approach for reducing laboratory errors. The laboratory's leadership team is responsible for reducing phlebotomist related errors and enhancing patient safety. Quality in laboratory medicine must be clear to warranty that all the steps in the TTP are properly implemented. A clear quality process will guarantee medical decision making and effective patient care (Plebani, 2012).

Scope of the Study

The realization that the test results delivered by the CLSes or the pathologists are related to patient's treatments, and protecting patients from harm has provided an opportunity for clinical laboratories to make reducing their error rates a priority (Agarwal et al., 2011). Technology improvements and automation systems have cut down responsibilities in laboratory testing, have reduced the analytical errors, and have improved the integrity of test results. Yet, according to the literature, the majority of laboratory errors happen before testing (Chhillar, Khurana, Agarwal, & Singh, 2011). Considering the lack of study on pre-analytical errors, investigating this issue is critical for evaluating the possibility of eliminating this problem, and for evaluating its relation to patient safety. Setting priorities for preventing these errors and measuring the correlation of them on promoting patient safety, and eliminating health care related costs are the scope of this study. The majority of pre-analytical errors in the laboratory diagnostics might not result in patient harm and injury, but these errors generally make additional work, and the expenses involved can be considerable. In this research study, the aim of the researcher was to summarize the evidence based on rates of pre-analytical errors in the laboratory testing.

Limitations of the Study

The limitations of a study can offer an opportunity for a follow up research to the future researchers who may implement similar studies. In this study, the researcher's goal was to test the hypothesis that emphasize phlebotomists' skill and experience as the reasons for hemolyzed and clotted specimens. The aim was to request all the rejected coagulation and hematology specimens be re-tested by another lab assistant or to be sent to the in-patient lab for a second opinion. This monitoring system can help to accept or reject this hypothesis. This can provide an opportunity to evaluate the reliability of the automation system, lab assistants, and the CLSs' skill and knowledge. Because all steps in the laboratory services may alternate patient safety, an efficient approach is necessary to minimize the laboratories' deficiencies (Agarwal et al., 2012). Consideration of multiple factors besides what was taken up in this research may offer further explanation of what drives laboratory pre-analytical errors. For the purpose of this study, the results and interpretation was based on the data presented.

In this study, research questions addressed operations system, technology, transportation, communication, and phlebotomists' workload . Ideally, studying phlebotomists' pre-analytical errors in all three locations—inpatient, outpatient, and skilled nursing facility—would be optimum. However, operation systems, procedures and computer systems in the three locations are not the same. Therefore, the researcher was limited to studying the pre-analytical errors in the outpatient group only. This decreased the sample size from 200 to 110. The smaller sample size may have decreased the ability to generalize the results to other laboratory settings.

The current study was limited because the inpatient phlebotomists did not participate in this study. Participation of inpatient phlebotomists would have added a large insight to this study because the inpatient phlebotomists are not involved with ordering or processing the blood. Inpatient phlebotomists' job duty is only draw the blood. They do not register the patients, therefore, dealing with the insurance or billing requirements are not part of their duties. Inpatient phlebotomists also do not have to order the test requested by the physician. Therefore, the wrong test or miss test ordering is avoided. They do not see the requisition and misinterpretation of bad handwriting is also eliminated. Hospital lab, inpatient phlebotomists are sending the patient's samples directly to the lab for processing and all the processing errors are eliminated.

Second, the researcher did not receive the error rate data from the inpatient lab manager. The inpatient data would give a clear perspective to the researcher about the transporting relationship to the pre-analytical errors because the transporting and delay is eliminated for inpatient draws. Future study is suggested to find the effect of transporting, timing, and heat on the samples.

Delimitations of the Study

Delimitation is a factor that is under researcher control. Delimitation in this research refers to the scope of the study. Only phlebotomists working in the draw stations were observed. Other health care providers such as, nurses, medical assistants, physician assistants, and other phlebotomists who are not working in the laboratory department have been excluded as study participants. This study focused more on outpatient phlebotomist's errors and the root cause of errors because most of the participants were from Patient Service Centers (PSC). This study was confined to administering a PPS

survey at the in-house meeting within the phlebotomists working in the laboratory department.

Summary

Pre-analytical mistakes are a risk to patient safety. In delivery of health care services patient safety approach is necessary to study the total testing process in the laboratory diagnostics (Plebani & Piva, 2011). In total testing process any potential deficiency that might have a harmful effect on the patient safety such as patient identification error, wrong order entry, missed test, and improper blood collection and handling need to be investigated. Hard work is needed to continue reducing the frequency of errors in the pre-analytical phase of the laboratory diagnostic process. An analysis of reported laboratory errors in the pre-analytical phase provided information that would help provide a better perspective on why such errors occur and provide possible answers to address circumstances contributing to laboratory errors.

In this chapter, the researcher introduced the project. Chapter One explained the problem background, problem statement, propose statement, significance and nature of the study, aim, objectives, rationale, research questions and the hypotheses. The importance of the project and the main reason behind the project were also explained.

The goal of Chapter 2 was to provide in detail analysis of previous studies that could highlight a summary structure for this study. The need to capture, report, and analyze errors in laboratory testing effectively and properly is becoming more critical to the efficient patient service in laboratory medicine and to patient safety. The idea is not

new, but the sensitive demands of suitable research to identify the laboratory elements that produces the errors is critical and warrant additional study.

Chapter 2

Review of the Literature

Burns and Grove (2007) defined a literature review as a "summary of current theoretical and empirical sources to generate a picture of what is known or not known about a particular problem" (p. 533). This literature review provided an overview of tendencies observed in pre-analytical errors in the laboratory field and the phlebotomist's work experience, skills, knowledge, work load or stress, and miscommunication among healthcare team members. The pre-analytical phase of laboratory diagnostic procedure is where the most laboratory errors happen. Pre-analytical errors can arise at the time of patient preparation, test order entry, patient identification, specimen collection, specimen transport, or specimen delivery in the laboratory.

Selection of Topic

The laboratory errors often happen before and after the analytical step (Nutting et al., 1996). Over 6 months, 180 laboratory errors were reported from 49 practices by 124 laboratory clinical scientists. Of these 180 mistakes 55.6% of the errors happened before testing (pre-analytical phase), 27.8% after testing (post-analytical phase), and 13.3% in the diagnosing part of total testing process (Nutting et al., 1996).

Nutting et al (1996) reported that 27% of the 180 mistakes reported were determined to have had relation to the patient care. Bonini, Plebani, Ceriotti, and Rubboli (2002) reported that the pre-analytical errors in the laboratory increased from 31.6% to 75% in the last decade. Bonini et al. (2002) suggested that a better description of laboratory errors and their sources is necessary. Chawla, Goswami, Tayal, & Mallika (2010) implemented a 1-year study in the clinical chemistry laboratory on the rate of pre-

analytical errors for both inpatients and outpatients. They reported that the pre-analytical error rate among inpatients was 1.9%. The highest frequency of errors was noted in the category of specimen hemolysis at 1.10%. The error rate reported for outpatients was 1.2%, and the highest frequency rating was in the category of insufficient volume for testing (Chawla et al., 2010). Ordering tests on the wrong patient, ordering the wrong test, missing tests, choosing the inappropriate collection container, or labeling containers improperly, clotted and hemolyzed specimens were the other common errors identified before analytical phase in the laboratory.

In this study, the researcher's purpose was to identify and to categorize the most frequent pre-analytical sample errors from different blood drawing staff to calculate the numbers and percentage of pre-analytical errors. The researcher attempted to identify the challenges of pre-analytical errors and patient blood work safe delivery in the clinical practice by reviewing multiple regression studies. Chapter Two of this research placed the investigation in context by reviewing relevant literature. Reviewed research examined among the literature was related to laboratory errors, human errors, advanced technology and other factors that may cause errors. The pre-analytical procedures were evaluated in outpatient service centers (PSC), inpatient service centers, skilled nursing facilities (SNF) and emergency rooms (ER) and their relationship with the risk of errors that could be related to patient safety. All the hypotheses in the study were designed to answer the research questions as well the correlation among the dependent and independent variables.

Key Word Search

To obtain sufficient resources to become familiar with current data in the previous studies about the topic of concentration and to locate previous studies for guidance and comparison with the present study, multiple literature searches were conducted. The sources used included: medical databases such as ProQuest, PubMed, MEDLINE, Clin Chem Lab Med, free databases such as OmniMedicalSearch.com, scholarly journals, Free Medical Journals Site, and the public and hospital library systems and government database searches and reports. Additional literature searches were conducted to recognize instruments that measured job stress and perceived workload. Throughout the literature searches, related articles cited in the reference sections of relevant peer-reviewed journal articles were also reviewed. Terms used in the literature searches included key words such as: *laboratory error, pre-analytical errors*, *medical error*, *phlebotomist role*, *system error*, *CPOE, job stress*, *workload*, *laboratory test orders*, *laboratory test order errors*, *hemolyzed blood*, and *clotted blood*.

Role of the Phlebotomist in Laboratory Diagnosis

The primary responsibility of the phlebotomist is to collect specimen for laboratory testing. Their role is essential to patient diagnosis and treatment (McCall & Tankersley, 2011). But in modern multi-skilled phlebotomy practice, phlebotomists jobs include a number of additional duties such as registering the patients, verifying the insurance coverages, and other paperwork related to registration or the insurance. While observing the change in the phlebotomist's daily tasks through studies, nearly half of the responsibilities analyzed as not being essential compared to what they were a decade ago. According to Flynn (2005) phlebotomists might be obligated to complete other jobs such

as specimen preparation. Phlebotomy technicians should know the requirements for both routine and exceptional specimen handling, as well as collection and transportation procedures for each department of the laboratory (Flynn, 2005). Another duty of the phlebotomist is to interact and communicate with patients and other health care teams. The completed phlebotomist's job responsibilities and their correlation with the total testing processes in the laboratory testing are in Appendix F.

In consideration of the expanded role of the phlebotomist, more than one half of the lab technicians greet patients, update the demographics, enter and update the insurance information and other clerical duties. Performing venipuncture is the duty reflected in most of the phlebotomist job descriptions.

Laboratory Errors

Laboratory practice can be sorted into three levels: pre-analytical, analytical, and post-analytical. Although studies have indicated that errors in the analytical step have decreased considerably over time, errors in the laboratory field still exist (Plebani & Piva, 2010; Majkic-Singh & Sumarac, 2012; Rin, 2010). Burnett et al. (1996) stated that analytical mistakes accounted for < 10% of all mistakes. Plebani and Carraro (1997) published that laboratory error rates have declined over 10 years from 0.47% in 1987 to 0.33%. The analytical variability 40 years ago was 20 times more than what it is now (Carraro, Servidio, & Plebani, 2000).

Lapworth and Teal (1994) pointed out that most laboratory mistakes happen in the pre, and post-analytical phases. Errors in the laboratory testing could be any fault starting with ordering the test to reporting results, or reading and responding to the results (Bonini et al., 2002). However, the pre-analytical errors comprise the majority in the

laboratory, ranging from 31.6% to 75% (Zardo, Secchiero, Sciacovelli, Bonvicini, & Plebani, 2000). As mentioned earlier, some of the common sources of pre-analytical error are the following: ordering the wrong test, missing tests, misidentifying the patient, choosing the inappropriate collection container, labeling containers improperly and mishandling. Every laboratory needs to have a policy for recognizing pre-analytical errors. The pre-analytical part is an essential section of entire laboratory quality and that fact that pre-analytical variables are causing changes in laboratory results must be recognized (Gruyter, 2006).

Human Error

The goal of human factors theory was to identify and to improve human actions by describing known human strengths and weaknesses and by emphasizing the environment in which the individual is placed within the organization (Isaac, Straeter & van Damme, 2004; Vincent, Taylor-Adams, & Stanhope, 1998). Understanding factors contributing to laboratory errors is critical if they are to be addressed and resolved. Yet, the tendency has been to blame individuals in healthcare rather than analyze the problem or error (Institute of Medicine, 2004; Reason, 2000). Work environments have been reported as being a major relation to the health care errors (Sanghera, Franklin, & Dhillon, 2007).

The most common medical errors have been happening due to providers rushing the orders, distraction, carelessness, ignorance, inexperience and lack of knowledge (Baldwin, Dodd, & Wrate, 1998). According to Choo, Hutchinson, and Bucknall (2010), human errors are the person approach, which focuses on the error-prone behavior related to lack of attention, forgetfulness, carelessness, negligence or recklessness. With this

result, errors can be reduced by modifying human performance. Of course, human error has many causes and it would be improper to overlook the fact that so many situations exist that are worthy of in-depth discussion. Delivery of health care requires higher cognitive purposes, good judgment, complex decision- making, memory, awareness, information management, and communication skills. Fatigued workers try unsuccessful solutions to problems and may forget critical activities (Lerman et al., 2012).

Phlebotomist Skills and Techniques for Collecting and Submitting Samples

As noted earlier, in laboratory testing, majority of mistakes are known as occurring in pre-analytical stages (Gruyter, 2006). In the pre-testing stage, the occurrence of patient or specimen identification errors and the possibility of specimen rejection because of clotting, hemolysis, or insufficient quantity, symbolize a phlebotomy threat for patient safety (Gruyter, 2006; Plebani, 2012).

Techniques for collecting specimens and submitting samples are critical because analyzing poor specimens can result in inaccurate information that possibly will change patient treatments. Phlebotomy techniques are an important pre-analytical part that should be restricted and carefully controlled to make sure that results reflect the patient's condition. To stop any errors, the laboratory staff needs to implement a rigorous procedure for training (Bonini et al., 2002). Through review of the regular basis reports of disqualified samples and grouped causes related to specimen rejection, it is possible to avoid mistakes and maintain continuous quality improvement of laboratory service (Bonini et al., 2002).

One of the most frequent reasons for rejection in laboratories is hemolysis, which occurs five times more often than the second most frequent reason (Jones et al., 1997).

Another study done by Chawla et al. (2010), confirmed that hemolysis causes the majority of rejections in the laboratory. Some of the reasons causing hemolyzed samples are forcing the blood through a needle, especially when a draw is performed with a syringe; inverting the tubes too strongly, or spinning (centrifuging) the blood sample before clotting is complete (Chawla et al., 2010). The phlebotomists' skill is a necessary requirement for stopping errors in the pre-analytical steps.

Recent tremendous progress has been made in the laboratory field for the standardization of pre-analytical phase processes and procedures and it has significantly changed the realization of laboratory results. For instance, applying a tourniquet and fist clenching can cause high potassium (Gruyter, 2006). According to Hawkins (2010), there is no considerable relationship between the presence of hemolysis and patient age or gender. Provider skill can also be one of the causes of hemolyzed specimen. Hawkins et al. (2010) pointed out standard training and competency assessment will reduce hemolysis. Jones et al. (1997) reported that the incidence of rejected specimens collected in microcollection tubes is higher than in other tubes. He also noted that in-hospital personnel groups submit significantly fewer rejected specimens than outpatient phlebotomy groups (Jones et al., 1997).

Phlebotomist Lack of Training/Knowledge

According to Pandey, Chaudhary, Tondon, and Khetan (2007) errors in pre-analytical phase mostly occur by trained staff. They pointed out that trained phlebotomists make major errors at the rate of 27.8%. Technical errors are frequently made by trained staff (73.2%), but mostly staff with less experience are responsible for clerical mistakes (58.5%). Considering that trained staff made errors, there is a need for

consistent proficiency testing, and a dynamic method for recording the errors (Pandey et al., 2007). The guideline of literature reviews indicated that the job examination should emphasize visible job performance and show of responsibilities and work techniques (Gomez-Mejia, Balkin & Cardy, 2010).

The updating of current and exact job-role descriptions is useful for the purposes of guidance in training and continuing education courses development (Fidler, 2007). Some special steps in the blood drawing procedure prevent mistakes more than others, and more particular education is necessary to decrease them (Brennan et al., 1991). The use of common pre-analytical handling procedures for all blood specimens suggests that the phlebotomy procedure itself is the likely cause of improper specimens (Lippi, Blanckaert, & Bonini, 2008). Plebani (2012) suggested that a better training and education is an effective decrease of hemolyzed samples.

Some companies ask, "What if we invest money on employee training, and our employees leave" (Keller, 2008, p. 40)? The price of not training the employees is more expensive than having the trained employees leave (Keller, 2008). Training and development in today's health care setting is an imperative process that must be matched within an organizational structure (Novis, 2011). A common result of training is that it will continue to develop the job responsibilities. Because prompt modifications might happen in material or skills and in technology, it is essential that certification programs occasionally analyze performance, responsibilities related information, and the staff's qualification to guarantee that they are up to date (Gomez-Mejia et al., 2010). Written policies and protocols with clearly defined duties and job tasks are crucial in any department. Standardization of polices and procedure will help to reduce errors (Gomez-

Mejia et al., 2010). Order entry and patient identification errors are fewer in hospitals that include order verification and confirmation as part of their policies and procedures (Novis, 2011).

