DETERMING SOLUTIONS TO BLOOD RECOLLECTION RATES
AT SPECTRUM HEALTH ZEELAND COMMUNITY HOSPITAL

MSA 699 Project Report

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for the Degree of
Master of Science in Administration
(Concentration in Healthcare Administration)

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Executive Summary

The purpose of this experimental study was to test the theory of how education, training, and the utilization of electronic medical records correlate to higher recollections in the clinical laboratory department. The controlled variables in the study are lab tests ordered and performed by Spectrum Health Zeeland Community Hospital laboratory staff on blood and non-blood specimens. The target population was the phlebotomy staff employed at the Spectrum Health Zeeland Community Hospital laboratory. Preexisting data was captured from two sources: specimen processing error log, and custom Cerner report out of the analytics module.

Data showed the top recollection categories that occur during the preanalytical phase of specimen collection. Proportional data was generated to see the percentage of each recollection reason contributed to the overall rate of rejected specimens. The study provided ways in which to resolve or minimize the rejected specimens collected by the phlebotomy staff. The data showed that phlebotomist employed at the Zeeland laboratory have opportunity to improve upon skills and technique to reduce the amount of rejected specimens. Phlebotomist should participate in formalized training and education provided by the Grand Rapids laboratory campuses. In current state, Zeeland laboratory does not provide a formalized training program that adheres to the best practices set forth by laboratory governing agencies.

Additionally, the laboratory leadership should be utilizing the reports available within the hospital’s EHR to track compliance and performance metrics in lieu of their current manual paper error log. Data that is included in the Cerner reports, are being gathered from the systems database, which provide a more accurate and robust reporting mechanism.
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Chapter I

The Problem

Introduction

Hospital laboratories are monitored by various regulating bodies such as College of American Pathologists (CAP) and The Joint Commission. The College of American Pathologists is tailored to the laboratory setting, whereas The Joint Commission covers other hospital departments outside of the laboratory. Regulating bodies are typically recognized nationwide which determines an organization’s commitment to quality and performance standards (The Joint Commission, 2017). Regulating bodies create standards of care for healthcare organizations, which departments such as laboratories are held to. At least every two years, the regulating body, The Joint Commission, performs an on-site survey at clinical or freestanding laboratories where performance standards are examined and measured.

Based on The Joint Commission’s findings, the laboratory receives an accreditation or a certification. It is important for a clinical laboratory to receive accreditation for the following reasons: strengthens patient safety efforts, provides a competitive edge, may reduce costs associated with liabilities, provides deeming authority for Medicare certification, recognized by third party and other insurers, provides framework for organizational structure, and provides an objective assessment of clinical excellence (The Joint Commission, 2016).

One assessment measured by The Joint Commission, surrounding patient safety, includes recollection rates. Laboratories participating in accreditation or certification programs need to provide accurate documentation of recollection rates to determine if their data meets the criteria set by the regulating body. The majority of recollections performed by a laboratory are avoidable through standardization, effective phlebotomy training, robust laboratory test catalog,
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positive patient identification, adhering to blood collection standards of care, and the utilization of a laboratory information system.

**Background of Problem**

According to researchers from the College of American Pathologists (2010), the most laboratory errors, such as mislabeling and identification defects, occur during the preanalytical phase. There are typically three phases that a specimen goes through when being processed in a clinical laboratory. The phases include the preanalytical, analytical, and postanalytical. Preanalytical phase is prior to specimen testing or the process of obtaining the specimen. Analytical phase is the actual process of testing the specimen in the laboratory setting. Postanalytical phase occurs after the test results have been reported or published in the laboratory information system. Blood and non-blood specimens that are submitted to the clinical laboratory may be rejected for a variety of reasons which may include incorrect labeling, identification or defects with the quality of the specimen (Karcher & Lehman, 2014).

In January 2017, the Medical Laboratory Observer, a peer-reviewed source, reported benchmarks for laboratory professionals. According to Anthony Kurec (2017) the average error rate for pre-analytical phase was between 46%-68%; analytical phase 7%-13% and post-analytical phase 18%-47%. Numerous variables are attributed to error rates in each phase of the blood and non-blood specimen lifecycle.

Spectrum Health owns and operates several facilities in the western portion of Michigan. Primarily stationed in Grand Rapids, Michigan, Spectrum Health also owns several regional hospitals, including Big Rapids, Ludington, Greenville, Pennock, Gerber and Zeeland. Most of the regional hospitals owned by Spectrum Health have their own clinical laboratory that collects and results specimens for both outpatient and inpatient settings. While the Grand Rapids
Spectrum Health laboratory campuses are accredited and regulated by College of American Pathologists, not all laboratories owned by Spectrum Health use the same regulating body. Spectrum Health Zeeland Community Hospital is accredited and regulated by The Joint Commission. Regardless of the regulating body, the primary goal is ensuring correct patient and sample identification (CAP, 2010).

One of the standards of care, set forth by The Joint Commission, is adhering to Performance Improvement standard PI.01.01.01, The laboratory collects data to monitor its performance. More specifically, the element of performance 23 states that the laboratory collects data on the following: processes or outcomes related to handling specimens, including specimen collection, labeling, preservation, transportation and rejection (The Joint Commission, 2017).

The current method of capturing recollection is through manual entry on a paper template where the reason and solution is documented. At the end of the month, the Medical Lab Technologist Lead, manually tallies the recollections and reports them out via e-mail to the Zeeland laboratory leadership, which includes the Medical Director. This manual process may lead to erroneous data, which is then reported out to The Joint Commission.

The current process of notification for a specimen recollection performed by the clinical laboratory starts with the Medical Lab Technologist. The Medical Lab Technologist would determine if a recollection if required based on various thresholds and requirements. The specimen would be canceled by the Medical Lab Technologist including a rationale for the recollection and a new order would be placed in the laboratory information system. New labels would be printed and a phlebotomist would be notified of the recollection in the hospital setting. If the specimen needing to be recollected was obtained through the out-patient setting, the patient would need to be notified to return to the laboratory for a recollection of the specimen.
Specimens considered “precious samples”, such as cerebral spinal fluid, that are not easily recollected, may be recollected at the discretion of the Medical Lab technologist who is performing the testing.

The recollection error log captured, tallied and distributed by the medical lab technologist lead, include the following categories: corrected reports, technologist errors, instrument errors, mislabeled specimen, unacceptable specimen, ERS submitted, miscellaneous, invalid LDL, urine dip results, result entry errors, add comments, order entry errors and collection time. Recollection categories that can be potentially avoided are: mislabeled specimen, unacceptable specimen, collection time and order entry errors - assuming the specimen was collected by the laboratory staff.

Recollections can be costly to the laboratory and remains a patient dissatisfier as it causes inconvenience and delay for critical laboratory results. Ramifications of a mislabeled specimen could result in a wrong medical diagnosis and treatment while another patient gets treated for a diagnosis they don’t have. Recollections may require more supplies, equipment and reagent to be used at the laboratory’s expense.

**Purpose of the Study**

The purpose of this experimental study is to test the theory of how education, training, and the utilization of an electronic medical record correlates to high recollections in the clinical laboratory department. The controlled variables in the study are lab tests ordered and performed by Spectrum Health Zeeland Community Hospital laboratory staff on blood and non-blood specimens. Other specimens collected by other departments are hard to monitor or control.

The independent variables include training, education and utilization of electronic medical record to decrease the amount of recollections, or the dependent variable. An effective
recolletion is defined as decreasing the number of specimens recollected by the laboratory staff. Re-education, robust training and meaningful captured data provided in automated reports are the intervening variables.

By using pre-existing data captured from the laboratory information system, the data proved that not all recollections are being accounted for in comparison to the manual error log. When the Medical Lab Technician cancels and re-orders the test to generate new labels, that recollection information is captured. The honor system is used when completing the paper error log by staff that fears possible retribution. This results in skewed data, which is being reported to The Joint Commission. Recollections are expensive to the organization.

The average cost of a recollection by pre-analytical errors from inpatient, outpatient and emergency department type patients was estimated to be about $349 per episode across all medical institutions (Kurec, 2017). The average cost per episode can reach even higher for critically ill or terminal patients. By reducing recollections, the quality of patient care would increase and the costs associated to recollections would decrease.

Questions to be Answered

The background research has laid the platform to address how education, training, and the utilization of an electronic medical record would decrease the amount of recollection at Spectrum Health’s Zeeland Community Hospital laboratory. By examining the paper error logs and analysis provided by the Medical Lab Technologist Lead, critical data has shown which preventable recollection categories would be the primary focus. After those categories were identified, the research delved into the finer details of the rejected specimens to provide opportunities for remediation. Remediation of rejected specimens would not only become cost
effective to the laboratory but also increase the regulating body’s primary goal of national patient safety.

This experimental study addressed the following research questions:

1. What are the top three reasons for recollections that have the largest impact?
2. What techniques can phlebotomists perform to decrease their amount of recollections related to the top four recollection reasons?
3. Does data entered into the laboratory information system match the paper error log?

Numerous research studies have been conducted to analyze why recollections occur and investigate root causes in hopes of decreasing the occurrence. There is financial motivation to decrease controllable recollections where policies and procedures were not followed. Customer satisfaction is also a high motivator in which to decrease the amount of recollections, as precious time and resources are affected. Taking into account all of the research, possible solutions and positive outcomes, laboratory leadership would have the tools they need to implement changes in their department.

