

The University of San Francisco
**USF Scholarship: a digital repository @ Gleeson Library |
Geschke Center**

Master's Projects and Capstones

Theses, Dissertations, Capstones and Projects

Spring 5-19-2016

Breast Cancer Specimen Collection, Handling & Adherence to ASCO/CAP Guidelines

Vicki F. Rocconi

vicki.rocconi@johnmuirhealth.com

Follow this and additional works at: <https://repository.usfca.edu/capstone>

 Part of the [Perioperative, Operating Room and Surgical Nursing Commons](#)

Recommended Citation

Rocconi, Vicki F, "Breast Cancer Specimen Collection, Handling & Adherence to ASCO/CAP Guidelines" (2016). *Master's Projects and Capstones*. 322.

<https://repository.usfca.edu/capstone/322>

This Project/Capstone is brought to you for free and open access by the Theses, Dissertations, Capstones and Projects at USF Scholarship: a digital repository @ Gleeson Library | Geschke Center. It has been accepted for inclusion in Master's Projects and Capstones by an authorized administrator of USF Scholarship: a digital repository @ Gleeson Library | Geschke Center. For more information, please contact repository@usfca.edu.

N653 Prospectus: 1-10

Breast Cancer Specimen Collection, Handling & Adherence to ASCO/CAP Guidelines

Vicki Rocconi, RN, OCN, CBCN

University of San Francisco, San Francisco, California

School of Nursing and Health Professions

Breast Cancer Specimen Collection, Handling &
Adherence to ASCO/CAP Guidelines

Background/Introduction

Reports that some breast cancer specimens were not being placed in formalin consistently in a timely manner was identified as a quality issue within our health system, and was the impetus for this quality improvement project. Specimens removed from their blood supply begin to degrade immediately. Specimens are placed in formalin to halt the process of degradation. Under-exposure of specimens to formalin can result in false positive immunohistochemical test results for estrogen receptors and progesterone receptors (Hammond et al., 2010) and over-exposure of specimens to formalin can result in false negative test results for Her-2/neu receptors (Hicks & Schiffhauer, 2011). These test results are used to decide appropriate systemic therapy (chemotherapy, endocrine therapy and biologic response modifiers) for breast cancer patients (Harris et al., 2016). Basing systemic treatment on inaccurate test results could result in the under treatment or over treatment of some patients with breast cancer, which has the potential to result in harm.

In an effort to ensure the preservation of specimens and the quality of pathology test results, the American Society of Clinical Oncologists (ASCO), and the College of American Pathologists (CAP) have established guidelines for the collection and handling of breast cancer specimens (College of American Pathologists, 2013). These guidelines for breast cancer specimen collection & handling identify critical times associated with breast cancer surgery that must be documented to ensure monitoring of quality results. Two of the three critical times are usually recorded by surgical nurses, and one is recorded by the pathologist. These critical times are used to verify that a process that was consistent with national guidelines was implemented in

collecting and handling the specimen and whether the specimen was under-exposed or over-exposed to formalin. The critical times that must be document include the exact time the specimen was removed from the blood supply, the time the specimen was initially placed in formalin, and the total time the specimen remained in formalin. In addition to the documentation of these critical times, ASCO/CAP Guidelines also recommend that after initial removal from the blood supply, breast cancer specimens be placed in formalin as soon as possible, but not to sixty minutes from the time of removal. They have also established a guideline for the total time a specimen remains in formalin, which is currently is a minimum of six hours and no longer than seventy-two hours before it is microscopically analyzed by a pathologist (College of American Pathologists, 2013). The documentation of these critical times and these guidelines became the primary indicators for our quality improvement project, which will be discussed in detail in the methodology section.

In 2014, several incidences occurred to bring problems with the collection and handling of breast cancer specimens to the forefront. The incidents led to further inquiry, multidisciplinary team formation and a quality improvement project. This prospectus describes the first three PDSA Cycles of that quality improvement project. Initially, the leadership framework and theory used to underpin the project will be reviewed. The global aim statement and problem statement will then be defined, followed by an overview of the project. The project overview will include the goals and objectives of the project, the project plan and the specific aim statement. The rationale for the project will then be discussed and will include assessments, analysis and other tools utilized to identify the problem and possible causes, and will end with a thorough cost analysis. The methodology of the project will be delineated, followed by the literature review strategy and a description of selected articles and how they support the project.

The project timeline will then be described, and in conclusion, the expected or anticipated results will be reviewed followed by the author's perspective on the significance of the project.

Clinical Leadership Theme

Leadership Framework, Magnetism Forces & Competency

The clinical leadership theory that was used for the framework of this project is transformational leadership. To successfully make changes that affect a variety of disciplines in multiple departments of a health system, transformational leadership was chosen due to the need for a clear vision, effective communication, multidisciplinary team involvement and motivation to function at a high level of performance (Harris, Roussel & Thomas, 2014). The CNL leadership competency for this project is to “effect change through advocacy for the profession, interdisciplinary health care team and the client by identifying clinical and cost outcomes that improve safety, effectiveness, timeliness, efficiency, quality and client-centered care.” (American Association of Colleges of Nurses, 2013). In addition, this project is also related to two of the fourteen magnetism forces. Those two forces are quality of care and quality improvement. Quality of care was chosen, as it is the driving force for nursing and the magnet organization in an environment that benefits patient outcomes. Quality improvement was chosen because the healthcare setting of this project has two magnet hospitals that both place high importance on quality improvement and have structures and processes in place to measure and improve patient care and services. Magnet status is an award given by the American Nurses' Credentialing Center (ANCC), an affiliate of the American Nurses Association, to hospitals that participate in a survey process and also meet a set of criteria designed to measure the strength and quality of their nursing care and services (American Nurses Credentialing Center, 2016).

Global Aim Statement

The collection and handling of breast cancer specimens will be timely and consistent with guidelines developed by the American Society of Clinical Oncologists, (ASCO) and the College of American Pathologists, (CAP) throughout the health system.

The global aim of this project is to improve safety, timeliness, accuracy, documentation and compliance with ASCO/CAP Guidelines in the collection and handling of breast cancer specimens removed during surgery at all inpatient and outpatient surgical sites within the John Muir Health System in 90% of cases or above by December 31, 2016.

The process begins with the removal of the specimen from the blood supply by the surgeon, documentation of the time of removal by the surgical nurse, orientation of the specimen by the surgeon with pins and/or stitches, handoff to a surgical nurse in the surgery department or outpatient surgery center, placement of the specimen in a container of formalin, labeling of the specimen container with the patient identifiers, documentation of the time the specimen was placed in formalin, completion of the form that accompanies the specimen to pathology and ends with the microscopic evaluation and diagnosis by a pathologist, who ends the process by including the cold ischemic time and the total number of hours the specimen spent in formalin within the pathology report. The quality indicators that will be measured include:

Documentation of the time the specimen was removed from the blood supply; documentation of the time the specimen was initially placed in formalin; documentation of the cold ischemic time (time interval in minutes between when the specimen was removed from the blood supply and the initial placement in formalin); whether the cold ischemic time was 60 minutes or less; documentation of the total time the specimen spent in formalin, expressed in hours; whether the total time the specimen remained in formalin was within the range of a minimum of six hours

and a maximum of seventy-two hours. A benchmark of 90% will be utilized to measure compliance, as 90% is the benchmark used by the College of American Pathologists in certification of pathology laboratories, (2013). The last quality indicator will be the Her-2/neu positivity rate, which is currently 15 – 20% (Wolf et al., 2013).

As a result of this project, we expect to improve safety and accuracy by decreasing the risk of false negative or false positive test results for biomarkers specific to breast cancer, which include estrogen receptors, progesterone receptors and Her-2/neu receptor amplification. We expect to improve timeliness by decreasing the cold ischemic time and the total time the specimen remains in formalin. Documentation of the critical times used by pathologists to determine compliance with ASCO/CAP Guidelines will also be improved, along with compliance with ASCO/CAP Guidelines. A benchmark of 90% or above has been set for each indicator. Cost will also be reduced by decreasing the number of tests for biomarkers performed on core biopsy specimens, and then repeated on the definitive surgical specimen.

Statement of the Problem

Problem Statement

Improper specimen collection and handling procedures are a safety and quality issue, and national guidelines have been developed to prevent inaccurate test results, prevent harm to patients and to certify pathology laboratories.

A problem with breast cancer specimens being placed in formalin in a timely manner consistent with ASCO/CAP Guidelines was identified. In addition, documentation of the critical times and information necessary for pathologists to determine if specimens had been handled in compliance with guidelines were inconsistent. In order to prevent false negative or false positive biomarker test results, a thorough review of the process of breast cancer specimen collection and

handling was initiated. We investigated possible causes and contributing factors of the problem, followed by interventions to correct the process, and identified necessary changes to the policy and procedure to ensure breast cancer specimens are collected and handled consistent with ASCO/CAP Guidelines.

Project Overview

Background

In 2014, several incidences occurred to bring problems with the collection and handling of breast cancer specimens to the forefront. The first incident was a casual comment from a breast surgeon expressing her frustration with a delay in breast cancer specimens being prepared for and transferred to the pathology department in a timely manner without her directing the surgical team to place the specimen in formalin. The next impetus occurred at a dinner and presentation on Breast Cancer and Biomarkers sponsored by Genentech and given by an Advanced Oncology Certified Nurse and Clinical Nurse Specialist through the California East Bay Oncology Nursing Society (CEBONS), our local chapter for the Oncology Nursing Society. During her talk, one slide addressed the importance of proper breast cancer specimen collection and handling which referenced the most current guidelines. The CNS also mentioned that a delay in fixation and/or under-exposure or over-exposure to formalin could cause positive or false negative results of the biomarker tests that are performed on every breast cancer specimen, and are used to determine a patient's systemic therapy. This was new information, and in light of the recent report of delays in breast cancer specimen collection and handling within the health system, the importance of looking into the issue was raised. The last was a serious incident report that came from one of four surgical sites within the health system that detailed a major breach in procedure which lead to a surgical specimen remaining in an operating room from a

Friday afternoon until it was discovered on Monday morning. The surgical specimen had not been placed in formalin, and was seriously degraded. Although the specimen was not a breast cancer specimen, such a breach in procedure caused concern for all specimens and warranted additional information to determine the scope of the problem and how it might affect patients with breast cancer, my cohort of patients. The incidents led to further inquiry, multidisciplinary team formation and a quality improvement project as described below.

Confirmation of the Problem

Following the three incidents that focused attention on a problem with breast cancer specimen collection and handing, the issue was discussed at the Breast Health Services Core Team Meeting, which meets weekly to discuss program planning, patient issues, quality improvement and any other concerns that affect breast health, breast cancer patients and/or Breast Health Services. The Core Team consists of three nurses, one physician and a Certified Cancer Registrar. Respectively, their positions are, the Executive Director of the Oncology Service Line, the Nurse Practitioner for Breast Health Services, the Nurse Navigator for Breast Health Services, the Medical Director of Breast Health Services, and the Manager of Cancer Registry. Before proceeding with an expensive and time consuming quality improvement project, the Core Team wanted additional confirmation of an ongoing problem versus isolated incidents. To obtain additional evidence, it was decided that the Medical Director would discuss the issue further with other surgeons and pathologists, and the Nurse Navigator was tasked with obtaining feedback from several surgical nurses from each of the four surgical sites. The Nurse Navigator was also asked to perform a spot check of a minimum of ten charts of patients who had undergone definitive surgery for breast cancer. The Medical Director discussed the issue with several other breast surgeons and the Medical Director of Pathology. Two of the three

surgeons confirmed delays in breast cancer specimens placed in formalin, and the pathologist confirmed the delays and also reported issues with documentation of the essential times necessary to calculate the cold ischemic time, which is required for compliance with ASCO/CAP Guidelines (Wolff et al., 2013). Discussions with four surgical nurses revealed that although each of the nurses knew the importance of placing specimens in formalin early, only one of the four nurses were able to state a time interval of less than one hour and none of the four nurses were able to state the rationale for doing so. The results of the retrospective audit of ten patient charts are discussed in depth in the rationale section of this report. However, the results also confirmed a need to proceed with a quality improvement project.

The First PDSA Cycle

The planning phase of the first PDSA cycle was done by the Breast Health Services Core Team, with input from additional surgeons, a pathologist and surgical nurses. The do phase of the first PDSA cycle was the spot check of ten consecutive charts of patients who had either undergone mastectomy or lumpectomy for breast cancer and the collection of data. The indicators for the first PDSA cycle were also measured in the second and third PDSA cycles, however addition indicators were added in the subsequent cycles. Criteria for the second and third PDSA cycles are discussed in goals and objectives. The three criteria for the first PDSA cycle were: Documentation of the time the specimen was removed from the blood supply, documentation of the time the specimen was placed in formalin and the cold ischemic time. The cold ischemic time is defined as the interval time, expressed in minutes, between when the specimen was removed from the blood supply and the time the specimen was initially placed in formalin (Hammond et al., 2010). To comply with ASCO/CAP Guidelines, the cold ischemic time should be 60 minutes or under (College of American Pathologists, 2013). A benchmark of

90% was set for each of the three indicators and it was decided that if a benchmark of 90% or above was found, the quality improvement study would not proceed. If the results for any of the three indicators were below 90%, a multidisciplinary task force would be assembled, and a full quality improvement study would be performed. The data results and analysis is discussed thoroughly in the rationale section. The results for all three indicators were under 90% and a more comprehensive multidisciplinary team was formed to review and analyze the data and plan the next steps and interventions.