In the health care setting, training and development of each health care expert is vital to successful delivery of care to patients and their families as well as organizational and individual development. The benefit of the investment from a training program can result in decreased the human errors, improve quality of care, promote patient safety, and increased patient satisfaction. An effective learning plan can cover job-specific training. It can include mentoring or training from an employee who has formerly held a similar job or still working in the same job field (Keller, 2008).

The key to fixing errors is to first identify and stop them. Management should be in constant communication with staff to check for errors in an effort to resolve them and make adjustments immediately (Henneman et al., 2010). Review of policies and procedures must be a part of ongoing training. A team of staff leaders should do regular research on best practices and procedures to stay current.

Phlebotomist Experience

The way to identify errors is to know the policies and procedures and to check and update them regularly, know the patients, know the staff, and know the plans of care (Henneman et al., 2010). It is important to stop errors that are occurring or prevent them before occurring. Employees with experience and confidence have the ability to catch errors and correct them. Having a good team mix of new and experienced staff during shifts is important. For instance, incorrect tourniquet procedure is common; the lack of

observance of the newer protocol regarding the usage of tourniquet might change the integrity of some test results, and thus alternate the treatment (Lima-Oliveira et al., 2011).

As noted earlier, hemolyzed samples are one of the most comment errors in the pre-analytical level. Another element that could contribute to differences in hemolysis rates includes the choice of collection device and vascular access site (Hawkins, 2010). Breakage of red blood cells during venipuncture, which causes hemolysis of the specimen, can happen from different sources including using smaller gauge needles (e. g., 25 gauge), incorrectly positioning the needle inside the vein causing in a slow blood flow, inverting the blood sample too aggressively, and exerting extreme drawing force on the syringe plunger (Lippi et al., 2006). According to Mayo Clinic (2008) if red blood cells are presented in the plasma or serum it calls hemolysis, If <50 mg/dL – not hemolyzed >100 mg/dL – moderate hemolyzed. If Appearance of serum degree of hemolysis is >300 (dark red) marks grossly hemolysis.

Applying tourniquet for a long time can also cause hemoconcentration. Hemolyzed specimens display falsely elevated potassium in the blood and falsely elevated intracellular enzymes (Hawkins, 2011). To reduce the impact of hemolyzed specimens (hemoconcentration) when drawing blood, the tourniquet must be released quickly after blood starts flowing (Lippi et al, 2006). The maximum recommended time to leave the tourniquet on patient's arm is 60 seconds (Lippi et al, 2006). Phlebotomists should advise the patient to avoid strong hand pumping. This practice should be discouraged because strong hand pumping may also change the results in certain tests (e.g. potassium). For venipuncture, the order of draw should be followed to prevent additive carryover (CLSI, 2003). Filling up the tubes in the correct order, and mixing

sufficiently based on the tube manufacturer's guidelines is important (Lippi et al., 2006). Container preservative carryover is not noticeable by the laboratory, but it may lead to changes in the results for the patient, which can be harmful when health decisions are influenced by test results. Collection tubes in different sizes should be available to guarantee lowest fill requests are met if the patient is a hard draw (Lippi et al., 2006).

Phlebotomist Workload

Task factors for a job include the theory of workload as a possible source of stress (Yerkes & Dodson, 1908). Divisions of workload are known as measurable overload, resulting from the employee being given too many responsibilities to complete in a specific period. On the other hand, qualitative overwork is when the individual does not feel proficient to complete the given task due to lack of skills. Mostly, medical errors are caused by increases in workload (Choo et al., 2010; Kozer et al., 2006).

Work environments have been reported as being a major reason of health care errors (Sanghera et al., 2007). The most common medical errors have happened due to providers' hurry, distraction, pressure to finish quickly, carelessness, ignorance, inexperience, and lack of knowledge (Baldwin et al., 1998). Errors can be a direct reflection of organization shortage. Mistakes and improper patient care may arise from employee shortages; this might not be directly obvious, but will turn out to be harmful in the long term.

Philibert and Taradejna (2003) and Fisher (2011) found that fatigue and errors are related. Workplace factors are measured as directly related to the performance of the employees and organizations. These may include policies and procedures, staffing,

budgeting, work assignments, and management and supervision (System and Human Factors Influences, 2005).

Pandey et al. (2007) did a review in phlebotomy area and found that the technical errors were 55% and the remaining 44.9% were clerical. But continuing to use new technology, unexpected problems and unintentional mistakes such as order entry errors, mismatched patients, poor compliance with new policies and procedures, added stress for staff members, and created negative effects on workload (Carraro & Plebani, 2007; Georgiou, Ampt, Creswick, Westbrook, & Braithwaite, 2009; Hwang, Park, & Bakken, 2002; Kuperman & Gibson, 2003; Lindenauer et al, 2006; Scanlon, 2004). Hawkins (2010) reported that the greatest relation of hemolysis rates in the outpatient setting appears to be the volume of work performed at each collection site. This suggests that workload may be an important determinant of competency in phlebotomy performance. But the non-normal distribution of graphical assessment for a group, suggests that workload is not the sole determinant of hemolysis rates at all collection sites (Hawkins, 2010).

In this study, the correlation between workload or phlebotomist overload was evaluated by collecting the phlebotomists' perspective of workload. Medical laboratories are places where a large number of specimens are being collected and analyzed. Laboratory workers are expected to carry a heavy workload. However, no previous report on the incidence of psychological stress of the laboratory workers has been written.

Phlebotomist Job Stress

Stress, a mental and physical response, occurs when individuals feel particular challenges or circumstances beyond their managing skills. When stress is compared to

particular components or elements of a work environment, this stressor is referred to as *job stress* (Kiani, Samavtyan, Poorabdiyan, & Jafari, 2012). Job stress is not an unusual occurrence. Three stressors are related with job stress: job factors, individual factors, and organizational factors. Each factor is responsible for an individual's cumulative stress within a job or work environment. Job stress is the unsafe physical and emotional response occurring from a poor match between job demands, skills and resources within a workplace (Wu, 2011).Work environments have been reported as being a major influence in medical errors (Choo et al., 2010). Stress decreased as work experience increased (Isikhan et al., 2004). High levels of stress can increase the probability of human errors in less experienced personnel even during routine tasks (Levin et al., 2006). Also, high levels of job stress can have a damaging impact on emotional, security and safety (Paterniti, Niedhammer, Lang, & Consoli, 2002).

Work-related stress occurs when people may be presented with work demands and forces that are not matched to their knowledge and abilities and that challenges their ability to cope. Job stress is defined by the American National Institute for Occupational Safety and Health (NIOSH) as"The harmful physical and emotional responses that occur when the requirements of the job do not match the capabilities, resources or needs of the worker" (NIOSH, 1999, p. 6). Stranks (2005) stated that stress is a pressure placed on a person beyond the ability to manage.

Great evidence has indicated that the pressure in medical field can harmfully affects health care workforces. Stress can also damage professional effectiveness and reduce responsiveness (Smith, 1990), moderate awareness (Askenasy & Lewin, 1996), affect managerial abilities (Klein, 1996), and decrease staff's capabilities to create good

connections with patients (Pastore, Gambert, Plutchik, & Plutchik, 1995). Supporting health care staff is necessary to address the various elements that cause stress in their job.

The literature study confirms that the rate of elements causing stress related to the levels of observed anxiety (DiClemente, Fairhurst, & Piotrowski, 1995). In this study the researcher contributed to understanding the relationship between the stress and pre-analytical errors in laboratory testing by providing awareness into the relationship between stress and pre-analytical errors in the laboratory testing. The hypothesis that relates the pre-analytical errors to job stress was investigated. Also, the hypothesis that stress is primarily due to work pressure (Sutherland & Cooper, 1990) was evaluated.

System/Operations Errors

Healthcare needs to move from a culture of blame to an organizational approach that supports and fosters preventing errors (Barach, 2003; Institute of Medicine, 2000 :2004). The system approach focuses on the work environment and looks at errors as results of system problems within the phlebotomists' job setting such as staff shortage, increased workload, and missed breaks. The system approach is more beneficial to changing practices that cause the errors instead of blaming the individual (Choo et al., 2010). Previous studies have agreed that most errors within the pre-analytical phase result from system defects, and errors are a direct reflection of system insufficiency or system failure (Pandey et al., 2007).

Errors are not always the result of individual ineffectiveness, but can occur due to the system failure in health care. Any error can show lack of effective policies and procedures; it might not lead to challenging measures in certain circumstance, but may be related to a patient injury to some extent in different situations (Plebani & Piva, 2010).

Poor or inconsistent processes or procedures for patient registration, sample collection, specimen handling, including transportation and keeping specimens at an appropriate temperature, account for up to 93% of the errors happening inside the laboratory total testing process (Lippi et al., 2006).

Brennan et al. (1991) suggested that, to avoid human error, a system in place for each process and procedure, and having clear strategies (step-by-step) for a particular task are necessary. Faults frequently occur because of the way individuals work together in a practice and could be related to underlying or characteristic fault in an organization due to the system design or the individual decision making (Zardo et al., 2000). For instance, the order entry system used by the laboratory staff in the current study, known as Horizon Lab system (HLAB), requires the user to select desired laboratory tests from a database that contains more than 3,000 test names and their common synonyms. For example glucose (GLU) and fasting blood sugar (FBS) are often used interchangeably. The phlebotomists need to enter the first three letters of a test name to get a list of tests starting with those letters. Test names may be similar such as CRP (C-reactive protein), and CRP-HS (coronary risk marker) or may identify the test name with a specimen source like protein-blood and protein-urine. If the user is hurried and is not paying close attention, the wrong test can easily be selected from this look-alike list. Or when registering the patient, the phlebotomist needs to enter three letters of the patient's last name and three letters of the first name. If the two patients have the same last name and first name or even if the name is just similar, phlebotomists can make a mistake and choose the wrong patient. The same scenario can happen when the phlebotomist chooses the ordering provider or the source facilities.

Pandey et al. (2007) did a study monitoring errors in phlebotomy area for 8 months. They indicated that errors in pre-analytical phase of laboratory included clerical and technical errors (Pandey et al., 2007). Out of all the errors, 55.1% were clinical and 44.9% were clerical errors. Out 55.1% technical errors, 57.7% were identified as minor, whereas 42.3% were major. The majority (89.9%) of clerical errors were classified as minor (Pandey et al., 2007). Valenstein and Meier (1999) reported that 4.8% of outpatient requisitions have at least one laboratory order entry error type, including differences in the test ordered, physician's name, and test priority status.

As mentioned earlier, mistakes can happen in any part of the total process and by any one of the health professionals involved in the process. Klienpall (2001) pointed out that the problem is not a case of poor professionals, but the poor systems they work in. Before analyzing the relationship between the phlebotomist and the errors, it is necessary to understand the phlebotomist job setting in the laboratory field. The College of American Pathologists (CAP) reported that within the years of 2007 and 2011 the major cause of CAP proficiency testing (PT) was clerical errors (as cited in Shearer, 2012). Patient safety and work design for the health care workers are important. Re-designing the phlebotomist work place can be a key in making a phlebotomist's job more effective and proficient. It can grant opportunities to reduce chances for mistakes. Brownlee (2007) stated that to reach to the point of an outstanding patient care, various people are responsible to perform their tasks correctly all the time. Quality in laboratory testing should be clear that each single step during the total testing process is accurately completed and, thus, guarantee important medical decision-making and efficient patient care (Lippi et al., 2009).

Transportation or Specimen Handling

One of the potential areas of pre-analytical errors in laboratory diagnostic is specimen handling and transportation from patients to the laboratory. Specimen quality can be compromised by temperature change or substantial forces during transportation. Felder (2011) stated that it is well understood that uncontrolled temperature can cause errors and these kinds of errors can be prevented by using environmentally controlled transportation containers. The relation of extreme physical forces on specimens is poorly researched (Felder, 2011). To maintain the quality of collected specimens, handling the specimen during transportation and processing is critical. Delivering the specimen to the laboratory at the correct temperature is required; exposure to cold or heat, shaking, situation of samples, and time to for testing can significantly alternate test results. Plebani and Zaninotto (2011) stated that harsh physical forces can contribute to pre-analytical errors; it can cause a breakup of plasma or cause hemolyzed blood sample.

During specimen transportation, the factors such as standard specimen transport environments, customary sample types, specimen stability, and temperature are important. Each specimen type has standards and environment for transportation to sustain its reliability for testing. For instance, some specimens must be protected from light, or some specimens need to be kept at body temperature, whereas some need to be refrigerated or frozen; some samples are time sensitive and should be transported quickly. Transporting and processing interruption can make a specimen unacceptable for analysis. A specimen's priority is important in laboratory testing; for example, samples collected in emergency room, or STAT orders should to be delivered to the laboratory immediately.

Communication

Poor communication and lack of interoperability are two of the causes of medical errors (Choo et al., 2010; McGowan & Healey, 2009). The laboratory requisition form is the key communication between clinician and laboratory personnel (Gyawali, 2012). An error, lack of required information, or insufficiency in the order request form can affect communication of laboratory standards such as wrong results or delay in turnaround time. Therefore, poor communication between laboratory professionals and clinicians is recognized as the primary issue relating to the quality of laboratory services during the pre-analytic and post-analytic phases (Howerton & Astion, 2008). Thus, one of the factors related to quality and causing mistakes in the laboratory testing is lack of effective communication. Several studies show that 80% of main medical errors are the result of miscommunication between health care staff and a lack of collaboration in the health care delivery (Adams & Boscarino, 2004).

Brownlee (2007) stated that lack of collaboration between the personnel in the present health care services is one of the major reasons of the medical errors in health care. Hearing that miscommunication between health care professionals is the major cause of medical errors is disappointing. Eventually, one of the sources of the problem in health care setting is miscommunication among all the members in the healthcare field: physicians, pharmacists, laboratory staff, and nursing staff (McGowan & Healey, 2009).

Types of communication problems. Miscommunication in pre-analytical phase of laboratory includes poor laboratory–clinician communication and communication with other health care providers (nurses) during test ordering. Poor communication at shift change regarding specimens that remains unprocessed or transported remains a problem.

In the analytical phase, lack of communication between analytical phase (CLSs or pathologists) and pre-analytical phase (phlebotomist) about the change of a test requirement can cause errors. Pre-analytical error avoidance needs outstanding communication and teamwork between the members of the laboratory team: from the phlebotomist who draws the blood and collects the samples, to the courier who transports the samples to the laboratory for testing, to the processing department and the staff who receives the specimen, and the CLSs who analyze the tests.

Training and providing the phlebotomists with the new information, and other healthcare professionals who are involved in dealings with specimen collection, processing, and transporting is critical to understanding the correlation of pre-analytic variables on sample reliability. Most large diagnostics labs are designed with many analytic divisions such as hematology, coagulation, and chemistry that do not share their best practices for quality improvement. The laboratory testing is more complicated now and health care providers should have more support in using the new laboratory knowledge and equipment (Lippi & Guidi, 2007). The need of this support will increase as even more complex testing becomes available. Thus, laboratory experts must improve their relationships professionally with the providers who order laboratory tests (Centers for Medicare and Medicaid Services, 2012). Some primary care physicians recognize that the opportunity of level of care expected of them is beyond their current knowledge base, and they reportedly seek additional information when ordering tests. Medical and scientific advances, such as in genetic testing, will multiply challenges associated with ordering the tests. This requires correctly interpreting results and incorporating this information into clinical practice. Therefore, ordering providers should consult with the

clinical scientists for appropriate test ordering and interpretation (Burke, 2003). Communication and quality relationship between the laboratory and other departments where lab draws are done are essential to help make sure everyone is in agreement (Lusky, 2003).

Improving communication among health care professionals and reinforcement of different departments' cooperation is necessary to reduce the error and promote patient safety. Promoting the culture of patient safety is needed for the solution to this problem in health services delivery (McGowan & Healey, 2009). The strategy to fixing errors is first to categorize and to stop them from progressing. Reporting and documenting the errors in a comfortable practical manner will improve the quality of care in an organization. If errors are not reported or moderated, the true reflection of what is happening will be absent, thus improvements will not take place (Henneman et al., 2010). According to Brennan et al. (1991), one of the steps that will prevent errors is the need for feedback to staff through a non-punitive approach. Management should be in regular communication with staff to check for errors, find resolution, and make adjustments immediately (Henneman et al., 2010).