Assumptions

Serval assumptions were established for the study of decreasing recollections in the Spectrum Health Zeeland Community Hospital laboratory. Phlebotomists collect and obtain the majority specimens collected by the lab. One of the key assumptions for phlebotomy staff is that they were all initially trained in the same material. The second key assumption is phlebotomists are 18 years of age or older and possess a high school degree or equivalent. The last assumption is that all phlebotomist working in the laboratory can read, write and speak English.

In addition to the phlebotomy staff meeting the required qualifications for the Lab/Path Assistant position, it is also assumed that this entry-level position has a high turnover due to low
wages. According to the U.S. Bureau of Labor Statistics (2017), the national annual mean wage for phlebotomists working in the general medical and surgical hospitals was $32,830 with an hourly rate average of $15.79. The starting rate of pay for Spectrum Health Lab/Path Assistant is $10.72, which for one adult would be considered a livable in Michigan according to the Living Wage Calculator (Glasmeier, 2017). A large percentage of phlebotomists who work in hospital settings use their position as a stepping stone to a higher paying position or to gain clinical experience if they are pursuing a degree in medicine such as nursing or pre-med.

Furthermore, it was assumed that Medical Lab Technologists possess the minimum requirements to qualify for the position as posted by Spectrum Health. Education would require a Bachelor’s degree or equivalent in Clinical Laboratory Science or related field. Preferred qualifications included experience gained through skills, knowledge, abilities in related field. Licensing required a certification from the American Society of Clinical Pathologists (ASCP) or National Credentialing Agency (NCA). Medical Lab Technician positions require different qualifications.

Medical Lab Technician positions require basic qualifications that include an Associate’s degree or equivalent in Medical Technology program, chemistry, biology, clinical laboratory science or related field. Licensing required possession of national MLT Registry or be Registry eligible based on Spectrum Health entity and department. Certification from the American Society of Clinical Pathology (ASCP) or National Credentialing Agency (NCA) or equivalent would be accepted. Lastly, the researcher also assumed that both Medical Lab Technicians and Medical Lab Technologist can read, write and speak English.
Theoretical framework

To decrease the rates of recollections in the preanalytical phase of specimen collections, changes need to be made. There are numerous theories surrounding change adoption in the healthcare setting. The theoretical framework for this research came from Lippitt’s model of change. The change model included seven phases: diagnosing the problem, assessing motivation and capacity for change, assessing change agent’s motivation and resources, selecting progressive change objectives, choosing appropriate role of the change agent, maintaining change, and terminating the helping relationship (Lippitt et al., 1958). Utilizing these seven phases in the laboratory setting created improvements.

For the change to be successful, leadership engagement and support needs to be firmly established. The democratic leadership style would complement Lippitt’s theory of change, as this type of leadership builds resonance and gathers buy-in through participation and commitment (Goleman et al., 2013). Ongoing evaluation would also need to take place to ensure that the changes made, become a part of the culture in the laboratory.

Definition of Terms

CLIA – Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans, except clinical trials and basic research (American Association for Laboratory Accreditation, 2013).

CLSI – Clinical and Laboratory Standards Institute (CLSI) brings together global laboratory community to foster excellence in laboratory medicine (Clinical and Laboratory Standards Institute, n.d.).
Hemolysis - Hemolysis is the breakage of the red blood cells (RBC’s) membrane, causing the release of the hemoglobin and other internal components into the surrounding fluid (Arzoumanian, 2003).

Mislabeled Specimen – Any specimen collected and transported to the lab for testing with improper patient identification.

NAACLS – National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) is an international agency for accreditation and approval of education programs in the clinical laboratory sciences and related health care professionals (NAACLS, 2016).

Phlebotomy - The act or practice of opening a vein for letting of drawing blood as a therapeutic or diagnostic measure; venesection; bleeding (dictionary.com, 2017).

Precious Specimen – Any specimen collected by an invasive procedure (except venipuncture, arterial or capillary blood collection). Example would be a cerebral spinal fluid and surgical specimens. Any specimen collected during a unique clinical circumstance where a new specimen collected at a different time would not give information critical for patient diagnosis or management. Exceptions must be approved by the clinical pathologist.

Recollection – Is any specimen that met criteria for rejection due to mislabeling, unlaveling, specimen improperly collected and/or persevered, hemolyzed, lipemic, volume not sufficient for testing, contamination, or patient not properly prepared for test.

Redraw – Once the Medical Laboratory personnel has determined the blood specimen to be unfit for testing, they would order a redraw on the patient to collect a new blood specimen from patient.

The Joint Commission - An independent, not-for-profit organization, The Joint Commission accredits and certifies 21,000 health care organizations and programs in the United
States. Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization’s commitment to meeting certain performance standards (The Joint Commission, 2017).

**Unlabeled Specimen** – Any specimen collected and transported to the lab for testing missing patient identification.

**Venipuncture** - Is the collection of blood from a vein, usually for laboratory testing (MedlinePlus, 2010).

**WHO** – World Health Organization (WHO), whose goal is to build a better, healthier future for people all over the world (WHO, 2017).

**Scope of the Study**

The scope of this study was decreasing the rate of recollections at Spectrum Health Zeeland Community Hospital’s laboratory. The laboratory is located in Zeeland, Michigan and employs about 30 lab staff including medical technologist, medical lab technicians, phlebotomists and a manager. The Zeeland laboratory is a regional hospital under the Spectrum Health umbrella. The laboratory averages about 21,000 specimens per month and 700-800 specimens per day. The specimens that are tested in the lab can be collected by phlebotomists, medical technologists, medical lab technicians, emergency department nurses, medical surgical nurses, surgeons, doctor offices and nursing homes. However, this study focused on the preanalytical phase of specimens collected by the laboratory staff.

**Researcher’s Credentials**

The researcher was a phlebotomy trainer for over seven years and a practicing phlebotomist collectively for over 10 years. For two years, the researcher was a Preanalytical Services Manager in the laboratory at Holland Hospital. In that role, the researcher managed
over 60 entry level phlebotomist and specimen processors and was responsible for staffing and maintaining seven off-site draw stations. During that time, the researcher also revised the phlebotomy training program to improve patient safety and specimen integrity.
Chapter II

Review of Related Literature

Historical & General Background

This chapter included general and historical background covering phlebotomy, the venipuncture procedure, best-practices in the clinical laboratory setting around sample collection, the Joint Commission and other supporting laboratory bodies that help set the groundwork for laboratory standards. Existing studies, methodologies, instrumentation, and statistical approaches were discussed in this chapter from articles, journals and websites focusing on specimen integrity and recollections.

Background of Phlebotomy

Phlebotomy has been practiced for centuries and is still one of the most common invasive procedures in health care (World Health Organization, 2010). Breaking down the word phlebotomy in Latin, phlebo means vein and tomy means to cut. The definition of phlebotomy in science means the act or practice of opening a vein by incision or puncture to remove blood (Random House, Inc., 2017). The practice of phlebotomy or “bloodletting” dates back around 1,000 B.C. with the ancient Egyptians (CCI Training Center, 2016). It was believed that letting of blood would cure diseases and possibly cast out evil spirits. Greeks and Roman incorporated the practice during the medieval era. Barber-surgeons took on the role of bloodletting in the middle ages among other duties such as teeth extractions and amputations. Physicians didn’t develop until later on in time.

During the 1800’s physicians started the actual procedure of making incisions in either a vein or artery to cure diseases such as asthma, diabetes and many more. Obviously, there is little to no proof that bloodletting actual cured diseases such as these. One of the only medical
conditions that routinely undergo bloodletting is polycythemia. Polycythemia is disease where the materials in bone marrow grow too rapidly and increase the mass of red blood cells and hemoglobin (Bruckheim, 1989). In all other cases blood-letting too much can cause anemia and sometimes death in patients. In current time, phlebotomy isn’t used to lose blood to cure a disease, but rather collect a sample to run diagnostic testing to aid diagnosing patients. For this chapter, the researcher has focused on the venipuncture procedure.

The dictionary defines venipuncture as a puncture of a vein, as for drawing blood, intravenous feeding, or the administration of medicine (Random House, Inc., 2017). Clinical laboratories, especially phlebotomist, do not provide services around intravenous feeding or the administration of medicine. In regard to clinical laboratory specimen collection, the focus of puncturing a vein to obtain a quality sample of blood to conduct diagnostic testing is the primary goal.

The following paragraph described a successful venipuncture procedure in the best-case scenario not figuring in hospitalized patients, comorbidities, physical limitations. The first step before the patient even arrives to the lab to have specimens collected; a doctor’s order needs to be provided (Abbas, M., Mukinda, FK., Namane, M., 2017). The laboratory cannot process testing on samples until a doctor’s order is captured. This can be done through various ways. The most common form of receiving a doctor’s order for blood work can be on a paper requisition form or electronically utilizing an electronic health record.

Patient positioning is extremely important when collecting a blood specimen. CLSI regulations state that specimens should be drawn with the patient seated comfortably in a chair or lying down in a supine position (Lima-Oliveira, Volanski, Lippi, Picheth & Cesare Guidi, 2017). Changes in patient posture during a phlebotomy procedure can create bias in some blood tests.
Having the patient clench their hand repeatedly can also affect lab values. Pediatric patients can add a level of complexity when obtaining a blood specimen. Depending on the pediatric patient age, the parents lap could be a viable positioning option or lying on their back properly restrained by trained staff so that the patient isn’t in danger of hurting themselves or others during the phlebotomy procedure.

