PROCESS IMPROVEMENT IN LABORATORY MEDICINE

FOR PATIENT SATISFACTION

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ABSTRACT

In today's health care reformation, called ObamaCare, patient satisfaction plays a prominent role. When facing the increased demand for quality patient care and safety, quality medical service must be improved in various ways by medical professionals and ancillary staff, including clinical laboratory personnel. From the perspective of laboratory medicine, patient satisfaction can be achieved by consistently delivering accurate and reliable laboratory results in a timely manner. This study examines the correlation between patient satisfaction and laboratory personnel job satisfaction levels. Process observation by utilizing root cause analysis and Lean tools is used to investigate whether implemented process improvements promote the efficiency of laboratory service. Statistical data analysis is used to draw conclusions on whether the implemented process improvement has a significant impact on employee and patient satisfaction. This thesis highlights the importance of maintaining continuous process improvement over an extended period of time to achieve and sustain patient satisfaction.

CHAPTER 1

INTRODUCTION

Background

The quality of health care in the United States (U.S.) changed significantly during the past century. After the Civil War, the federal government became involved in health care; presidential administrations also played a key role in health care reformation, although many of them were unsuccessful. Both the Truman administration in 1945 and the Kennedy administration in 1961 attempted health care reformation, but both had a very limited impact on society. The Johnson administration then successfully created and implemented the Medicare and Medicaid systems in 1965 (Daemmrich, 2011).

One of the examples of the government's involvement was through the Veterans Administration (VA), which provided medical, surgical, and rehabilitative care to veterans. In the mid-1990s the VA was known as the single largest health care provider in the nation–serving 1.1 million hospital admissions and 24 million outpatients per year (Daemmrich, 2011). However, the VA was criticized for low quality and expensive care, and it was not until a few years later (between 1995 and 1999) that the VA underwent a major transformation to improve the quality and timeliness of care. The VA was able to accomplish this by upgrading its facilities and introducing electronic patient medical records (Kizer & Dudley, 2009).

In 2013, the current health care reformation under the Obama administration, the Patient Protection and the Affordable Care Act (also known as ObamaCare), was initiated.

Based on Obamacarefacts (obamacarefacts.com), one of the key elements in the Obama Health Care Plan was focusing on quality of patient care as follows (2013):

> ObamaCare's new Medicare Value-based Purchasing Program means hospitals can lose or gain up to 1% of Medicare funding based on a quality vs. quantity system. Hospitals are graded on a number of quality measures related to treatment of patients with heart attacks, heart failures, pneumonia, certain surgical issues, re-admittance rate, as well as patient satisfaction. (p. 8)

Patient satisfaction is rated on the performance of the entire hospital. With this approach, the care given in each department of a patient care facility impacts patients' perceptions of the overall care received. This global perception includes those departments having no direct interaction with patients such as laboratory medicine. However, the first step to improving this aspect of health care quality in the laboratory is to shift the focus from specimens to patients (Otto & Pendergraph, 2013). Even though they have no visible or direct contact with patients on a daily basis, laboratory personnel delivering laboratory service to clinicians, surgeons, pathologists, and other health care providers have no less impact than those interacting with patients. Every specimen being received in a laboratory represents every patient's safety and well-being; therefore, it is essential for laboratory technologists to have the mindset of "patient care first" and handle each sample as if they are taking care of patients directly.

From the perspective of laboratory medicine, patient satisfaction can be achieved by consistently delivering accurate and reliable laboratory results in a timely manner. The main objectives are to reduce medical errors, increase laboratory productivity and efficiency, and, at the same time, decrease the turnaround time (TAT) of laboratory test reports.

Statement of the Problem

It was important to examine the internal quality of the laboratory and to properly implement a process improvement (PI) project. This study evaluated how the implementation of a laboratory PI project impacted the internal quality of laboratory personnel, the laboratory process workflow, and the organizational culture.

Over a three-year period, the writer as the researcher for the laboratory that is the focus of this study identified the PI project in a histology laboratory, using proven root cause analysis (RCA) and Lean tools to improve patient care and employee satisfaction. The sub-problems were: (1) to determine the current process workflow and its preexisting PI project, (2) to assess and study how the implemented PI impacted the efficiency of the workflow processes, and (3) to analyze employee job satisfaction levels, based on the data collected from an annual employee culture survey. The survey was conducted in both the year prior to and the year immediately after the PI project was implemented.

Purpose of the Study

In a continuation of correlation studies between customer satisfaction and employee satisfaction, this study explored the connection between the job satisfaction level of laboratory personnel and laboratory PI and patient satisfaction. In prioritizing patient care and safety, the key element was to start with how laboratory personnel perceive their work duties.

Furthermore, this study focused on how laboratory PI impacted employee and patient satisfaction by evaluating the effectiveness of the PI project in the histology laboratory and analyzing laboratory personnel job satisfaction levels, based on the implemented PI project. In summary, this thesis examined the following three levels of internal quality:

- Level One: Performer, Job, or Task-design. This level focused on the quality of laboratory personnel and how changes made through process improvement influenced laboratory personnel's productivity and efficiency.
- Level Two: Process. This level evaluated how laboratory personnel's engagement related to better and effective workflow.
- Level Three: Organizational. This level studied the significance of creating a desirable work environment that was fear-free and motivating.

Theoretical Bases and Organization

Customer satisfaction is believed to start from employees who are satisfied with their jobs. When they are content with their work, they perform better, thus satisfying more customers. Studies show that higher employee job satisfaction leads to higher customer satisfaction; in the same manner, lower employee job satisfaction causes lower customer satisfaction (Evan & Lindsay, 2012).