Technology/Computerized Physician Order Entry (CPOE)

The communication between health care providers and the laboratory personnel for requesting a test is through the ordering system. Ordering system includes paper order or electronic orders through Electronic Medical Record (EMR) using a computer system. An electronic medical record (EMR) is health documentation in electronic format. Increased usage of general health care data and electronic laboratory test orders has the potential to eliminate some types of pre-analytical laboratory errors. Unclear,

uncompleted, unsigned orders, bad handwriting, and abbreviation using hard copy orders are different forms of miscommunication between the health care providers and laboratory department. Misinterpretations of abbreviations and misunderstandings of handwriting cause errors in the healthcare field (Choo et al., 2010). "The handwriting of some doctors is a joke. Unfortunately, it's a deadly serious one. That's no laughing matter" (Adams & Boscarino, 2004). Several lab requisitions with different styles and designs lead to increased test order entry errors. Missed or wrong test ordering can contribute to medical errors at the point care (Meier & Jones, 2005; Ehrmeyer & Laessig, 2007).

Laboratory technology has evolved to greatly reduce the time needed to analyze a patient's specimen and report the results back to the provider (Georgiou Westbrook, & Braithwaite, 2006) primarily through the use of computerized physician order entry (CPOE) methods. However, computerized laboratory test order entry errors, along with other pre-analytical errors, make up the largest percentage of medical errors reported in the literature (Kazmierczak, 2003; Gile, 2006; Plebani & Carraro, 1997). CPOE has improved the overall quality of patient care by reducing errors stemming from poor handwriting or inaccurate transcription (Doolan & Bates, 2002; Georgiou et al., 2006). Although CPOE system has decreased the errors, human errors such as lack of knowledge, disruptions, inexperience, and typing errors still exist (Diwas & Terwiesch, 2009).

Computerized order entry systems. CPOES permit practitioners to order electronically and to see the patient's history, including laboratory results (Kratz, Salem, & Van Cott, 2007). Increased use of CPOE and Electronic Health Records (EHRs) may

prevent or decrease incorrect order entry errors, and improve point of care testing. Computerized physician order entry systems have been supported as a resource of reducing errors, increasing the quality of care, and improving efficiency (Lechleitner, Pfeiffer, Wilhelmy, & Ball, 2003). Since the implementation of CPOE systems in the clinical laboratory, many errors associated with paper test requisitions have been eliminated, but human errors still occur. For example, Cerner, ADM, or Web Outreach, the computer system chosen by the laboratory where the current study was done, has not been able to eliminate the errors.

Technology has touched the clerical side of the laboratory system. Although the technology line between the laboratory and the provider is critical, the transition between ordering a test and laboratory analysis is associated with the highest frequency of error (Shaw & Strombler, 2005). Although this is a technological advancement age, phlebotomy remains a human physical process, needing important human skills and judgment that will never be robotic or computerized (Ernst & Ballance, 2006). Collection of routine blood specimens has been performed with tourniquet (Lippi et al., 2007). According to Lima-Oliveira et al. (2011) usage of a tourniquet can give erroneous results, and will cause the doctors to implement unnecessary treatments.

Lima-Oliveira et al. (2011) pointed out that transillumination (vein viewer) devices could be considered as a proper instrument to reduce vein collapse and to increase the reliability of process in pre-analytical phase especially phlebotomy procedures. The transillumination devices have been suggested as a valued device for finding a vein for venipuncture in children and in patients with small or difficult veins (Lima-Oliveira et al., 2011). Transillumination devices can provide the benefit of

replacing the tourniquet for blood draw and can help to eliminate the anxiety and possibility of false results that tourniquet can cause (Lima-Oliveira et al., 2011). Some of the results of leaving the tourniquet on for longer than 60 seconds are: "major increases for the platelet count, red blood cell count, hemoglobin, hematocrit, white blood cell count, neutrophils, monocytes and eosinophils" (Lima-Oliveira et al., 2011, pp. 457-62). Another issue of leaving the tourniquet longer than 60 seconds is falsely elevated potassium (K+).

Health Care Cost and Laboratory Testing

Proper procedure for economical laboratory testing will increase significant treatment decision making (Klein & Kant, 2006). Rational support systems must help ordering providers in requesting laboratory tests properly and more proficiently. IOM (2000) provided a series of recommendations to increase the outcome of patient care during the next decade. The report set out an inclusive strategy for reducing medical errors through a mixture of technologic, policy, regulatory, and financial strategies intended to make health care safer (Sultz & Young, 2010).

As mentioned earlier, IOM (1999) reported that the costs for preventable medical errors are about half of the direct health care costs. One year later, IOM (2000) announced that the effect of unnecessary health care correlated cost to the government budget is from $17 to $29 billion each year. Of the $29.5 billion medical error costs in the United States, $17 billion accounts for increased medical care and $1.1 billion relates to lost productivity due to short-term disability claims (Ledue, 2010).

Another report from the Institute of Medicine (2006) estimated that about $ 3.5 billion is paid every year in the U.S. healthcare system because of medical errors. The

estimations did not include errors in nursing homes, private doctor's clinics, and pharmacies (Institute of Medicine, 2006). According to CAP (2006) $200 to $400 million is spent per year in redraws, re-testing and additional treatments for the hospitals. De Rezende, Or, Com-Ruelle, and Michel (2012) reported $17.1 billion as the cost of medical errors that harmed patients in 2008. Van Den Bos et al. (2011) in another report pointed out that the cost of health care in 2008 was 2.39 trillion and 0.72% was spent on medical errors. Centers for Disease Control (2007), reported that laboratory error rate is about 2.3% of medical errors. With consideration of laboratory diagnostic's role in health care quality, the relation of laboratory testing on the cost and quality of health care is much greater. Laboratory medicine can help to improve usage of health care dollars and eliminate short and long-term expenses of care (McGlynn, Asch, & Adams, 2003).

Ordering electronically (CPOE) by ordering providers will simplify ordering system instead of paper requisition order (Smith, Cokkinides, & Eyre, 2003). CPOE will help the laboratory experts save time rather than spending time finding some specific tests. This tool will improve quality of life and reduce the costs (Smith et al., 2003). Introducing an electronic ordering system for laboratory tests by primary care physicians resulted in cost savings (Poley et al., 2007). The key point is that once utilization of COPE is implemented the knowledge of using it should be continuously revised and maintained. Clear procedures should be written and communicated with the ordering physician and the laboratory users.

The College of American Pathologists (1995) reported that among 577 organizations 97.1% of physicians' test orders that were sent to the laboratory were completed by the laboratory. Reports showed that the reasons failure were: 4.1%

physician handwriting was unclear, 12.8% test requisition improperly filled out, 41.8%, failure to enter orders correctly into hospital computers, and 1.4% failure to enter orders correctly in laboratory computers (College of American Pathologists, CAP, 2013). Use of CPOE (as compared to conventional ordering) resulted in statistically significant decrease in the numbers test ordering for blood count, chemistry, serum, and STAT tests. When CPOE was linked to additional decision support features, including the patient's medical record, test numbers decreased from 9.5% (per patient per day) to 45.6% (per hours per patient day). Costs associated with laboratory ordering also decreased up to 28% for certain tests (Wolcott, Schwartz, & Goodman, 2008).

Safety and Quality Improvement

Patient safety is the key component of medical practice. Patient safety is the decrease of preventable injury related to health care (Runciman et al., 2009). Lack of patient safety is preventable. Talking about safety refers to protecting patients from injury during the treatment that is proposed to help them, and protecting health care workforce from injury while providing care. Patient safety has been lacking in the long run and needs to be rebuilt (cite).

In the time that stress is on patient safety progress with monitoring organizations, such as The Joint Commission (TJC) and Agency for Healthcare Administration (AHCA), the need for higher quality of standard is highlighted. Laboratory errors can have a great effect on patient care (Agarwal et al., 2012). Laboratory diagnostics have an important role in decreasing the possibility of injury when patients are correctly identified, samples are labeled correctly, and are collected properly, proper procedure are followed to prevent specimen contamination, procedure to control the specimen are

performed during analytic practices, and results are finalized clearly and reported logically (Behal, 2007).

Quality assurances in laboratory medicine should be structured under strategies for verifying harmless phlebotomy performance, following the correct procedure such as patient identification, diagnostic accuracy, and follow up with providers on the subject of test results, or health consequences (Behal, 2007; Hilborne, 2006; Institute of Medicine, 2006). Suppliers must be persistent in their hard work to decrease the possibility of harm, targeting for no injury, and motivated to build an organization that is responsible for everyone to provide a high-quality healthcare (DHHS, 2011). Reaching this kind of healthcare system needs the strategy of regular operative processes, staff with various balancing expertise, amount of work that permit sufficient time for mistakes to be fixed or moderated, and management that encourages constant progress (DHHS, 2011). Eliminating errors might be difficult in healthcare, as in any other human action, but it is possible to reduce them.

Conclusion

The literature review in this study proves the statement that, majority of laboratory errors are happening in the pre-analytical phase. The first phase in the laboratory testing begins with testing request, patient identification, sample collection, sample identification, specimen handling, and transporting the collected specimens to the associated department of the laboratory.

Summary

In the pre-analytic phase of the laboratory diagnostics, the occurrence of patient or specimen identification errors, and the occurrence of potential sources of rejecting the

samples (hemolysis, clotting, quantity not sufficient, etc.) symbolize a significant threat for patient health protection. Stopping inaccuracies and mistakes in the pre-analytical phases needs mutually technical improvements, effective networking with the scientific world to reach an operative team-working collaboration.

Table1 shows all of the factors related to quality-related issues that are preventable. The data in this report was collected between the years of 2004-2012 by an accredited organization, voluntarily. In the report, data shows the frequently acknowledged sources for sentinel events appraised by The Joint Commission. The full reports by category are available as the Appendixes to the end of this study (Appendixes H-Y).

Table 1

Root Cause Analysis of Events in Health Care, 2010, 2011, and 2012

2010 (N=802)		2011 (N=1243)		2012 (N=901)	
Leadership	710	Human Factors	899	Human Factors	614
Human Factors	699	Leadership	815	Leadership	557
Communication	661	Communication	760	Communication	532
Assessment	555	Assessment	689	Assessment	482
Physical Environment	284	Physical Environment	309	Information Management	203
Information Management	226	Information Management	233	Physical Environment	150
Operative Care	160	Operative Care	207	Continuum of Care	95
Care Planning	135	Care Planning	144	Operative Care	93
Continuum of Care	112	Continuum of Care	137	Medication Use	91
Medication Use	86	Medication Use	97	Care Planning	81

Note. The specific gaps in healthcare delivery illustrated on the table. This report shows the human relation such as, a team with skill mixture, employee orientation, work-related training, proficiency evaluation, fatigue, and distraction in approximately 87% of all sentinel events (Joint Commission, 2013).

Chapter 3

Methodology

The purpose of this quantitative correlational study was to define the relationship between the pre-analytical errors in the laboratory diagnostics (dependent variable) and the operation, or system errors, job stress, work load, human errors, communication, technology, and transportation (independent-variables). In the current study researcher employed survey design to evaluate the phlebotomists' workload and their job stress level for the study. The survey was implemented at two departmental in-service meetings among 200 phlebotomists. Four existing instruments, which included the PPS, OCQ, QWI, and ICAWS, were used to gather phlebotomists' responses concerning job stress, workload causes, and pre-analytical errors. To obtain the data about other independent variables, phlebotomists' skill, experience, knowledge, and training (human errors), communication, technology, system design, and transportation, the researcher analyzed the existing data from the hospital database that captured the total and type of the errors in the years 2011, 2012, 2013, and 2014. The survey designs were tested in a pilot study before the implementation between the sample groups. The software that was used in this study for analyzing data is SPSS version 21. Additional statistical data was collected on four different pilot projects for 1 month in winter 2015 to measure the correlation of the operational system, effective communication, ongoing training, and advanced technology on the phlebotomists' job performance.

The goal of this research was to investigate the relationship of pre-analytical errors in the laboratory field, with patient safety, and health care costs. Four research questions were constructed to guide the study. Research questions served to address the

purpose of the study and to limit the subject matter into components compacted enough for meaningful statistical analysis. This study used multiple regression analysis, Pearson's correlation coefficient and ANOVA for hypotheses testing.

Chapter Three of this study reviewed the research questions, and hypotheses guiding the study, describes the research design, survey design, sample population, statistical methods, data sources, and data analysis plan. Included in the chapter are descriptions of the population, geographic location, sampling methods, and sources of data. This chapter also contains a discussion of the study technique and design appropriateness. The chapter also includes a discussion of how data was collected and analyzed, instruments, and issues related to reliability, and validity.

Hypotheses and Research Questions

The hypotheses tested in this study were as follows:

RQ1. What is the relationship between laboratory pre-analytical errors and the phlebotomist's (human factors) skills, experience, training, knowledge, communication, and transportation?

Hypothesis 1a (null). Laboratory pre-analytical errors are not related to the phlebotomist's skills, experience, training, knowledge, communication, and transportation as, human factors.

Hypothesis 1a (alt). Laboratory pre-analytical errors are related to the phlebotomist's skills, experience, training, knowledge, communication, and transportation as human factors.

RQ2. What is the relationship between the laboratory pre-analytical errors and the operations system?

Hypothesis 2a (null). Laboratory pre-analytical errors are not related to the operations system.

Hypothesis 2a (alt). The key to reducing pre-analytical errors is related to the operations systems in the laboratory.

RQ3. What is the relationship between technology and laboratory pre-analytical error rates.

Hypothesis 3a (null). Pre-analytical errors are not related to the technology system.

Hypothesis 3a (alt). Pre-analytical errors can be reduced by advance technology.

RQ4. What is the relationship between the phlebotomists workload and job stress and the errors in the pre-analytical phase in laboratory testing?

Hypothesis 4a (null). Phlebotomist workload and job stress is not related to the errors in the pre-analytical phase.

Hypothesis 4a (alt). Phlebotomist workload and job stress is related to the errors in the pre-analytical phase.

Research Method

This study utilized a quantitative study method using correlational design. The use of quantitative research methods was considered to complete the projected purpose of this study and to complement the choices for examining the relationship between the operation/system errors, human errors, communication, technology, and transportation (independent-variables) to pre-analytical phase laboratory errors (dependent variable). Existing data from the hospital database that captured the total and type of errors in the

years 2011, 2012, 2013, and 2014 were analyzed as the secondary data using SPSS version 21.

This study examined the hypothesis using a multiple regression technique to assess the correlation of all the independent variables on laboratory pre-analytical errors (dependent variable). According to Person (1908) the purpose of multiple regression is to study the relationship between several independent or analyst variables and a dependent or principle variable. The laboratory made adjustments to the operations design in four pilot locations to test the hypotheses. The data collection period was 1 month in the winter of 2015. Observing the rejected samples systematically and categorizing reasons related to the rejection might help to decrease the mistakes and promote patient safety. As Lippi et al. (2006) pointed out, to stop errors and to improve quality of the laboratory diagnostics, the phase of investigation and analysis of the errors is necessary. Finding the root causes will help designing resolutions, form effective methodologies for avoiding errors, and develop learning policies and procedures. Implementing educative actions based on new policies and procedures should be considered.

Research Design

A correlational design was chosen for the this study to test the relationship between the operation or system errors, human errors, communication, technology, and transportation to the pre-analytical errors in the laboratory testing. A correlational study design was beneficial for conclusion of the relationships between variables and describing a phenomenon (Cook & Cook, 2008). Multiple regression technique was used to analyze and estimate the magnitude between pre-analytical errors (DV), and human errors, job stress, phlebotomists work load, operations/system errors, miscommunication,

technology, and transportation (IDVs) in the laboratory diagnostics. Analysis of variance (ANOVA) was used to define whether there are any statistically significant variances among the means of unrelated independent groups (Fisher,1920).

Appropriateness of design. The researcher evaluated a number of different study design choices for this study. Several statistical analyses were considered that would achieve the study's anticipated goal. The relevance of the quantitative method with correlational design was evaluated versus the value of qualitative option study methods. Quantitative instruments collect statistical and numerical information by trials, survey responses, or experimental scores. Quantitative methods rely more heavily on the concept of testing a hypothesis to achieve desired results (Benz & Newman, 1998; Kerlinger, 1973). Following this approach, the researcher's main goal was to investigate a phenomenon to verify or invalidate a given hypothesis. Researchers engaging in quantitative exploration generally derive a theory that must be tested using some form of observational design to establish relationships between multiple dependent and independent variables (Benz & Newman, 1998).

***Experimental designs*.** Experimental designs include the use of casual or non-random tasks of study questions for a prearranged set of circumstances or testing environments (Benz & Newman, 1998). Many quantitative analyses are "steeped in historical custom" and involve weighting research data using complicated research designs and statistical analysis (Benz & Newman, 1998). In this experimental design, the researcher obtained information under controlled conditions about experience with practical reality. Samples were phlebotomist working at the draw stations and were randomly assigned to test the human error theory, knowledge and training,

operations/system errors, miscommunication, technology, and transportation in the laboratory diagnostics.