Multidisciplinary Team Review

Prior to this project, Breast Health Services had an existing multidisciplinary team that met approximately six to ten times a year to guide program development, quality control and compliance with standards for accreditation through the National Accreditation Program for Breast Centers, (NAPBC). For this project, a decision was made to expand this team by adding key stakeholders from pathology and the surgical facilities, which included a pathologist, surgical nurses and representatives from management. This team, the Breast Cancer Specimen Collection & Handling Task Force met on February 18, 2014. After presentation of the background information, (information gathered through informal interviews and the data gathered from the first retrospective chart audit), a comprehensive discussion ensued. From that discussion, the multidisciplinary team concluded that the primary cause of problems with breast cancer specimen collection and handling was due to a large turnover in surgical nursing staff and a high percentage of new nurses in the department for less than one year. The task force recommended mandatory education on specimen collection, handling and adherence to ASCO/CAP Guidelines for all surgical nursing staff in all inpatient and outpatient surgical settings, review and update of the policy and procedures for all inpatient and outpatient surgical

settings, and a second retrospective chart audit of one-month's breast cancer surgeries to be performed after all nursing education sessions were completed. A Fishbone diagram was created based on the discussion and findings of the Task Force meeting, and it is included in appendix A. Four mandatory nursing in-services were conducted between July 21, 2014 and July 25, 2014 at the Walnut Creek and Concord campuses. On the Walnut Creek Campus, two in-services were conducted, one for the nurses that worked in the inpatient surgery department, and one for the outpatient surgery center. On the Concord Campus, the in-services were designed to accommodate both nurses that worked in in-patient and out-patient surgery areas. Two in-services were conducted, one for nurses that worked in the mornings, and one for nurses who worked in the evenings. A total of eighty-six nurses attended the mandatory educational in-services.

The Second PDSA Cycle

Following the mandatory in-services for nurses, the multidisciplinary team had planned for a retrospective chart audit of an entire month of surgeries and expanded the criteria. The project plan was written on January 29, 2015. The retrospective chart audit and data collection began on February 9, 2015 and was completed on April 14, 2015. Data analysis and review by the Breast Program Leadership Committee occurred between April 16 through April 24, 2015.

Although improvements were seen in the indicators measured in the second PDSA cycle when compared to the results from the first PDSA cycle, not all of the criteria met the 90% benchmark. The findings, which will be discussed in the rationale section were submitted in a report on April 29, 2015. The report included the team's plan for an intervention and a third PDSA cycle, because the benchmark of 90% was not met for all the indicators. Since the data collected in the second PDSA cycle indicated a possible knowledge deficit among physicians, an

educational seminar for surgeons, pathologists and the entire breast health services team was planned. Arrangements with Genentech to sponsor a dinner webinar on Specimen Collection, Handling & Adherence to ASCO/CAP Guidelines was planned and presented by David G. Hicks, M.D., an expert in Pathology and primary contributor in the development of the National guidelines. The webinar along with a discussion for improving the process for breast cancer specimen collection, handling and adherence to ASCO/CAP Guidelines occurred on September 17, 2015. Soon after the webinar, the plan for the third PDSA Cycle was initiated.

The Third PDSA Cycle

The criteria and benchmarks for the third PDSA Cycle were the same as the second PDSA cycle as was the plan. The retrospective chart audit and data collection began on February 1, 2016 and was completed on March 15, 2016. Although the data has been collected, the data has not been analyzed or reviewed by the multidisciplinary team. The Breast Program Leadership Committee is scheduled to review and analyze the data on April 20, 2016, at which time, either a plan to formalize changes or another intervention will be initiated.

Goals and Objectives

We aim to improve the timeliness, accuracy, documentation and compliance with ASCO/CAP Guidelines in the collection and handling of breast cancer specimens removed during surgery at all surgical sites within the John Muir Health System.

The process begins with the removal of the specimen from the blood supply, orientation of the specimen by the surgeon, by marking the superior, posterior and other borders of the specimen with sutures and/or pins, handoff to a surgical nurse in the surgery department or outpatient surgery center, who documents the time of removal, places the specimen in a container of formalin, labels the specimen contain with patient identifiers and documents the

time the specimen was placed in formalin on a form that accompanies the specimen to pathology. The specimen is transferred to the pathology department. The pathologist then marks between four to six margins of the specimen with different colors of dye to ensure that the location of any positive margins can be identified. The specimen is then serially sectioned to enhance fixation, and again placed in formalin for a minimum of six hours and not more than seventy-two hours. The process ends with the microscopic evaluation and diagnosis by a JMH pathologist and documentation of the cold ischemic time and the total time the specimen spent in formalin in the pathology report.

By working on the process, we expect to improve timeliness and efficiency by decreasing the time interval from when the specimen is removed from the blood supply until it is initially placed in formalin. The time that specimens will be placed in formalin will not exceed 60 minutes in 90% of specimens, and breast cancer specimens will remain in formalin for at least six hours and not to exceed seventy-two hours for 90% of specimens, based on ASCO/CAP Guidelines (Wolff et al, 2013).

We expect to improve documentation of the time the specimen was removed from the blood supply and the time the specimen was placed in formalin in a minimum of 90% of specimens. In addition, the cold ischemic time and the total time the specimen spent in formalin will be recorded on a minimum of 90% of all pathology reports.

Safety will be improved by prevention of false positive or false negative results of biomarkers for breast cancer, which include immunohistochemical results for estrogen receptors, progesterone receptors (Hammond et al., 2010). and HER-2/neu receptor amplification (Hicks & Schiffhauer, 2011). False positive or false negative results will be prevented by compliance with the time frames established by ASCO and CAP to prevent under or over exposure in formalin in

a minimum of 90% of specimens. The rate of invasive breast cancers that test positive for Her-2/neu amplification will be consistent with the National rate of Her-2/neu positivity, which is currently 15 – 20%.

Cost will be reduced in the third PDSA cycle by eliminating redundant testing of immunohistochemical assays for estrogen receptors, progesterone receptors and HER-2/neu receptors and/or fluorescence in situ hybridization, (FISH). Before the third PDSA cycle, these tests were performed on the core biopsy specimen at the time of diagnosis, and repeated on the definitive surgical specimen. As a result of the comprehensive literature review and multidisciplinary discussion with David G. Hicks, M.D., in the second PDSA Cycle, a decision was made to perform these tests for biomarkers on definitive surgical specimens only beginning January 1, 2016. A decision that tests for biomarkers on core biopsy specimens would not routinely be performed, and only done if ordered by a physician or requested at Breast Tumor Board. Through compliance with ASCO/CAP Guidelines, cost can also be lowered by reducing the number of equivocal test results, which require additional, more expensive tests, such as FISH. Equivocal test results can be caused by over exposure of the specimen in formalin. By adhering to guidelines that limit formalin exposure to a maximum of seventy-two hours, equivocal test results can be reduced.

Quality Improvement Project Plan

The Breast Cancer Specimen Collection, Handling & Adherence to ASCO/CAP Guidelines project has three separate PDSA cycles. The project overview and rationale contain additional information about the impetus and actions prior to the initiation of the study. Therefore, the project plan begins with the multidisciplinary team formation. After the multidisciplinary team established the goals and objectives and determined the criteria and

benchmarks, a plan for a retrospective chart audit and data collection, followed by data review and data analysis in each of the three PDSA Cycles. Interventions based on the data analysis would follow, and the PDSA cycles would repeat until all benchmarks were met at 90% or above. We aim to improve the timeliness, accuracy, documentation and compliance with ASCO/CAP Guidelines in the collection and handling of breast cancer specimens removed during surgery at all surgical sites within the John Muir Health System. In addition, a cost savings component was identified in the second PDSA Cycle and implemented in the third PDSA Cycle. This first PDSA Cycle began in early 2014 and the project will continue until all criteria meet or exceed the benchmark of 90%. We are currently at the end of the data collection phase in the third PDSA Cycle. Data analysis by the multidisciplinary team is scheduled for April 20, 2016. Additional interventions will then be planned or a plan for sustainability will be created, depending on the data analysis results.

Specific Aim Statement

The global aim of this project is to improve safety, timeliness, accuracy, documentation and compliance with ASCO/CAP Guidelines in the collection and handling of breast cancer specimens removed during surgery at all inpatient and outpatient surgical sites within the John Muir Health System in 90% of cases or above by December 31, 2016.

The specific aim statement is to monitor the documentation of critical times and the process of breast cancer specimen collection and handling through PDSA Cycles with planned interventions in each cycle that will ensure compliance with ASCO/CAP Guidelines in all four surgical sites within John Muir Health by December 31, 2016. By completing the PDSA Cycles, planned interventions and improving the process of breast cancer specimen collection and

handling to be consistent with ASCO/CAP Guidelines, we will achieve our specific and global aim statements.

Rationale

Needs Assessment

As described more thoroughly in the background of this paper, three incidences were the impetus for this quality improvement project, which were an initial report from a breast surgeon of a delay in specimens being placed in formalin, an unanticipated acquisition of knowledge regarding the importance of timeliness of placing specimens in formalin and the potential effects if they were not, followed by a serious incident report of a surgical specimen not placed in formalin and left in a surgical suite from Friday through Monday.

Following these three incidents that focused attention on a problem with breast cancer specimen collection and handing, it was necessary to confirm there was a problem with the process or whether the incidences were isolated. Confirmation of a problem was accomplished through interviews with surgeons, a lead pathologist and surgical nurses. Two of the three other surgeons confirmed delays in breast cancer specimens placed in formalin, and the pathologist confirmed the delays and also reported issues with documentation of the essential times necessary to calculate the cold ischemic time, which is required for compliance with ASCO/CAP Guidelines (Wolff et al., 2013). Discussions with four surgical nurses revealed that although each of the nurses knew the importance of placing specimens in formalin early, only one of the four nurses was able to state a time interval of less than one hour and none of the four nurses were able to state the rationale for doing so.

The interviews were followed by a retrospective chart audit of ten patient charts who had undergone definitive surgery for breast cancer in January, 2014. The first ten consecutive

definitive surgeries that were performed in January, 2014 were selected for retrospective chart audit. The criteria for the first PDSA cycle included the time the specimen was removed from the blood supply, the time the specimen was placed in formalin and the cold ischemic time, which is the interval time between the time the specimen was removed from the blood supply and the time the specimen was initially placed in formalin, which was calculated in minutes. A benchmark of 90% was set for each of the three indicators, and the maximum time allowed for the interval between time the specimen was removed from the blood supply until it was placed in formalin was 60 minutes, which is consistent with ASCO/CAP Guidelines (Wolff et al, 2013). The data collected for this indicator was expressed in minutes. The retrospective chart audit results were as follows: The time the specimen was removed from the body was documented in seven out of ten charts, or 70%. The time the specimen was placed in formalin was documented in six out of 10 charts, or 60%. Therefore, the cold ischemic time could only be calculated in 60% of the specimens. Out of the six charts in which there was documentation of the times necessary to calculate the cold ischemic time, four of the six times met the benchmark of under 60 minutes, or 66%. The cold ischemic time, which again should be 60 minutes or less, ranged from 33 minutes to 79 minutes, and the average was 54 minutes. The benchmark of 90% was not met for any of the criteria, which was additional confirmation of a problem and justification for a quality improvement project.

Fishbone Diagram

During the first PDSA Cycle, a Fishbone Diagram was created from the information obtained from the interviews, particularly with nurses. The Fishbone Diagram for the Breast Cancer Specimen Collection & Handling Study is featured in Appendix A. The causes and contributing factors were divided into the following categories.

Process. During the evaluation of the process of breast cancer specimen collection and handling in the four different surgery sites, it was clear that there was no standardization of the process. There were four different policy and procedures, none of which were specific to breast cancer and all the policy and procedures were outdated and not based on current evidence.

Environment. The environments in all four surgical sites were of course all different. Some of the environments had space for storage of some supplies in the OR, but nurses shared that one of the biggest reasons for a delay in placing specimens in formalin is that the containers and formalin were kept outside of the OR and unless they were brought into the OR in advance of the surgery, placing the specimen in formalin usually was done after the surgery was complete.

People. The multidisciplinary team with input from surgical services management concluded that there had been a large turnover in nursing staff, especially in the outpatient surgery sites. There were a large number of new nurses with minimal experience and there had been a loss of experienced nurses that had been mentors to newer nurses due to retirement.

Equipment & Supplies. In assessing equipment and supplies, proximity and access to supplies was again mentioned. Nurses also shared that it was difficult to plan ahead and gather the container and formalin prior to surgery because the size of the specimen is unknown, and specimens must be placed in a container that allows complete coverage with a 10:1 ratio between formalin to breast tissue specimen.