Benjamin Schneider and David Bowen, in their studies, also conclude that there is a significant relationship between employee and customer satisfaction. Their report emphasizes the "satisfaction mirror" principle. More familiarity with customers' requirements and expectations and greater opportunity to resolve issues lead to higher productivity and better quality outcomes; therefore, employee satisfaction when achieved reflects customers' satisfaction as demonstrated in Figure 1.

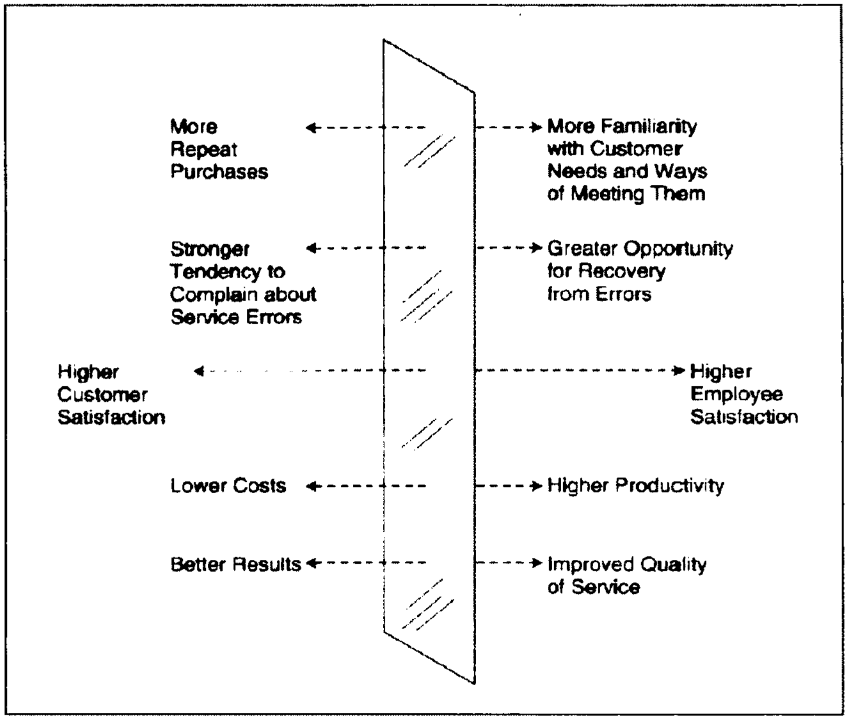


Figure 1. Satisfaction "mirror." Adapted from "The Service Profit Chain: How Leading Companies Link Profit and Growth to Loyalty, Satisfaction, and Value," by Heskett, Sasser, and Schlesinger, 1997.

Johnson and Gustafsson (2000), in *Improving Customer Satisfaction, Loyalty, and Profit,* state that employee attitudes toward their jobs and the company directly influence their behavior and retention. In return, employee behavior relates to the perceptions of customers and consequently impacts end-customer satisfaction. When health care providers are content with their work, they perform better. Therefore, to achieve better patient satisfaction in the laboratory, it is essential to achieve laboratory personnel satisfaction first.

Limitations

This study was based on the observation of a representative of hospital laboratory medicine. The result of this study was restricted to clinical laboratory testing only, particularly the histology laboratory. Internal quality evaluation and laboratory PI proposed in this thesis were in accordance with the employee's observation of clinical testing. The details were based on a condition of the normal range of workload with no staff shortage issues.

Furthermore, with the location of the laboratory inside the hospital, the work processes were directly associated with pathologists requesting the clinical testing and clinicians, physicians, or surgeons working closely with pathologists. Since patient satisfaction was based on the overall rating of the hospital, the satisfaction level was not solely dependent on the good work of one department such as the laboratory; in fact, the collaboration of various departments was required. This study specified the collaboration within laboratory medicine in itself without looking at all the other departments.

Definition of Terms

Five Whys: By asking "why" five times, this problem-solving tool identifies the root cause of a problem encountered and shows the relationship between causes.

Ishikawa or Fishbone Diagram: This is a cause-and-effect diagram used to organize and categorize various possible causes about a problem.

Just-in-Time (JIT): This is a Lean flow management system that is used for producing and delivering the right items at the right time in the right amount.

Kaikaku: This Lean terminology refers to radical improvement to eliminate waste in pursuing perfection.

Kaizen: This is Lean terminology for continual improvement to eliminate waste in pursuing perfection.

Muda: This Lean terminology refers to any resource-consumed activity that creates no value.

Process Improvement (PI): Process improvement is the streamlining of the laboratory workflow, utilizing *kaikaku* and *kaizen* projects.

Root Cause Analysis (RCA): This problem-solving tool is used to investigate the underlying factors causing adverse events.

Sentinel Event: This term refers to an unexpected incident involving death or serious physical or psychological injury not caused by a patient's illness.

Sort, Straighten, Shine, Standardize, and Sustain (5S): This is a Lean organizational method used for continuous improvement.

Supplier-Input-Product-Output-Customer (SIPOC): This term refers to the summary of a cross-function set of activities within a single diagram.

CHAPTER 2

REVIEW OF RELATED LITERATURE

Sources

A literature review was conducted by utilizing various resources, including articles, textbooks, and presentations. The selected resources reviewed provided a basis of understanding for: (1) patient satisfaction and quality, (2) patient satisfaction and medical errors, (3) patient satisfaction and contributing factors, (4) root cause analysis in a laboratory, and (5) Lean methodology applications in a laboratory.