Experiments give researchers the opportunity for finding relations between source and outcome. They allow examination of variations in one variable while controlling for one or two other variables. An experiment controls situations that one or more variables can be related to test a hypothesis. In this study hypotheses 1, 2, and 3 were tested using the existing data from the hospital database that captured the total and type of errors occurred in the years 2011, 2012, 2013, 2014. An experimental design was conducted for an additional statistical data on four different pilot projects for 1 month in the fall of 2015 to measure the relation of the operational system, effective communication, ongoing training and advanced technology on the phlebotomists' job performance. According to Gay and Airasian (2003) an experimental research study was described as being directed by one hypothesis that positions a probable correlation among two variables. The experiment was piloted to approve or back up or reject the experimental hypothesis. The independent variable or the cause was manipulated to determine the special effects on the dependent variables. Samples were randomly assigned to experimental treatments rather than recognized in logical occurring groups.

Population, Geographic Location, Sampling Size, and Statistical Power

The population of this study was about 260 the phlebotomists working in outpatient service centers (PSCs), skilled nursing facilities (SNFs), in-patients, and emergency rooms (ERs). One hundred phlebotomists work in the out-patient service centers (PSCs), 100 phlebotomists serve the skilled nursing facilities (SNF), and 60 phlebotomists were working in the laboratory in-patient setting and emergency room. All

the phlebotomists working within the laboratory department participated in the survey experiment. But, to test the study hypothesis, researcher selected potential study participants (phlebotomists) from work areas who were likely to order laboratory testing. In some locations based on the patient volume, the patient registration system were different than others.

The location of the study was an outreach laboratory service of a non-profit hospital with two campuses that has about 850 licensed beds, trauma center, cancer care, cardiac care, in-patient draw stations, and out-patient draw sites (PSC) in the San Francisco Bay area. The laboratory services employed more than 700 employees in a variety of laboratory disciplines, which included support staff, couriers, phlebotomists, medical lab technicians (MLTs), clinical laboratory scientists (CLSs), pathologists, and the leadership team. The name of the study location stayed anonymous. This research involved the study of existing data (collected prior to the research for other purposes). According to Collaborative Institutional Training Initiative (2007) if the data is publicly available or recorded by the investigator, the subjects cannot be identified (Section 2.1.2.2).

A-priori sample size calculator for multiple regression study from a free web-based sample size calculator was used to determine the effect size of participants for multiple regression analysis (Abramowitz & Stegun, 1965; J. Cohen, P. Cohen, West, & Aiken, 2003; J. Cohen, 1988; Soper, 2013), and to obtain representative samples of the population. The values entered are those commonly used in social science studies: a priori alpha level of .05, a beta level of .80 and a medium effect size of .15 (Pallant, 2005). The number of conjecturers entered into the calculator is 10; equivalent to the

independent variables of phlebotomist's skill, education or training, knowledge, experience, work load, job stress, communication, technology, operation systems, and transporting. The online calculator returned a minimum sample size of 140 participants (Abramowitz & Stegun, 1965; J. Cohen et al., 2003; J. Cohen, 1988; Soper, 2013).

According to Cohen (1992), a correlation coefficient with an absolute value between .10 and .29 indicates a small effect between two variables; a correlation between .30 and .49 is a medium effect; and 50 to 1.0 is a large effect. Using G*Power and correlation analysis, a .50 (large) effect size and 95% confidence level would provide a power of 83% for a sample size of 100. SPSS version .21 was used for all inferential tests, and a 95% level of significance was set for all analyses with rejection of the null hypothesis when $p < .05$.

Data Collection

Two different types of data are obtainable; primary sources provide data for the first form and secondary sources provide data for the second form (Nicholson & Terrence, 2008). In this study, the researcher gathered primary data for the objective of this study. In this study, data was collected through historical data, a survey and observation. Both set of data was captured from the same sample group for the two phases of the project. The historical data was used to analyze the pattern of the errors in the past. This mix data collection design may provide the best achievement for this research.

Historical data studies. Historical data is the basis that is present in a research design to discover for the future; what has happened in the past may happen again (Marshall & Rossman, 1998; Wyche et al., 2006). In this study, historical data shown the

activities that followed in the past and over time and helped the researcher to understand in which area most errors has happened, and what types of resolutions have been done previously. This archived data was recorded in Microsoft Excel, and worked as the codebook to help the researcher identifying, how the mistakes that are happening now were rooted in the past. This investigation used the historical data reports regarding the errors from the years 2011, 2012, 2013, and 2014. A confidentiality statement was signed by the researcher and was presented to the organization where this research was implemented. The director of the outreach operations signed the statement as the witness (Appendix D).

Quantitative survey approach. The use of a survey design arranged several custom survey to gather information from a sample group with the goal of simplifying the results to a greater population (Sprinthall, 2006), in this framework, laboratory providers involved in pre-analytical phase.

In this research, the use of a quantitative survey was the best proper and possible method for this researcher to measure phlebotomists' job stress levels and work load. The purpose of the survey was to capture the phlebotomists' perspectives of their work environments where the contributors felt relaxed to express their insights. The survey was administered at departmental in-service meetings. As a result, the Provider Perceptions Survey (Appendix C) format best integrated the use of a quantitative, non-experimental design to collect data on the participants' comments of the phlebotomist job stress, and work load factors. In this study hypothesis 4 was tested using survey design. The survey being using in this study targeted specific groups and topics while also achieving the scientific of validity, reliability, and generalizability (Haynes, 2004).

***Benefit of the survey*.** One of the benefits of one–on-one questionnaire is that it make instant feedback available, and furthermore the method that a score scale is considered equivalence during assessment. Alternative value is the point that it is cost effective. The benefit of mass mailing is that it is a good way to cover a large geographical area. This allows the participants to complete the survey at their own pace. The advantage of an electronically based survey is that it is cost effective and easy to conduct and has a fast delivery time anywhere around the world and allows the respondents to complete at their own pace.

Disadvantages of survey. A few difficulties of a questionnaire are if it is mass mailing, often the return rate is low and a low percentage is only accepted. When questionnaire is done in person, the participants can be affected by the way the facilitator's tone of voice or how the facilitator may think of the responses.

Instruments and Demographic Survey

Two hundred phlebotomists working in the PSCs and SNF received a survey package (Appendices A, B, and C) in the monthly in- house meeting. This package consisted of five separate pages. The first page of the package included the participant's invitation, explanation of the purpose of the study and the privacy statement. The second page (Appendix B) included questions pertaining to the participant demographics information, type of job they do, the location where they were working, experience as a phlebotomist, and average errors they have made monthly. Pages three to five were the Provider Perceptions Survey (PPS; S. Cohen et al., 1983; W. I. Lazarus, 1999; S. Cohen, 2013, Appendix C)

The survey instruments (Perceived Stress Scale, Interpersonal Conflict Scale, Organizational Constraints Scale, and Workload Scale) that were used in this study did not require permission for the academic researches. According to S. Cohen (2013) permission for use of perceived stress scale (PSS) is not required when use is for nonprofit educational study or nonprofit academic purposes. "The stressor (Interpersonal Conflict Scale, Organizational Constraints Scale, and Workload Scale) scales can be used free of charge for noncommercial educational and research purposes" (Spector & Jex, 1998, p. 356-367).

The PPS was used to assess job stress responses, and the phlebotomists' perceptions of workload. The PPS package included questions that can be related to the job environment (S. Cohen & Williamson, 1988; S. Cohen, 2013). Questions 1-11 came from the Organizational Constraints Scale (OCS), Questions 12 through 16 in the Workload section were taken from the Quantitative Workload Inventory (QWI), questions 17-20 came from the Interpersonal Conflict at Work Scale (ICAWS; Specter & Jex, 1997). Questions 21-30, from the Perceived Stress Scale (PSS; S. Cohen et al, 1983; S. Cohen, 2013), determine individual opinions of stress. Each question was designed to analyze how random, non-random and increased workload can be related to individual performance.

The Organizational Constraints scale (OCS) measured conditions or equipment that hampered job performances at the workplace. The QWI section is a 5-item measure designed to assess the quantity or amount of work in a job. The ICAWS was a four-item scale, considered to question about how well the participant gets along with others in the workplace, including arguments with others and how frequently others offend the

respondent. Participants were asked to select how often their job is challenging or unmanageable because of each item. Answer choices range from 0-4 with zero = *never*, 1 = *rarely*, 2 = *sometimes*, 3 = *often*, and 4 = *very often*. High scores show high levels of controls, with a possible range of scores from 11 to 55. These three factors have been continually discovered to be central mechanisms of the experience of stress (Averill, 1973; S. Cohen & Williamson, 1988; R. S. Lazarus, 1966; W. I. Lazarus, 1997). The survey focuses on an individual's particular evaluation of his/ her capability to tolerate the stresses.

Protection of Human Participants

To keep participant's confidentiality in this study, consent form was given to each individual along with the survey. The cover letter of this survey gave participants the necessary evidence for the consent form (Appendix A). Individuals participating in this study received a description of the research and possible benefits related to the research. It was explained to participants that individual responses will not be linked to their identity. Privacy of the information provided by the participants will maintain confidential. Only statistical results related to the group was reported. Consent to participate was indicated by returning the survey; participants were informed that the survey will be anonymous, and that the results of the survey is not related to their jobs and the data will be kept confidential with access being restricted to the researcher.

Validity and Reliability of the Research Instrument

This research, reliability refers to the extent to which the survey would give the same results if used over and over again with the same group under the same conditions. The survey questions in this study used the survey questions that were adjusted from

formerly authorized studies, the internal reliability of the Job Stress and Perceived Workload used in this study were confirmed by SPSS v21using the Reliability Analysis function. The original study of Cohen and Williamson's 1988, the Perceived Stress Scale was Crohnbach's $\alpha = .78$ while in this study the Crohnbach's α of .94 was greatly exceeded. The Workload subscale also was validated with a Crohnbach's α of .81, and the result was almost the same as Spector and Jex internal consistency = .82, in 1997(internal consistency = .82). Therefore, the internal reliability can be measured satisfactory.

Reliability and Validity: Internal and External

Polit and Beck (2010) stated internal validity refers to the extent to which it is possible to make an inference that the independent variable is truly causing or influencing the dependent variable. It can be determined that internal validity is referring to causal relationships between the variables that are being studied. A number of threat factors related to internal validity may have relation to the experiment and it is difficult to conclude the findings.

Internal reliability. Internal reliability refers to the tenacity of the reliability or truth of the statistics surrounded in the source. Test administrators would calculate the correlation between the two ratings to determine the level of internal reliability (Cherry, 2010). Because this study used survey questions that were modified from previously validated studies, the internal consistency of the Job Stress and Perceived Workload subscales of the PPS used in this study were validated using the Reliability Analysis function of SPSS. The Job Stress subscale yielded a Crohnbach's Alpha of .94 which

greatly exceeded that of S. Cohen and Williamson's (1988) 10-question Perceived Stress Scale (Crohnbach's alpha = .78).

External validity. External validity has emerged as a major concern in evidence based practice because it is important to generalize evidence from controlled research settings to real world practice settings. According to Shadish, Cook, and Campbell (2002), external validity questions may take on several different forms. Another aspect of external validity is the adequacy of the sampling design. If the research sample is representative of the population, then generalization is straightforward. The best sampling method usually preferred is the randomization method. In quantitative study, the focus of sampling is to choose participants who represent a population, so that outcomes can be universal (external validity). Issues of external validity or delimitations are most applicable to experimental design or effects of an intervention application (Winsett et al., 2007). External validity in this study was tested by evaluating the associations among the job stressors and some work factors which, can be considered to be measures relating to laboratory errors.

Pilot Study

Mugenda and Mugenda (1999) defined the pilot study as a process that enable the researcher to assess the clarity of the research instruments to either discard or modify them to improve the quality of the research instrument thus increasing its reliability. A pilot study is an abbreviated study designed like the full study done on a smaller scale to see if changes need to be made in the study design or in the assessment instruments. The pilot study ensured that changes are made in the survey if necessary or in the experimental design to ensure its validity. It is also known as a probability study that will

be done to assess the possibility of the research. The pilot study offers the chance to measure the relevance of the data collection approaches and other measures and to make changes if necessary.

In this study, the survey were pre-tested in the pilot study to ensure that the survey is appropriate for the samples study before the main study, in case of any inconsistencies. The pilot study also ensured that the methods of collecting data were in line with the study objectives. This study was tried out on a few participants to decide whether the study is practical and whether it is valuable enough to continue. Ten phlebotomists working at one draw station with high patient volumes were asked to take this survey. The feedback from the team was positive. They all indicated that the questions were clear and easy to understand. Also, the phlebotomists who took the survey emphasized that, the questions were very well designed with their work conditions in terms of workload and stress level.

Data Analysis

The data analysis for the current quantitative correlational study consisted of the relationship of the outcome status of independent variables and dependable variable. Statistical methods for this study were the multiple regression techniques, Pearson's correlation, coefficient the Pearson product-moment correlational technique, and the one-way analysis of variance (ANOVA). Microsoft Excel worked as the codebook and version 21 of the Statistical Program for the Social Sciences (SPSS, Inc) was used to calculate descriptive statistics. The description of the variables and the codes that were input in the database were as follow: independent variable(s), variable name, type of variable and measurement. Both null and alt hypotheses were tested using ANOVA with

a standard alpha level of significance of 0.05 (Simon, & Francis, 2004). Descriptive statistical analysis including maximums, minimums, means, and standard deviations (SD) was calculated and reported for all study variables.

The provider perspective about job stress scale and work load surveys was coded in Microsoft Excel and was analyzed in SPSS v21. Results from the survey were analyzed using 2-tailed Pearson product-moment correlation. If the calculated *p*-value is less than .05, the null hypothesis was rejected. However, if the *p*-value exceeded .05, the null hypothesis was supported.

Multiple regression analysis. The reason of multiple regressions is to learn more about the relationship between numerous independent or predictor variables and a dependent or principle variable (Barrett, & Sansonetti, 2006). The multiple regressions in this study is used, because the researcher wishes to determine the best results the study among multiple variables. Multiple regression analysis also was implemented to define the relation between the dependent variable and independent variables. The results of multiple regression analysis indicated in this study, which, variable(s) were best able to forecast laboratory pre analytical errors.

Generally, *p*-value measures the correlation of a multiple regression equation (Triola, 2001). If *p*-value is low, it indicates that a specific multiple regression equivalence has a strong correlation and is valuable for making calculations. According to Triola (1997, p. 365), "if the *p*-value is less than .01 (highly statistically significant), is a very strong evidence against the null hypothesis. If the *p*-value is between .01 to .05 (statistically significant) is adequate evidence against the null hypothesis. If *p*-value is greater than .05, there is not sufficient evidence against the null hypothesis.

Pearson's correlation coefficient. Pearson's correlation coefficient was employed to study the relations amongst the individual and combined variables measuring observed independent variables that is related to dependable variables (pre-analytical errors), as stated in the hypotheses. For all hypotheses, the correlation and the strength of the relationship was described in relations of strong, moderate, weak, or very strong. Weak correlations range from r± .10 to ± .29, moderate correlations range from r± .30 to ± .49, and strong correlations range from r = ± .50 to ± 1.0 (Cohen, 1988).

Analysis of variance (ANOVA). The educational level and work experience variables for this study were tested to verify if there is a relationship between the phlebotomists' demographic variables and pre-analytical errors. ANOVA is one of the techniques that the researchers will employed to determine whether there is a relationship between two variables. ANOVA uses a between-groups variance measure to describe the mean differences between all groups (Steinberg, 2008, p. 268).

The description of the dependent variable, variable name, type and the measurement code are shown in Table 2. The picture of the independent variables and the programmers who inputted the data in the database are shown in Table 3. The research hypotheses, variable names, variable types, and the statistical tests that were employed to test the stated hypotheses also are shown in Table 3. The matrix for correlations and strength is shown in Figure 4.