The next step after the patient is properly positioned is to assemble the equipment appropriate for the patient’s age and tests being ordered. The items need to be in safe reaching distance and can include the following: vacuum-extraction blood tubes, well-fitted gloves, assortment of blood-sampling devices (winged infusion device, straight needle-evacuated tube system, syringe, blood transfer device), tourniquet, alcohol hand rub, 70% alcohol swabs for skin disinfection, gauze or cotton-wool ball, specimen labels, writing equipment, lab forms if appropriate, leak-proof transport bags or containers, and a puncture-resistant sharps container (World Health Organization, 2010).

Identifying the patient is the next step in the phlebotomy procedure sequence. If the patient is alert and conscious the patient would be asked to introduce themselves including their first and last name. The lab orders were validated with the patient’s name to ensure accurate identification. It’s best to ask the patient if they have had complications with blood draws in the past to see if there is history of fainting or phobias in connection to the phlebotomy procedure. One of the phlebotomist’s roles is to calm an anxious or frightened patient (Abbas, Mukinda, & Namane, 2017). The procedure should be explained so that the patient knows what to expect.

Once the patient is comfortably positioned, properly identified, and procedure has been explained, selecting a site to obtain the blood specimen is next. The patient would be asked to extend their arm so that the phlebotomist can examine the antecubital fossa or forearm for good
sized, visible straight veins. The size of the selected vein determines which needle is appropriate to use during the phlebotomy procedure. Once the vein is selected, the tourniquet should be applied about 4-5 finger widths above the venipuncture site in order to re-examine the vein (World Health Organization, 2010). It’s important that the phlebotomist avoids puncturing nerves, tendons or arteries during the venipuncture procedure. The tourniquet is removed until the phlebotomist has performed proper hand hygiene and donned well-fitted gloves.

The tourniquet is re-applied and the puncture site is disinfected with an alcohol prep swab and allowed to dry completely. The vein is anchored by holding the patient’s arm and placing the thumb below the venipuncture site (World Health Organization, 2010). The vein can become more prominent if the patient makes and holds a fist. The vein should be entered with the appropriate sized needle at a 30-degree angle or less. After the required amount of blood is collected for the ordered tests, the tourniquet should be removed before withdrawing the needle. Leaving the tourniquet on too long can alter lab values and cause discomfort to the patient.

Once the tourniquet is removed, the needle is carefully removed from the patient’s vein, sheathed to avoid needle stick injury, and clean gauze is applied with firm pressure to the puncture site. While the patient is holding pressure on the gauze to their arm, the phlebotomist fills the laboratory sample tubes depending on the collection needle mechanism. The predefined order of sample tubes reduces risk of cross-contamination of additives between tubes (Lima-Oliveira et al., 2017). The sample tubes are gently inverted to mix thoroughly and labeled at the bedside. Any sheathed needles need to be disposed in puncture-resistant sharps containers and any contaminated surfaces need to be properly disinfected.

The phlebotomist performs proper hand hygiene and rechecks the labels, sample tubes and orders before transporting the specimens to the lab. The patients arm is checked for bleeding
and bandaged. The phlebotomist gauged the patient’s wellbeing following the venipuncture procedure, and validate that the patient is ready to leave the service center. The blood samples are transported to the lab for testing in the leak-resistant bags or containers. The venipuncture procedure is complete. There are certainly risks involved to not only the patient but to the phlebotomist during a venipuncture procedure, so it’s imperative that the phlebotomist is well trained. The WHO or World Health Organization has produced phlebotomy guidelines that are used to improve the quality of blood specimens and the safety of phlebotomy for health workers and patients (2010).

**Top Redraw Categories**

Due to the fact that 70-80% of all diagnoses are made in conjunction with lab tests, it is important that the phlebotomy procedure is followed with precision (Abbas, Mukinda & Namane, 2017). Cadamuro, von Meyer, Wiedemann, Klaus Felder, Moser, Kipman, Haschke-Becher, Mrazek and Simundic’s, (2016) research showed that errors in blood collection were due to incorrect phlebotomy practice, lack of knowledge and non-compliance of the phlebotomist which may lead to decreased sample quality. According to the WHO, the three major issues resulting from errors in the pre-analytic collection phase are hemolysis, contamination and inaccurate labelling (2010).

Hemolysis is defined as the rupture of red blood cells with the release of hemoglobin and the cellular constituents into the plasma, or liquid portion of whole blood which can affect levels of potassium, inhibit some enzymes and interfere with chemical methodologies (Nova Scotia Health Authority, 2017). There are varying degrees of hemolysis with a blood sample and it is the Medical Laboratory Technologists responsibility to report the degree of severity and presence
on the lab results report. There are several ways to avoid hemolyzing a specimen during the phlebotomy procedure.

In order to prevent hemolysis during a venipuncture procedure the phlebotomist needs to ensure the site is completely dry after disinfecting the puncture site. Using the largest bore needle appropriate for the vein size assists in reducing the prevalence of hemolysis. The phlebotomist should never draw from a bruised site or hematoma (World Health Organization, 2010). Removing the tourniquet as soon as possible decreased the amount of force put on the vein during the venipuncture procedure. If using a syringe method for phlebotomy, the phlebotomist needs to ensure that the needle is securely fastened to the syringe to avoid frothing and drawing too forcibly on the plunger. Once the blood samples have been collected the phlebotomist should invert gently and avoid mixing too vigorously which would rupture the blood cells (World Health Organization, 2010).

In addition to hemolyzing a blood specimen, contamination should also be avoided to eliminate altering lab values. Drawing sample tubes in the correct order can assist in avoiding contamination between tube additives. The recommended order of blood draw: blood culture tube; coagulation tube; serum tube with or without clot activators, with or without gel; heparin tubes with or without gel; EDTA tubes; glycolytic inhibitor tubes and other tubes (e.g. trace elements) (Cornes, van Dongen-Lases, Grankvist, Ibarz, Kristensen, Lippi, Nybo & Simundic, 2016). While hemolysis and cross-contamination can alter lab values, inaccurately labeling a specimen is a serious issue.

The College of American Pathologists Q-probe conducted research surrounding blood bank specimen mislabeling. Mislabeled a patient’s blood specimen creates opportunity for laboratory testing personnel to mistake one patient’s specimen for a specimen from a different
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patient which can result in acute hemolytic transfusion reactions (Novis, Lindholm, Ramsey, Alcorn, Souers, & Blond, 2017). Outside of blood bank specimens being mislabeled, other testing performed on mislabeled patient’s samples, can lead to misdiagnosis and treatment or delay of correct diagnosis and treatment. The American Association of Blood Bank standards requires that patient blood sample tubes have affixed to them labels bearing at least two unique patient identifiers and the date of collection.

The College of American Pathologists (2010) said that if the mismatch or abnormal result is not caught by the laboratory, the error can remain undiscovered until the clinician questions the atypical result as these errors have low deductibility but significant consequences. Most hospital clinical laboratory policies require at least two patient identifiers on specimens and the blood specimens collected need to be labeled at the patient’s bedside after proper identification has been validated.

Additionally, recollecting or redrawing specimens causes additional costs at the expense of the hospital’s laboratory. Outside of costs associated with the actual recollection of the specimen, there are increases in patient treatment hours. One study found that the average cost of a pre-analytical error from all patient types estimated to cost the organization about $349 per episode, however, for a critically ill patient the costs can reach up to and exceeding $2,700 (Kurec, 2017). The study also stated that collectively, these extra expenses can add up to slightly more than one percent of a hospital operating budget (Kurec, 2017).

Causes of Specimen Rejection

There are several more reasons outside of hemolysis, contamination and inaccurate identification to reject a specimen in the clinical laboratory (Pathology Laboratory, 2017). Specimens can be rejected for various reasons related to quality errors and quantity errors. It is
up to the discretion of the Medical Laboratory personnel to determine if a specimen needs to be rejected and recollected. Some common causes of interference with lab results include hemolysis, lipemia and icterus specimens.

Lipemia, is the increase of fat concentration in the blood resulting in a milky appearance in the plasma or serum (Giri, 2016). Lipemic results usually stem from when a patient presents to have their blood drawn and hasn’t followed the fasting instructions. Some blood tests including fasting glucose and lipid profile produce the most accurate results when the patient has been fasting for at least 10-12 hours prior to the blood draw. This would be considered a physical interference.

Icterus is the presence of high levels of bilirubin in the serum or plasma, which give the specimen a range of color from dark to bright yellow (Giri, 2016). Normally plasma or serum color is characterized by a straw color. Any color differences can mean a quality error with the blood specimen. Bilirubin is the brownish yellow substance found in bile within a human being, and is produced when the liver breaks down old red blood cells (WebMD, 2017). When bilirubin levels are high enough to alter the quality of a specimen, this may mean that the patient has liver disease, blood disorders or a blockage of the bile ducts. It is important that the Medical Laboratory Technician report the visible color on the report to the physician.

When collected blood samples were slow to fill, prolong usage of a tourniquet, and overly manipulated vein by the needle can develop a clot (Favaloro, Funk, & Lippi, 2012). Clots can also occur when sample tubes with additives for anti-coagulation have not been inverted or mixed properly. Most modern laboratory analyzers are equipped to detect clots in the specimen, but sometimes the Medical Laboratory Technician take two wooden applicator sticks, insert
them into the sample tube to find the presence of a clot. Presence of clots in the sample tube is cause for specimen rejection.

Inappropriate specimen containers can be collected by not only the laboratory personnel but by, clinical staff and doctors’ offices that transport specimens to a clinical laboratory. Examples of inappropriate specimen containers are glass tubes for frozen specimens, improper transport medium for microbiology specimens, and improper specimen containers like using a sterile container for microbiology specimens (Pathology Laboratory, 2017). Frozen specimens cannot be placed in glass tubes as they crack and shatter. Microbiology specimens, typically need a certain medium to make conditions right to grow bacteria, that is why if a microbiology specimen is placed in a sterile container, there is no presence of a medium in which to encourage bacteria to grow.