Management. The most obvious variable regarding management was that there were four different managers. Most of which were open to multidisciplinary review and change, but at least one that was resistant to the process.

Measurement. The retrospective chart audit in the first PSDA Cycle concluded that only 66% of specimens were placed in formalin within 60 minutes. In addition, the time the specimen was removed from the blood supply was only recorded in 70% of cases, and the time the specimen was placed in formalin was only recorded in 60% of cases.

SWOT Analysis

A SWOT Analysis of the Specimen Collection, Handling & Compliance with CAP Guidelines revealed the following strengths, weaknesses, opportunities and threats.

Strengths. One of the strengths of the project is volume. Because there are over one-hundred mastectomies performed and approximately four hundred and fifty lumpectomies for breast cancer performed a year within the health system, this project has the potential to impact a large number of patients. The health system places a high priority on quality care. They participate in MediCare's program for Accountable Care Organizations, they have Magnet Certification on both their Walnut Creek and Concord Campuses and administration is highly supportive of this quality improvement project. Multidisciplinary participation by all stakeholders will improve the likelihood that this project will be successful and is another strength of the project. By including all surgical sites, both inpatient and outpatient, it will also allow us to standardize the policy and procedure for breast cancer specimen collection, handling and compliance with national guidelines throughout the health system. In addition, the project will improve our specimen collection and handling process, minimize errors in test results due to under or over fixation of specimens and therefore deliver safer care to patients (Koury, Sait & Hwang, 2009). We will be able to improve timeliness and efficiency with placement of breast cancer specimens in formalin sooner, and we will be able to eliminate duplicate testing for estrogen receptors, progesterone receptors and Her-2/Neu receptor amplification, which were

being performed on core biopsies and then repeated on the specimen from the patient's definitive surgery in most cases. Due to the heterogeneous nature of tumors, immunohistochemical assays on core biopsies are much more likely to be false positive or negative, and for most patients, these tests should be run on the definitive specimen (Potts, Krueger & Landis, 2012).

Weaknesses. A weakness, or challenge of the project is that we will be attempting to standardize a process in four surgical settings, two outpatient centers and two inpatient surgical units with different management, diverse cultures and a considerable difference in what is required between the inpatient and outpatient settings. There is also a higher percentage of newer nurses in the outpatient surgical areas when compared to the inpatient units, and higher turnover rates, which have the potential to affect the project. Access to formalin has also been identified as a weakness, as it is a carcinogen and must be stored in specific conditions and exposure must be limited to meet federal safety standards (OSHA, 2016). Therefore, storage is almost always away from the operating rooms and nurses must either prepare for specimen collection before the surgery or wait until after the surgery is over. This has the potential to effect timely placement of breast cancer specimens in formalin. Sustaining change has been identified as a potential weakness.

Opportunities. Opportunities include standardizing one policy and procedure for the health system, creating a policy and procedure that is evidence-based, potentially adding to existing literature, identifying champions or Nurse Leaders at each surgical site in an effort to ensure sustainability, utilizing the electronic health record to document the time the specimen is removed from the blood supply and the time the specimen is placed in formalin and adding a hard stop in the electronic health record to ensure these critical times are recorded by nursing.

Threats. Threats include workarounds, a drift back to non-compliance with ASCO/CAP guidelines and buy-in by surgical management, surgeons and nurses to change. Pathologists must also be willing to discuss coverage on weekends so that surgeries performed on Thursdays and Fridays do not exceed the 72 hour limit of specimens remaining in formalin, which has the potential to alter test results (Yildiz-Aktas, Dabbs & Bhargava, 2012).

Cost Analysis

While there should be no difference in cost associated with specimen collection and handling consistent with National guidelines, there is considerable costs when performance needs to be measured and evaluated. In addition, the costs associated with assembling a team that involves multiple disciplines and departments, and implementing training programs can become excessive.

The costs of this project have been separated into costs per PDSA Cycle. There are two teams that met and continue to meet associated with this project, a small group that consists of the medical director, the executive director, nurse practitioner, cancer registry manager and the Nurse Navigator/CNL student. The cost associated with this meeting is \$525.00. This group meets approximately twice a month. Six meetings occur per cycle, for a total of eighteen meetings, at a cost of \$9,450.00. The second team is an interdisciplinary team with members from multiple departments. This group has met once during this cycle of the project, and it will meet once more in April for data analysis and planning for implementation of improvements. Some of the physicians on this team are not contracted with the hospital and receive no compensation for time spent on the team. The cost of physicians contracted with the hospital and employees per meeting is \$1,650.00. Therefore, the entire cost of the interdisciplinary team is \$9,900.00.

The other main cost of this project is the time spent on chart audits and nursing time coordinating the project. Nursing time was 28 hours in the first PDSA Cycle and 34 hours in the second PDSA Cycle. To date in the third PDSA Cycle, nursing time has been 14 hours, and another 16 hours are anticipated, for a total cost of \$6,900.00 for nursing time associated with the project.

In the first cycle of this project, a mandatory in-service was required for all surgical nurses at three of the surgical sites. Paid time for the 86 nurses that attended the in-service totaled \$5,590.00. Additional office related costs associated with the in-services that included refreshments for staff at a cost of \$550.00 and miscellaneous handouts and printing at \$75.00. In the second cycle of the project a dinner and webinar presentation for all the pathologists, surgeons and other physicians and team members involved was given at Ruth Chris Steakhouse, with an expert in pathology, David Hicks, M.D. Forty-one physicians attended the dinner. Because proper specimen collection and handling is essential to selecting treatment for women with breast cancer, we approached Genetech, who underwrote the cost for the dinner and speaker. Office supplies in the second cycle cost \$150.00, and approximately \$75.00 to date in the 3rd cycle, for a total cost of \$300.00. The cost of the entire CQI study is projected to cost \$32,890.00.

One unanticipated result of this project that came about because of the literature review and a vigorous discussion at the webinar dinner with Dr. Hicks in September, 2015 was whether testing for estrogen receptors, progesterone receptors and Her-2/neu biomarkers by IHC should be done on the core biopsy vs. the definitive specimen. Ordering physicians wanted the testing done on the core biopsy, but these tests were usually repeated on the definitive surgical specimen because of the heterogeneity of cancer and the inability to see variations in small, core biopsy

specimens. The costs for estrogen receptor testing by IHC is \$167.00. The cost for progesterone receptor testing by IHC is \$168.00, and the cost for Her-2/neu by IHC is also \$167.00. When Her-2/neu is testing by fluorescence in situ hybridization, (FISH) is also performed due to equivocal results, the cost is \$375.00. These are considerable redundant costs, and at the meeting, it was decided that these tests would not be routinely run on the core biopsy specimens, unless specifically ordered by the physician beginning January 1, 2016. Over 700 patients are diagnosed and treated for breast cancer at John Muir Health per year. To be conservative about the savings due to this change in practice, we estimated that approximately 400 of those cases would only have testing done on the definitive specimen, and 300 specimens would still have redundant testing due to orders by physicians who want earlier access to the results for treatment planning. This project would conservatively eliminate 400 redundant tests for estrogen receptors, 400 redundant tests for progesterone receptors, and 400 redundant tests for Her-2/neu amplification by IHC. Since some specimens are tested by IHC and some require additional testing by FISH. We estimated approximately one-quarter of the 400 patients would require the additional testing. Based on these estimates, the savings due to the elimination of redundant tests would be \$238,550.00 in one year. A plan is in place to calculate the actual savings for 2016. The estimated cost benefit for this project is estimated at \$205,660.00. A detailed Projected Cost Analysis & Cost Benefits Analysis is depicted in Table 1 in Appendix F.

Data Sources

In summary, the data and information that was used to justify this quality improvement project included verbal reports of a problem, incident reports, interviews with stakeholders, data from chart audits, multidisciplinary discussions and data analysis, review of the policy and procedures, literature review, Fishbone Analysis (Appendix A), Process Mapping (Appendix B),

SWOT Analysis (Appendix C) and Stakeholder Analysis (Appendix D). After the second PDSA Cycle, a cost analysis and cost benefits analysis were performed, (Appendix E & F). The timeline for the project is documented in a Gantt chart (Appendix G). In addition, Appendix H is a link to a FMEA tool that was utilized for this project and published on the Institute for Healthcare Improvement (IHI) website (IHI, 2015).

Methodology

Approach

The Breast Cancer Specimen Collection & Handling quality improvement project consists of three PDSA Cycles. Each PDSA cycle has a planning phase with a multidisciplinary team, a retrospective chart audit and data collection phase, multidisciplinary team review of the data, data analysis and planning of next steps, with a minimum of one intervention in each of the PDSA cycles and a subsequent plan for follow-up. The last PDSA Cycle will end with a plan for sustainability. The methodology is best described for each of the PDSA Cycles.

The first PDSA Cycle

The first cycle began in early 2014 when a problem with breast cancer specimen collection and handling was first identified. Confirmation of a problem occurred through interviews, data collection and analysis. The data collection phase of the first PDSA cycle consisted of selection of ten consecutive breast cancer cases in which the patient had undergone either mastectomy or lumpectomy from the January, 2014 surgery schedules with inclusion of a minimum of two surgeries from each of the four surgical sites, also chosen consecutively. A retrospective chart audit was then performed and data was collected on three criteria: Documentation of the time the specimen was removed from the blood supply, documentation of the time the specimen was placed in formalin and the interval time in minutes between the

removal from the blood supply and placement in formalin, also known as the cold ischemic time. The benchmark used for documentation of times was 90% and the benchmark for the cold ischemic time was 60 minutes, which is consistent with ASCO/CAP Guidelines (Wolff et al., 2013).

The First PDSA Cycle Data Analysis. Following the retrospective chart audit, the percentages for each of the three criteria were calculated, resulting in the following findings. The time the specimen was removed from the blood supply was recorded in seven of the ten charts, or 70%. The time the specimen was placed in formalin was recorded in six of the ten charts, or 60%, and out of the six cases in which the cold ischemic time could be calculated, four were placed in formalin within 60 minutes, or 66% of specimens were placed in formalin within 60 minutes. None of the three criteria met the benchmark of 90%, which was justification to proceed with the quality improvement project.

The second PDSA Cycle

For the second PDSA cycle, the project was revised and the criteria were expanded. The study was rewritten on January 29, 2015. The criteria for the second PDSA Cycle included: Time the specimen was removed from the body. Time the specimen was initially placed in formalin. Time the specimen was sent to pathology and the interval time in minutes between the removal from the blood supply and placement in formalin, the percentage of cases in which the cold ischemic time was under 60 minutes, and the total number of hours the specimen remained in formalin before analysis by the pathologist. The benchmark for the following criteria was set at 90%. To calculate the interval times in minutes or hours, an application was utilized, timeanddate.com. In addition, the percentage of cases that were Her-2/neu positive was also calculated and compared to National averages, which is currently 15 – 20% (Wolff et al., 2013).

Her-2/neu is not currently measured for in situ cases, so all stage 0, ductal carcinoma in situ cases were excluded from the Her-2/neu positivity calculation.

In an effort to ensure that cases were selected similarly for all PDSA cycles, the following strategy was utilized. Lists of patients diagnosed with breast cancer in October, 2014 were obtained from Cancer Registry and Medical Imaging. The lists were merged and duplicates were eliminated. There were fifty-one patients identified for the second PDSA cycle. Cases in which the surgeries were not definitive, either mastectomy or lumpectomy, were excluded. Excluded cases were surgeries for re-excision, reconstruction and axillary lymph node dissection only. After the elimination of eleven cases that did not meet the selection criteria, forty cases remained, which was the denominator for the second PDSA Cycle.

The retrospective chart audit and data collection portion of the second PDSA Cycle began on February 9, 2015 and was completed on April 14, 2015. Data analysis and review by the multidisciplinary, Breast Program Leadership Committee occurred between April 16 through April 24, 2015 and the findings were submitted in a report on April 29, 2015. The report included the team's plan for an intervention and a third PDSA cycle. A third PDSA cycle was necessary because although improvements were seen in the indicators, not all of the criteria met the 90% benchmark. Since the data collected in the second PDSA cycle indicated a possible knowledge deficit among physicians, an educational seminar for surgeons, pathologists and the entire breast health services team was planned. Arrangements with Genentech to sponsor a dinner webinar on Specimen Collection, Handling & Adherence to ASCO/CAP Guidelines was planned and presented by David G. Hicks, M.D., an expert in pathology and primary contributor in the development of the National guidelines. The webinar along with a discussion on improving the process for breast cancer specimen collection, handling and adherence to

ASCO/CAP Guidelines occurred on September 29, 2015. Due to the fact that the benchmark of 90% for all of the criteria were not accomplished for all the indicators, a third PDSA cycle was planned.