Table 2

Description of Dependent Variables and Measurement Codes

Dependent Variable	Variable Name	Type of Variable	Measurement code
Laboratory pre-analytical error rate	LPAER	Continuous	Percent (Mean % - .5. Low % = 0;

	High% = 2

Table 3

Research Hypothesis, Variables and Statistical Test(s)

Hypothesis	IV Type	DV Type	*statistical Test(s)*	
H1a alt: Laboratory pre-analytical errors are related to the phlebotomist's skills, experience, training, knowledge, communication, and transportation as, human factors.	Human Errors	Continuous	Multiple regression	errors Clinical:1 Clerical:2 Low%=1; High%=2
H2 alt: The key to reducing pre- analytical errors is related to operations system in the laboratory.	System Error	Categorical	Correlation	r < or, = or >- 1.0 to +1.0. The closer r is to +1 or -1; the two variables are more closely related.
H3alt: Laboratory pre-analytical error can be reduced by advanced technology.	Technology	Categorical	ANOVA	Phlebotomist order entry:1, Provider Perceptions Survey Questions 1-10 Low%=1; High%=2
H4a alt: Phlebotomist workload and job stress is related to the errors in the pre-analytical phase.	Job Stress, workload	Continuous	Pearson's product moment correlation	

Chapter 4 contains the full explanation of data analysis and the results of the current study.

Conclusion

This study included four research questions and alternate hypotheses involving multiple independent variables and a single dependent variable. Table 3 lists the research

hypotheses, variable descriptions and types, and the statistical tests that were employed to test the stated hypotheses. For researcher in this study to achieve desired results from the tests used, the tests had to be reliable and valid. In this study, external validity was the generalizability of an inferred causal relationship over different type of health care providers, settings, manipulations (or treatments), and research outcomes. Internal validity was the reliability of statements about whether the independent variables are correlated to the pre-analytical errors outcome. The aim was to especially measure the ability to rule out probable opposing null hypotheses.

Summary

In quantitative research methodologies, data can be captured using experimental and non- experimental survey designs; this research study employed both designs for data collection. In any research study, it is important to make sure that these data gathering approaches and tools are both dependable and accurate because every method has its strengths and weaknesses. This chapter has discussed reliability and validity and explained how they can be applied to the research. Surveys were used to learn what people think, to identify relationships between job stress and work load, and pre-analytical errors in the laboratory testing. Experiments were used to test other hypotheses in this study about the relationships between human error, system or operations error, technology, communication, transportation, and pre-analytical errors in the laboratory diagnostic. In the following chapters researcher examined specific experimental and non-experimental designs for this study.

Chapter 4

Results

The motivation of this quantitative correlational research was to test whether there is a relation between factors such as operations or system errors, human errors, communication, technology, and transportation (independent-variables) and the pre-analytical errors (dependent variable) in the laboratory diagnostics. The reason for the quantitative correlational study is to support the need of changes in the pre-analytical phases for the laboratory testing in the United States and for leadership approval of operational changes to reduce the laboratory errors for patient safety. Use of the quantitative method brings awareness and scientific rigor to healthcare professionals. Chapter Four provide a complete analysis of the statistical approaches used to transform the data collected into a conclusion in response to the study questions and hypothesis. The foundlings of the research also are reported in this chapter, they are organized and responded by research questions, with the results of the hypothesis testing given, findings of the descriptive statistics, summary, and finally the conclusions.

Instrument

The research plan that was designated for this study project is non-experimental. Non-experimental strategy is useful to define characters and activities of study's members (Waruingi, 2010). The choice for selecting experimental, non-experimental, or quasi-experimental and participant's activities depend to the researcher's judgement (Waruingi, 2010). In this study, researcher has used the provider perspective survey (PPS) instrument as one of the instruments to measure the variables, and to categorize the demographic differences between phlebotomists such as gender, age, length of the

experience. The survey questions are also about the participant work status such as; full time or part-time status, work location, and experience.

The survey was used for data collection to include a quantitative, non-experimental design for gathering statistics on the phlebotomists' observations about job stress, workload causes, and pre-analytical errors. The study sample included 108 participants 64 phlebotomists working at the PSC (Patient Service Center), 44 SNF (Skilled Nursing Facilities) phlebotomists working in the laboratory department in the San Francisco area. The data collected from all 108 participants were used in this study analysis. The following research questions and hypothesis directed this study. Another tool that the researcher used in this research is the historical data that was collated in 2011, 2012, 2013, and 2014 to support the outcome of this research.

Research Questions and Hypothesis

The research questions addressed six key areas— phlebotomist skill, experience, training, or knowledge (human factors), phlebotomist's workload or stress, operations system, technology, communication/ miscommunication, and transportations to determine the relation of the perceptions of the survey respondents with regard to the culture of safety within their organizations. The survey data came from two surveys that were done at two in-house monthly meetings that were done within the phlebotomists working in the outpatient service centers (PSC) and skilled nursing facilities (SNF).

RQ1. What is the relationship between laboratory pre-analytical errors and the phlebotomist's (human factors) skills, experience, training, knowledge, communication, and transportation?

Hypothesis 1a (null). Laboratory pre-analytical errors are not related to the phlebotomist's skills, experience, training, knowledge, communication, and transportation as, human factors.

Hypothesis 1a (alt). Laboratory pre-analytical errors are related to the phlebotomist's skills, experience, training, knowledge, communication, and transportation as, human factors.

RQ2. What is the relationship between the laboratory pre-analytical errors and the operations system?

Hypothesis 2a (null). Laboratory pre-analytical errors are not related to the operations system.

Hypothesis 2a (alt). The key to reducing pre- analytical errors is related to the operations systems in the laboratory.

RQ3. What is the relationship between technology and laboratory pre-analytical error rates.

Hypothesis 3a (null). Pre-analytical errors are not related to the technology system.

Hypothesis 3a (alt). Pre-analytical errors can be reduced by advance technology.

RQ4. What is the relationship between the phlebotomists' workload and job stress and the errors in the pre-analytical phase in laboratory testing?

Hypothesis 4a (null). Phlebotomist workload and job stress is not related to the errors in the pre-analytical phase.

Hypothesis 4a (alt). Phlebotomist workload and job stress is related to the errors in the pre-analytical phase.

Pilot Survey

A pilot survey was conducted to fine tune the survey and to make sure the questions were clear and to the point. The pilot survey was essential to pinpoint developments in the survey and was directed to members experienced in the laboratory department and phlebotomy principles. Pilot surveys are needed to confirm that the survey is reasonable and state the focus of the research (Cooper & Schindler, 2006). The pilot survey could have revealed any unclear questions and made sure the questions have reliable meaning to the members.

To develop the power of a survey, it is essential that it be pretested under accurate settings (Fowler, 2009). The first draft of the survey was issued to 10 phlebotomists working in one of the busiest patient service centers. Pilot study data was collected and used only to revise the final survey. The final version of the survey is included in Appendix B and Appendix C. The leadership of the lab approved the final version of the survey. Upon receiving approval, data collection began. The answers to the pilot questions did not change the questions and no change was necessary. All participants believed the survey spoke to the correlation between laboratory errors and phlebotomy performance.

Data Collection

Data collection occurred in two in-house meetings among the phlebotomists working for SNF in different locations and the phlebotomists working in the outpatient service centers in March 2015. Phlebotomists participated in the study on a voluntary basis. The researcher began the survey by explaining the purpose of the study and the survey instrument to the participants. Once the phlebotomists verbally agreed to

participate in the study, the survey packets were distributed. Each participant was given the survey packet that contained the informed consent form (see Appendix A) and the survey instrument (see Appendix B & C). The participants were instructed to read and sign the consent form if they agreed to participate in the survey. The signed consent forms were then collected and maintained separately from the surveys. The participants then completed the survey. The participants returned the completed surveys to the researcher and the completed surveys were placed in a sealed envelope.

The data from the surveys were entered into Microsoft Excel spreadsheets and into statistical software. The demographic analysis was conducted in Microsoft Excel and the detailed descriptive analysis was conducted in SPSS software. A total number of 108 surveys were completed and no survey was removed from the sample. Of the 108 total completed surveys, there were four surveys that contained one or more missing or non-answered questions.

Demographic Data

The participants in this study were 108 phlebotomists and the majority were women (n = 64). The participants were between 19 and 60 years of age and had between 1 year and more than 20 years of experience working in the laboratory field. Table 4 indicated a mean age of the participants was 39.5 years, and the mean of sample's length of experience was 11 years. Age was widely disbursed and the standard deviation relative to years of experience was high. Participant demographics in this study were limited to personal information and were included gender, age, and years of experience within the laboratory field.

Table 4

Mean and Standard Deviations for Age and Experience of the Study Participants

Variable	*M*	*SD*
Age	39.5	9.6
Years' Experience	11	10.1

Table 5

Years of Experience and Percentage

Years of Experience	*N*	%
< 1	15	13.8
1-5	31	28.7
6-10	10	9.3
11-15	20	18.5
16-20	9	8.3
21-25	16	14.8
More than 25	7	6.5

Data Analysis

Of the 108 phlebotomists who completed the Provider Perspective Survey (PPS) (page 2 of Appendix B), 64 (59.25%) were women and 44 (40.74%) were men. The largest number of men (21) and women (17) were both found in the 31 to 40 age group, with 27% and 22% of the total number of contributors, respectively. The survey asked for generalized information such as worker category (Phlebotomist I, Phlebotomist II,

and lead), the phlebotomist work status (Full time, Part time, per diem), and phlebotomist category location (PSC, SNF, in patient lab or ER). This category required squeezing per diems and temporary employees (Temp) into one category although a large majority of participants were PSC phlebotomists (66; 61%), with 42 women (39%). The ER's phlebotomists were excluded from this study because of the very small number of participants working in the ER or inpatient lab (n = 8).

Question 6 of the PSS asked participants to indicate their work experience as a phlebotomist. Only four men and three women, 6.4% of the total study group, had more than 20 years of phlebotomy experience, so this group was combined into the 11-20 year group. Forty-two percent of participants reported less than 3 years of experience, 31% had between 4 and 10 years, and 27% had 11 or more years of healthcare provider experience.

Question 7 asked phlebotomists to check how often they were likely to make an error (order entry, hemolyzed, clotted, etc.). The responses to question 8 were: none (*n* =10, 10%); once a week (*n* =18, 17%); 1-2 days a week (*n*= 22, 20%); 1-2 times a month (*n*=24, 22%) and more than 2 times a month (*n*=34, 31%).

The historical data is used in this study, data regarding the participants work status and information from the surveys were documented by the researcher to an Excel sheet and then transmitted to SPSS 21 for all statistical analyses. Basic descriptive statistics were used, with category, and compared with variables. In all statistical analyses, the significance level was set at $P < 0.050$, all statistical tests and *P*-values were two-sided, and *P*-values were not corrected for multiple testing.

Testing Hypotheses

In this study, the researcher had used historical data to answer research questions 1, 2, 3 and to test hypotheses related to the research questions. This study was conducted pre-analytical errors in an Excel spreadsheet as well as data base for management reports. Also, all errors with details have been reported by the phlebotomists via a form called *Pre-analytical Nonconformance Form* (NCE, Appendix Z). The form has a space on the back for the phlebotomists to communicate with the management; the form asks, "why has this error occurred", and what is the root cause of the error in their point of view?

Table 6

Phlebotomist Feedback about the Root Causes of Error

Phlebotomist Feedback on the NCE forms	%
Most errors are related to human errors	3.7
Errors are related to system failures	3.6
Errors are related to communication failures	4.1
Team in my work area communicate well	3.5
Management style effecting my job performance	4.3
Communicating errors from others colleagues helps prevent errors (Training).	4.6

The researcher used data collected from phlebotomists' responses to the NCEs to test hypothesis 1, 2, 3.

Table 7

Phlebotomist's Responses to NCEs

Phlebotomist (Human Factor)	Miscommunication	Transportation	Technology	Others
Knowledge / Training Skill Experience	Internal External	Courier Temperature	System defect Human skill	
264160	283240	5683	243926	77031

Error rates were calculated quarterly for the recommended pointers, with their mean values, equaled to the total requested test volume. The process used for the calculations are summarized in Table 10. The Runs Test was useful to measure the trend of the series, supposing statistical significance at $P < 0.05$. To define volume of the tests annually, and significant indicators statistically, the base 100 key was calculated with detail to the first year valued, based on the Runs Test, the pointers were characterized by error rate.

RQ1. What is the relationship between laboratory pre-analytical errors and the phlebotomist's (human factors) skills, experience, training, knowledge, communication, and transportation?

Hypothesis 1a (null). Laboratory pre-analytical errors are not related to the phlebotomist's skills, experience, training, knowledge, communication, and transportation as human factors.

Hypothesis 1a (alt). Laboratory pre-analytical errors are related to the phlebotomist's skills, experience, training, knowledge, communication, and transportation as human factors.

Human error concept is a significant subject in healthcare fields and patient care and needs advanced study. This research used this concept as an agenda to discover pre-analytical errors from a laboratory diagnostics perspective. For this reason, the researcher has used the historical data gathered from the hospital database. The correlation between the pre-analytical errors and human factor were tested using multiple linear regressions. The significance level was set to $p < 0.050$. Because the outcomes of the data resulted in so many variable error rates, the total mean error rate (M = 823, 13.5%) was used in SPSS v.21 as an overall idea to sort over the error type into two clear-cut variables of: Low error frequency or High frequency. The laboratory error in pre-analytical phase was titled as shown is Table 8. All the historical data from years 2011, 2012, 2013, and 2014 were tallied and entered into the SPSS study database and it shown in Table 9.

Table 8

Error Detail by Name and Subcategory

Patien Registration Order Entry Errors												
Wrong Test Ordered	Missed Test	Duplicate Test Ordered	Expired Standing Order	Wrong Date of Service	ICD9 Missed	Wrong Encounter Used	Wrong Pt. selected **(SIE)**	Wrong Source Facility / MD **(HIPAA)**	Wrong MRN used	Pt Reg Order Ent Other	Pt. info not updated or entered wrong in STAR/LIS	Insurance not updated or wrong
Sample Collection												
Patien Identification error (**PIE**)	Hemolyzed	Clotted	QNS	Expired Container	Sample not collected	Sample not labeled **(SIE)**	Sample mislabeled **(SIE)**	Separate sample required	Sample temp incorrect	No collection date	Sample contaminated	Sample collection Other
Sample Handling												
Processing delay	Transport delay	Improper transport	Mishandled sample	Misplaced sample	Not spun on time	Stability exceeded	Sample Handling Other					

Table 9

Historical Data

Year-Quarter	Total Tests	Order Entry %	Clotted %	Hemolyzed %	QNS %	Transportation %	Other %	Total errors%	Patient Impact %	No Patient Impact %	Total critical errors
2011-1	37,340	11.9	1.63	1.93	1.42	0.11	0.52	17.5	0.024	0.035	0.059
2011-2	39,747	10.29	1.56	1.34	1.32	0.1	0.34	14.96	0.033	0.045	0.078
2011-3	34,716	10.38	1.79	1.59	1.2	0.06	0.41	15.42	0.023	0.009	0.032
2011-4	37,708	10.78	1.88	1.61	1.33	0.05	0.33	15.98	0.019	0.037	0.056
2012-1	40,554	13.44	1.73	1.62	1.45	0.1	0.4	18.75	0.015	0.015	0.03
2012-2	40,071	10.34	1.75	1.35	1.39	0.11	0.39	15.33	0.017	0.042	0.06
2012-3	34,906	7.68	1.64	1.25	1.41	0.05	0.49	12.53	0.017	0.017	0.034
2012-4	37,871	7.39	1.61	1.19	1.32	0.04	0.41	11.97	0.024	0.05	0.074
2013-1	39,496	7.64	1.71	1.22	1.11	0.04	0.39	12.11	0.013	0.02	0.033
2013-2	39,750	5.85	1.4	1.15	1.03	0.06	0.27	9.76	0.03	0.023	0.053
2013-3	34,700	5.65	1.53	1.46	1.19	0.07	0.33	10.22	0.026	0.012	0.037
2013-4	37,111	7.6	1.46	1.24	1.28	0.05	0.26	11.9	0.019	0.013	0.032
2014-1	40,803	8.19	1.7	1.17	1.06	0.05	0.28	12.45	0.039	0.02	0.059
2014-2	41,617	8.24	1.73	1.01	1.18	0.06	0.19	12.41	0.024	0.036	0.06
2014-3	35,773	7.68	1.49	1.4	1.43	0.05	0.26	12.3	0.011	0.011	0.022
2014-4	37,717	7.28	1.52	1.42	1.48	0.03	0.35	12.09	0.016	0.011	0.027
Mean	609,880	8.77	1.63	1.37	1.29	0.064	0.35	13.5	0.022	0.025	0.047
SD		2.18	0.13	0.23	0.14	0.03	0.09	2.54	0.01	0.01	0.02
P value of Runs Test		0.039	0.265	0.491	0.04	0.314	0.491	0.003	0.578	0.619	0.196

Tests performed during the period for the historical data used in this study were 609,880. Out of theses, 610 tests (13.5%) presented some type of pre-analytical error. The first four highest observed causes of pre-analytical errors were order entry (8.77%), clotted (1.67 %), hemolyzed (1.37%), and quality not sufficient (1.29%). The total error rate using historical data for this study was 13.54%, with a *P*-value for the Runs Test of 0.003. The lowest rate per 100 requests was for the indicator *transportation* (0.064%), followed by *other* (0.35%). The rates received for each pointer, the total specimen errors for these periods and the P-value for the Runs Test are shown in Table 9. The total error rate of pre-analytical serious mistakes was 0.047%, found from the average patient

impact critical error of 0.022% (since 2011), and the rate of 0.025% of no-patient impact errors. The Runs Test shown no changes in the tendency for any category of the errors. Of the 134 patient impact faults described, 50.74% of the samples did not match the test ordered by the physician; however, 44.03% of the tests related to a mistake made by the phlebotomists. All of these faults stayed in the phlebotomist responsibilities who failed to perform order entry or sampling collection correctly. In all the critical errors cases, a sample required for practical testing was canceled by wrong test was ordered, wrong patient was selected, improper collection, or improper transporting.