Other unacceptable conditions that cause the specimen to be rejected include: leaking tubes which compromise specimen integrity, improper transport or storage temperature, insufficient volume to perform testing, specimen collected with expired supplies, and incorrect specimen for test ordered (Pathology Laboratory, 2017). If the tube is leaking the correct volume to additive is compromised which in turn affect specimen results. Also, there is concern for contamination if the tube has leaked which could cause erroneous results. Improper transport and storage temperature causes interference which in turn causes erroneous results. When there isn’t enough volume of specimen to run the tests the doctor ordered or if there isn’t enough blood per additive ratio, the tests should not be conducted as it affects testing results. When specimens are collected with expired supplies, the test results may not be accurate which could cause a patient to be treated for an illness they don’t have. At times wrong specimens are collected for a test, an example of this would be a throat swab collected for a wound culture. The specimen
type is not correct and in turn the microbiologist cannot perform testing which results in the specimen needing to be recollected.

Both the Clinical and Laboratory Standards Institute and Clinical Laboratory Improvement Amendments organizations developed rejected sample criteria including both quality and quantity errors so that Medical Laboratory personnel can determine which tests should be rejected and which tests are deemed acceptable to perform testing. All of the criteria set forth by these organizations assist with protecting patients and healthcare workers alike. In addition to patient safety, the concepts and approaches improve the quality of clinical laboratory services.

**Risks for Health-Workers and Patients**

Performing phlebotomy can be both physically and emotionally exhaustive. Being a phlebotomist in an outpatient setting is vastly different than being a phlebotomist in an inpatient setting whether on a medical surgical floor or in the emergency room. Stressful situations, like needing to draw blood from a patient who is in cardiac arrest, can at times make a phlebotomist miss a step in the venipuncture procedure, which can potentially cause risk to the phlebotomist. Some risks that are associated with performing phlebotomy are needle or sharps injury, breakage or blood container splashes, exposure to blood and bodily fluids, and occupational injuries (World Health Organization, 2010).

The U.S. Department of Labor Occupational Safety and Health Administration (2017) stated that needle-stick injuries after blood draws are the most likely to occur while removing the blood-drawing needle from the patient’s arm or while disposing of an unprotected needle into a sharps container. Occupational Safety and Health Administration, also known as OSHA, has developed best practices for prevention of needle-stick injuries with phlebotomy procedures,
requiring that safety needles with protective sheaths are to be used. It has been estimated that approximately 5% of sharps injuries are related to phlebotomy needles (Perry & Jagger, 2003).

Needle-stick or sharps injuries can be high risk for contracting a bloodborne pathogen including but not limited to Hepatitis B, Hepatitis C and HIV (World Health Organization, 2010). It is imperative that when phlebotomists are performing a venipuncture procedure that they discard needles with a one-handed approach into a sharps container within arm’s reach. For cases in which a needle-stick or sharps exposure, all healthcare organizations have policies and protocols for exposure and reporting the incident. Post-exposure prophylactic medications may be used if the source of the blood has a known illness or disease. In order to avoid exposure to blood, phlebotomists are required to wear gloves and non-permeable lab coats and at times eye protection.

Patients undergoing a phlebotomy procedure are at risk for blood site infection, hematoma or thrombus, extensive bleeding, nerve damage, vasovagal reaction or syncope, and allergies to either latex, iodine or alcohol (World Health Organization, 2010). In order to decrease the rate of infection at the puncture site, phlebotomist should follow proper hand hygiene, cleanse the patient’s skin with alcohol prep pads, and use a sterile needle each and every time. To limit the number of hematomas and thrombus, it’s imperative that the phlebotomist use a 30 degree angle or less and use the appropriate size needle in relation to the patient’s vein. Applying direct, firm pressure to the injection site for at least 3-5 minutes minimizes bruising or pooling after the venipuncture is complete.

Even if proper venipuncture is followed, extensive bleeding can occur. It’s important to ask the patient if they are taking any medication that can have anti-coagulant properties and to use the appropriate size needle for the vein being used. Due to the fact that nerves and tendons
run alongside veins in the human body, accidentally puncturing a nerve can occur. It’s best to use the antecubital veins when possible and never dig around in the patients arm with a needle (Lima-Oliveira et al., 2017). Despite best efforts and proper technique, some patients experience vasovagal reaction or syncopal episode. If patients are known for fainting with prior blood draws, the patients should be laid down and the phlebotomist should ensure the patient is well hydrated and reduce anxieties that accompany the venipuncture procedure.

Most hospitals have done away with latex based products, but there are still a few items and supplies that are used in the hospital that contain trace amounts of latex. If a patient is allergic to latex or other hospital antiseptic items like iodine and alcohol, it’s important to utilize alternative skin antisepsis when cleansing the puncture site and using non-latex gloves such as nitrile (World Health Organization, 2010). Each and every time a phlebotomist conducts a venipuncture procedure, these risks are on the forefront of his or her mind. Their primary role is to keep themselves and their patient’s safe while providing quality care. Organizations such as CLIA, CLSI, WHO and Joint Commission provide guidelines based on best-practices to achieve this outcome.

The Joint Commission

Back in 1910, a physician by the name of Ernest Codman, proposed the end result system of hospital standardization (The Joint Commission, 2017). Between 1950-1951, The American College of Physicians, the American Hospital Association, the American Medical Association and the Canadian Medical Association joined together with the American College of Surgeons to create the Joint Commission for accreditation of non-for-profit hospitals, whose main purpose was to provide voluntary accreditation (The Joint Commission, 2017). Throughout the following
years, the Joint Commission has fine-tuned their standardization and grew in depth and breadth in the accreditations they provided.

Not until the late 1970’s did the Joint Commission establish an agreement with the College of American Pathologists to recognize CAP as an accrediting body for laboratory medicine. In the mid 1990’s, the federal government finally recognized Joint Commission laboratory accreditation as meeting the Clinical Laboratory Amendments of 1988 and also provided accreditation for freestanding laboratories. One of Joint Commission’s national patient safety goals for laboratory’s primary goals is to improve the accuracy of patient identification by the use of two patient identifiers (The Joint Commission, 2017). The Joint Commission releases evidence-based requirements to assist laboratories in reducing specific types of errors to improve patient safety and outcomes.

**Background of CLIA**

The Clinical Laboratory Improvement Amendments of 1988, also referred to as CLIA, includes federal standards that are used nationwide where human specimens are tested for health assessment or to diagnose, prevent, or treat a disease (Center for Disease Control and Prevention, 2015). CLIA regulates laboratory testing and requires clinical laboratories to be state certified through the Center for Medicare and Medicaid Services before the lab can accept a human specimen for testing. A few of the Center for Disease Control and Prevention’s responsibilities, in relationship to CLIA, include distributing information and educational resources, monitoring proficiency testing, conducting quality improvement studies in the laboratory, developing standards and practice guidelines for the laboratory, and finally, providing assistance with research and analysis.
In addition to the Center for Disease Control and Prevention, other government agencies such as the U.S. Food and Drug Administration, the U.S. Department of Health and Human Services, and the Center for Medicare and Medicaid Services (CMS), has a role with CLIA. The Food and Drug Administration develops rules and guidance for CLIA, where in contrast, CMS issues the laboratory certificates, collects fees, conducts inspections, enforces regulatory compliance, monitors proficiency testing, and publishes rules and regulations (U.S. Department of Health and Human Services, 2014). CLIA covers over 254,000 laboratory entities so collaboration of all of these agencies helps improve the safety and quality of the clinical laboratory (Centers for Medicare and Medicaid Services, 2017).

**Background of CLSI**

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit, member-based, organization, started in the late 1970’s, that facilitates a unique process of developing clinical laboratory testing standards that are based on consensus and input from the government, industry, and healthcare professionals (Clinical and Laboratory Standards Institute, n.d.). The Clinical and Laboratory Standards Institute mission is to develop clinical and laboratory practices and promote their use worldwide which is accomplished through its vision and values (Clinical and Laboratory Standards Institute, n.d.).

**Background of NAACLS**

The National Accrediting Agency for Clinical Laboratory Sciences is an international accredited agency for educational program in the clinical laboratory sciences and related health care professionals (NAACLS, 2016). This peer reviewed foundation offers accredited educational programs that include but are not limited to histology technician, Medical Laboratory Technologist and phlebotomy. When applying for positions in the clinical
laboratory, laboratory leadership monitors and validates that the applicants whose position requires a certificate or degree have graduated from an accredited program at university, college or certificate institute.

**Background of WHO**

Established in 1948, the World Health Organization, also referred to as WHO, consists of over 7,000 people occupying offices in more than 150 countries working alongside government agencies and other partners to ensure the highest attainable level of health for all people (World Health Organization, 2017). They work to combat disease, outbreaks and non-communicable diseases among the world’s population by providing food, clean water, breathable air, medicines and vaccines. The WHO’s main goal is to direct and coordinate international health within the United Nation’s system (World Health Organization, 2017).

**Background of EHR**

An Electronic Health Record or EHR is used to improve quality of patient care and reduce errors through the utilization of software. Numerous EHR software applications are available for hospital use. It behooves hospitals to utilize an EHR in order to participate with the Medicare and Medicaid Electronic Health Care Record Incentive Program, also referred to as Meaningful Use. This incentive program grants eligible hospitals and healthcare professional’s incentive payments for adopting an EHR (Pitrides, Bixho, Goonan, Bates, Shaykevich, Lipsitz, & Landman, 2017).