Patient Satisfaction and Quality

In *Out of the Crisis*, W. Edwards Deming (1900-1993), also known as the father of quality, defines quality in terms of a chain reaction (1986). When quality improves, it lowers costs, far less rework is required, and fewer mistakes and delays occur, allowing for more efficient use of time and resources. As a result, improved quality increases productivity, making employees take pride in their work (Deming, 1986). Another profound quality expert, Joseph Juran (1904-2008), elaborates on the definition of quality to offer: (1) products impacting sales and market share while consequently increasing customer satisfaction and (2) freedom from deficiencies, for increased quality enables a reduction in error rates, rework, and ultimately customer dissatisfaction. In short, Juran uses a simple phrase "fitness for use" to define quality (1992).

Based on definitions of quality by Deming (1986) and Juran (1992), it is believed that the main focus for reaching the best possible quality product and service should be on two sets of people–the employees who take pride in performing their work and the customers whose requirements and expectations are to be met. In the health care setting, improved quality is not primarily concerned with gaining a competitive edge; rather, the primary concern is patient safety.

There are two key elements associated with patient satisfaction: medical errors and patient safety (Institute of Medicine [IOM], 1999). The lower number of errors and the higher quality of care patients receive, such as accurate and reliable test results, lead to higher patient satisfaction levels. Quality patient care must be implemented by all health care providers at all levels, including those who have direct contact with patients, such as physicians and nurses, and those who have indirect contact, such as laboratory personnel.

Medical Errors

The first element impacting patient satisfaction is medical error. Error is defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (IOM, 1999, p. 54). There are two types of errors: (1) an error in execution where the correct action does not proceed as intended and (2) an error in planning where the original intended action is not correct. Errors can occur in all stages of patient-care delivery from diagnosis to treatment and preventive care.

Patient Safety

The second element impacting patient satisfaction is patient safety. Patient safety is defined as "freedom from accidental injury; this definition recognizes that this is the primary safety goal from the patient's perspective" (IOM, 1999, p. 58). The most effective way to promote a patient-care-first culture is by developing a system designed to be proactive in detecting and preventing errors as opposed to reactive systems focused on errors that already have happened. It is critical, therefore, to prevent future errors or recurrence of errors by incorporating safety into the medical system at all levels (IOM, 1999).

Patient Satisfaction and Medical Errors

In 1999, the Institute of Medicine (IOM) released a report "To Err is Human: Building a Safer Health System." This article showed surprisingly high mortality rates due to medical errors in hospitals within the U.S. with as many as 98,000 people dying each year (IOM, 1999). This article attributed medical errors as the eighth leading cause of death in 1999. The mortality number caused by medical errors was higher than motor vehicle accidents (43,458) or diseases such as breast cancer (42,297) and AIDS (16,516). This report became a wake-up call for all health care providers and their ancillaries to provide safer health care.

A related report "How Many Die from Medical Mistakes in U.S. Hospitals?" estimates that medical errors in the U.S. contributed "to the deaths of 180,000 patients in Medicare alone in 2010" (Allen & ProPublica, 2013, p. 1). In addition, based on current studies issued by the current *Journal of Patient Safety*, it is estimated that the number of patient deaths due to medical errors may be between 210,000 and 440,000 annually by 2014 (James, 2013). This figure is more than double the initial figures reported in "To Err is Human" by the IOM in 1999. This approximation is based on four studies that reviewed the medical records of more than 4,200 patients hospitalized between 2002 and

2008. The statistics highlighted in "A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care" demonstrate that the increased number of patient deaths reported demands an increased awareness to improve health care quality by reducing medical errors.

In response to "To Err is Human," the IOM published "Crossing the Quality Chasm: A New Health System for the 21st Century," prepared by the IOM's Committee on Quality of Health Care in America (2001). This document describes strategies to improve the delivery of health care service through six aims:

1. Safety: "Avoids injuries to patients from the care that is intended to help them" (IOM, 2001, p. 3).

2. Effective: "Based on scientific knowledge to all who could benefit, and refrain from providing services to those not likely to benefit" (IOM, 2001, p. 3).

3. Patient-centered: "Respectful of and responsive to patient's preferences, needs, and values" (IOM, 2001, p. 3).

4. Timely: "Reduce waits and harmful delays for those who receive and those who give care" (IOM, 2001, p. 3).

5. Efficient: "Avoids waste, including waste of equipment, supplies, ideas, and energy" (IOM, 2001, p. 3).

6. Equitable: "Does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status" (IOM, 2001, p. 3).

Patient Satisfaction and Contributing Factors

Patient satisfaction may be related to the satisfaction of the health care providers or employees. Patient satisfaction can be measured through health care providers' level of satisfaction with how favorable their work environment is for them to perform at their optimal level. "Patient Safety, Satisfaction, and Quality of Hospital Care: Cross Sectional Surveys of Nurses and Patients in 12 Countries in Europe and the United States," a study conducted by Aiken and colleagues (2012), describes a cross sectional survey of patients (130,000) and nurses (61,168) in more than one thousand hospitals throughout the U.S. and twelve European countries. This is a correlational study between nurse and patient outcomes, demonstrating that the poor quality of patient care and safety is highly related to burnout and dissatisfied nurses who are intending to leave. According to this survey, it is believed that "features of the hospital work environment (such as better staffing ratios of patients to nurses, nurse involvement in decision making, and positive doctor-nurse relations) are associated with improved patient outcomes, including mortality and patient satisfaction" (Aiken et al., 2012, p. 2).