Statistically, important variances were recognized by the Runs Test, adding to the total rate of error occurrences, for the categories *order entry (clerical)* and *sample collection, handling, and transporting (clinical)*. This study first measured serious errors, those which were happening the most, even with no patient impact. The second set of errors occurred from inaccuracies in the specimen collection process. These kinds of errors have correlation to analytical quality, caused delays, or required additional or repeated analyses. They are under the group of either patient impact or no patient impact.

As shown in previous tables, the trend continues in Table 9, with order entry having the highest overall error rate. Data from the historic data on this topic show that problems are not directly related to specimen collection. In this study, the main cause of the pre-analytical errors are order entries (clerical pre-analytical errors). All order entries in this study were done by phlebotomists. In the other hand, there are clinical pre-analytical errors that occur during phlebotomy and specimen collections.

Statistical Analysis

For proposed indicator, quarterly error rates were designed, with their relevant mean values, matched to the total size of activity, in relation to test requests. The techniques used for the indicators are shown in Table 10. The Runs Test was realistic to measure variations in the tendency of the runs, supposing statistical meaning at $p < 0.050$. To define the tests requested each year and statistically main indicators founded on the Runs Test, the improper 100 key was considered with detail to the first part criteria, and these pointers were signified as a result of incidence polygons.

Table 10

Methods for Design of Pre-analytical Pointers

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Indicator	Formula
Hemolyzed sample	Total of hemolyzed specimens × 100/Total number of requests
Clotted sample	Total of clotted specimens × 100/Total number of requests
Oder Entry	Total of order entry for each error type ×100/Total number of requests
QNS	Total of QNS for each sample type × 100/Total number of requests
Transportation	Total of transportation× 100/Total number of requests
Other	Total of samples other × 100/Total number of requests
Total errors	Total errors × 100/Total number of requests
Patient Impact	Total of patient impact × 100/Total number of requests
No patient Impact	Total of non-patient impact × 100/Total number of requests
Total critical errors	Total number of non-patient impact + Patient Impact errors × 100/Total number of requests

Each type of errors has a sub category and in this study the researcher only analyzed the errors by these categories. Only order entry, hemolyzed, clotted specimen, quality not sufficient, and transportation from the sample collection are used by each name, and all other type of errors are under the sub-name as other because of too many variable errors with different sub-names.

Relation between Pre-analytical Errors and Human Factors, Technology, and Operational Errors

In this study, the research questions outlined the hypotheses of this quantitative study to find the effect of human factors such as phlebotomist knowledge/training, phlebotomist skill, and experience, communication, transportation, operational errors, and technology as independent variables on laboratory pre-analytical errors as the dependent variable. To test the hypotheses of this study, a multiple regression analysis and one tailed ANOVA was used.

Table 11

Correlation between Human Factors and Laboratory Pre-analytical Errors

Human Factors	R
Education &Training	0.274**
Skill	0.245**
Experience	0.169**
Communication	0.555**
Transportation	0.335**
Operational errors	0.478**
Technology	0.508**

Note. $^{**}p < .01$

The human factors described a major percentage of variance in laboratory pre-analytical errors: ($R^2 = .681$, $F = 101.278$, $p < .001$). As a result, phlebotomist knowledge/training, phlebotomist skill, experience, communication, transportation operational errors, and technology explained 68.1% of the total variance in laboratory pre-analytical errors (Table 12).

Table 12

One Way ANOVA for the Effects of Human Factors on Laboratory Pre-Analytical Errors

Source	SS	df	MS	F	*P*
Between Group	54.145	8	6.768	101.27	0
Within Group	25.327	379	0.067		
Total	79.472	387			

Table 13 *Regression Analysis for Human Factor Variables Predicting Laboratory Pre–analytical Errors*

Variable	*B*	SD	β	t	p
Education & Training	0.131	0.012	0.323	10.796	.000***
Skill	0.092	0.026	0.144	3.517	.000***
Experience	0.0004	0.014	0.01	0.328	0.743
Communication	0.245	0.017	0.475	14.74	.000***
Transportation	-0.031	0.024	-0.045	-1.281	0.201
Operations	0.207	0.023	0.304	8.885	.000***
Technology	0.164	0.021	0.276	7.977	.000***

*** $p < .001$

As shown in Table 13, the result of regression analysis shows that the human factors significantly are correlated to laboratory pre-analytical errors , although the five factors such as phlebotomist education/ training, skill, communication, technology, and operations system have a very strong effect on the laboratory pre-analytical errors, but phlebotomist experience and transportation have no significant correlation on pre-analytical errors in the laboratory field and only can be accepted as whole under the human errors category. Therefore H1(alt) is accepted and H1(null) can be rejected.

In this study, the researcher with the approval of the laboratory management decided to test hypothesis 2 with two sets of continuous data gathering in two different ways of operational setting as a trial. Twenty-six phlebotomists were participants of this trial in four different PSCs. In each location one phlebotomist was responsible to perform all the clerical duties such as registering the patients in the system, verify the patient's demographic information, verify or input the insurance's information, and order the test(s). All the other phlebotomists were responsible to perform the venipuncture, process the blood, and transporting the samples. Errors were recorded in the same manner as the pervious error recording system for the same phlebotomists and same locations.

The data errors from January of 2015 to February 2015 captured based on draw for success. Draw for success system is the system that a phlebotomist is responsible to do the entire job related in the pre-analytical phase such as clerical responsibilities or clinical responsibilities. Phlebotomist's clerical duties are greeting the patient, inputting patient's information to the computer system, selecting the right ordering physician, ordering the tests, verifying patient insurance and all other required order entries. Phlebotomist clinical job duties are drawing the blood, processing the specimens based on the requirements, and preparing the blood for transportation based on the requirements.

In March of 2015 researcher implemented the trial and data was captured based on the operational change until April 2015. The data that was collected from January and February was compared to the data that was collected from March and April (see Table 14 and Table 15).

The total number of patients seen by phlebotomists in the selected patient services for the entire month of March and April 2015 ranged from 398 to 1156 (M = 265.2, SD = 202.5). Some locations had the highest number of patients seen (highest = 1156) compared to another with the lowest patient volume of 398. However, order entry had the highest mean (M = 308, SD = 178.4) among all other phlebotomist duty. Phlebotomist patient seen for the month of March and April 2015 were obtained from lab information system (LIS), Crystal report.

A laboratory test order error (clerical) was defined as the following: no order(s) placed in the computer, unsigned computer order(s), and/or incorrect order(s) such as selecting the wrong test or the wrong patient. Each instance was considered one order entry error. A pre-analytical clinical error was defined as the following: any clotted specimen, hemolyzed specimen, quality not sufficient or overall any rejected specimens.

In terms of the order entry errors and rejected samples, data showed that there was a significant statistical improvement between month of March and April compared to January and February (P < 00.05) (Tables 14 and 15). Data before the change showed that the total number of received requests was 31,944. The total error such as wrong test input in the system, missed test and duplicate test was 945 (2.97%), wrong source facility, wrong MD selected and any other order entry that was considered HIPAA-related 326 (1.75 %), missed diagnoses code (ICD9) 558 (1.75%), wrong encounter, wrong MRN 2028 (6.38%), and other clerical cause of error 3175 (9.94%). The data after the change showed that the total number of received requests received was 28,286. Wrong test input in the system, missed test, and duplicate test was 475(1.68%), wrong source facility, wrong MD selected and any other order entry that was consider HIPAA-

related 68(0.24 %), missed diagnoses code (ICD9) 184(0.065%), wrong encounter, wrong MRN 965 (3.41%), and other clerical cause of error 452 (1.60%).

Table 14

Frequency of Order Entry (clerical) Errors and the Percentage of Total Orders Received Before and After Changes

Error Category (Clerical)	Before Change (*N* = 31944)	After Change (*N* = 28286)	*P* value
Wrong Test Ordered/Missed Test/ Duplicate Test	949(2.97)	475(1.68)	0.001
wrong Source Facility/MD (HIPAA)	326(1.02)	68(0.24)	0.001
ICD9 Missed	558(1.75)	184(0.65)	0.001
Wrong Encounter/Wrong MRN	2028(6.35)	965(3.41)	0.001
Other	3176(9.94)	452(1.60)	0.001

P < 00.05

Table 15

Error Rate of Different Causes of Specimen Rejection (Clinical) and the Percentage of Total Received Sample Before and After Changes

Error Category(Clinical)	Before Change (*N* = 50440)	After Change (*N* = 45180)	*P* value
Clotted	494(0.98)	311(0.69)	0.001
Hemolysis	179(0.35)	95(0.21)	0.001
(QNS)	41(0.08)	32(0.07)	0.001
Transportation	16(0.03)	6(0.01)	0.001
Other	158(3.14)	841(1.88)	0.001

P < 00.05

Before the change, the total received specimens were 50,440, and the number of total rejected specimens were 2314 (4.59%), whereas the total received specimens after the change was 45,180 and the total of rejected specimens were 1285 (2.84%). The significant change on the result of this study shows that, the operation system in the laboratory field has a significant effect on the pre-analytical errors in the laboratory field.

RQ4. What is the relationship between the phlebotomists' workload and job stress and the errors in the pre-analytical phase in laboratory testing?

Hypothesis 4a (null). Phlebotomist workload and job stress is not related to the errors in the pre-analytical phase.

Hypothesis 4a (alt). Phlebotomist workload and job stress is related to the errors in the pre-analytical phase.

On Provider Perceptions Survey (Appendix B), questions 1-10 were intended to evaluate phlebotomist job stress by mutual work situations. Five choices of (*never* = 0, *rarely* = 1, *sometimes* = 2, *often* = 3 and *very often* = 4), were changed into numeric standards with a possible variety of 10-50 points (M = 28.35, SD = 8.18). Answers of 4 or 5 were telling of highest of stress level, whereas individuals who had a major amount of responses of 1 or 2 would be classified as their stress level is low. Suitability sample selection was attempted to select the sample of appropriate basics. The respondents are carefully chosen based on their job roles, be in the right place at the right time.

The job stress questions (1-10) of the Provider Perceptions Survey were modified from the 10-item Perceived Stress Scale developed by Cohen, Kamarck, and Mermelstein (1983). This scale had good psychometric properties (Cronbach's alpha = 0.78) and had been used in multiple studies. The Workload section included five answer choices for all

questions: *not at all*, *very little*, *sometimes*, *quite often*, and *almost always*. High scores represented a high level of workload with a possible range from eight to 45.

Table 16

Mean and Standard Deviation for Job Stress and Pre-analytical Errors

Error Source	*N*	MIN	MAX	Mean	*SD*
Interpersonal Conflict	100	1.25	4.25	3.495	0.62981
Organizational Controls	100	1.83	5	4.233	0.60422
Stress	100	1.5	4.25	2.845	0.44289

Based on Table 16, three items are correlated to laboratory pre-analytical errors. However, based on this finding, the most powerful was job stress with mean of 4.233.

Correlation between Job Stress and Laboratory Pre-analytical Errors

A 2-tailed Pearson product-moment correlation was applied to outline the correlation and tendency of the relationship among job stress variable and the error rates. Based on the results in Table 17, job stress ($p = 0.000$) was significantly related with errors in pre-analytical phase in laboratory field. That means there is a statistically important correlation between stress at job and errors to the organization. Hence, hypothesis 4a is acceptable. Although the correlation is significant, according to Burns and Bush (2005), a second test will be conducted, because there is a very weak relationship with ($r = 0.361$) between the two variables ($r = .36$, $n=100$, $p < .001$).

Multiple Linear Regressions (Second Test)

Table 17

Relationship among Work Stress and Pre-analytical Errors Coefficients

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	Variables	B	Std. Error	β		
1	Continues	2.331	.476		4.896	0
	Stress	.444	.165	0.361	2.683	0.01

Data shown in Table 17, laboratory pre-analytical errors: 2.33 1 + (+3.61) Stress; confirm that the value of β is +.361, which means that there is a positive relationship between stress and pre-analytical errors; therefore, the null hypothesis can be rejected.

PPS Survey-Perceived Workload Subscale

Questions 12-16 of the PPS contained within questions asking participants to define their level of workload to show how busy they feel their jobs is. This part of the PPS was talk about the provider's workload scale. The five choices were: 1 = *never*, 2 = *rarely*, 3 = *sometimes*, 4 = *often* and 5 = *very often*, with a range of 8 to 45. The mean was 29.85 and standard deviation was 4.54. No questions on this subscale were negatively worded; therefore, no recoding of participants' responses was necessary. If the responses were 1 and 2 it measured as low levels of observed workload and answers of 4 and 5 were considered as high workload.

Table 18

Mean and Standard Deviation for Workload and Pre-analytical Errors (N = 100)

Variable	low	high	*M*	*SD*
Dissatisfaction	1.75	4.50	3.650	0.67951
Lack of support	1.33	4.33	3.600	0.70630
Workload	2.25	4.75	3.852	0.47178

Based on the Table 18, there are three items correlated to laboratory pre-analytical errors among employees. The results show that all the outcomes have relationship with phlebotomists' errors rate in the laboratory field. However, the most influential based on this finding is workload with the mean of 3.852.

Correlation between Total Pre-analytical Errors and Workload

A two-tailed Pearson product-moment correlation analysis was done using overall workload score as the independent variable and total lab errors as the dependent variable. The relationship between the two variables was positive and of minimal strength, but did not reach statistical significance ($r = .719$, $n = 100$, $p < .05$). There is a significantly relationship ($p = 0.000$) between workload and laboratory pre-analytical errors. That means there is an important statistical correlation between workload and pre-analytical errors in laboratory field. Therefore, hypothesis 4b is acceptable. According to Burns and Bush (2005), there is an adequate relationship between the two variables with ($r = 0.719$).

Multiple Linear Regressions (Second Test)

Table 19

Relationship between Workload and Pre-analytical Errors Coefficients

Model	Variable	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std.Error	β		
1	Continues	1.636	.316		5.174	.000
	Workload	.623	.087	.719	7.163	.000

Data shown in Table 19, laboratory pre-analytical errors: 1.636 + (+.719) workload confirm that β = +.719, which means that there is a positively significant

relationship between workload and pre-analytical errors, therefore the null hypothesis can be rejected.

Summary

Chapter 4 has shown and described the outcomes of the studies shown in the research. It started with an analysis of the study, research questions and testing the hypotheses. Chapter 4 included detailed data arrangement, incidence rates, and graphic measurements for the survey. In this study, a Pearson product moment correlation with an alpha of .05 was used. A correlation study's advantages are to identify the existence of relationships among variables and define them in relative to the negative and positive trend and their power, minus presenting an involvement to alter the outcome variable (Cook & Cook, 2008). Also, the power and trend of the relations and analyses of results were shown in Chapter 4. The result of one-way ANOVA shows that five factors such as phlebotomist education/ training, skill, communication, technology, and operations significantly correlated to the laboratory pre-analytical errors and null hypothesis could be rejected; however, phlebotomist experience and transportation had no significant correlation on pre-analytical errors as individual variables. Therefore, further research is needed to fully develop a better understanding of these factors. It also presented that stress with the value of β=+.361 and workload with the value of β =.719, there is a positive significant correlation between stress and workload on pre-analytical errors. Therefore, the null hypotheses were rejected.

Chapter 5 reviews the questions of this study, the finding method and additional elaboration and analysis of the outcomes. It also presents the suggestions for future research.

Chapter 5

Conclusions and Recommendations

This correlational quantitative study providing data on the correlation between the pre-analytical errors in the laboratory field and independent variables, phlebotomists' skill, experience, knowledge, and training (human errors), communication, technology, system design, and transportation. The goal of this study was to define the elements that cause the pre-analytical errors at the laboratory testing. Chapter Five provides an overview of the results, limitations, delimitations, and findings, significance of the study, suggestions for laboratory leadership, recommendations for future study, and the summary.