There are numerous benefits outside of incentive payments when integrating an EHR into a health system. Utilizing an EHR assists with following patient data, delivers cost savings, contributes to the reduction of adverse drug events and increases patient-provider interactions. There are also benefits with having an integrated laboratory information system, or LIS, working
in tandem with an EHR (Pitrides et al., 2017). Several integrated laboratory information systems offer bolt on applications such as “PPID” or positive patient identification. In this scenario, a phlebotomist carries around a hand held device that collects the orders placed by the provider to tell them which tubes to collect for the required testing. Once the labels are printed and the blood is collected, the phlebotomist scans the barcodes on the labels to check the blood which provides more accurate turnaround times while decreasing incidences of miss-identification of specimens.

Implementing an interfaced EHR-LIS greatly reduced preanalytical errors and also causes fewer venipunctures as the system is able to lumps like tests together, and when specimens are collected and identified correctly at the bedside, the incidence of recollection decreases. Another study surrounding blood bank specimens confirmed that barcoding patient specimens reduced the specimen misidentification rates (Novis, et.al., 2017).

**Existing Studies**

Existing studies focusing on preanalytical errors affecting recollections have been conducted in the past. The researcher utilized two studies to articulate the need for this study which generated meaningful results. The first study was performed by the College of American Pathologists who conducted an analysis of 78 clinical laboratories. The objective of this analysis was to quantify the clinical consequences of specimen rejection and to determine the impact of policies and procedures on those consequences (Karcher & Lehman, 2014).

The design of the study included participants who reviewed blood and urine specimens, submitted to the clinical laboratories to identify rejected specimens in the chemistry and hematology departments. Rejected specimen’s data were collected which included patient’s age, specimen type, priority of test, rejection reason, specimen receipt, date, time, and result (Karcher
Laboratory policies and procedures regarding relabeling were revisited along with the amount of relabeled specimens that were mislabeled.

The results from the analysis showed that specimen rejections led to the primary cause of specimen recollection. Relabeling mislabeled specimens were found of little benefit towards reducing specimen rejection. The analysis concluded that specimen rejection had significant clinical consequences that included delays in results, high rate of specimen abandonment, and patient discomfort (Karcher & Lehman, 2014). Further conclusions stated that the practice of relabeling incorrectly labeled specimens is extremely dangerous considering the increased risk to patient safety. The second study focused more on phlebotomist success and reasons for specimen rejection.

The College of American Pathologists conducted another study on the outpatient phlebotomy successes and reasons for specimen rejection. The objective of this study was to compare the success rates for initial phlebotomy encounters to the rate at which the clinical laboratory personnel determine the specimen unsuitable for testing. The goal of the analysis was to find ways to decrease unsuccessful collections and rejected specimens. The method the study used was to measure the outcomes of outpatient phlebotomy procedures for three months or until there were 20 unsuccessful encounters (Dale & Novis, 2002).

The study used a questionnaire format that was administered to willing participants. The questionnaire covered topic areas including test ordering, patient preparation, and specimen collection. The measureable variable was obtaining the percentage of successful encounters and percentage of unsuccessful encounters with phlebotomy. Unsuccessful encounters were divided into the following categories: patient not fasting; requisitions missing information; difficult to obtain specimen; patient left before specimen could be collected; patient’s unprepared for testing
requirements outside of fasting; and patient presented at wrong time for specimen collection (Dale & Novis, 2012). The highest reason for unsuccessful phlebotomy was the result of patient’s not fasting as required for testing. The result of this study concluded that the majority of phlebotomy encounters are successful which resulted in specimens being acceptable for undergoing testing.

**Significant Study**

The most significant study located was, “Causes and impact of specimen rejection in a clinical chemistry laboratory,” by Cao, Chen, Phipps, Del Guidice, Handy, Wagar, and Meng (2016). The premise of this study was that the majority of specimen rejections occur in the pre-analytical phase of specimen collection and how recollecting specimens negatively impacts patient safety and quality of care. The objective of the study was to investigate factors that lead to specimen rejection and the impact it causes to the organization and the patient.

The analysis time frame included a period of one year where a total of 837,862 specimens were received in the lab. Out of the total number of received specimens, 2,178 were rejected due to the following criteria: contamination, inappropriate collection container, quantity not sufficient for testing, labeling errors, hemolyzed specimen, and clotted specimen (Cao, Chen, Phipps, Del Guidice, Handy, Wagar, & Meng, 2016). The study included costs associated with rejected specimens and the impact it has on the organization. It concluded that rejected specimens could be improved by providing training, quality assurance measures, and creating policies and procedures for specimen collection, transport and patient preparation.

**Summary of Literature Reviewed**

Phlebotomy has been around for many centuries but did not start out the way we know it today. Just like technology, healthcare is ever changing to stay current with best practices and
regulatory requirements. This chapter provided website documents, journal articles and research studies that highlighted the clinical laboratory, specimen rejection criteria, history of phlebotomy, history of venipuncture procedure, and history of regulating bodies, including government agencies. This framework laid the groundwork to assist in understanding how to decrease the rates of recollections for phlebotomy staff.

According to the research that was gathered, the phlebotomy role has changed significantly over the years. Knowing that the majority of errors are made during the preanalytical phase, focus is put on specimen collection and how to avoid rejected samples. The top controllable redraw categories were presented along with the effects rejected specimens have on healthcare organization’s finances. Understanding the financial and patient safety implications assisted in developing a plan to decrease rates of recollections made by phlebotomy staff in the inpatient and outpatient setting.

With the focus on minimizing risk and patient safety, federal and state regulatory agencies provide and enforce guidelines to protect not only the patients but the healthcare workers as well. The research proved that in order to reduce preanalytical errors, phlebotomy education should be implemented alongside of stringent quality control and adherence to departmental and organizational policies and procedures. Following the guidelines and quality measures and utilizing electronic health record software can greatly reduce specimen rejection and improve specimen integrity and patient outcomes.
Chapter III
Methodology/Procedures

Research Methodology

This chapter explained the research methods that were utilized to collect, analyze, and interpret the pre-existing data. This chapter is divided into sections consisting of: Target population, sampling frame, sampling methods, selection criteria for reports, and how the reports were accessed. The purpose of this study is to test the theory of how education, training, and the utilization of an electronic medical record correlates to high recollections in the clinical laboratory department at Spectrum Health Zeeland Community Hospital. In addition, decreasing the rates of recollections is the primary goal while maintaining patient and healthcare personnel safety while following best practice guidelines. This study used a Quantitative research methodology, through pre-existing data. Statistics Solutions (2017) described quantitative research as the use of deductive logic, in which the researcher starts with a hypothesis and then collects data which can be used to determine whether empirical evidence supports that the hypothesis exists. Quantitative research relies on numeric information and uses variables to measure the possible values (Statistics Solutions, 2017). Direct observation of quantitative data was collected by gathering reports out of Spectrum Health’s EHR, and through self-reported spreadsheets collected by the laboratory staff. Once the quantitative data was collected, it was reported into statistical reports and graphs. Results are reported as a percentage to reflect the break-down of recollections.

Target Population

The target population of this study was the laboratory personnel employed by Spectrum Health Zeeland Community Hospital. The laboratory is located in Zeeland, Michigan and
employs around 30 people. The Zeeland laboratory is a regional hospital under the Spectrum Health umbrella. The laboratory averages about 21,000 specimens per month and 700-800 specimens per day. The focus of this study primarily included the phlebotomy staff as the preanalytical phase produces errors and recollections. The phlebotomists at Spectrum Health Zeeland Community Hospital are employed under the job description, “Laboratory Assistant.”

The job description has a set of requirements that potential employees must meet to qualify for the position. The job description doesn’t require a state certification in phlebotomy or specimen collection, only a high school degree or equivalent, and valid driver’s license. Preferred qualifications include experience with the public, preferably in the medical or customer service field. Currently, the Zeeland lab has 14 phlebotomists working various shifts and shift lengths.

**Sampling Frame**

The sampling frame for the study came from the specimen processing error log that was provided by the Medical Technologist Lab Lead. The dates on the error logged ranged from April 25th, 2017 to May 11th, 2017. The same time frame was used to run the reports out of the inpatient EHR, Cerner. Depending on the date of a month, more specimens were collected as certain tests, for example, a Protime, which is an anticoagulant test, typically is drawn the first of the month for patients who are taking Coumadin. The sampling frame includes the first of May so this captured peak and lull patient volumes.

**Sampling Methods**

The sampling method used for this study was convenience sampling. Convenience sampling, also known as availability sampling, was used as the pre-existing data that was collected by the Medical Technologist Lab Lead was made conveniently available to us in this
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According to Dudovskiy (2016), convenience sampling is a specific type of non-probability sampling method that relies on data collection from population members who are conveniently available to participate in the study.

Advantages of using convenience sampling include the ease of research, helps with hypothesis generation, data collection can be facilitated in a short time frame, and it is the least expensive to implement over alternative sampling methods (Dudovskiy, 2016). Spectrum Health Zeeland Community Hospital was selected as it was a smaller regional hospital that was not in the midst of transitioning to a new EHR. Disadvantages of using convenience sampling is a high vulnerability to biases and influences, can have a high sampling error, and at times studies with convenience samplings can have little credibility.