Similarly, "A Survey of the Impact of Disruptive Behaviors and Communication Defects on Patient Safety," by Rosenstein and O'Daniel (2008), summarized the impact of disruptive behaviors on communication and collaboration and ultimately on patient care. It was conducted by more than 1,400 non-profit hospitals in the U.S. for a period of three years. Although the survey particularly focused on disruptive behaviors between physicians and nurses, its implication was applicable to any relationship in a health care setting. It could be concluded that there was a high correlation between disruptive behaviors and medical errors and poor quality care.

Additionally, *Silence Kills: The Seven Crucial Conversations for Healthcare*, written by Maxfield et al. (2005), states that the root cause of medical errors is interpersonal miscommunication, which includes the following:

- Broken rules: Eighty four percent of physicians and 62% of nurses and other health care providers watch their peers take short cuts that could harm patients.
- Mistakes: Ninety two percent of physicians and 65% of nurses and other health care providers work with some people who have trouble following instructions.
- Lack of support: Fifty three percent of nurses and other health care providers report and complain that their colleagues are reluctant to help.
- Incompetence: Eighty one percent of physicians and 53% of nurses have concerns with their peers and other health care providers' competencies and capabilities.
- Poor teamwork: Eighty eight percent of nurses and other health care providers work with one or more teammates who gossip and cause group division.
- Disrespect: Seventy two percent of nurses and other health care providers work with some people who are condescending, insulting, or rude.
- Micromanagement: Fifty two percent of nurses and other health care providers work with abusive authority.
- Overall: Interpersonal miscommunication contributes to more than 60% of the medical errors primarily to sentinel events.

Studies presented above indicate that human factors play a critical role in patient safety (Maxfield et al., 2005). Disruptive behaviors negatively impact the collaboration and communication among health care providers, which in turn can harm patients and "lead to potentially preventable adverse events, error, compromises in safety and quality, and patient mortality" (Rosenstein & O'Daniel, 2008, p. 467). The statistics reported by Maxfield et al. (2005) highlight how interpersonal miscommunication among health care providers significantly influences patient care and safety.

The working environment is not the only factor playing a major role in delivering quality patient care. Another factor is the conduct and behavior of health care providers.

This information can be utilized in analyzing how the personal qualities of health care providers have an impact on their work performance and productivity and ultimately on delivering patient care. In short, the articles in this section of the review of literature highlight the direct relationship between an unhealthy organizational culture and workers' job performance and satisfaction, which in turn can negatively affect patient safety and satisfaction. In the same manner, laboratory personnel job satisfaction levels can be measured and utilized to confirm its correlation with patient satisfaction.

Root Cause Analysis in a Laboratory

In determining why a problem occurs, RCA is an effective problem solving process to identify the true root cause of a problem (Ketola & Roberts, 2003). Completion of a full investigation is necessary to avoid symptoms, identify the true root cause, and consequently execute effective corrective actions. Therefore, in dealing with errors regarding patient specimens, it is crucial for laboratory personnel to perform a thorough evaluation of all possible variables that may have led to the error.

The RCA method is recommended by the Agency for Healthcare Research and Quality (AHRQ). This method categorizes contributing factors into three domains, including: (1) technical–equipment, forms, and software, (2) organizational–procedures, policies, and protocols, and (3) human–knowledge-based, rule-based, and skill-based (Weaver, 2014). Narrowing down potential causes of the problem into three specific domains is useful in distinguishing system flaws from human factors.

Additionally, the data from the RCA can be informative in improving the processes through: (1) data analysis–"looking at the collected data for trends and insights which can be helpful when the team's focus is in primarily on improving process effectiveness" (Weaver, 2014, p. 21) and (2) process analysis–"analyzing the process itself through process maps and value stream maps, which can help identify bottlenecks and wasted steps that can be eliminated, improving process efficiency" (Weaver, 2014, p. 21).

The primary tools for conducting an RCA investigation are fishbone diagrams and the Five Whys questioning technique. The fishbone cause-and-effect diagram is also known as the Ishikawa diagram, created by Kaoru Ishikawa in 1968. The fishbone diagram is "a graphical diagram which shows the various root causes that lead to a process problem or defect" (Weaver, 2014, p. 27). Each cause or reason that has contributed to a defect is identified as a source of variation or error. The contributing factors are grouped into several major categories to help identify them and assist in the creation of preventative or corrective measures. The potential causes can be categorized as follows: (1) people–personnel involved with the process, (2) methods–how the work process is performed including policies, procedures, or regulations, (3) machine–any equipment, computer programs, or devices utilized to accomplish the task, (4) materials–raw materials, parts, or inputs used to create the outputs or final product, (5) measurements–data collected or generated by the process or data used to evaluate the quality of the product, or (6) environment–physical conditions such as time, temperature, or culture that has impact on operating the process (Weaver, 2014). The potential causes are gathered most often during brainstorming sessions along with the Five Whys technique that can be useful in the identification of root causes by asking "why" questions at least five times. The Five Whys questioning technique aids in demonstrating the relationship between causes and identifying the root cause of the problem (Ketola & Roberts, 2003).

Lean Methodology Applications in a Laboratory

Since the early 2000s, Lean has been increasingly utilized in the field of medicine. The Lean process, as we know it today, has evolved from the Toyota Production System. The foundations of Lean go back to the early 1900s when Henry Ford introduced the Ford manufacturing system. The so-called "mass production," in which Ford implemented the moving assembly line, is also known as flow production. More than a half century later, subsequent to World War II, Eiji Toyoda and Taiichi Ohno developed the Toyota Production System (TPS) by incorporating the Ford production system and some principles such as Just-In-Time, which is producing and delivering the right items at the right time in the right amounts, *jidoka*, which is automation, and *kaikaku* and *kaizen*, which are radical and continual improvement (Womack & Jones, 2003).