The Second PDSA Cycle Data Analysis. There were forty charts of breast cancer patients that underwent definitive surgery and required a comprehensive chart audit. The data collected showed that the time the specimen removed from the body was recorded in thirty-five out of forty charts, or 87.5%. This is under the 90% benchmark and required multidisciplinary review. While looking for patterns, four out of five of the surgeries that did not have a time of removal were performed by one surgeon. Documentation of the time the specimen was placed in formalin was present in thirty-two of the forty charts, or 80%, which is also under the 90% benchmark and needs multidisciplinary review. The cold ischemic time could be calculated in thirty-three of the forty charts, or 82.5%. It was noted that all seven surgeries in which the cold ischemic time was not documented were performed by two surgeons. The cold ischemic times in thirty-two of thirty-three cases were within sixty minutes or less, or 97%, which exceeds the benchmark of 90%. One case had a cold ischemic time of sixty-five minutes, slightly over the benchmark of sixty minutes. The actual time the specimen was sent and/or arrived in pathology could not be found in the electronic health record (EHR). On the majority of the pathology reports, the time of arrival in pathology was documented at 00:00 on the date of surgery. The actual number of hours that the specimen spent in formalin was also not documented on the pathology report or in the EHR. Instead, the recommended guideline of 6 – 72 hours was recorded, making it impossible to calculate the actual warm ischemic time. Out of the 40 pathology reports, all but one had a documented warm ischemic time of 6 to 72 hours, with one case in which the specimen required new testing due to a prolonged time in formalin that

exceeded 72 hours. Lastly, we calculated the Her-2/neu positivity rate of all the invasive breast cancers. Cases of ductal carcinoma in situ (DCIS) were eliminated from this calculation, as Her-2/neu testing is not currently performed on specimens of DCIS. There were 7 of the 40 specimens that were DCIS only. Out of the 33 patients who had an invasive breast cancer, 5 tested positive for Her-2/neu, or 15%, which meets the low range of anticipated Her-2/neu positivity of 15 – 20% (Wolff et al., 2013).

The Third PSDA Cycle

In an effort to select cases similar to cases reviewed in the second PSDA Cycle, cases for the third PSDA Cycle were selected in the same manner as they were in the second PSDA Cycle by initially obtaining lists of patients from Cancer Registry and Medical Imaging, merging those lists and eliminating duplicates. The month of study for the third PSDA Cycle was October, 2015. After eliminating duplicates, there were fifty-seven identified cases for the third PSDA Cycle. Cases in which the surgeries were not definitive, either mastectomy or lumpectomy, were excluded. Excluded cases were surgeries for re-excision, reconstruction, axillary lymph node dissection only and one case was eliminated because no cancer was found in a mastectomy specimen following neoadjuvant chemotherapy. Fifteen of the fifty-seven cases did not meet the selection criteria and were excluded, leaving a total of forty-two cases that met the criteria for inclusion and a comprehensive chart audit. The third PSDA cycle of chart audits began on February 1, 2016 and was completed on March 15, 2016. An interval upgrade of the electronic health record made the third cycle of data collection more efficient. In addition to the data collection criteria listed below, documentation of basic patient identifiers, the day of the week the surgery was performed, the surgeon who performed the surgery and the pathologist were documented for the possible identification of patterns.

The criteria for the third PDSA Cycle were the same as the second PDSA Cycle, and included: Time the specimen was removed from the body. Time the specimen was initially placed in formalin. Time the specimen was sent to pathology and the interval time in minutes between the removal from the blood supply and placement in formalin, the percentage of cases in which the cold ischemic time was under 60 minutes, and the total number of hours the specimen remained in formalin before analysis by the pathologist. The benchmark for the following criteria was set at 90%. To calculate the interval times in minutes or hours, an application was utilized, which was timeanddate.com. In addition, the percentage of cases that were Her-2/neu positive will also be calculated and compared to national averages, which is currently 15 – 20% (Wolff et al., 2013). Her-2/neu is not currently measured for in situ cases, so all stage 0, ductal carcinoma in situ cases will be excluded from the Her-2/neu positivity calculation.

The Third PDSA Cycle Data Analysis. Although the data collection phase of the third PDSA Cycle concluded on March 15, 2016, the data has not undergone multidisciplinary review or data analysis, which is scheduled to occur on April 20, 2016. The results of the data analysis will be detailed in the summary of the prospectus.

Specific Changes

The changes that will be implemented are to standardize the process, policy and procedures across four surgical sites in the health system, and to ensure the changes are evidence-based and consistent with ASCO/CAP Guidelines for breast cancer specimen collection and handling. The criteria that will be utilized to measure change are documentation of the time the specimen was removed from the body and the time the specimen was initially placed in formalin. In addition, the calculated cold ischemic time will be under 60 minutes (number of minutes from excision to placement in formalin), and the total number of hours the specimen

remains in formalin before analysis by the pathologist. A benchmark of 90% will determine if the criteria is met or further interventions are required. For all invasive breast cancer cases (excluded in situ cases), the percentage of patients that were Her-2/neu positive will also be calculated and compared to National averages, which is currently 15 – 20%.

Change Theory

The change theory that underpins this quality improvement project is Lewin's Theory. Lewin's Theory, or the Force Field Model of Change describes a dynamic balance of forces working in opposing directions. These forces include driving forces, which move people and organizations in the direction of change, restraining forces, which move people and organizations against change and equilibrium, a state in which the driving forces and restraining forces are equal resulting in no change (Nursing Theory, 2015).

Driving forces of the Specimen Collection, Handling & Adherence to ASCO/CAP Guidelines project include. Sharing of the data analysis that identified areas that were under the established benchmark and creating awareness of a problem. Another driving force is comparison of our data with established National Guidelines to create a sense of urgency regarding the issue. Development of a strong interdisciplinary team with respected members that can effect change is also a driving force of the project.

Restraining forces of the project include selecting a project in which the problem was identified incidentally, and had not been identified as an area of high priority. Information on how improper specimen collection and handling techniques affect the accuracy of tests utilized to decide treatment decisions will help counteract this restraining force, as will the sheer volume of patients that could be affected, as breast cancer accounts for approximately one-third of all the cancers diagnosed and treated in our health system. Another restraining force is that the project

involves multiple disciplines and multiple sites within the health system in which breast cancer specimens are collected. Those sites vary in that some are inpatient and some are outpatient, both with different leadership, policy and procedures and requirements. In addition, there are a variety of ways in which specimens are transferred to pathology, which also has three sites in which specimens are analyzed. Including members from every discipline and site in the team and effective team leadership skills is our strategy to counteract problems that will effect implementation related to this restraining force. Because this project has strong driving force and strong restraining forces, there is a risk of equilibrium. Therefore, the implementation process must maximize the driving forces and minimize the forces that would restrain it.

Currently, the Specimen Collection, Handling and Adherence to ASCO CAP Guidelines project remains in the unfreezing stage of Lewin's Theory and will not be completed until after analysis of the data collected in the third PDSA cycle. Although, during this stage we have done some of the work in the moving stage. During the unfreezing stage, we have focused on building awareness of the problem and preparing employees for change, we have shared data from the first and second PDSA cycles, and we have shared how our data compares with national guidelines and benchmarks to raise awareness of the problem. We assembled an initial interdisciplinary task force that eventually led to a larger team that has been educated on all aspects related to the issue. We have utilized tools to more thoroughly understand the problem, which included a SWOT Analysis, Fishbone Diagram, Process Mapping and a Force Field Analysis to identify our driving and restraining forces. We have conducted mandatory in-services for all surgical nursing staff at every site that specimens are collected. To educate our surgeons, pathologists and other healthcare professionals that provide services to breast cancer patients, we brought in an expert in the pathology of breast cancer, David Hicks, M.D. who is a

major contributor to the literature on the issue of specimen collection and handling and who also collaborated in the development of the national guidelines. After analysis of the data collected in the Third PDSA Cycle, we will determine if our past interventions have improved performance, and the results of the data analysis will also be shared with all stakeholders.

As we transition into the moving stage of Lewin's Change Theory, which will involve implementation of the changes, we have clearly identified the problem, identified the goals and objectives, and the multidisciplinary team is scheduled to review the data collected in the third PDSA Cycle, analyze the data and write an action plan on April 20, 2016. Will then initiate that action plan and implement the changes.

The Re-freezing stage will occur after we implement our changes. Since this stage includes actions that prevent a return to previous practices, we have anticipated some measures that might prevent the process returning back to the status quo. These include gaining consensus on a new policy & procedure for the process that works in both the inpatient and outpatient settings. Identifying and eliminating any workarounds to the new process and investigating using technology to enhance performance, such as bar coding of specimens and creating hard stops in the EHR that will not allow a process to move forward if vital information is not entered. We will develop a plan for sustainability, and we anticipate that periodic monitoring of the criteria will be necessary to verify that the changes have been incorporated into routine practice.

Literature Review

Literature Sources

In addition to accessing articles through the Gleeson Library and CINAHL, articles were also obtained through Google Scholar, PubMed and MedlinePlus.

PICO Search Statement

The following PICO search strategy was utilized for a literature search:

P: Women with breast cancer undergoing surgery

I: Fixation of breast cancer specimen tissue in formalin within 60 minutes & documentation of the cold ischemic time

C: Delay in fixation of breast cancer specimens and the effect on biomarker results.

O: Compliance with CAP/ASCO Guidelines for breast cancer specimen collection & handling.

This PICO strategy returned numerous articles from journals that were specific to breast cancer specimen collection and handling and how improper specimen collection and handling procedures effect the quality of the biomarkers used to decide treatment for women with breast cancer. However, there were some challenges. The first challenge was that there is not a lot of articles written by nurses on the subject. In fact, only two articles authored by nurses were found, published in the Journal of PeriOperative Registered Nurses that addressed the nurse's role in proper breast cancer specimen collection and handling. The second challenge was the timeliness of the articles. The first publication of the ASCO/CAP Guidelines was in 2007, and then revised guidelines were published in 2013. There was a wealth of interesting and practice-changing articles that were published from the 2005 through 2010, that were used as the scientific basis for writing the ASCO/CAP Guidelines, but it was challenging to find literature within the 2011 to 2016 time frame.

Literature Review from Annotated Bibliography

In an article on oncogenes by Arteaga & Engelman, (2014), the authors discuss the role of the human epidermal growth factor receptor family, also known as the ErbB family, or HER family and how their signal pathways drive replication, growth and differentiation. It further

discusses how aberrant signaling pathways influence carcinogenesis. Within the last five years, more understanding of the prominent role of these receptors role in the initiation and maintenance of several solid tumors, especially HER-2 amplified breast cancer, has led to the development of specific ErbB inhibitors as breast cancer therapies, which has paved the way for individualized, targeted treatments for breast cancer.

An article written by Hammond et al., (2010) describes the process in which a group of international experts convened by the American Society of Clinical Oncology and the College of American Pathologists conducted a systematic review and evaluation of the literature in partnership with Cancer Care Ontario, and published recommendations for optimal immunohistochemistry (IHC) testing for estrogen receptors (ER) and progesterone receptors (PgR) testing. In the article, they developed guidelines to improve the accuracy of IHC testing of these receptors. The authors determined that up to 20% of IHC testing for ER/PgR are inaccurate, and guidelines to improve accuracy are necessary, as these test results are used as predictive markers and to decide treatment for patients with breast cancer.

In an article written by a panel of experts selected to make recommendations for the appropriate use of breast tumor biomarker assay results to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast. Towards this end, the authors performed a literature search that included metaanalyses, randomized controlled trials, prospective and retrospective studies, and prospective comparative observational studies published from 2006 through 2014 on the subject of the use of breast cancer biomarkers in determining systemic treatment that were published between 2006 through 2014. The literature search identified 50 relevant studies. The authors had particular interest in outcomes that included overall survival and disease-free or recurrence-free survival. Recommendations were then developed to guide

oncologists in the use of specific breast cancer biomarkers in selecting appropriate treatment. They recommended that in addition to estrogen and progesterone receptors and human epidermal growth factor receptor 2 (HER-2), additional biomarkers that were useful in guiding the selection of treatment included the biomarker assays Oncotype DX, EndoPredict, PAM50, Breast Cancer Index, and urokinase plasminogen activator and plasminogen activator inhibitor type 1 in specific subgroups of breast cancer. However, no biomarker except for estrogen receptor, progesterone receptor, and HER-2 were found to guide choices of specific treatment regimens. (Harris et al., 2016).

An article by Hicks & McCarthy, (2011) on breast cancer predictive factor testing and the importance of standardizing tissue handling, argues that with the emerging use of biomarkers in making systemic treatment decisions for women with breast cancer, older laboratory practices must be updated and standardized to preserve the possible presence of macromolecules that are in the tissue. A discussion of the need to better define specimen handling requirements in an effort to improve the quality of specimen samples and ultimately the pathology results.

Authors, Hicks & Schiffhauer, (2011) discuss the problems with immunohistochemistry, (IHC) tests routinely performed on breast cancer specimens in their article on standardized assessment of the HER2 status in breast cancer by IHC. In the article, they discuss problems with reproducibility, lack of standardization and poor concordance between laboratories. Their focus was specifically on the current inaccuracy of routine testing for human epidermal growth factor receptor 2 (HER2) in specimens from breast cancer patients. They discuss pre-analytic and analytic variables and how they can be minimized, and they introduce a new algorithm for test interpretation. The authors also endorse the guidelines set by the American Society of Clinical Oncologists (ASCO), and the College of American Pathologists (CAP), and maintain

that as these guidelines are followed, variation in breast cancer pathology results will decrease and accuracy will improve.