Chapter One of this study presented the background of the problem, problem statement, and purpose of this research. The nature of the study is the quantitative multiple regression approach guided by central research questions, hypotheses, and conceptual framework. The goal of Chapter Two was to provide in detail analysis of previous studies that highlighted a summary structure for this study. The need to capture, report, and analyze errors in laboratory testing effectively and properly is becoming more critical to the efficient patient service in laboratory medicine and to patient safety. The idea is not new, but the sensitive demands of suitable research to identify the laboratory errors' root causes are critical and warrant additional study. Chapter Three of this study reviewed the research questions, and hypotheses guiding the study, described the research design, survey design, sample population, statistical methods, data sources, and data analysis plan. Included in the chapter were descriptions of the population, geographic location, sampling methods, and sources of data. This chapter also contains a discussion

of the study technique and design appropriateness. Chapter Three also included a discussion of how data was collected and analyzed, instruments, and issues related to reliability, and validity.

The results of the analyses conducted in the study were presented in Chapter Four. Chapter Four answered the research questions and presented the results of testing the hypotheses. The findings of the study, based on the analysis of correlation coefficient, were included. The major pre-analytical errors of concern were order entry, hemolyzed specimen, clotted specimens, and specimens with quality not sufficient. Chapter Five provides analysis of the results, limitations, delimitations, and findings, significance of the study, suggestions for laboratory leadership, recommendations for future study, and the summary.

Interpretation of Results

According to the results of this study, the framework of this study is acceptable with a few changes. The result shown that there is a significant correlation between independent variable of this study and the dependent variable. In this study, the correlations are not be interpreted as showing cause-and-effect relations because correlation analysis is not designed to detect cause and effect, only indicate associations. Direct (positive) correlations indicate the values of two variables that move in a like manner, where values either increase or decrease similarly. An indirect (negative) correlation point out the values of two variables that move in opposing directions; when the values of one variable increase, the values of the other variable decrease.

Data showed that the majority of pre-analytical errors in this study are the result of phlebotomist fault or human error, but numerous other factors such as faulty system,

inadequate workplace, poor communication, and technology factors also can be the cause of the human errors, too. According to the data collected from phlebotomist's feedback, faulty system, inadequate workplace, communication, and technology are also the root cause of the phlebotomist's mistakes. The data in this study showed that other factors can play a major role in control of human error also. The human factors described accounted for a major percentage of variance in laboratory pre-analytical errors: (R^2 = .681, F = 101.278, p < .001). As a result, phlebotomist knowledge/training, phlebotomist skill, experience, communication, transportation operational errors, and technology explained 68.1% of the total variance in laboratory pre-analytical errors.

The total historical data for error rate used for this study was 13.54%, with a P-value for the Runs Test of 0.003. The human factors accounted for a major percentage of variance in laboratory pre-analytical errors were 44.03% under four main observed categories as, order entry (8.77%), clotted specimen (1.67 %), hemolyzed specimen (1.37%), and Quality Not Sufficient (1.29%). The result showed, although phlebotomist work experience and the sample transportation add value to the total pre-analytical error rate, these two variables did not have a significant effect on the laboratory errors. Based on the study results presented on the Tables 16–19, the phlebotomist's job stress and workload had a positive linear correlation to pre-analytical errors.

Implications

Reducing the number of errors in the pre-analytical phase and accomplishing the standards of high quality needs special considerations. It is a natural responsibility of the phlebotomists to ensure the accuracy and validity of the details of the patient identification and, hence, this must be done with high awareness. Standardization of the

policies and procedures and monitoring pre-analytical variables is critical and is related to having well-organized laboratories with the emphasis on quality patient care. Performing a good phlebotomy is essential for an appropriate specimen, and an accurate test result. In the pre-analytical phase of the laboratory, it is essential to monitor any variations that may raise laboratory errors. Based on the results of this study, the human factors cannot change the settings that phlebotomists work, but they can be improved and controlled by setting up a correct operational system. The ongoing training, ability, and implication of the experts are necessary for phlebotomy performance. The result of the study showed that education and training were found to be important factors in improvement of skills in the organizations. The two improvement changes implemented in the study laboratory have reduced the number of errors in the two periods of the study and have been validated by this study.

Preventing errors in the pre-analytical steps requires excellent communication, closer relationships among all members of the health care team (laboratory personal, physicians and nurses) and technological developments including electronically ordering system, automation and computer systems that guide the phlebotomists through the process of order entry or processing the samples. Using computerized physician order entry/computerized provider order entry (CPOE) and appropriately implemented technology could reduce problems with illegible orders, transcription errors and other written communication. Such technology would be an asset to the communication processes among healthcare. Although technology improvement is a factor for error improvement, but deploying technology needs an arrangement of many individuals with various talents and skills including leadership, management, intensive preparation,

investment of adequate financial resources, education and training to be successful however, advanced technology offer better reliability and the possibility for better communication and control, but still they need human control and hand. Mainly at times of failure, systems depend on human operators.

Recommendations

In this study, the researcher attempted to identify the elements of the errors in the laboratory field, and describing human error factor as an independent factor. The result of this study shows that, "Human Errors" is just a term that covers all the defected results in the pre-analytical phase of the laboratory. However, in this study the root cause of the human errors is not defined, and a follow up study is strongly recommended to identify the root causes of the human errors.

Based on the findings of this study, the researcher has made several recommendations to the organization where this research was done. In any health care system, patient safety and the elements that promoting this culture should be an initiative and a priority. The laboratory diagnostics, as the gate keepers of the health care system, needs to promote patient safety culture among their employees also. Many laboratory organizations have educational programs for their employees, but the quality institutions need to evaluate these programs. The quality institution, yet, may possibly develop a record of current operational practices for reducing errors, especially in pre-analytical phase of the laboratories to eliminate harm to the patients from laboratory inaccuracies.

Effective patient safety practice in pre-analytical phase of laboratory systems need to be monitored by quality control entities by requiring an error system reporting from the laboratories. In addition, the quality control entity could have more dynamic instructed

assignments and take responsibility for the operation of best practices for the laboratories in United States.

Implementing different process-improvement methods are necessary to pinpoint incompetency and unproductive care. Each of these methods could include a study into possible advances in technologies that may reduce error, a study regarding managerial structures that promote patient safety, and human factors analysis to recognize structures to improve the quality and safety of health care. Operational design problems that have negatively correlation on increasing errors need to be evaluated when studying mistakes. Improving operational policies can develop patient safety and improve operational environments for healthcare providers. The implementation of technology to reduce pre-analytical errors and improve patient safety is recommended, although there are challenges to teach healthcare workers when implementing technology.

In healthcare, there has been an arrangement of low expectations related to middle management education and knowledge. Healthcare providers have become used to promoting their clinical employees to supervisory and management roles without any expectation for higher education in leadership roles. These organizations may not be able to resolve system deficiencies. They possibly need to emphasize continuing education for employees to be promoted. Organizations can improve error reduction with the goal of patient safety by clearly defining expectations related to higher education within the middle management to effective coaching and mentoring the employees.

The importance of human factors in the error reduction process should be considered by organizations. Organizations may need to look in to their culture of employee job promotion. Healthcare leaders may need to set some further training and

expectation among employees for stepping to a leadership role. Healthcare administrations may perhaps consider that poor behavior and lack of knowledge can influence the competency and as the result, it will impact the capability of others to get their jobs done. In health care field, patient safety is the primary goal. Such standards recognize that effective leadership is required to develop a culture of patient safety among the employees. An effective leadership team can provide the foundation for excellent performance. In this study, many pre-analytical errors could be prevented with a proper operational setting, and also with an effective communication and education between the middle management and the phlebotomists.

Summary/Conclusion

This study found that the pre-analytical errors in the laboratory field were created as an outcome of including order entry, hemolyzed sample, clotted sample, quantity not sufficient (QNS). The result of this study has shown an overall error rate is related to different factors such as phlebotomists' knowledge and skill, operations system, technology, communication, stress, and workload. Therefore, this study suggests training of healthcare personnel as an essential step in decreasing sample error ratios and improving quality of the total testing process in the clinical laboratory and promoting patient-centered health care service because laboratory testing plays an essential part in the transfer of health care services. As a result, any work to improve patient safety and advance health care products must cover the providers of laboratory services. A set of descriptions and principles are necessary for successful improvement in the areas of improving the quality of laboratory services and reducing pre-analytical errors and promoting patient safety.

To have a precise error detection programs, laboratories management could support the phlebotomists by giving proper training and have a good communication system in place. Designing a smooth operations system and user-friendly technology system at workplace will reduce the workload and stress level of the phlebotomists. Phlebotomists' error defined in this study as human errors were correlated to complex operational system and technology defects. The system defect not only results in overall error, but also serves as a source of increasing mental pressure and stress and human error.

The results of this study and the review of pre-analytical errors during this study show that there is a need for better definition of laboratory error and the causes of laboratory errors. It is critical to correlate laboratory errors to possible effects on patient safety. Laboratory errors and a universal reporting system may need to be defined by the laboratory leaders. Future studies about risk of error in the clinical laboratory may be essential to be implemented. The review of this research study of pre-analytical errors in laboratory testing determined that it is significant to outline techniques to decrease laboratory technicians' error and perhaps entirely prevent errors that have important harmful effects on patients' safety.

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Appendix A: Informed Consent Form and Introductory Letters

Informed Consent Form for the Study of:

Root Cause Analysis of Pre-analytical Errors in Laboratory Diagnostics

Dear Laboratory Provider (Phlebotomist):

You are invited to participate to this research study conducted by Zahra Bolandbala, MBA-HCM, LSSMBB to achieve the requirement for the Doctoral of Health care Administration degree from University of Phoenix. You are receiving this letter along with the survey, because you are a credentialed health care provider associated with the laboratory work stations. A minimum of 140 providers are needed to participate in this study.
You may decide not to be part of this study or you may want to withdraw from the study at any time. If you want to withdraw, you can do so without any problems.

PURPOSE AND USE OF THIS SURVEY

The purpose of this survey is to collect your perceptions about how busy and stressful you feel your work environment is. The objective of this study is to gain a better understanding if there is any relationship between the laboratory pre-analytical errors and job stress or workload. The possible benefit of the study is to learn what would be the outcome of the laboratory pre-analytical errors on patient safety, quality and healthcare costs.

PRIVACY STATEMENT

Public Law 93-579, called the Privacy Act of 1974, under the authority of Title 10, United States Code, sections 136 and 2358, requires that you be informed of the purposes of this survey and of the uses to be made of the information collected. Any personally identifiable information that is obtained from this survey will remain confidential and will be disclosed only with your permission or as required by law. Your individual survey responses will remain anonymous and will not be shared with other providers, your chain of command or the management.

"By signing this form, you agree that you understand the nature of the study, the possible risks to you as a participant, and how your identity will be kept confidential. When you sign this form, this means that you are 18 years old or older and that you give your permission to volunteer as a participant in the study that is described here."

Signature of the participant_____ Date _____

THANK YOU FOR PARTICIPATING IN THIS STUDY!

Appendix B: The Participant's Demographics

1. Gender: Male Female
2. Age: < 30 31-40 41-50 51-60 >60
3. Worker category: Phlebotomist 1 Phlebotomist II Lead Phlebotomist
4. Worker type: Full time Part time Per diem (as needed)
5. Main area of practice (Circle the option(s) that describes where you work most often): a)Phlebotomist working in outpatient lab(PSC) b) Phlebotomist working in Skilled Nursing Facilities (SNF) c)Phlebotomist working at in patient lab d)Phlebotomist working in Emergency Room (ER)
6. Length of experience as a phlebotomist: a) less than one year b) 1- 3 yrs c) 4-10 yrs d)11-20 yrs e) > 20 yrs
7. In a month, how often do you make error(s): (order entry, hemolyzed, clotted, etc) a)None b) once a week c)1-2 times a week d)1-2 times a month e) more than 2 times a month

THANK YOU FOR PARTICIPATING IN THIS STUDY!

APPENDIX C: Provider Perspective Survey

INSTRUCTIONS:
The questions in this scale ask you about your feelings and thoughts during THE LAST 3 MONTHS. In each question, please indicate your response by placing an "X" over the circle representing HOW OFTEN you felt or thought a certain way.

Provider Perceptions Survey

	Never	Rarely	Sometimes	Often	Very Often
	0	1	2	3	4
In the past 3 calendar months, how difficult was it to get your work done because of inadequate help from others?	○	○	○	○	○

Organizational Constraints Scale, OCS

How often do you find it difficult or impossible to do your job because of.....?

	Never	Rarely	Sometimes	Often	Often
	0	1	2	3	4
1. Poor equipment or supplies.	○	○	○	○	○
2. Organizational rules and procedures.	○	○	○	○	○
3. Other employees.	○	○	○	○	○
4. Your supervisor	○	○	○	○	○
5. Lack of equipment or supplies.	○	○	○	○	○
6. Inadequate training.	○	○	○	○	○
7. Interruptions by other people.	○	○	○	○	○
8. Lack of necessary information about what to do or how to do it.	○	○	○	○	○
9. Conflicting job demands.	○	○	○	○	○
10. Inadequate help from others.	○	○	○	○	○
11. Incorrect instructions	○	○	○	○	○

Quantitative Workload Inventory, QWI

	Never	Rarely	Sometimes	Often	Very Often
	0	1	2	3	4
12. How often does your job require you to work very fast?	○	○	○	○	○

13. How often does your job require you to work very hard?	○	○	○	○	○
14. How often does your job leave you with little time to get things done?	○	○	○	○	○
15. How often is there a great deal to be done?	○	○	○	○	○
16. How often do you have to do more work than you can do well?	○	○	○	○	○

Interpersonal Conflict at Work Scale, ICAWS

	Never	Rarely	Sometimes	Often	Very Often
	0	1	2	3	4
17. How often do you get into arguments with others at work?	○	○	○	○	○
18. How often do other people yell at you at work?	○	○	○	○	○
19. How often are people rude to you at work?	○	○	○	○	○
20. How often do other people do nasty things to you at work?	○	○	○	○	○

Perceived Stress Scale, PSS

	Never	Rarely	Sometimes	Often	Very Often
	0	1	2	3	4
21. In the last 3 months, how often have you been upset because of something happened unexpectedly at work?	○	○	○	○	○
22. In the last 3 month, how often have you felt that you were unable to control the important things in your work?	○	○	○	○	○
23. In the last 3 month, how often have you felt nervous and "stressed" at work?	○	○	○	○	○
24. In the last 3 month, how often have you felt confident about your ability to handle problems in your job?	○	○	○	○	○
25. In the last 3 month, how often have you felt that things were going your way at work?	○	○	○	○	○
26. In the last 3 month, how often have you felt that you could not manage all the things that you had to do at work?	○	○	○	○	○
27. In the last 3 month, how often have you been able to control irritations in your job?	○	○	○	○	○
28. In the last 3 month, how often have you felt that you were on top of things at work?	○	○	○	○	○

29. In the last 3 month, how often have you been angered in your work because of things that were outside your control?	○	○	○	○
30. In the last 3 month, how often have you felt difficulties at work were piling up so high and you could not overcome them?	○	○	○	○

Appendix D: Permission to Use an Existing Survey

The survey instruments (Perceived stress scale, Interpersonal Conflict Scale, Organizational Constraints Scale, and Workload Scale) that will be used in this study does not require permission for the academic researches.

"Permission for use of perceived stress scale (PSS) scale is not necessary when use is for nonprofit academic research or nonprofit educational purposes" (Cohen, 2013).

"The stressor (Interpersonal Conflict Scale, Organizational Constraints Scale, and Workload Scale) scales can be used free of charge for noncommercial educational and research purposes" (Spector and Jex, 1997: 2014.)