Ohno also introduced seven types of *muda*, which is the Japanese word for "waste." Instilling the focus of waste minimization resulted in greater productivity and better quality. By adopting concepts from Ohno's seven types of waste, Yu (2013) in his presentation, "Basics of Lean and Six Sigma for the Laboratory," identifies the sources of waste in the laboratory setting:

- Waiting: Idle time between processes (For example, specimens batching can be counteracted with continuous processing.)

- Excess motion: Unnecessary movement because of inefficient workflow during operation overproduction, producing more than customer requests (For example, duplicate laboratory test orders)
- Defect correction: Time and resource requirements for repairing or rework
- Excess processing: Unnecessary steps in a process, which do not add value, such as unnecessary levels of authorization or approval
- Excess movement of materials: Unnecessary transport of specimens or materials from one place to another
- Inventory: Excessive stockpiling of laboratory supplies in storage

In addition to these seven types of waste, Yu believes that lost creativity can be considered a waste, because, without creativity, laboratory personnel are unable to keep up with today's change and innovation to increase productivity and faster TAT.

Ohno also promotes the ideal Lean one-piece-at-a-time workflow, with continual movement through the process steps and minimal wait times. This is one of the practical applications of the Lean method in the histology laboratory–substituting batch processing with continuous flow. Continuous flow is "a processing state in which a product moves through the stages of the process without stopping or moving backwards for rework" (Weaver, 2014, p. 38).

The essence of Lean is "to compress time from receipt of an order through receipt of payment, it yields greater productivity, shorter delivery time, lower costs, improved quality, and increased customer satisfaction" (Czarnecki & Loyd, 2002, p. 1). Lean thinking is a practical approach for quality process improvement, and its main focus is the elimination of waste. Lean thinking can be summarized in five principles: (1) precisely specify the value of specific products by designing on the basis of customers' needs, (2) identify the value stream for each product by creating a map for every single process involved or spaghetti chart, (3) make the value flow without interruptions by reducing batches to single piece flow and, at the same time, reducing wait times (bottlenecks), (4) let the customer pull value from the producer by integrating the concept of JIT, in which shifting demands for product and service can be provided when the customer is in need, and (5) pursue perfection by promoting *kaizen* for continual incremental improvement (Womack & Jones, 2003).

Precisely Specify Value by Specific Product

In the health care setting, value is defined by the patients who are the customers. Delivering laboratory services with accurate and reliable results in a timely manner is the ultimate goal of laboratory staff in contributing to patient satisfaction. In the histology laboratory, pathologists are the primary internal customers; therefore, it is crucial for the laboratory personnel to understand and meet their requirements. Pathologists are the ones specifying the value of laboratory services and products. For example, one of the pathologists considers the submitted histologic stain valuable when it helps with diagnosis; another pathologist considers laboratory services valuable when they are consistently good quality with a short turn-around time (F. Gilles & H. Shimada, personal communication, February 28, 2013).

Identify the Value Stream for Each Product

For examining the current state of laboratory workflow, functional diagrams, such as Supplier-Input-Process-Output-Customer (SIPOC) and process mapping, can be utilized to provide a wide range of information by evaluating the process from a big-picture perspective with a high level of details. The SIPOC displays a summary of what the process does, including the starting and ending points of the process, the process input and output, the suppliers of the process, and the customers of the product. Process mapping gives more details in viewing the process by walking through the process; therefore, it enables one to capture the process step by step from the start to completion.

General process mapping in the histology laboratory can be visualized as shown in Figure 2. There are many steps and personnel involved, including the pathologist assistants and histology team who receive accession, gross, and process specimen–converting them into readable histologic stains; then, slides are read by pathologists who determine the patient diagnosis. For this study, the focus of analytical process activities is restricted to the histology laboratory portion, specifically from the load processor step to the staining and cover-slipping step.