An article by Hicks, (2014) on the standardization of tissue handling from the OR to the laboratory claims that the process of specimen collection and handling from the OR through the delivery of the specimen to the laboratory involves significant patient safety issues and concerns. The author maintains that issues are due advances in clinical practice, and a current lack of updated knowledge and understanding of what is required to deliver a high quality, optimal specimen to the pathology laboratory by perioperative personnel. The author proposes that accurate evaluation of tissue is highly dependent on the quality of specimens, especially when targeted cancer therapies are being considered, and particularly with breast cancer. He claims that we are advancing into a new era of individualized cancer care in which molecular analysis of specimens are more clinically important, and the accuracy and reliability of the tissue analysis is dependent on the quality of the clinical specimens and how they are collected and handled. He maintains that the policies and procedures in many hospitals and clinics are decades old and do not consider these clinical advancements. In the remainder of the article, a review of how they implemented a procedural change to comply with new national guidelines at the University of Rochester Medical Center in New York is discussed.

An article by Loi et al., (2011) on uniform collection of biospecimens from neoadjuvant breast cancer clinical trials make recommendations for standardizing breast cancer specimen collection with particular emphasis to both the type of specimens and timing of their collection with the aim of standardizing the collection of high-quality specimens that would be utilized in neoadjuvant breast cancer trials. The neoadjuvant breast cancer trials for which these recommendations for uniform breast cancer specimen collection were developed were the Breast

International Group (BIG) and the National Cancer Institute-sponsored North American Breast Cancer Group (NABCG). In addition to standardizing the process of breast cancer specimen collection for specimens associated with these breast cancer trials, the authors proposed that standardization would improve the quality of the specimens collected and would enhance and allow integration of results obtained from neoadjuvant trials done by several groups.

In an article on the genetic identification of four main types of breast cancer, the author, Park, (2012) describes a major genome study that identified four main subtypes of breast cancer, which include Luminal-A, Luminal-B, Triple Negative, Basal-Like & HER-2 Type, which exhibit different biological characteristics, behaviors, responses to treatment and clinical outcomes. These subtypes of breast cancer hold promise for the development of tests that predict response to treatment, risk of recurrence and new targeted therapies for breast cancer. The author predicts that breast cancer treatment will no longer be based on the location in the body where the cancer originated, but instead will be based on genetic characteristics of the breast cancer.

Timeline

The timeline for the Breast Cancer Specimen Collection & Handling Study began in early January, 2014 when an initial problem with issues related to timeliness was reported. An initial literature search occurred in early January, 2014 followed by interviews with surgeons, a pathologist and surgical nurses in late January & early February, 2014. A chart audit of 10 charts was also conducted in February, 2014 and the multidisciplinary team was formed and met in mid March, 2014. An intervention was planned, which was mandatory in-services for all surgical nurses. The planning and preparation for these in-services occurred from April through July, 2014, and the actual in-services were completed in the week of July 28 – 30, 2014. A plan

for follow-up occurred in November, 2014, which included planning for a second PDSA Cycle to begin in 2015. A comprehensive literature review occurred in early 2015 followed by revision of the study on January 29, 2015, which included additional criteria for measurement. The retrospective chart audit and data collection began on February 9, 2015 and was completed on April 14, 2015. Data analysis and review by the multidisciplinary, Breast Program Leadership Committee occurred between April 16 through April 24, 2015 and the findings were summarized in a report on April 29, 2015. Multidisciplinary team review occurred in May, 2015, which resulted in a planned intervention for physician education with focus on breast surgeons and pathologists. Planning for a dinner/webinar occurred from May through July, 2015, but the webinar was delayed due to difficulty in securing the expert speaker in the field of breast cancer pathology. The dinner/webinar occurred on September 29, 2015, and in November, 2015 a plan to repeat another PDSA Cycle was determined. No changes were made to the study plan for the third PDSA Cycle. Patients were selected in January, 2016 and the retrospective chart audits and data collection began on February 1, 2016 and was completed on March 15, 2016. The multidisciplinary team is scheduled to review the data on April 20, 2016. Further information on activities for each of the PDSA Cycles are included in Appendix G.

Expected Results

This Breast Cancer Specimen Collection, Handling and Adherence to ASCO/CAP Guidelines is not scheduled to end until all criteria meet the benchmark of 90% or above. It is our hope that the benchmarks will meet or exceed the 90% benchmark in all or most of the criteria when the data analysis by the multidisciplinary team on April 20, 2016. At which time, either further interventions will be planned, or a plan to formalize the process, change and

standardize the policy and procedures will occur, which will conclude the third PDSA Cycle. If all the benchmarks are met at that time, a plan for sustainability will be written.

Nursing Relevance

With the exception of nurses that work in surgical settings, nurses do not usually give a lot of thought to how surgical specimens are collected beyond using aseptic technique. However, Clinical Nurse Leaders are prepared to identify and respond to problems within their microsystem, and anywhere else their cohort of patients are provided healthcare services. A problem with the collection and handling of breast cancer specimens that had a potential to cause harm to patients was identified and confirmed. It was therefore relevant to further investigate the issue and initiate interventions to improve the process.

In the past, breast cancer treatment was based primarily on the site of origin, size of the tumor, stage and the estrogen receptor and progesterone receptor status. As more and more tests for breast cancer biomarkers, other receptors such as the human epidermal growth factor receptor family, (also known as the ErbB family or HER family) and their signal pathways that drive replication, growth and differentiation, (Arteaga & Engelman, 2014) along with genomic assays, such as Oncotype DX, MammaPrint and Mammostrat are developed, it is possible to predict which breast cancers are more likely to recur, and breast cancer treatment is becoming more individualized to treat the specific cancer itself (Breastcancer.org, 2015). In a major genome study, four subtypes of breast cancers have been identified, suggesting that instead of treating cancer based on the location in the body where they originated, treatment should be based on the genetic characteristics instead (Park, 2012). This makes the accuracy of these specific tests much more important and there is already enough evidence to show that how quickly specimens are placed in formalin and how long specimens stay in formalin can affect the results of such

tests and may cause false positive, false negative or variations in intensity of the tests if established guidelines are not followed. This makes it imperative that nurses not only understand the conditions that can affect the quality of test results, but they must also have a knowledge of the guidelines developed for breast cancer specimen collection and handling, and nurses must incorporate these guidelines into practice and the care they provide to patients.

Summary Report

AIM Statement of Project

The collection and handling of breast cancer specimens will be timely and consistent with guidelines developed by the American Society of Clinical Oncologists, (ASCO) and the College of American Pathologists, (CAP) throughout the health system.

The specific aim statement is to monitor the documentation of critical times and the process of breast cancer specimen collection and handling through PDSA Cycles with planned interventions in each cycle that will ensure compliance with ASCO/CAP Guidelines in all four surgical sites within John Muir Health by December 31, 2016. The quality indicators that will be measured include:

Documentation of the time the specimen is removed from the blood supply.

Documentation of the time the specimen is initially placed in formalin.

Whether or not the cold ischemic time could be calculated.

The calculated cold ischemic time is sixty minutes or less.

The total time the specimen remained in formalin is over six hours and less than seventy-two hours.

The benchmark for the above indicators was set at 90%, consistent with ASCO/CAP Guidelines (College of American Pathologists, 2013).

The Her-2/neu positivity rate will also be calculated to assure that the results are consistent with expected rate based on evidence, which is currently 15 – 20% (Wolf et al., 2013).

By completing the PDSA Cycles and planned interventions we will improve the process of breast cancer specimen collection and handling to be consistent with ASCO/CAP Guidelines.

Population and Setting

The population for the microsystem is adult women undergoing breast cancer screening and diagnostic services and women diagnosed with breast cancer. Since 1% of breast cancer occurs in men (ACS, 2016), occasionally men are also included in the population.

The macrosystem has two main hospitals, both with Magnet status, and both are listed by U.S. News among the top 100 hospitals in America, (2015).

The microsystem includes breast health services provided throughout the health system, which includes two Breast Health Centers, both of which are accredited through the National Accreditation Program for Breast Centers. Within the health system, there are nine breast cancer screening and diagnostic sites under the direction of Medical Imaging. These sites are certified as Breast Imaging Centers of Excellence through the American College of Radiology. Women who need diagnostic services and women that are diagnosed with breast cancer are also seen in multiple departments throughout the health system, including, but not limited to Medical Imaging, Nuclear Medicine, two inpatient surgical centers, two outpatient surgical centers two Radiation Oncology Departments, one out-patient infusion center and two inpatient oncology units. The areas of the macrosystem that were the primary focus of the Breast Cancer Specimen Collection and Handling Project were the two hospital-based surgical units, two out-patient surgical centers and the pathology department with labs at each of two hospitals.

Methods & Materials

In an effort to select cases similar to cases reviewed in the second PDSA Cycle, cases for the third PDSA Cycle were selected in the same manner as they were in the second PDSA Cycle by initially obtaining lists of patients from Cancer Registry and Medical Imaging, merging those lists and eliminating duplicates. The month of study for the third PDSA Cycle was October, 2015. After eliminating duplicates, there were fifty-seven identified cases for the third PDSA Cycle. Cases in which the surgeries were not definitive, either mastectomy or lumpectomy, were excluded. Excluded cases were surgeries for re-excision, reconstruction, axillary lymph node dissection only and one case was eliminated because no cancer was found in a mastectomy specimen following neoadjuvant chemotherapy. Fifteen of the fifty-seven cases did not meet the selection criteria and were excluded, leaving a total of forty-two cases that met the criteria for inclusion and a comprehensive chart audit. The third PDSA cycle of chart audits began on February 1, 2016 and was completed on March 15, 2016. An interval upgrade of the electronic health record made the third cycle of data collection more efficient. In addition to the data collection criteria listed below, documentation of basic patient identifiers, the day of the week the surgery was performed, the surgeon who performed the surgery and the pathologist were documented for the possible identification of patterns.

The indicators for the third PDSA Cycle were the same as the second PDSA Cycle, and included: Documentation of the time the specimen was removed from the body. Documentation of the time the specimen was initially placed in formalin. Documentation of the cold ischemic time, (the interval time in minutes between the removal from the blood supply and placement in formalin), the percentage of cases in which the cold ischemic time was under 60 minutes, and the total number of hours the specimen remained in formalin before analysis by the pathologist. The benchmark for the following criteria remained at 90%. To calculate the interval times in minutes

or hours, an application was utilized, which was timeanddate.com. In addition, the percentage of cases that were Her-2/neu positive were also calculated and compared to national averages, which is currently 15 – 20% (Wolff et al., 2013). Her-2/neu is not currently measured for in situ cases, so all stage 0, ductal carcinoma in situ cases were excluded from the Her-2/neu positivity calculation.

Third PDSA Cycle Data Analysis

There were forty-two cases of breast cancer patients that underwent definitive surgery and met the selection criteria for a comprehensive chart audit. The data collected showed that the time the specimen was removed from the body was recorded in forty of forty-two charts, or 95%. This was an improvement from 87.5% in the Second PDSA Cycle, and exceeded the benchmark of 90%.

Documentation of the time the specimen was placed in formalin was present in thirty-eight of the forty-two charts, or 90%, which met the benchmark of 90%, an improvement from 80% in the Second PDSA Cycle.

The cold ischemic time could also be calculated in thirty-eight of the forty-two charts, or 90%. This was an improvement from 82.5% in the Second PDSA Cycle, and also met the 90% benchmark.

The cold ischemic times in forty-two of forty-two cases were within sixty minutes or less, or 100%, which was an improvement from 97% in the Second PDSA Cycle.

As was the case in the Second PDSA Cycle, the actual number of hours that the specimen remained in formalin was not recorded on the pathology reports in the Third PDSA Cycle. Instead, the guideline of six to seventy-two hours is included in the pathology reports. In the Third PDSA Cycle, an upgrade in the electronic health record allowed for review of the time the

specimen was sent to pathology and the time the specimen arrived in pathology. In addition, the cold ischemic time, and the time the specimen was analyzed by the pathologist are routinely recorded within the pathology report. These times allowed us to calculate an approximate cold ischemic time and the approximate total number of hours the specimen spent in formalin when actual times were not recorded.

Out of the forty-two pathology cases, 100% were in formalin longer than six hours, but only twenty of the forty-two cases were in formalin for seventy-two hours or less, or 48%. Therefore, 52% of the cases did not meet the benchmark. The range for hours spent in formalin was from twenty-nine to one hundred and forty-four hours, and the average was eighty-two hours. In looking for patterns, no relationship between the cases that spent excess time in formalin could be associated with the assigned surgeon or the assigned pathologist. However, in looking at the days of the week in which the surgery was performed, we determined that twelve of the twenty-two cases in which the specimen spent over seventy-two hours in formalin were performed on Thursdays, accounting for 55%, and an additional five cases in which the specimen spent over seventy-two hours in formalin were performed on Fridays, or 23%. Since a total of 78% of the specimens that spent excessive time in formalin were from surgeries performed on a Thursday or Friday, we have established that surgeries that occur at the end of the week are at higher risk for over-exposure to formalin.