Selection Criteria for Reports

Reports that were selected for the study were identified to match as closely to the specimen processing error log sheet. Numerous reports are built in Cerner Discern Analytics for the laboratory module, PathNet. The specific canned report that was used for this study was the, “Cancelled Lab by Order Date.” The data that was extracted for this table include: medical record number of patient, accession number of laboratory specimen, test name, order date, patient name, collection date, personnel who collected the specimen, personnel’s position, cancel date, personnel who canceled the specimen and their position, cancel reason, encounter type, facility, nurse unit and order ID.

How the Reports Were Accessed

Cerner is currently the inpatient EHR used at Spectrum Health. The canned report used for this study, “Cancelled Lab by Order Date,” is a custom Cerner Command Language (CCL) report ran out of Spectrum Health Zeeland Community Hospital’s EHR. Cerner CCL (Cerner
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Command Language) is the Cerner Corporation’s fourth generation programming language that is expressed in the Cerner Discern Explorer solution (Tyukin, 2016). Cerner’s CCL is patterned after Structured Query Language, also known as SQL.

The deployment model and infrastructure for Cerner at Spectrum Health is remote-hosted, which means the hardware and software deployed to the data center is managed by Cerner themselves (Tyukin, 2016). Onsite analysts at Spectrum Health can either build a CCL script or use Cerner’s reporting tool to extract data from tables in the system, to generate a report. These reports can be scheduled to run and also deposited as a file on a secure FTP site. Cerner reports are built to analyze data and monitor metrics. The researcher had access to the Cerner EHR as an analyst so the information was readily available.

**Data Processing and Analysis Procedures**

Once the specimen processing error log and Cerner report were collected, the data was entered into a Microsoft Excel spreadsheet. The data entered into the spreadsheet was categorized into recollection buckets and percentages of recollections were calculated. The proportion statistical model was used. Proportions are the simplest statistical model for categorical data (Epigeum Ltd, 2014). The spreadsheet software provided functions to create graphs and charts.

**Methodological Limitations**

Known methodological limitations were identified for this study. The preexisting data is limited to the age of the data that was available. Many of the research articles, journals and website documents were usually more than one-year old. Technology changes so rapidly that the information available was dated or no longer accurate.
Second limitation could be misrepresentation of target population. Spectrum Health Systems owns and operates over seven hospital locations. The main campuses, Butterworth and Blodgett, located in Grand Rapids, Michigan, collect more specimens and employ more phlebotomists in comparison to Zeeland Community Hospital’s campus which may lead to miscalculation of proportion distribution (Datt & Datt, 2016). Another limitation consists of on the job training for phlebotomy staff.

Phlebotomists at the Zeeland Community Hospital campus do not receive the same formalized phlebotomy training as phlebotomists who work at Butterworth and Blodgett campuses. Educational training information that was collected was made available in chapter 4 and recommendations are presented in chapter 5. The last limitation is regarding the staffing turnover in the phlebotomy position at Zeeland Community Hospital.

Phlebotomy positions typically are an entry level position, so the turnover rate can be high. The average phlebotomy turnover rate is 36%, which is the highest in the clinical laboratory setting (Karni, 1993). Typically, nursing and medical students apply for clinical positions like phlebotomy, to gain experience and knowledge, and after graduation they leave move on to their educational track positions. Due to the fact that there tends to be a high turnover in phlebotomy staff, recently hired phlebotomists, may not have the education and know-how an experienced phlebotomist would possess, which can contribute to errors.

**Ethical Considerations**

For this study, the specimen processing error log and the Cerner report’s patient identification information was removed. Also, to eliminate any punitive ramifications, the collector, or phlebotomist, who contributed to the recollected specimen, was removed. Anytime patient health information is used during research, the patient information must be de-identified
in accordance to the Internal Review Board at Spectrum Health and the HIPAA government regulations. This is performed to reduce risk to the organization and liability to the researcher.
Chapter IV

Findings

Introduction

The findings is a meta-analysis of specimen processing paper error log and custom Cerner CCL report of recollections for the designated sampling frame. The data from the two reports will be represented in table format. The following pie charts proportions portray the breakdown of the recollection reasons for the rejected specimens to the Spectrum Health Zeeland Community Hospital laboratory. The collection of this data will help answer the research questions and spur possible solutions to the problems that were discovered.

What are the top three reasons for recollections that have the largest impact.

The specimen processing manual error log, provided by the lab, provided results for the top three recollection reasons in order of highest to lowest. It concluded number one with highest percentage was no specimen received. Number two was mislabeled specimen and a tie for number three with unlabeled specimen and wrong order. A total of seven errors were recorded on the paper log. Table one shows depicts the breakdown of redraw categories for the sampling frame.
The custom Cerner CCL report that was pulled from Discern Analytics determined there was a total of 61 specimens that were rejected and requested for recollection. The top four reasons for recollection from the Cerner report included: order entry error, specimen not received, and tie for third with specimen unacceptable and specimen not available. An order entry error consists of the wrong test being ordered for the test that was requested. In these situations, an incorrect tube can be collected which results in the patient needing to be redrawn. Specimen not received occurs when an order is placed by a physician but no specimen was collected in the lab to run testing. It is unclear what rejection criterion needs to be met for a specimen to be canceled for falling under specimen unacceptable. Specimen unacceptable maybe an “other” category where specimen not available would occur when a provider ordered a test on a patient but the specimen wasn’t available for testing. Table two displays the recollection breakdown for the sampling frame.
The results from the specimen error log and the custom CCL report were similar to results found in the analysis of causes for specimen rejection by Cao, Chen, Phipps, Del Guidice, Handy Wagar and Meng (2016). According to the findings, labeling errors, clotted, and hemolyzed specimens were among the top specimen rejected causes. However, their findings calculated contamination by IV fluids or TPN the most prevalent rejected specimen reason, whereas Spectrum Health Zeeland Community Hospital’s laboratory reported order entry errors (Cao et al., 2016).

**Trends and themes.** Comparing the two tables, it is clear that the specimen processing error log, which is manually completed by lab staff, does not accurately reflect the same amount of recollections that the Cerner report returned. The tables both list order entry errors and specimen not received. Still a fair percentage of clotted, unlabeled and hemolyzed specimens accounted for. One of the recollections documented on the specimen processing error log, was for two patients where the specimens got mixed up and had the wrong patient label applied to both specimens. This situation resulted in both patients needing to be redrawn.
Analysis. According to CAP (2010), the most prevalent reported specimen rejection cause was mislabeled specimens. This is similar in findings from Spectrum Health Zeeland Community Hospital laboratory. Unlabeled and mislabeled specimens accounted for almost 42% of rejected specimens in the Zeeland Hospital’s laboratory. Misidentified specimens cost the laboratory financially and regulatory. With the Joint Commissions National Patient Safety Goal of improving the accuracy of patient identification, it’s becoming even more important for clinical labs to accurately identify laboratory specimens (CAP, 2010).

What techniques can phlebotomists perform to decrease their amount of recollections related to the top four recollection reasons.

Findings from the specimen processing error log showed the four recollection reasons were: no specimen received, mislabeled specimens, unlabeled specimens, and wrong order. No specimen received, means the test was ordered and requested to be collected, but no specimen was delivered to the laboratory. Phlebotomists can ensure that all specimens are collected when they compared the orders and the specimens at the patient’s bedside. Labeling at the bedside after confirming patient identification would eliminate or decrease misidentification errors significantly.

Mislabeled and unlabeled specimens are handled per policy that has been established by the Zeeland laboratory. According to the patient identification policy, at least two patient identifiers, name and date of birth, are used whenever taking blood samples and other specimens for clinical testing (Spectrum Health, 2016). In addition to using two patient identifiers, specimens must be labeled at the patient’s bedside to avoid mislabeled or unlabeled specimens.
Before the phlebotomist collects the specimens, they should be confirming with what is written on the requisition to which orders were placed in the EHR before collecting. Catching wrong orders come with experience and knowledge of the laboratory.

Order entry errors, specimen not received, specimen unacceptable and specimen not available were the top four reasons for specimen recollection from the custom Cerner CCL report. When phlebotomists obtain requisitions in the outpatient setting or a specimen is sent to the lab with paper orders, phlebotomists need to ensure that they are correctly placing orders in the EHR. The phlebotomists have numerous resources available at their disposal.

One resource available, is contacting the Grand Rapids campus, laboratory customer service department. The laboratory customer service department can be reached by phone, and can help facilitate an answer to an ordering question. Another resource is the laboratory order catalog which is available through Spectrum Health’s internal website. The only order catalog lists all of the available tests that Spectrum Health’s laboratories provide, requirements and other pertinent information that phlebotomists would need to know. Lastly, phlebotomists can consult with the Medical Technologists or Medical Laboratory Technologists if they have questions related to ordering tests performed in Zeeland’s laboratory.

The laboratory not receiving the specimen can occur for a few reasons. The most common reason is the test was ordered and collected but never arrived in the laboratory for testing. This more commonly occurs from departments outside of the lab who order laboratory tests, like the emergency department and inpatient medical surgical floors.

Unacceptable specimens typically are collected in the wrong container, or special handling was not followed. The order catalog, customer service line and Medical Technologists or Medical Laboratory Technologists, can assist phlebotomists with this information. In
addition, when tests are built in the EHR, specimen collection requirements, like tube type and special handling, are included on the specimen labels that are printed. These printed labels are what phlebotomists use to confirm patient identification, with the patient’s wristband or verbally to the outpatients.

Specimens that are not available, for a recollection reason, did not provide the level of detail to understand why it was rejected by the clinical laboratory. An example of a specimen not available would be when a repeat sample is not available for testing. Another example would be if the specimens were already completed in the lab, and a physician wanted to add another test on the blood stored in the lab, but the ordered couldn’t be added since the patient was discharged. There are situations that can be prevented and some situations that are going to be out of the control of the phlebotomist.