Appendix E: Phlebotomist's Job Responsibilities and Their Influence on the Total Testing Processes

Phlebotomy Process and Procedure	Consequence on Testing
Identify the patient	Identification of the patient is critical for accurate test results
Paperwork and supplies for each patient	Ensure quick and accurate processing of forms and analysis of results
Verify patient's fasting status, diet restrictions, and medication dosage	Some tests require fasting specimen or elimination of certain foods from the diet prior to blood draw
Sanitize hands, select appropriate gloves and tourniquet	Reduce spread of infections Hypersensitivity to latex can cause severe reaction. Use none latex supplies where appropriate.
Assemble necessary supplies and appropriate collection tubes according to test requests	Inspect all supplies for defects and expiration dates Select appropriate needle gauge Select appropriate blood collection system
Position the patient	For patient comfort and safety, collect specimens with the patient seated in an appropriate chair or lying down
Apply tourniquet and select the venipuncture site and vein	Tourniquet placement should not exceed 1 minutes, which may result in hemoconcentration and erroneously increased levels of protein-based analyses, packed cell volume, and other cellular elements
Put on gloves	Part of universal precautions to protect phlebotomists and other health care workers from exposure to blood-borne pathogens
Cleanse the venipuncture site and allow to dry	Prevent microbiological contamination Introduction of alcohol into specimen may cause hemolysis of specimen
Perform venipuncture; once blood flow begins, request the patient to open his/her hand	Blood flow should be uninterrupted Immediately mix collection tube containing additives by gentle inversion (end-to-end mixing 5–6 times) Numerous inversions or vigorous shaking can cause hemolysis
Fill tubes using the correct order of draw	Recommended order of draw • Blood culture tube • Coagulation tube (light-blue top) • Serum tube with or without clot activator, with or without gel (red top) • Heparin tube (green top) • EDTA tube (lavender or pearl top) • Glycolytic inhibitor tube (grey top)

Phlebotomy Process and Procedure	Consequence on Testing
	• Plastic or glass serum tubes containing a clot activator may cause interference in coagulation testing. Glass no additive serum tubes or plastic serum tubes without a clot activator may be drawn before the coagulation tube.
Release and remove the tourniquet	Remove as soon as possible after the blood begins to flow
Place the gauze pad over the puncture site	Cotton balls are not recommended because of the possibility of dislodging the platelet plug at the venipuncture site
Remove the needle, activate any safety feature, and dispose of the device	Follow manufacturer's directions
Apply pressure to the site, making sure bleeding has stopped and then bandage the arm	Watch for continued bleeding
Label the tubes and record time of collection	The patient and the patient's specimen must be positively identified at the time of collection Tubes must be labeled after filling with a label bearing at least the following: • Patient's first and last names • Identification number • Date of collection • Time of collection • Identification of phlebotomist
Special handling requirements (if any)	•Special handling possibilities • Specimen chilling Transport at 37 degrees C (Room Temperature/Ambient) • Protect from light
Send properly labeled blood collection tubes to the laboratory	Maintain proper transport conditions to preserve specimen integrity

Appendix F: Root Cause Information for Delay in Treatment Events

(Resulting in death or permanent loss of function)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=790) ***The majority of events have multiple root causes***	
Communication	634
Assessment	619
Human Factors	545
Leadership	535
Information Management	247
Continuum of Care	212
Care Planning	141
Physical Environment	134
Medication Use	61
Patient Rights	20

Appendix G: Root Cause Information for Transfusion-Related Events

(Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=114) ***The majority of events have multiple root causes***	
Leadership	82
Information Management	70
Human Factors	69
Communication	53
Medication Use	40
Assessment	37
Physical Environment	13
Operative Care	5
Care Planning	3
Performance Improvement	3

Appendix H: Root Cause for Wrong-Patient, Wrong-Site, Wrong Procedure

Reviewed by The Joint Commission, 2013

2004 through 2012 (N=928) ***The majority of events have multiple root causes***	
Leadership	770
Communication	634
Human Factors	618
Information Management	338
Operative Care	313
Assessment	311
Physical Environment	89
Patient Rights	55
Anesthesia Care	46
Continuum of Care	36

Appendix I: Root Cause Information for Anesthesia-Related Events

(Resulting in death or permanent loss of function)

Reviewed by The Joint Commission, 2013

2004 through 2012 (N=94) ***The majority of events have multiple root causes***	
Assessment	56
Anesthesia Care	53
Human Factors	50
Communication	48
Leadership	41
Information Management	16
Medication Use	16
Physical Environment	15
Continuum of Care	8
Care Planning	5

Appendix J: Root Cause Information for Elopement-Related Events

(Resulting in death or permanent loss of function)
Reviewed by The Joint Commission, 2011

2004 through 2012 (N=79) ***The majority of events have multiple root causes***	
Communication	57
Assessment	54
Physical Environment	52
Leadership	51
Human Factors	40
Care Planning	17
Continuum of Care	11
Information Management	7
Special Interventions	7
Medication Use	5

Appendix K: Root Cause Information for Fall-Related Events

(Resulting in death or permanent loss of function)

Reviewed by The Joint Commission, 2013

2004 through 2012 (N=538) ***The majority of events have multiple root causes***	
Assessment	400
Leadership	309
Communication	299
Human Factors	297
Physical Environment	209
Care Planning	116
Information Management	71
Continuum of Care	45
Special Interventions	37
Patient Education	36

Appendix L: Root Cause Information for Fire-Related Events

(Resulting in death or permanent loss of function)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=98) ***The majority of events have multiple root causes***	
Communication	46
Leadership	44
Physical Environment	41
Human Factors	37
Assessment	33
Operative Care	30
Patient Education	20
Care Planning	19
Anesthesia Care	14
Information Management	11

Appendix M: Root Cause Information for Infant Abduction Events

(Any individual receiving care, treatment or services)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=26) ***The majority of events have multiple root causes***	
Leadership	22
Physical Environment	21
Communication	20
Human Factors	13
Assessment	11
Information Management	8
Continuum of Care	4
Care Planning	3
Performance Improvement	3
Patient Education	1

Appendix N: Root Cause Information for Infection-Related Events

(Resulting in death or permanent loss of function)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=153) ***The majority of events have multiple root causes***	
Leadership	75
Surveillance, Prevent. & Ctrl of Infect.	73
Human Factors	71
Communication	70
Assessment	53
Information Management	33
Physical Environment	27
Care Planning	25
Continuum of Care	17
Medication Use	17

Appendix O: Root Cause Information for Maternal Events

(Resulting in death or permanent loss of function)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=107) ***The majority of events have multiple root causes***	
Human Factors	57
Communication	54
Assessment	48
Leadership	44
Information Management	22
Physical Environment	17
Continuum of Care	14
Care Planning	13
Medication Use	13
Anesthesia Care	6

Appendix P: Root Cause Information for Medical Equipment-Related Events

(Resulting in death or permanent loss of function)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=193) ***The majority of events have multiple root causes***	
Human Factors	144
Leadership	124
Physical Environment	121
Communication	113
Assessment	104
Information Management	25
Care Planning	21
Operative Care	10
Medication Use	7
Patient Education	7

Appendix Q: Root Cause Information for Medication Error Events

(Resulting in death or permanent loss of function)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=378) ***The majority of events have multiple root causes***	
Medication Use	334
Leadership	284
Human Factors	271
Communication	270
Assessment	160
Information Management	144
Physical Environment	67
Care Planning	40
Continuum of Care	37
Patient Education	10

Appendix R: Root Cause Information for Op/Post-Op Complication Events

(Resulting in death or permanent loss of function)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=719) ***The majority of events have multiple root causes***	
Human Factors	443
Communication	388
Assessment	357
Leadership	299
Information Management	140
Operative Care	103
Physical Environment	80
Care Planning	76
Medication Use	70
Continuum of Care	61

Appendix S: Root Cause Information for Prenatal Events

(Full-term infant 2500g or > and absence of obvious congenital abnormality; resulting in death or permanent loss of function)
Reviewed by the Joint Commission, 2013

2004 through 2012 (N=239) *The majority of events have multiple root causes*	
Human Factors	176
Communication	162
Assessment	158
Leadership	141
Information Management	51
Physical Environment	42
Care Planning	27
Medication Use	20
Continuum of Care	19
Patient Education	8

Appendix T: Root Cause Information for Radiation Overdose Events

(Cumulative dose > 1500 rads to a single field, or any delivery of radiotherapy to the wrong body region or > 25% above the planned radiotherapy dose)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=30) ***The majority of events have multiple root causes***	
Human Factors	25
Leadership	25
Communication	18
Information Management	15
Assessment	12
Physical Environment	12
Care Planning	5
Operative Care	3
Medication Use	1
Patient Education	1

Appendix U: Root Cause Information for Restraint-Related Events

(Resulting in death or permanent loss of function)
Reviewed by The Joint Commission, 2013

2004 through 2012 (N=117) ***The majority of events have multiple root causes***	
Human Factors	94
Communication	81
Assessment	74
Special Interventions	74
Leadership	73
Physical Environment	47
Care Planning	23
Information Management	23
Medication Use	17
Continuum of Care	13

Appendix V: Root Cause Information for Suicide Events

(Suicide of any individual receiving care, treatment or services in a staffed around-the-clock care setting or within 72 hours of discharge)

2004 through 2012 (N=685) ***The majority of events have multiple root causes***	
Assessment	551
Communication	398
Human Factors	364
Leadership	341
Physical Environment	309
Information Management	166
Continuum of Care	132
Care Planning	126
Medication Use	22
Special Interventions	19

Appendix W: Root Cause Information for Transfer-Related Events

(Resulting in death or permanent loss of function)
Reviewed by The Joint Commission, 2013

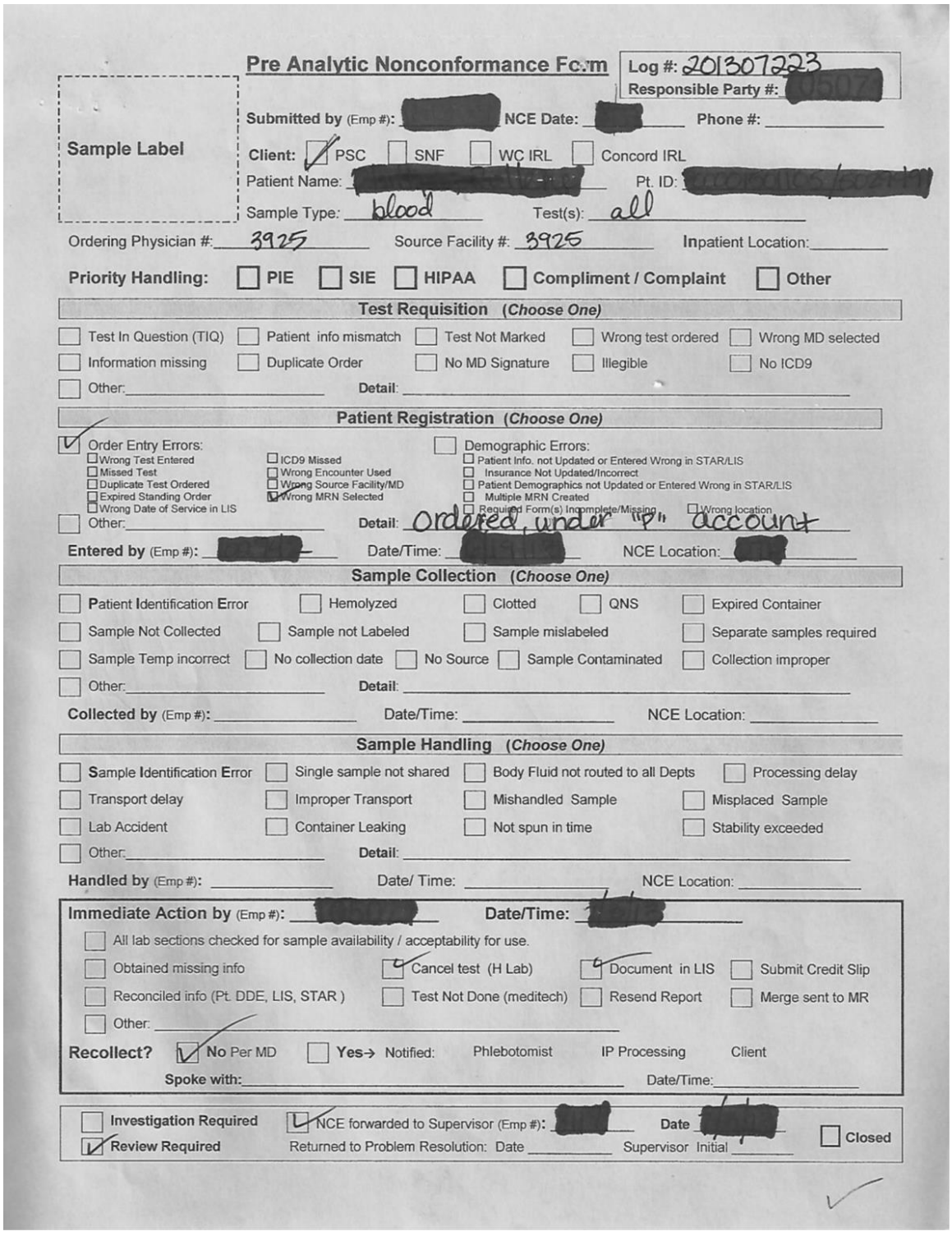
2004 through 2012 (N=24) ***The majority of events have multiple root causes***	
Continuum of Care	19
Communication	18
Leadership	15
Assessment	13
Human Factors	12
Care Planning	6
Information Management	4
Physical Environment	3
Special Interventions	2
Anesthesia Care	1

Appendix X: Root Cause Information for Unintended Retention of Foreign Object events

Reviewed by The Joint Commission, 2013

2004 through 2012 (N=773) ***The majority of events have multiple root causes***	
Leadership	614
Human Factors	502
Communication	496
Operative Care	436
Assessment	195
Physical Environment	174
Information Management	127
Continuum of Care	21
Performance Improvement	13
Care Planning	8

Appendix Y: Pre-analytical Nonconformance Form (NCE)



Pre Analytic Nonconformance Form

Log #: 201307223
Responsible Party #: [redacted]

Sample Label

Submitted by (Emp #): [redacted] NCE Date: [redacted] Phone #: _____

Client: ☑ PSC ☐ SNF ☐ WC IRL ☐ Concord IRL

Patient Name: [redacted] Pt. ID: [redacted]

Sample Type: blood Test(s): all

Ordering Physician #: 3925 Source Facility #: 3925 Inpatient Location: _____

Priority Handling: ☐ PIE ☐ SIE ☐ HIPAA ☐ Compliment / Complaint ☐ Other

Test Requisition (*Choose One*)

☐ Test In Question (TIQ) ☐ Patient info mismatch ☐ Test Not Marked ☐ Wrong test ordered ☐ Wrong MD selected
☐ Information missing ☐ Duplicate Order ☐ No MD Signature ☐ Illegible ☐ No ICD9
☐ Other: _____ Detail: _____

Patient Registration (*Choose One*)

☑ Order Entry Errors:
☐ Wrong Test Entered ☐ Missed Test ☐ Duplicate Test Ordered ☐ Expired Standing Order ☐ Wrong Date of Service in LIS
☐ ICD9 Missed ☐ Wrong Encounter Used ☐ Wrong Source Facility/MD ☑ Wrong MRN Selected

☐ Demographic Errors:
☐ Patient Info. not Updated or Entered Wrong in STAR/LIS ☐ Insurance Not Updated/Incorrect ☐ Patient Demographics not Updated or Entered Wrong in STAR/LIS ☐ Multiple MRN Created ☐ Required Form(s) Incomplete/Missing ☐ Wrong location

☐ Other: _____ Detail: Ordered under "P" account

Entered by (Emp #): [redacted] Date/Time: [redacted] NCE Location: [redacted]

Sample Collection (*Choose One*)

☐ Patient Identification Error ☐ Hemolyzed ☐ Clotted ☐ QNS ☐ Expired Container
☐ Sample Not Collected ☐ Sample not Labeled ☐ Sample mislabeled ☐ Separate samples required
☐ Sample Temp incorrect ☐ No collection date ☐ No Source ☐ Sample Contaminated ☐ Collection improper
☐ Other: _____ Detail: _____

Collected by (Emp #): _____ Date/Time: _____ NCE Location: _____

Sample Handling (*Choose One*)

☐ Sample Identification Error ☐ Single sample not shared ☐ Body Fluid not routed to all Depts ☐ Processing delay
☐ Transport delay ☐ Improper Transport ☐ Mishandled Sample ☐ Misplaced Sample
☐ Lab Accident ☐ Container Leaking ☐ Not spun in time ☐ Stability exceeded
☐ Other: _____ Detail: _____

Handled by (Emp #): _____ Date/ Time: _____ NCE Location: _____

Immediate Action by (Emp #): [redacted] **Date/Time:** [redacted]

☐ All lab sections checked for sample availability / acceptability for use.
☐ Obtained missing info ☑ Cancel test (H Lab) ☑ Document in LIS ☐ Submit Credit Slip
☐ Reconciled info (Pt. DDE, LIS, STAR) ☐ Test Not Done (meditech) ☐ Resend Report ☐ Merge sent to MR
☐ Other: _____

Recollect? ☑ No Per MD ☐ Yes→ Notified: Phlebotomist IP Processing Client

Spoke with: _____ Date/Time: _____

☐ **Investigation Required** ☑ NCE forwarded to Supervisor (Emp #): [redacted] Date [redacted]
☑ **Review Required** Returned to Problem Resolution: Date _____ Supervisor Initial _____
☐ **Closed**