Lastly, we calculated the Her-2/neu positivity rate of all the invasive breast cancers. Cases of ductal carcinoma in situ (DCIS) were eliminated from this calculation, as Her-2/neu testing is not currently performed on specimens of DCIS. Out of the forty-two cases, there were six cases that had a diagnosis of ductal carcinoma in situ only. Out of the thirty-six patients who

had an invasive breast cancer, seven tested positive for Her-2/neu amplification, or 19%, which is within the range of anticipated Her-2/neu positivity of 15 – 20%. (Wolff, et al., 2013).

The data analysis results of the indicators with a 90% benchmark are depicted in a graph in Appendix H, and the Her-2/neu positivity rates are depicted in Table 3, also in Appendix H.

Evaluation

The Breast Program Leadership Committee met on April 20, 2016 at which time, the results from the data collection were analyzed. There was evidence that the interventions in the First and Second PDSA Cycles were effective in improving the performance in five out of the six indicators. The quality indicators that met the benchmark of 90% or above included:

Documentation of the time the specimen was removed from the body. Documentation of the time the specimen was initially placed in formalin. Documentation of the cold ischemic time, (the interval time in minutes between the removal from the blood supply and placement in formalin), and the percentage of cases in which the cold ischemic time was under 60 minutes. The Her-2/neu positivity rate was also calculated and compared to national averages. The national average is currently 15 – 20% (Wolff et al., 2013), and our results were 19%, which is consistent with the national average. The Breast Program Leadership Committee discussed actions to maintain the improvements made in these five indicators, which will be discussed more fully in the Plan for Sustainability.

There was one remaining indicator that had not met the 90% Benchmark. The indicator that did not meet the 90% benchmark was the total time the specimen remained in formalin. ASCO/CAP Guidelines recommend that specimens remain in formalin a minimum of six hours, and should not exceed seventy-two hours (College of American Pathologists, 2013). The Breast Program Leadership Committee reviewed the data collected on this indicator and determined that

since 100% of the specimens remained in formalin longer than six hours, under fixation of breast cancer specimens was not an issue. However, twenty-two out of forty-two specimens remained in formalin longer than seventy-two hours, which accounted for 52% of specimens. The range of hours that specimens spent in formalin was also reviewed. The range was twenty-nine to one hundred and forty-four hours, and the average was eighty-two hours. During the data analysis, a pattern was identified regarding this indicator. The day of the week in which the specimen was initially removed from the body was recorded for all specimens. When the twenty-two specimens that had spent over seventy-two hours in formalin were separated out and the days of the week on which the surgery was performed was looked at, it was found that twelve of the twenty-two cases in which the specimen spent over seventy-two hours in formalin were performed on Thursdays, accounting for 55%, and an additional five cases in which the specimen spent over seventy-two hours in formalin were performed on Fridays, or 23%. Since a total of 78% of the specimens that spent excessive time in formalin were from surgeries performed on a Thursday or Friday, we determined that surgeries that occur at the end of the week are at higher risk for over-exposure to formalin due to the fact that no pathology services are available on weekends. Work on this last remaining indicator will be continued and further planning will occur at the next Breast Program Leadership Committee Meeting in June, 2016.

Conclusion

The Breast Cancer Specimen Collection & Handling quality improvement project has so far required three PDSA cycles to reach a point where five of the six indicators have successfully met their benchmarks. Each PDSA cycle included a planning phase, a data collection phase that consisted of a retrospective chart audit, data analysis, an intervention, and additional planning before moving on to the next PDSA Cycle. Five of the six indicators will move on to the plan

for sustainability, which will be discussed in depth in the next section. The one remaining indicator that did not meet benchmark will continued to be investigated as discussed previously in the preceding section with the goal to initiate a plan for improvement by December 31, 2016.

Plan for Sustainability

Sustainability requires support from leadership but must also engage all stakeholders and employees for long term success. Regular feedback regarding the status of improvement projects is critical to sustaining quality improvement over time. In order to achieve this, there must be some form of tracking system, monitoring and reporting process and/or the improvement must be incorporated into daily operations. (Association of State and Territorial Health Officials, n.d.) With regards to the Breast Cancer Specimen Collection and Handling Project, one indicator or metric has not met the 90% benchmark and will require additional planning for improvement. The metrics or indicators that successfully met their benchmarks and require a plan for sustainability include:

Documentation of the time the specimen was removed from the blood supply. (The benchmark was 90% or above and the results of the third PDSA cycle was 95%)

Documentation of the time the specimen was initially placed in formalin. (The benchmark was 90% or above and the results of the third PDSA cycle was 90%)

Documentation of the cold ischemic time. (The benchmark was 90% or above and the results of the third PDSA cycle was 90%)

The cold ischemic (total time from excision to placement in formalin) is 60 minutes or under. (The benchmark was 90% or above and the results of the third PDSA cycle was 100%)

The Her-2 positivity rate within a range of 15 to 20%, by IHC or FISH testing. The benchmark was between 15 to 20%, which is consistent with the national rate of Her-2 positivity, and the

results for the 2nd PDSA Cycle was 15%, and the results for the 3rd PDSA Cycle was 19%, both within the expected range. (Wolff, et al., 2013)

After data analysis by the Breast Program Leadership Committee, the following recommendations were made for sustainability.

Revision of all four different policies and procedures to comply with national guidelines, preferably one policy and procedure that is acceptable to all surgical sites.

Identify at least one nursing leader at each of the four surgical sites to keep a pulse on nursing turnover, education needs and mentor new employees on proper breast cancer specimen collection and handling. These nurse leaders would also report a need for education should there be a large turnover in nursing staff or any other identified reason for nursing education.

Request the pathologist department set up a system to monitor compliance with documentation of the time the specimen is removed from the blood supply, documentation of the time it is placed in formalin, documentation of the cold ischemic time, compliance with the cold ischemic time that is 60 minutes or less, and the Her-/neu positivity rate between 15 – 20%. In addition, we would ask that the pathologist that is a member of the Breast Program Leadership Committee to report the results of monitoring these indicators to the committee every other month at each of the meetings.

Investigate whether a hard stop in the EPIC electronic health record system could be introduced that would not allow a nurse to move forward in a patient's post-surgical chart without entering the time the specimen was removed from the body, the time it was placed in formalin and the cold ischemic time.

Review of the form that accompanies the specimen to the pathology department, determine whether the documentation of the times should be entered directly into the EPIC system, and whether the form is essential or whether it can be eliminated. If the form is necessary, consider standardizing it across all four surgical sites.

For the indicators that just met the benchmark of 90%, develop a plan to monitor compliance with additional chart audits until sustainability has been confirmed by meeting or exceeding the benchmarks consistently. The number of chart audits are to be determined by the team and the results of subsequent chart audits.

References

American Cancer Society. (2016). *Breast cancer facts & figures 2015 -2016*. [Website]

Retrieved from:

<http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-046381.pdf>

American Nurses Credentialing Center. (2016) *History of the magnet program: Forces of magnetism*. Retrieved from:

<http://www.nursecredentialing.org/Magnet/ProgramOverview/HistoryoftheMagnetProgram/ForcesofMagnetism>

American Association of Colleges of Nursing. (2013). *Master's Essential and Clinical Nurse Leader Competencies*. Retrieved from [http://www.aacn.nche.edu/cnl/CNL-](http://www.aacn.nche.edu/cnl/CNL-Competencies-October-2013.pdf)

[Competencies-October-2013.pdf](http://www.aacn.nche.edu/cnl/CNL-Competencies-October-2013.pdf)

Arteaga, C.L. & Engelman, J.A. (2014). ERBB receptors: From oncogene discovery to basic science to mechanism-based cancer therapeutics. *Cancer cell*. 2014 Mar 17;25(3):282-303. doi: 10.1016/j.ccr.2014.02.025. Retrieved from:

<http://www.ncbi.nlm.nih.gov/pubmed/24651011>

Breastcancer.org. (2015) *Genomic assays: Oncotype DX, mammaprint & mammostrat*.

Website. Retrieved from:

http://www.breastcancer.org/symptoms/diagnosis/genomic_assays

College of American Pathologists (CAP). (2013). Summary of ASCO/CAP ER and PgR Guideline Recommendations. Retrieved from:

http://www.cap.org/apps/docs/laboratory_accreditation/summary_of_recommendations.

Hammond, M.E., Hayes, D.F., Dowsett, M., Allred, D.C., Hagerty, K.L., Badve, S., ... Wolff,

A.C., et al. (2010). American Society of Clinical Oncologists/College of American Pathologists guideline recommendations for immunohistochemical testing of estrogen and progesterone receptors in breast cancer. *Arch Pathol Lab Med.*2010;134:907-922
Retrieved from:

http://www.cap.org/apps/docs/laboratory_accreditation/summary_of_recommendations.

Harris, J., Roussel, L., Thomas, P. *Initiating and sustaining the clinical nurse leader role.*

Jones and Bartlett, Sudbury, MA; 2014, pp. 493-494.

Harris, L.N., Ismaila, N., McShane, L.M., Andre, F., Collyar, D.E., Gonzalez-Angulo, A.M., ...

Hayes, D.F. (2016). *Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early stage invasive breast cancer: American society of clinical*

oncology clinical practice guideline. Published online before print February 8, 2016,

doi: 10.1200/JCO.2015.65.2289. Retrieved from: [http://www.instituteforquality.org/use-](http://www.instituteforquality.org/use-biomarkers-guide-decisions-adjuvant-systemic-therapy-women-early-stage-invasive-breast-cancer)

[biomarkers-guide-decisions-adjuvant-systemic-therapy-women-early-stage-invasive-breast-cancer](http://www.instituteforquality.org/use-biomarkers-guide-decisions-adjuvant-systemic-therapy-women-early-stage-invasive-breast-cancer)

Hicks, D.G., Kushner, L.A., & McCarthy, K. (2011). *Breast cancer predictive factor testing:*

The challenges and importance of standardized tissue handling. *Journal of the national*

cancer institute. ISSN: 1745-6612, 2011; Vol.2011 (42), pp. 43-5. PMID: 21672896.

Retrieved from: <http://jncimono.oxfordjournals.org/content/2011/42/43.long>

Hicks, D.G. & Schiffhauer, L. (2011). *Standardized assessment of the HER2 status in breast*

cancer by immunohistochemistry. *Lab Med.* 2011;42:259-467. Retrieved from:

<http://labmed.oxfordjournals.org/content/42/8/459>

- Hicks, D.G. (2014). *Standardization of tissue handling from the OR to the laboratory*. AORN Journal, 2014; 99(6): 810-813. 4p. ISSN: 0001-2092 PMID: 24875214. Retrieved from: [http://www.aornjournal.org/article/S0001-2092\(14\)00306-8/pdf](http://www.aornjournal.org/article/S0001-2092(14)00306-8/pdf)
- Institute for Healthcare, (IHI). (2015) *Failure Modes and Effects Analysis Tool: Breast Cancer Specimen Collection & Handling Study*. Retrieved from: <http://app.ihl.org/Workspace/tools/fmea/ProcessDetailDataReport.aspx?ToolId=19543&ScenarioId=21483&Type=1>
- Loi, S., Symmans, W.F., Bartlett, J.M., Fumagalli, D., Van't Veer, L., Forbes, J.F., ... Esserman, L. (2011). *Proposals for uniform collection of biospecimens from neoadjuvant breast cancer clinical trials: Timing and specimen types*. Lancet Oncology, Nov2011; 12(12): 1162-1168. Retrieved from: [http://www.thelancet.com/journals/lanonc/article/PIIS1473-0245\(11\)70117-6](http://www.thelancet.com/journals/lanonc/article/PIIS1473-0245(11)70117-6)
- Nursing Theory (2015). *Lewin's change theory*. Retrieved from: <http://www.nursing-theory.org/theories-and-models/Lewin-Change-Theory.php>
- Occupational Safety & Health Administration (OSHA). (2016). Formalin Standard 29 CFR 1910.1048. Retrieved from: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10075&p_table=STANDARDS
- Park, A. (2012). *Genetic study identifies four main types of breast cancer*. Time. Retrieved from: <http://healthland.time.com/2012/09/24/genetic-study-identifies-four-main-types-of-breast-cancer/>
- Perez, E.A., Cortes, J., Gonzalez-Angulo, A.M. & Bartlett, J.M. (2014). *Laboratory clinic interface: HER2 testing: Current status and future directions*. Cancer treatment

reviews. March, 2014 40(2):276-284. Retrieved from:

<http://www.sciencedirect.com/science/article/pii/S0305737213001904>

Potts, S., Krueger, J., Landis, N., Eberhard, D., Young, G., Schmechel, S. & Lange, H. (2012).