There was little to no data focusing on decreasing recollections due to no specimen received, wrong order, order entry error, specimen not received, or specimen not available. This told the researcher that the majority of the research typically focused on sample integrity and not recollections as a whole. The findings from the available research focused on rejected specimens due to unlabeling, mislabeling and specimen integrity issues.

Results from Cadamuro, Von Meyer, Wiedemann, Fleder, Moser, Kipman, Haschke-Becher, Mrazek and Simundic (2016) study, stated that accurate phlebotomy is one of the most critical steps in preanalytical quality assurance. Findings confirmed by Lima-Oliveira, Volanski, Lippi, Picheth, and Guidi that all blood specimens should be accurately identified. Research has shown that to ultimately preventing preanalytical errors, every effort should be made to focus on phlebotomy education and implement stringent quality control and standard operating procedures (Cao et al., 2016).
Trends and themes. The average cost of a misidentified specimen was $712, not including intangible costs associated with patient anxiety, discomfort, and delays in diagnosis and treatment (CAP, 2010). In order to decrease the rates of recollections among phlebotomist, the first step is education and training. Current state of phlebotomy training at Spectrum Health Zeeland Community Hospital consists of time spent with a preceptor, reading departmental policies and procedures, and successfully completing 100 draws on patients with a small percentage including pediatric patients.

Analysis. The available research provided examples for preanalytical errors around misidentification and specimen integrity issues. Little research was made available to decrease order entry errors, wrong orders, or specimens missing from the lab. However, one research article found that the monthly average of the top four inpatient phlebotomy pre-analytic errors: mislabeled, unlabeled, wrong specimen received, not specimen received; decreased significantly from integrating laboratory information system to the EHR. This isn’t comparable because Zeeland’s laboratory is not using the PPID (Positive Patient Identification) software that is available with Cerner.

Does data entered into the laboratory information system match the paper error log. Data returned by the specimen processing error log only returned a total of seven specimens within the sampling frame. The total specimen breakdown for rejected specimens from the error log included: two mislabeled, one unlabeled, one wrong order, and three no specimens received.

The data returned by the custom Cerner CCL report generated over 60 recollected specimens by the phlebotomists. The breakdown included: two unexpected results, 37 order
entry errors, five specimens not available, three clotted, five unacceptable, one unlabeled, seven not received in lab, and one hemolyed.

The research data showed favorable data that there are multiple benefits utilizing an EHR. The Medicare and Medicaid Electronic Health Care Record Incentive Program grants eligible hospitals, such as Spectrum Health Zeeland Community Hospital, incentive payments for adopting a certified EHR (Petrides et al., 2017). Another benefit of utilizing an EHR is access to healthcare analytics.

Healthcare analytics provide the necessary capabilities to enable a system-wide quality improvement and cost reduction effort (Health Catalyst, 2016). The EHR captures and stores data. Using Cerner’s Discern analytics module, assist departments and leadership in understanding what is going on in the Spectrum Health system. Automated processes of gathering and reporting data in understandable forms, is more accurate and reliable than relying on manual processes for accurate results.

**Trends and themes.** The data returned by the Cerner report and the information manually documented on the specimen processing error log were inconsistent with the total number of recollected specimens. The error log only accounted for seven recollections in the sampling frame. The Cerner generated report provided over 61 recollected specimens the phlebotomists working in the Spectrum Health Zeeland Community Hospital laboratory.

**Analysis.** It is unclear why the laboratory staff utilizes a manual process to capture and document recollections in the EHR. The reported percentage by the laboratory manager, quoted their monthly percentage or recollections was between 1-5% (I. Bracelly, personal communication, May 12, 2017). It is difficult to quantify how many of the 20,000 specimens collected each month, on average, were collected by phlebotomy staff. This would provide a
more accurate recollection percentage for the preanalytical phase as the majority of the recollected specimens sent to the Zeeland laboratory come from the physician offices and emergency room nursing staff.
Chapter V

Summary, Conclusion, Recommendations

Summary

This experimental study analyzed how to decrease the rates of recollections in the Spectrum Health Zeeland Community Hospital laboratory. The purpose of this study was to show how education, training, and the utilization of an electronic medical record correlates to high recollections in the clinical laboratory department. The controlled variables that were used in this study included lab tests ordered and performed by Spectrum Health Zeeland Community Hospital laboratory staff on blood and non-blood specimens. Specimens collected by other departments outside of the laboratory were not included in this study.

In order to determine the current rates of recollections, the research obtained permission from the Laboratory Services Manager and the Ancillary Laboratory Department. In addition, a determination letter was granted by the Spectrum Health Systems Internal Review Board to access patient information located in the hospitals EHR. The specimen processing error log was provided by the Medical Laboratory Lead Technologist and the Cerner CCL report was obtained from the EHR analytics module. The error logs are reviewed by the laboratory Medical Director and the Medical Laboratory Lead Technologist on a monthly basis.

The error log provided only seven recollections between the sampling frame and the Cerner report returned more than 60. Combining the two data collection documents, the top four recollection reasons were: wrong order (60.6%), specimen not available (8.2%), mislabeled specimens (28.5%), and unlabeled specimen (14.2%). All of these recollection reasons can occur during the preanalytical phase in the laboratory. Currently, only informal counseling is administered to phlebotomists who contributed to a specimen recollection.
The results from the proportional calculations from both forms of data collection, showed that utilizing an EHR to capture recollection data is more robust and reliable that a manual paper process. The Cerner report reported 54 more recollected specimens that the error log. The report also provided more information pertaining to the specimen, than the error log. Manual processes are dependent upon staff to take ownership in completing the necessary information required for reporting purposes. Incomplete data has been reviewed each month which can contribute to miscalculations of quality metrics, which are reported to The Joint Commission for Performance Improvement requirements.

The findings from the study were consistent with the research that was presented in the literature review. Kurec stated that emergency department contributes the highest amount towards the specimen recollection rate (2017). This is also true for the Zeeland laboratory. Fundamentals of phlebotomy were also mentioned in the research that was collected. Also, the rejection sample criteria were similar to the recollections reported on the error log and the generated Cerner report. Cao, L., Chen, M., Phipps, R., Del Guidice, R., Handy, B., Wagar., E., and Meng, Q (2016), stated that in order for a specimen to be accepted it required complete order entry information and completed paperwork, which explains why the largest percentage of specimen recollection in the Zeeland laboratory was order entry errors.

The majority of the studies presented described the top most commonly rejected reason for specimen recollections which matched up with the findings of this study. Hemolyzed, clotted, unlabeled and mislabeled specimens, along with order entry errors, were commonly referenced in the research material in the literature review. Additionally, the study showed the same findings from the research, that the majority of the specimens being rejected were collected during the preanalytical phase.
Conclusions

This study demonstrated that the majority of the rejected specimens requiring recollection occurred during the preanalytical phase. However, the findings from the study had order entry errors as the highest percentage of recollections when other forms of research typically reported their highest specimen rejection reason of contaminated by intravenous fluids or total parenteral nutrition (Cao et al., 2016). Similar rejection criteria for collected specimens were used throughout the research. Also, the data analysis and results from the research were consistent with the findings in this study. Therefore, the researcher concluded that the Zeeland lab struggles with the same preanalytical errors as other clinical laboratories that perform patient testing.

The researcher also concluded, that phlebotomy education is essential to ensuring specimen integrity and minimize risk with patient and personnel safety during specimen collection. The recollection findings from the data collection are all rejection criteria that can be avoided or eliminated through education and training. In addition to phlebotomy education, the findings showed that utilizing and EHR to capture accurate data for performance metrics is superior to utilizing manual paper error logs. There are inconsistencies in departmental training and education among the laboratories owned and operated by Spectrum Health Systems. Each clinical laboratory has its own medical director who oversees the clinical operations. Without having best-practices or standardization, each laboratory operates in a silo and can contribute to varying levels of specimen integrity and resulting.
Recommendations

While this study provided consistent results in relationship to the research that was presented, Spectrum Health Zeeland Community Hospital laboratory has opportunities to improve upon workflow, education, recollection follow-up, retraining, and utilization of the laboratory information system. The existing EHR, Cerner, has a bridge medical device used for specimen collection called, Positive Patient Identification Device, or PPID for short. This software can be used for positive identification of specimen collection and blood transfusions (CAP Today, 2013).

The PPID software is available to the Zeeland laboratory but hasn’t been implemented into the department. This utilization of software would decrease the amounts of mislabeled, unlabeled, and wrong container specimens. “Correct patient and specimen identification is a prerequisite to obtaining and reporting the correct results for each patient, which is a major patient safety goal for The Joint Commission,” (Cao et al., 2016). Additionally, the implementation of an interfaced EHR-laboratory information system significantly reduces the preanalytical errors (Pitrides et al., 2017). Novis, D., Lindholm, P., Ramsey, G., Alcorn, K., Souers, R., & Blond, B. (2017) emphasized that barcoding patient specimens reduces specimen misidentification. This could potentially have a positive financial impact on the Zeeland laboratory.

Another area of opportunity is to utilize the canned reports that are available in the inpatient EHR, Cerner’s, Discern analytics module. Leveraging data can drive efficiency and increase positive outcomes. Cerner provides an analytic and reporting module called, Discern (Cerner Corporation, 2017). Generating customized CCL reports out of Discern in Cerner, allows analyst and programmers to retrieve data stored in the database and display it in a user-
friendly way. The Cerner reports can be to create, analyze and execute queries, reports and programs (Cerner Corporation, 2017). Departments like the laboratory can access these queries and reports assist in increase metrics and performance. Canned reports, or reports created by Cerner, are available in the Discern module for staff to generate. In lieu of using paper error logs, the Cerner reports should be utilized by laboratory leadership to provide more accurate and detailed data directly from the systems database. Errors cannot be corrected unless and until you determine where and when they are occurring. Once the extent of the problem is understood, the progress of the institution is trackable (CAP, 2010).