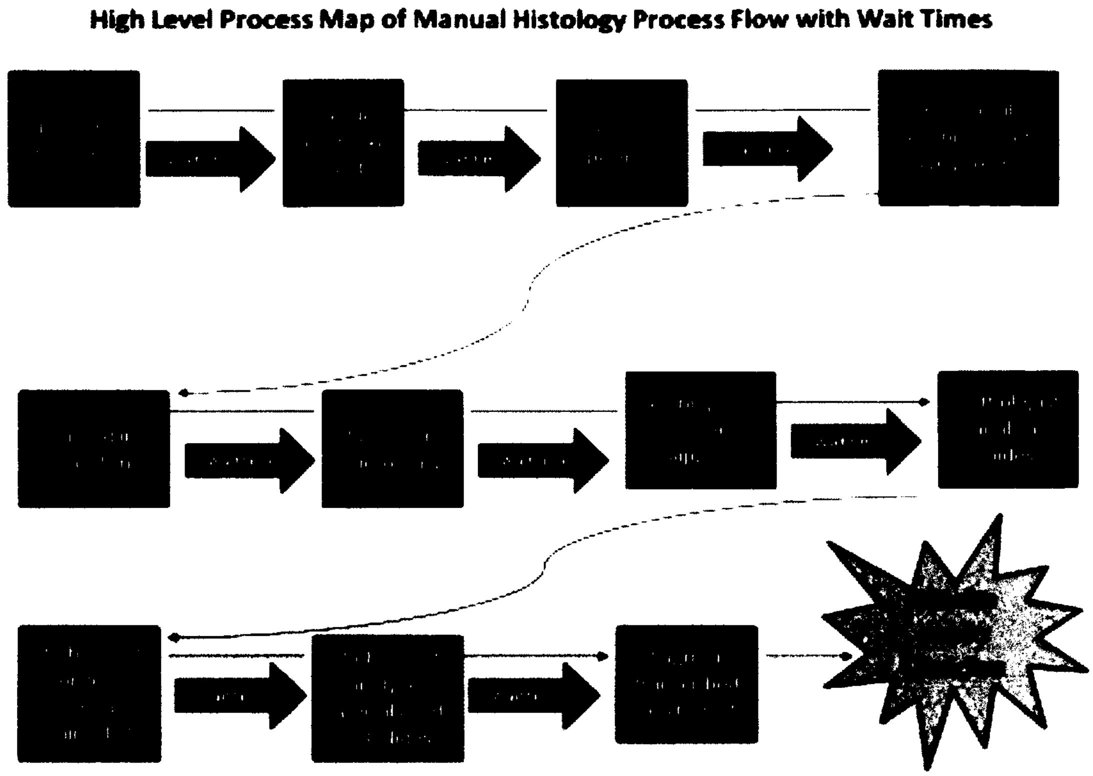


Figure 2. Process mapping in general in the histology laboratory. Adapted from "Understanding and Utilizing Lean and Six Sigma in the Histology Laboratory," by Weaver, 2014, *MediaLab, Inc.*

Make the Value Flow
Without Interruptions

In promoting continuous flow, Ohno states, "the ideal workspace layout for continuous flow is a straight line or modified U shape" (Weaver, 2014, p. 38). Continuous flow can be demonstrated by creating a spaghetti chart, which is "a map of the path taken by a specific product as it travels down the value stream in a mass-production organization. It is aptly named because the product's route typically looks like a plate of spaghetti" (Womack & Jones, 2003, p. 352). The spaghetti chart enables the user to determine how the flow of process activities is carried on and to create a single piece flow.

Let the Customer Pull
Value from the Producer

The concept of JIT is introduced by shifting demands so the product and service can be provided when the customer is in need. Laboratory services are delivered when requested by either the pathologists or the patient. Without creating a more efficient workflow, requests cannot be completed in time; therefore, applying continuous workflow as recommended by Ohno can enhance efficiency in the laboratory (Weaver, 2014).

Pursue Perfection

Important to promoting continuous improvement or *kaizen* is the 5S tool, which stands for Sort, Straighten, Shine, Standard, and Sustain. This is one of Lean's organizational methods, which establishes the beginning steps for continuous improvement; it is a systematic method for creating an efficient and safe work environment (Yu, 2013). The first step is to Sort and remove any unnecessary items that are obsolete, defective, or in excess. The Straighten step, which is also referred as "set-in-order," arranges items to allow for easy access during the daily operation (For example, implementing a proper labeling system for reagent containers). The Shine step deals with the physical outlook of the laboratory, including clean floors, workstations, storage, and equipment. The Standardize step identifies job duties for maintaining a clean and orderly laboratory. The last and most difficult step in 5S is Sustain, for it requires self-discipline and commitment by both management and laboratory personnel to the 5S principles for continuous improvement.

CHAPTER 3

METHODOLOGY

Design of Investigation

This study investigated two major aspects of PI. First, process observations examined how the implemented PI project in the histology laboratory influenced laboratory work performance and job satisfaction levels. By comparing two different laboratory workflow settings, the effectiveness of the PI project was rated. Second, the perception of the laboratory personnel in the PI project was identified. This was achieved by comparing employee satisfaction survey results from the previous year to the survey results from the year immediately following the PI project. The connection between employee and customer satisfaction was evaluated by collecting, measuring, and analyzing employee satisfaction survey data.

In addition, this thesis was supported by related literature reviews and was created by utilizing a wide range of quality concepts and tools that included adopting quality principles from quality experts such as W. Edwards Deming and Joseph Juran, emphasizing the concept of employee satisfaction and patient satisfaction, and evaluating the application of RCA as a quality tool and Lean as a quality strategy.

The design of the investigation was comprised of: (1) taking a small histology laboratory as the representative of a clinical laboratory in the hospital, (2) obtaining the observed result of the Lean application as the implemented PI project's finding, (3) assuming that majority laboratory personnel actively participated in annual hospital surveys, and (4) analyzing data based on statistical quality control.

Project-based Investigation

Process observation in the histology laboratory was initiated by setting up a histology team, consisting of a histology supervisor, a few senior histotechnicians, and a histotechnologist. The histology team members held the credibility for making changes in the laboratory, for they were the ones performing the work on a daily basis, obtaining both formal and informal Lean training and experience, and working in a Lean work environment setting. The researcher was the writer who actively monitored and recorded process observations and who was also on the histology team.

The initial step prior to the redesign was to conduct brainstorming sessions; therefore, the very first data collected was based on the histology team members' brainstorming ideas in evaluating histology laboratory processes, particularly concentrating on the issues of inefficient workflow. These ideas were listed as possible causes and organized into several categories, including personnel, process, equipment, work environment, and management, which, therefore, contributed to a structural fishbone diagram generation. Additionally, in developing the fishbone diagram, a Five Whys table with a series of questions and answers was created to explain the causal relationships contributing to the root cause. These RCA tools enabled the team to find the root cause of the issue of inefficient workflow and, therefore, to design and create potential strategies for initiating a PI project.