Evaluating tumor heterogeneity in immunohistochemistry-stained breast cancer tissue.

Lab Invest. 2012;92(9):1342-1357. Doi:10.1038/labinvest.2012.91. Retrieved from:

<http://www.ncbi.nlm.nih.gov/pubmed/22801299>

Robb, J.A., Gulley, M.L., Fitzgibbons, P.L., Kennedy, M.F., Cosentino, L.M., Washington, K.,

... Lapham, R.L. (2014). *A call to standardize preanalytic data elements for*

biospecimens. Archives of pathology & laboratory medicine. Apr2014; 138(4): 525-37.

Retrieved from: [https://www.archivesofpathology.org/doi10.5858/arpa.2013-0250-](https://www.archivesofpathology.org/doi10.5858/arpa.2013-0250-CP?url_ver=Z39.88-2003&rfr_id+ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed)

[CP?url_ver=Z39.88-2003&rfr_id+ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed.](https://www.archivesofpathology.org/doi10.5858/arpa.2013-0250-CP?url_ver=Z39.88-2003&rfr_id+ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed)

Robb, J.A, Bry, L., Sluss, P.M., Wagar, E.A., & Kennedy, M.F. (2015). *A call to standardize*

preanalytic data elements for biospecimens, part II. Archives of pathology & laboratory

medicine, Sep;139(9): 1125-1128, 4p. Retrieved from:

[http://www.archivesofpathology.org/doi/10.5858/arpa/2014-0572-CP?url_ver=Z29.99-](http://www.archivesofpathology.org/doi/10.5858/arpa/2014-0572-CP?url_ver=Z29.99-2003&rfr_id=ori:rid:crossref.org&rfr_dat+cr_pub%3dpubmed)

[2003&rfr_id=ori:rid:crossref.org&rfr_dat+cr_pub%3dpubmed](http://www.archivesofpathology.org/doi/10.5858/arpa/2014-0572-CP?url_ver=Z29.99-2003&rfr_id=ori:rid:crossref.org&rfr_dat+cr_pub%3dpubmed)

Sapino, A., Goia, M., Recupero, D. & Marchio, C. (2013). *Current challenges for HER2 testing*

in diagnostic pathology: State of the art and controversial issues. Front Oncol.

2013;3:129. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/23734345>

U.S. News. (2015). *U.S. news & world report: U.S. news best hospitals 2015 – 2016.* Retrieved

from: <http://health.usnews.com/best->

[hospitals/search?hospital_name=John+Muir+Medical+Center&city=&distance=25](http://health.usnews.com/best-hospitals/search?hospital_name=John+Muir+Medical+Center&city=&distance=25)

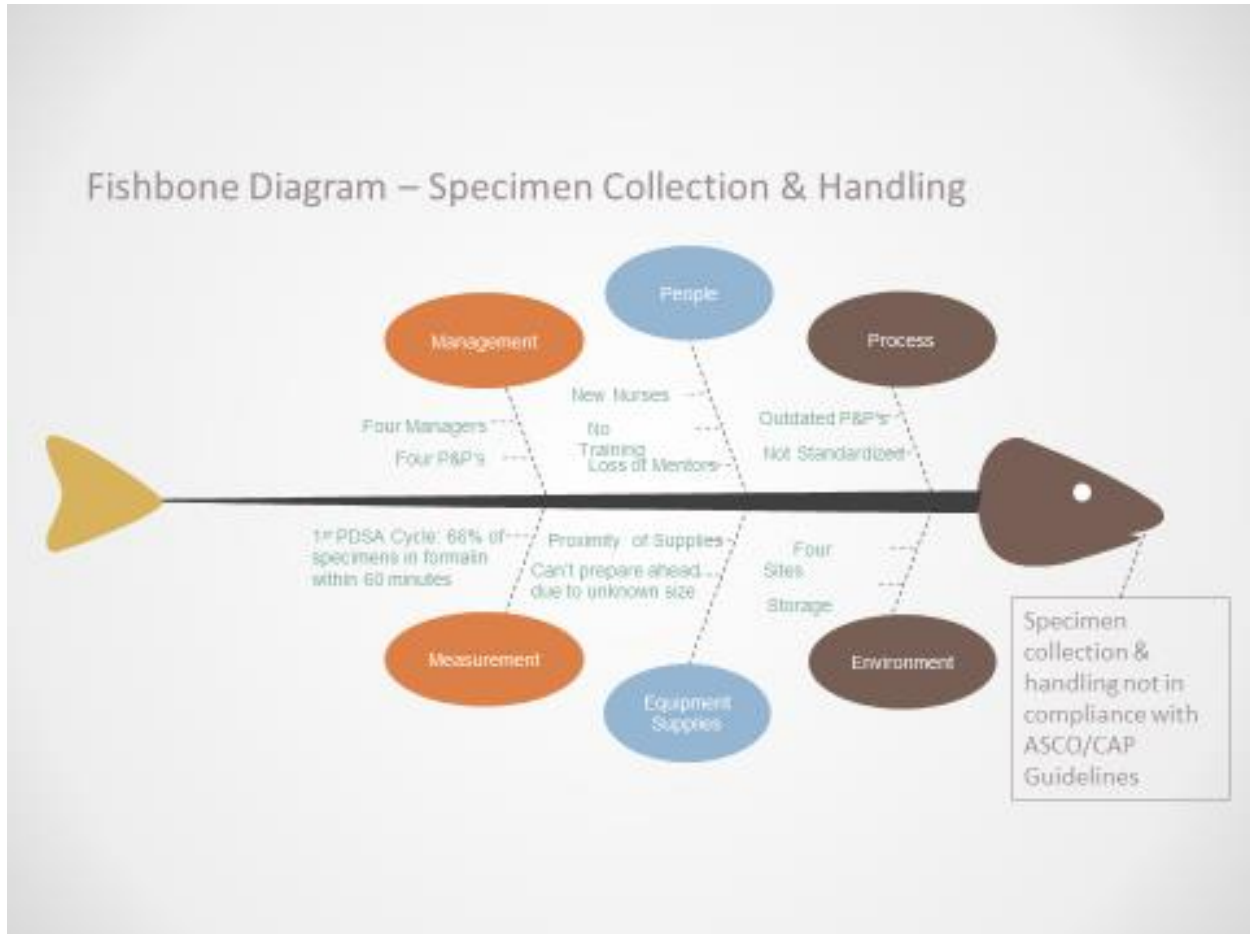
- Van Wicklin, S. (2015). *Back to basics: Specimen management*. Association of perioperative registered nurses journal, May2015; 101(5): 558-565. 8p. ISSN: 0001-2092: PMID: 25946181. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/25946181>
- Varga, Z., Noske, A., Ramach, C., Padberg, B. & Moch, H. (2013). *Assessment of HER2 status in breast cancer: Overall positivity rate and accuracy by fluorescence in situ hybridization and immunohistochemistry in a single institution over 12 years: A quality control study*. BMC Cancer. 2013;13:615. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/24377754>
- Volmer, K.E., Idowu, M.O., Souers, R.J. & Nakhleh, R.E. (2015). *Molecular testing in anatomic pathology and adherence to guidelines*. Archives of pathology & laboratory medicine. Sep2015; 139(9): 1115-1124. 10p. ISSN: 0003-9985 PMID: 26317453. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/26317453>
- Volmar, K.E., Idowu, M.O., Souers, R.J., Karcher, D.S. & Nakhleh, R.E. (2015). *Turnaround time for large or complex specimens in surgical pathology*. Archives of pathology & laboratory medicine. Feb2015; 139(2): 171-177. 7p. ISSN: 0003-9985 PMID: 25611100. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/25611100>
- Wolff, A.C., Hammond, M.E., Hicks, D.G., Dowsett, M., McShane, L.M., Allison, K.H., ... Hayes, D.F. (2013). *Recommendations for Human epidermal growth factor receptor 2 testing in breast cancer: American society of clinical oncology/college of american pathologists clinical practice guideline update*. Journal of clinical oncology. Retrieved from: <http://jco.ascopubs.org/content/31/31/2997.full.pdf>
- Yildiz-Aktas, I.Z., Dabbs, D.J., & Bhargava, R. (2012). *The effect of cold ischemic time on the immunohistochemical evaluation of estrogen receptor, progesterone receptor, and HER2*

expression in invasive breast carcinoma. Modern Pathology. 2012;25:1098-1105.

Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/22460807>

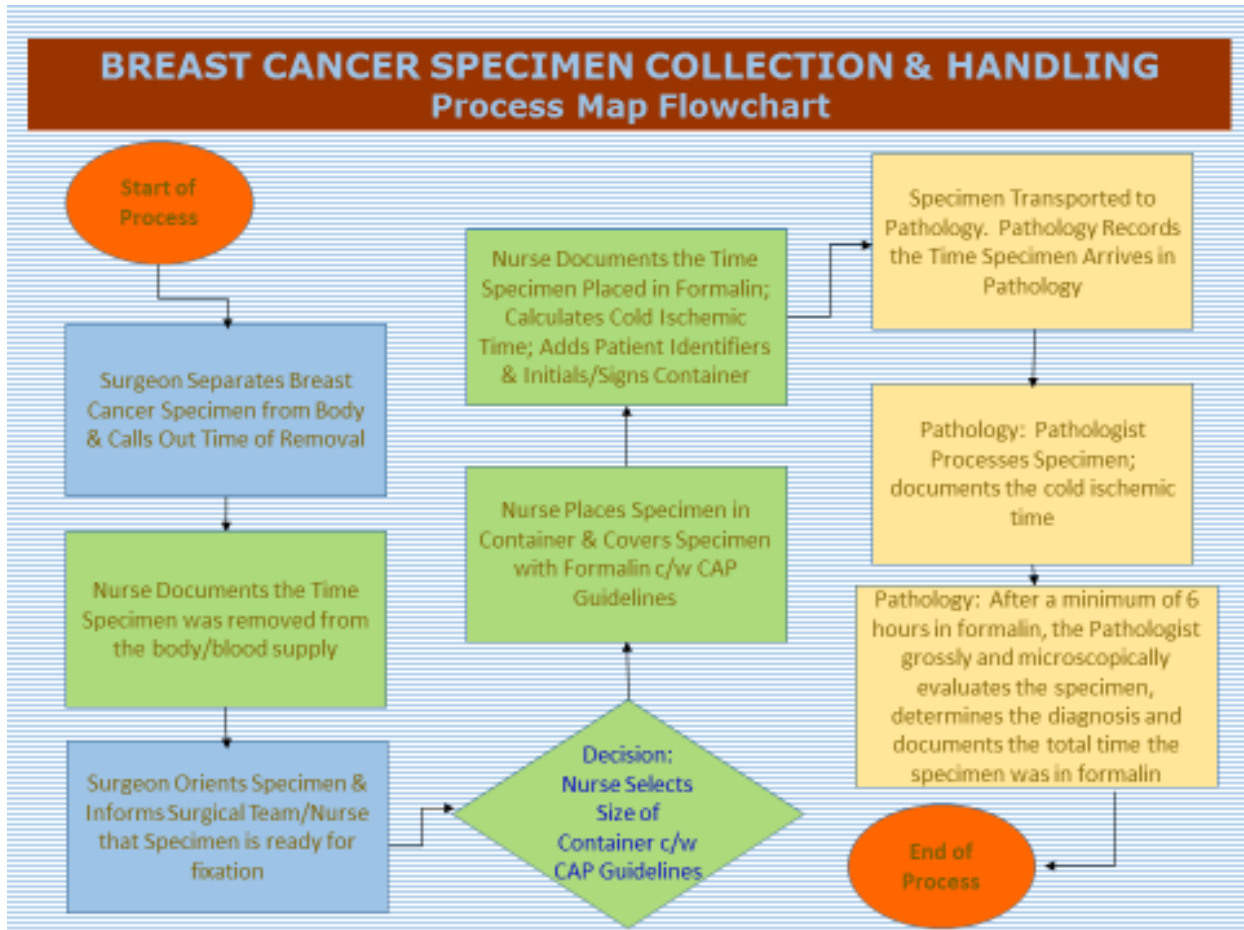
Appendix A

Cause and Effect: Fishbone Diagram



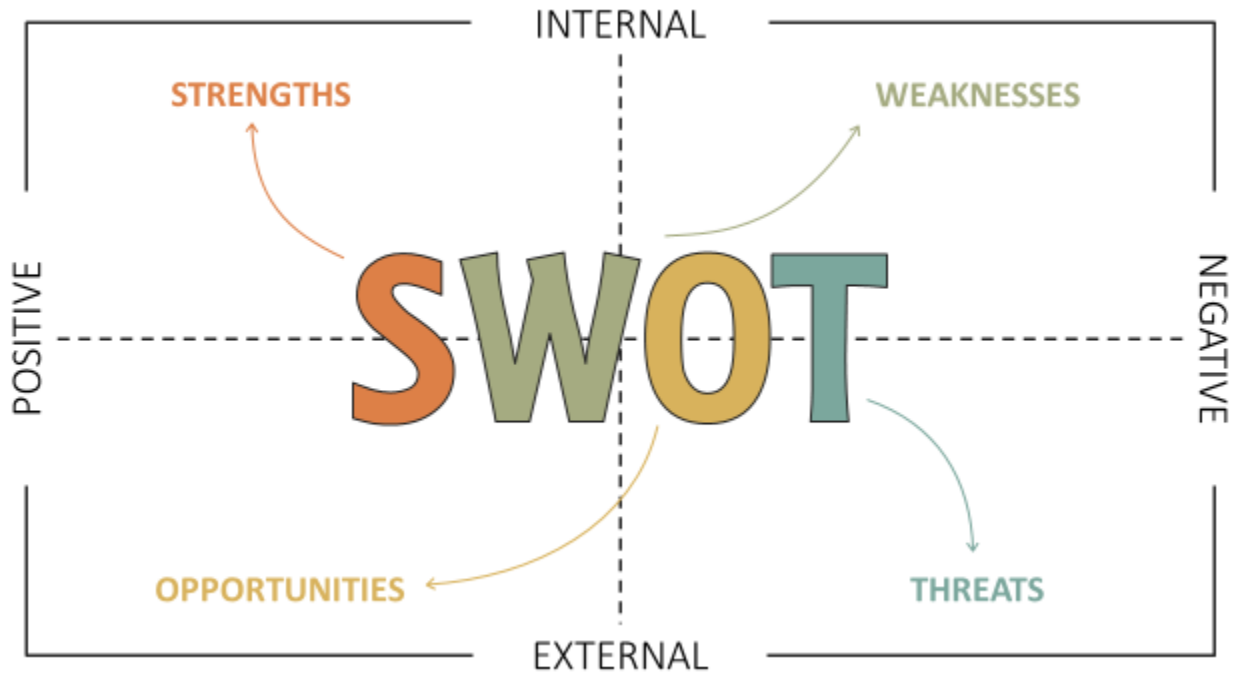
Appendix B

Process Map Flowchart



Appendix C

SWOT Analysis







	INTERNAL	
STRENGTHS		WEAKNESSES
<ul style="list-style-type: none"> • High Volume • Administrative Support • Multidisciplinary Participation • Improved Efficiency • Cost Savings • Standardizes Process for Health System 	<ul style="list-style-type: none"> • Four Sites with different Management • Resistance to Change • High Percentage of New Nurses • Frequent Turnover in Outpatient Sites • Access to Supplies Sub-optimal • Sustaining Change 	NEGATIVE
POSITIVE		
<ul style="list-style-type: none"> • Document Times in EHR • Create Hard Stop in EHR • Identify Champion/Nurse Leaders at each Surgery Site • Update P&P's (Evidence-Based) • Standardize P&P's throughout System 	<ul style="list-style-type: none"> • Develop a Standardized Process that Works Well at each Site • Workarounds • Knowledge Deficit • Process Drift Back to Non-compliance • Surgeon Buy-In 	
NEGATIVE		
OPPORTUNITIES	EXTERNAL	THREATS

Appendix D

Stakeholder Analysis

Stakeholder Analysis

	Stakeholder: Patients <ul style="list-style-type: none">• Impact of Change on Patient: Significant• Impact of Stakeholder on Change: None
	Stakeholder: Surgeons <ul style="list-style-type: none">• Impact of Change on Surgeons: Minimal• Impact of Stakeholder on Change: Significant
	Stakeholder: Surgical Nurses <ul style="list-style-type: none">• Impact of Change on Nurses: Moderate• Impact of Stakeholder on Change: Significant
	Stakeholder: Pathologists <ul style="list-style-type: none">• Impact of Change on Pathologists: Significant• Impact of Stakeholder on Change: Significant

Appendix E

Failure Modes and Effects Analysis (FMEA)

Link to: Failure Modes and Effects Analysis Tool: Breast Cancer Specimen Collection & Handling Study.

<http://app.ihl.org/Workspace/tools/fmea/ProcessDetailDataReport.aspx?ToolId=19543&ScenarioId=21483&Type=1>

Appendix F

Projected Cost Analysis & Cost Benefits Analysis

Table 1.

John Muir Health - Breast Cancer Specimen Collection & Handling CQI Study - Anticipated Costs						
Description	Unit Cost	Multiplier	PDSA Cycle 1 2014	PDSA Cycle 2 2015	PDSA Cycle 3 2016	Total
Variable Costs						
Labor Costs per Core Team Meeting	525.00	6 per cycle	3,150.00	3,150.00	3,150.00	9,450.00
Labor Costs per Multi-disciplinary Team Meeting	1650.00	2 per cycle	3,300.00	3,300.00	3,300.00	9,900.00
Paid Time Mandatory Nursing In-services (Avg)	65.00	86	5,590.00	0.00	0.00	5,590.00
Paid Nurse Time - Chart Audits & Coordination	75.00	92	2,100.00	2,550.00	2,250.00	6,900.00
Catering/Refreshments			550.00	0.00	0.00	550.00
Second Intervention Physician & Team Webinar	Sponsored		0.00	0.00	0.00	0.00
Office Supplies			75.00	150.00	75.00	300.00
Software/Applications			50.00	0.00	150.00	200.00
Total Variable Costs			14,815.00	9,150.00	8,925.00	32,890.00
Description	Unit Cost	Multiplier			Anticipated Savings - 2016	Total
Anticipated Cost Savings Resulting from Project						
IHC Testing for Estrogen Receptors	167.00	400			66,800.00	66,800.00
IHC Testing for Progesterone Receptors	168.00	400			67,200.00	67,200.00
IHC Testing for HER-2/neu Receptor Amplification	167.00	400			66,800.00	66,800.00
FISH Testing for HER-2/neu Receptor Amplification	375.00	100			37,750.00	37,750.00
Total Anticipated Savings						238,550.00
Cost Benefit Analysis: Savings - Costs = Anticipated Cost Benefit						238,550.00 - 32,890.00 =
						205,660.00

Appendix G

Table 2

Breast Cancer Specimen Collection & Handling Tasks, Dates & Responsible Person/Team					
Task Name	Start Date	End Date	Responsible Person/Team	Duration	Percentage
Section 1 - Initial Identification of Problem	01/06/14	01/29/14		18d	100%
Sub-task 1 - Complaint from Surgeon Received	01/06/14	01/06/14	Medical Director	1d	100%
Sub-task 2 - Initial Literature Search	01/07/14	01/14/14	Nurse Navigator	6d	100%
Sub-task 2 - CEBOBS Presentation - Referenced National Guidelines & Issues with False Positives/False Negatives	01/22/14	01/22/14	Nurse Navigator	1d	100%
Sub-task 3 - Incident in 1 of 4 Surgery Sites: Specimen not placed in Formalin. Left in surgery from Friday - Monday	01/27/14	01/29/14	Core Team	3d	100%
Section 2 - Verification of Problem with Specimen Collection & Handling	01/27/14	02/19/14		18d	100%
Sub-task 1 - Interviews with Breast Surgeons & Lead Pathologist	01/27/14	01/31/14	Medical Director	5d	100%
Sub-task 2 - Interviews with Surgical Nurses	02/03/14	02/07/14	Nurse Navigator	5d	100%
Sub-task 3 - Initial Chart Audit - 10 Charts of Breast CA patients	02/10/14	02/19/14	Nurse Navigator	8d	100%
Section 3 - First PDSA Cycle	03/03/14	12/22/14		211d	100%
Sub-task 1 - Multidisciplinary Team Formation	03/03/14	03/19/14	Core Team	13d	100%
Sub-task 2 - Multidisciplinary Team Meeting	03/19/14	03/19/14	Multi disciplinary Team	1d	100%
Sub-task 3 - Multidisciplinary Review & Planning	03/19/14	03/19/14	Multi disciplinary	1d	100%
Sub-task 4 - Intervention: Mandatory Education for Surgical Nurses Planning	03/31/14	07/07/14	Nurse Navigator	71d	100%
Sub-task 5 - Mandatory In-services for Surgical Nurses x 5	07/28/14	07/31/14	Genentech AOCN RN	4d	100%
Sub-Task 6 - Re-evaluation Plan for 2nd PDSA Cycle	08/04/14	12/22/14	Multi disciplinary Team	101d	100%
Section 4 - Second PDSA Cycle	01/05/15	11/16/15		226d	100%
Sub-Task 1 - Collected Lists of Patient for Chart Audit	01/05/15	01/19/15	Nurse Navigator	11d	100%
Sub-task 2 - Revision of Study, Additional Criteria	01/29/15	01/29/15	Core Team	1d	100%
Sub-task 3 - Retrospective Chart Audit & Data Collection	02/09/15	04/14/15	Nurse Navigator	47d	100%
Sub-task 4 - Initial Data Analysis & Identification of Trends	04/14/15	04/16/15	Nurse Navigator	3d	100%
Sub-task 5 - Comprehensive Data Analysis by Multidisciplinary Team	04/16/15	04/24/15	Multi disciplinary Team	7d	100%
Sub-task 6 - Intervention & 3rd PDSA Cycle Planning	05/20/15	07/29/15	Core Team	51d	100%
Sub-task 7 - Intervention: Physician & Team Webinar & Discussion/Expert Pathologist David G. Hicks, M.D.	09/29/15	09/29/15	Nurse Navigator	1d	100%
Sub-task 8 - Re-evaluation & Plan for 3rd PDSA Cycle	11/16/15	11/16/15	Core Team	1d	100%
Section 5 - Third PDSA Cycle	01/18/16	04/20/16		68d	
Sub-task 1 - Collected Lists of Patient for Chart Audit	01/18/16	01/20/16	Nurse Navigator	3d	100%
Sub-task 2 - Retrospective Chart Audit & Data Collection	02/01/16	03/15/16	Nurse Navigator	32d	100%
Sub-task 4 - Comprehensive Data Analysis by Multidisciplinary Team	04/20/16	04/20/16	Multi disciplinary Team	1d	0%
Section 6 - Study Completion & Plan for Follow-up (If all criteria => 90%)	04/20/16	05/31/16		30d	

Appendix H
Data Analysis Results

Breast Cancer Specimen Collection & Handling Study
Retrospective Chart Audit Data

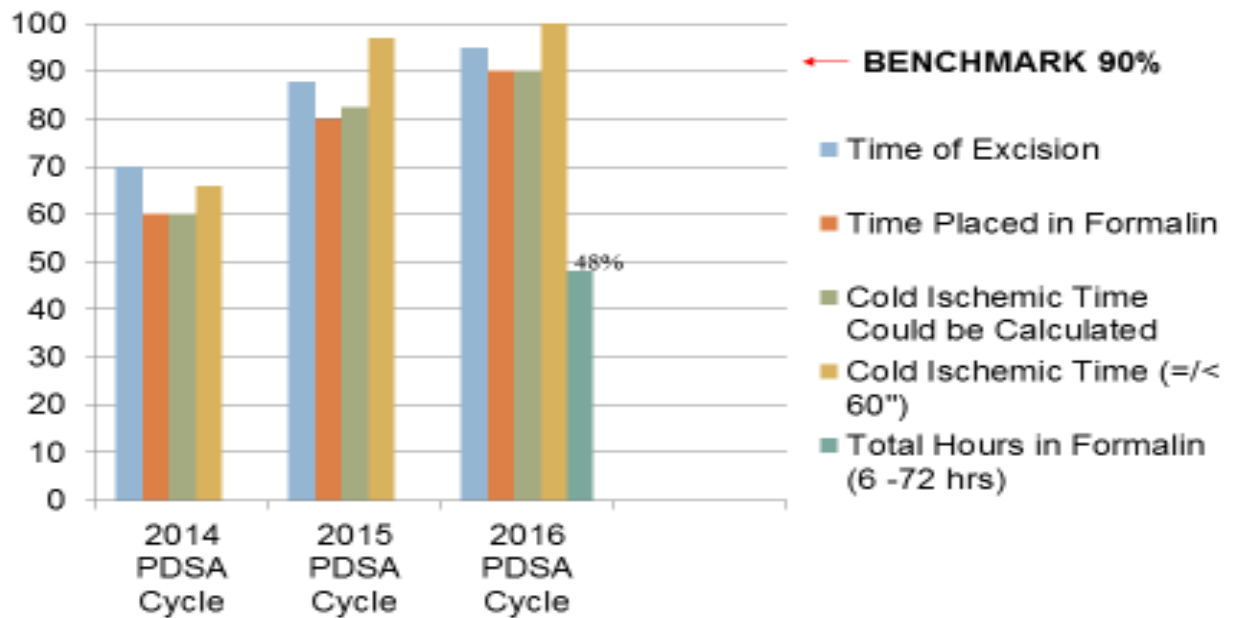


Table 3

Percentage of invasive carcinoma specimens that are Her-2/neu Amplified		
2014	2015	2016
1st PDSA Cycle	2nd PDSA Cycle	3rd PDSA Cycle
n/a	5/33 15%	7/36 19%

Benchmark: Rate of Her-2 Positivity 15 - 20% (Wolff, et al., 2013)