Research in the literature review stated that blood sample rejection is predominantly related to incorrect phlebotomy technique (Cadamuro et al., 2016). Phlebotomy training should be patterned off of best practices set out by the WHO, CAP, and The Joint Commission. The current phlebotomy onboarding process and training does not include topics that were emphasized by the governmental agencies. The researcher underwent a venipuncture procedure at the Zeeland laboratory for blood tests. During the procedure, the phlebotomist left the tourniquet tied around my upper arm while she assembled the equipment she was going to use to collect my blood sample. After the blood sample was collected using a 23-gauge winged set attached to a syringe, she used the needle to puncture the tops of the mint and lavender tube. While filling the tubes with the winged set needle she used her thumb to force the plunger down to force the blood into the vacuum tubes.

The first observation that was a potential healthcare worker risk is the phlebotomist failed to use a blood transfer device to fill the vacuum tubes with the blood sample from the syringe. This could have led to a needle stick injury for the phlebotomist. Secondly, the gauge needle used to fill the vacuum tubes is too small of a bore, so this could potentially put too much force
on the blood, rupture the red blood cells and cause the sample to be hemolyzed. Phlebotomists should force blood into vacuum tubes as this can cause hemolysis or cause the cap to blow off from the force and potentially lead to a blood exposure. Last observation is the phlebotomist didn’t label the blood sample tubes at the researcher’s side. A bandage was affixed to the puncture site and researcher was thanked for using the lab. In order to eliminate a rejected blood sample due to misidentification or lack of identification, phlebotomists must label the specimens at the patient’s bedside after identification has been confirmed.

Formalizing phlebotomy training and ongoing education should be implemented within the next year. The Grand Rapids hospitals under the Spectrum Health System provide a more formalized phlebotomy training program. The inpatient phlebotomy educator stated that new phlebotomists, who are hired, train for four to six weeks depending on their availability. The first two days is dedicated to classroom time where the new phlebotomists learn the basic fundamentals as well as poking a training arm. A packet of educational materials is distributed that covers the classroom material so that the phlebotomy staff is seeing the information in two different ways.

Once the phlebotomists are ready to perform venipunctures, they start on the existing phlebotomy staff. One day a week the new phlebotomists go to the inpatient floors to observe interactions with patients as well as get used to a routine with supplies, orders, and palpating patient veins. After a few days of observation, the new phlebotomists start performing venipunctures on patient. A daily log is kept on how many venipunctures were performed and what device was used, whether it was a vacutainer or butterfly. Additional information included in the daily log is what went well with the venipuncture and what could have gone better to find areas of improvement and coaching.
At the end of the training there is an official check off with the shift coordinator to ensure the new phlebotomists is proficient in all skills. As a department, the new phlebotomists have periodical checks at six months and then 12 months to ensure bad habits haven’t been formed. National or State certification is not required, but the Grand Rapids laboratories pay an additional 25 cents per hour if the phlebotomist obtains a certification. Regional phlebotomists are not included in the phlebotomy training performed at the Grand Rapids hospital laboratories.

When new phlebotomists are hired at the Zeeland lab, the phlebotomists should undergo the training offered by the Grand Rapids hospital laboratories. Shadowing opportunities and precepting are required in both the inpatient and outpatient setting, to gain experience and skills necessary to become proficient and knowledgeable with specimen collection and venipuncture. This created standardization among the phlebotomist’s skills and abilities among the various laboratories with a centralized training facility. Ongoing training and rechecks should be performed every 6 months through skills fairs and one-on-one touch bases with the phlebotomy educator. Following best practices in phlebotomy technique and safety, harbor an environment that decreases the rates of recollections by increasing the patient outcome.

In addition to a formalized phlebotomy training program, phlebotomists who have been identified as having reoccurring incidences of recollected specimens, should be coached and educated to enhance skills and technique. With certain rejected specimens, such as mislabeled or unlabeled specimens, repeat offenders should receive punitive course of action, as identifying a patient and labeling at the bedside is a core function of the phlebotomist role. If the phlebotomist fails to meet this core function, the behavior goes against several departmental policies and procedures including: Phlebotomy: Collection of Diagnostic Blood Specimens by Venipuncture; Laboratory Specimens – Collection Priorities, Labeling and Transport; and Patient Identification
Policy. If misidentifying patient samples repeatedly results in counseling and corrective action, the phlebotomist is held accountable for performing their position safety and proficiently.
References


Appendices

Appendix A  Request to Conduct Research Letter
Appendix B  Permission Letter
Appendix C  Determination Letter
Appendix A

DECREASING RECOLLECTION RATES

Appendix A

RESEARCH REVIEW APPLICATION
FOR MSA 685/699 AND EDU 776 CAPSTONE COURSE PROJECT

Project title: Determining Solutions to Blood Recollection Rates at Spectrum Health Zeeland Community Hospital

Student name: Heidi S. Allen  
Student ID#: 405037

Email address: patte1hs@cmich.edu  
Work phone: 616-486-4301  
Home phone: 616-405-5820

Concentration: MSA-Health Services Administration

Instructor’s name: Dr. Calvin Lathan  
Instructor email: latha1ca@cmich.edu  
Course MSA 699:  
BPIN: 22164375

Program center: Mt. Pleasant, MI

Do you intend to use human subjects or human subjects data in your project? Yes ☐ No ☑

Do you intend to publish your project or present project results outside of your organization? Yes ☐ No ☑

If you answered “yes” on both questions, you are required to complete CITI training and seek approval through CMU’s Institutional Review Board (IRB). The IRB process requires registration in IRBNet and submission of your application materials and supporting documents through IRBNet. Please consult with your instructor and the appropriate program office for assistance.

If you answered “no” to one or both questions, you may use this form for your research review. Read the following directions:

Human subject research

In the box below, describe the purpose of your research, the source of your data, the number of subjects, and the selection criteria. Specify your relationship to the subjects, if any. Attach a consent form or other documentation to confirm that these requirements have been met.

Nonhuman subject research

In the box below, describe the purpose of your research, the source of your data, the number of subjects, and the selection criteria. Attach a consent form or other documentation to confirm that these requirements have been met.

List the APA reference page version of the 3-5 articles you will use in this Secondary Data study (pre-existing data)


Please check all that apply:
☐ My project is work-related  ☑ My project is related to my concentration  ☐ My project is not related to my work or to my concentration. Please provide a rationale for a project that is not work-related or concentration-related: ______

Directions: Type in your name as verification/approval of the information presented in this application. Your signature also confirms your commitment to appropriate research ethics while conducting this research. Submit this form and applicable attachments to your instructor. Please wait for written approval prior to beginning data collection.

Student signature: Heidi S. Allen 5/23/17 ____________________________ Date: ______

Instructor signature: Dr. Calvin A. Lathan III 5/23/17 ____________________________ Date: ______

Program approval signature: ____________________________ Date: ______
Letter of Ancillary Service Support

To: Heidi Allen
   Principal Investigator/Project Director Name

From: Iselle Bracelly, Lab Services Manager, Spectrum Health Zeeland Laboratory
       Name, Title, and Department Representing

Date: 5/24/17

Project Name: Determining Solutions to Blood Recollection Rates in Zeeland Lab

I have been given a description of the project and any other pertinent information (e.g. availability of compensation, etc.), and agree that our Department will provide support as requested. The type and scope of our Department’s support includes:
Providing error logs from recollections and JACHO lab standards.

Should circumstances change, I reserve the right to further conversation and will give adequate notice if we are no longer able to support this project.

Signature: ________________________________ Date: 5/24/17
Appendix C

NON HUMAN RESEARCH DETERMINATION

May 31, 2017

Heidi Allen MSA
4700 00Th St Se,
Kenwood, MI, 49512

SH IRB#: 2017-114

PROTOCOL TITLE: MSA 699 Capstone Research Thesis

SPONSOR: Investigator

Dear Mrs. Allen,

On May 31, 2017, the above referenced project was reviewed. It was determined that the proposed activity does not meet the definition of research as defined by DHHS or FDA.

Therefore, approval by Spectrum Health IRB is not required. This determination applies only to the activities described in the IRB submission and does not apply if changes are made. If changes are made and there are questions about whether these activities are research involving human subjects, please submit a new request to the IRB for a determination.

A quality improvement project may seek publication. Intent to publish alone is insufficient criterion for determining whether a quality improvement activity involves human subject research. However, please be aware when presenting or publishing the collected data that it is presented as a quality improvement project and not as research.

Please be advised, this determination letter is limited to IRB review. It is your responsibility to ensure all necessary institutional permissions are obtained prior to beginning this project. This includes, but is not limited to, ensuring all contracts have been executed, any necessary Data Use Agreements and Material Transfer Agreements have been signed, documentation of support from the Department Chief has been obtained, and any other outstanding items are completed (i.e. CMS device coverage approval letters, material shipment arrangements, etc.).

Your project will remain on file with the Office of the IRB, but only for purposes of tracking research efforts within the Spectrum Health system. If you should have questions regarding the status of your project, please contact the Office of the IRB at 616-486-2031 or email irb@spectrumhealth.org

Sincerely,

Jeffrey Jones MD
Chair, Spectrum Health IRB