In resolving the inefficient workflow issue in the laboratory, the implemented process improvement was conducted based on Lean principles by: (1) conducting radical improvement (*kaikaku*) in streamlining the laboratory workflow by redesigning the model histology laboratory and (2) adopting 5S–Sort, Straighten, Shine, Standardize, and Sustain–in rearranging the laboratory from equipment to reagent storage for continual improvement (*kaizen*).

A *kaikaku* PI project started as changes in the laboratory were initiated–not only renovating the physical outlook of the laboratory such as new flooring, painting, and changing main countertops but also streamlining the analytical workflow process. Redesigning the histology laboratory took considerable time and effort from everyone involved. This not only included the histology team but other departments as well, including Security and Safety, Transport, Construction, and other laboratory departments. During the month and a half of construction, the histology laboratory was relocated to another temporary location. The major change of the redesign was to combine two working areas that were physically separate, but interdependent on one another, into one large room. During redesigning, there were trial and error periods where small rearrangements were made to test the *kaizen* PI project, based on the 5S concept that included sorting out the obsolete or out-of-date devices and not-in-use or expired reagents and standardizing each workstation according to its necessity.

Lean tools, including process mapping and the spaghetti diagram, were selected as the best approaches to evaluate laboratory workflow settings for both pre- and post-redesigning because these tools provided a step-by-step scope from a broad perspective to specific details. The first step of process mapping was to create a SIPOC diagram. The SIPOC diagram provided a broad perspective of the laboratory process. Process mapping could be useful in understanding the current workflow and viewing each process step with a high level of detail by identifying the starting and ending point of the process to be mapped.

The data set gathered was based on an assessment of workflow processes at pre- and post-redesigning settings by the histology team. The five most common workflow processes called "staining" were identified, including Routine, Special, IHC, Cytology and Muscle staining (see the analytical process activities for each type of staining from one station to another listed on Table 1). Since each staining station required different equipment and preparation steps (specimen, slide, and reagent), every staining required different workflow routes to complete; however, they all had a common starting point and ending point. The starting point included receiving requests ordered through the laboratory information software program, called CoPath, by which laboratory personnel could process the request according to a specific order. The final station included checking the histologic staining results under the microscope to ensure the quality of the stain was at an optimal level prior to submission to the pathologist.

Table 1

Analytical Process Activities in the Histology Laboratory

Station #	Routine Staining	Special Staining	IHC Staining	Cytology Staining	Muscle Biopsy Staining
1	Computer 1	Computer 1	Computer 2	Computer 1	Computer 1
2	Processor	Stainer Computer	Stainer Computer	Specimen Preparation	Specimen Preparation
3	Embedding Center	Slide Preparation	Slide Preparation	Slide Preparation	Slide Preparation
4	Specimen Preparation	Microtome	Microtome	Cytology Machine	Cytology Machine
5	Microtome	Slide Preparation	Slide Preparation	Reagent Preparation	Reagent Preparation
6	Slide Preparation	Reagent Preparation	Reagent Preparation	Open Counter 1	Open Counter 2
7	Reagent Preparation	Special Auto-Stainer	IHC Auto-Stainer	Microscope	Microscope
8	Routine Auto-Stainer	Microscope	Microscope	Quality Control	Quality Control
9	Microscope	Quality Control	Quality Control		
10	Quality Control				

Specimen preparation could include obtaining specimens from the embedding center station, block filing cabinets, or freezer. Slide preparation could be comprised of pulling quality control slides, getting slide-racks from designated shelves, or putting slides in ovens for a certain period. Reagent preparation could cover pulling required reagents from the shelves, fridge, or freezer to be put in the machine or mixing reagents to be manually processed on open counter areas.

In evaluating process activities, the entire histology team participated in obtaining data, which measured the distance of every station required to complete each task. By counting the number of steps needed to perform each type of staining, data collected from histology team members were gathered, entered, and calculated in a Microsoft Excel spreadsheet. A histogram chart was generated by the researcher, and, in further analysis, process mapping of pre- and post-redesigning was created to provide a detailed process map with steps from the first station to the last, based on the analytical process activities listed in Table 1.

In the same manner, analytical histology activities and process mapping for every staining could be transposed to a spaghetti diagram. The spaghetti diagram was useful in demonstrating a visual layout of the floor plan and the workflow of each task in the form of thread-like or spaghetti-like routes; this diagram could be utilized to measure the efficiency level of workflow at pre- and post-redesigning phases. A comprehensive histology laboratory floor plan with spaghetti diagrams also was developed, based on the analytical process activities of each staining performed in the histology laboratory, as shown in the Appendices.

Spaghetti diagrams were constructed by utilizing computer software called AutoCAD. Floor plans of histology laboratory pre- and post-redesigning were sketched and drawn with a scale of one-eighth inches equivalent to one foot. By placing every workstation, equipment, and other devices in detail, it gave a clear visualization of how the laboratory setting was arranged. By drawing workflow routes in a spaghetti-like form from one station to another, it provided more clarification on how workflow processes were performed and comparisons between pre- and post-redesigning settings could be analyzed.

Through process observations utilizing RCA methods such as the fishbone diagram and Five Whys and Lean tools–including process mapping and spaghetti diagram–data obtained in pre- and post-redesigning settings were recorded, compared, and analyzed. The application of these tools for evaluating the histology laboratory is discussed in detail in Chapter Four.

Survey-based Investigation

After the redesign was completed, the job satisfaction of laboratory personnel was assessed and measured through an annual survey. There were three annual surveys conducted in the hospital, including culture, patient safety, and nursing surveys. This study utilized some key components from the culture and patient safety surveys. The culture survey used was adapted from a survey developed by the Senn-Delaney Leadership Consulting Group (2013), a consulting company that focused exclusively on culture transformation. The Senn-Delaney Group was credited for having a positive impact on organizational culture within the network of hospitals and health care providers (Senn-Delaney Leadership Group, 2013).

In gaining a greater understanding of the Senn-Delaney Survey background and its utilization, the researcher conducted a brief interview with the vice president of Ancillary and Support Services at the hospital. From the interview, it could be surmised that Senn-Delaney provided the best fit for tools required by the organization to embrace change as needed during current health care reformation, the Affordable Care Act, and to adopt a nimble management style needed for facing the changing health care market. The Senn-Delaney Survey offered an essential value set of–performance, collaborative, change, and ethnics or integrity, as well as organizational and customer values–aligned with the hospital's mission statement and core values. For example, one of the hospital's core values, "We achieve our best together," demonstrated the value of collaboration in promoting teamwork (K. Hobbs, personal communication, August 29, 2014). The survey questions were designed and created, based on these essential values. The Senn-Delaney

Survey was not only used to measure and report employee job satisfaction but also to help the organization understand its true identity as a team of health care professionals, identify the organization's need to change, and promote organizational learning (2013).

Changes made during the period of time prior to redesign (pre-redesigning) and post redesign (post-redesigning) were compared constructively. In the same manner, job satisfaction levels of laboratory personnel toward the change were evaluated; therefore, the correlation study between laboratory personnel and patient satisfaction could be analyzed.

A comprehensive set of questions from the Senn-Delaney Survey assessed employee satisfaction levels (2013). The survey questions were sorted into several categories. They covered a wide range of areas including Leadership and Direction, Committed Engagement, Change, Collaborate, Customer, Ethics, Organizational Health, Performance, and Strategic Alignment. This survey concentrated on how employees perceived changes made in the laboratory, how they collaborated within their team, and how they performed in delivering service to customers (Senn-Delaney, 2013). Table 2 shows the three categories of survey questions selected for discussion in Chapter Four: (1) Change, (2) Collaborate, and (3) Customer.

Table 2

Senn-Delaney Survey Questions Based on Three Categories

Category	Survey Questions
Change	We have two-way, frequent and open communications. There is great openness to change. People are encouraged to innovate -- creativity is welcomed. We have high levels of feedback and coaching.
Collaborate	Teamwork/ mutual support and cooperation is the norm. People are flexible/ fluid and empowered. There is a high level of trust and openness among people. Decisions are made for the greater good of the overall organization.
Customer	There is a high level of awareness and focus on quality. There is a high level of service consciousness or focus on customer.

Adapted from "Senn-Delaney Survey," by the Senn-Delaney Leadership Consulting Group, 2013.

In addition, an internal hospital survey on patient safety was also a great resource for assessing the work performance on personnel in relation to patient safety. The survey was divided into two categories: Organizational and Work Area Specific. The Organizational category included the sub-categories of Overall Perception of Safety, Organizational Learning-Continuous Improvement, Hospital Management Support for Patient Safety, Teamwork across Hospital Units, and Hospital Hands-off and Transitions. The Work Area Specific category included the sub-categories of Frequency of Events Reported, Supervisor-Manager Expectations and Actions Promoting Patient Safety, Teamwork within Units, Communication Openness, Feedback and Communication about Errors, Non-punitive Responses to Errors, and Staffing. For this study, three sub-categories were evaluated: Overall Perception of Safety, Frequency of Events Reported, and Non-punitive Responses to Error.

Data collection was obtained internally from annual culture and patient safety survey results. The survey questions were distributed throughout the hospital to employees via e-mail with a link to the survey section. For the purpose of this study, electronic data on culture from the Senn-Delaney Survey were collected over two consecutive years with 108 laboratory personnel in the year 2012 and 174 in the year 2013. Similarly, internal hospital patient safety survey data were also collected for the years of 2012 and 2013.

The null hypothesis and research hypothesis of this study could be constructed by comparing the levels of employee satisfaction, based on the culture surveys, with patient safety in the year 2012, prior to the redesigning of the laboratory, and in the year 2013, after the redesigning of the laboratory. The null hypothesis of this study was, "There is no difference in employee job satisfaction levels between pre- and post-redesigning"; whereas, the research hypothesis was, "There is a difference in the employee job satisfaction level between pre- and post-redesigning."

Statistical tests such as a paired t-Test and p-values (significant level) were used to interpret and analyze the collected data. The paired t-Test was conducted to see the impact of the PI project by comparing the means of survey data from both pre- and post-redesigning periods. With the paired t-Test, a p-value could be identified to test the null hypothesis: "There is no difference of laboratory personnel job satisfaction levels between pre-redesigning in 2012 and post-redesigning in 2013." The p-value presented a probability of difference between pre- and post-survey results from the same group, which included laboratory personnel of the representative hospital. Quantitative data obtained by utilizing Microsoft Excel were also presented in histogram graphs and discussed in greater detail in Chapter Four.

CHAPTER 4

RESULTS AND DISCUSSION

Part I

There were two significant findings from this study to be discussed. First was a brief report of the results of the PI project implemented in the histology laboratory. Second was the statistical analysis of how the project was associated with the job satisfaction levels of laboratory personnel and how it related to the quality of patient care and safety.

The initial results obtained were based on the PI project implemented in the histology laboratory. Beginning with a structured approach, a cause-and-effect or fishbone diagram was constructed as a tool for performing a RCA to identify potential causes for the failure to achieve full efficiency through the analytical processes and consequently the negative impact on quality patient care and safety. Several potential causes were identified, as shown in Figure 3.

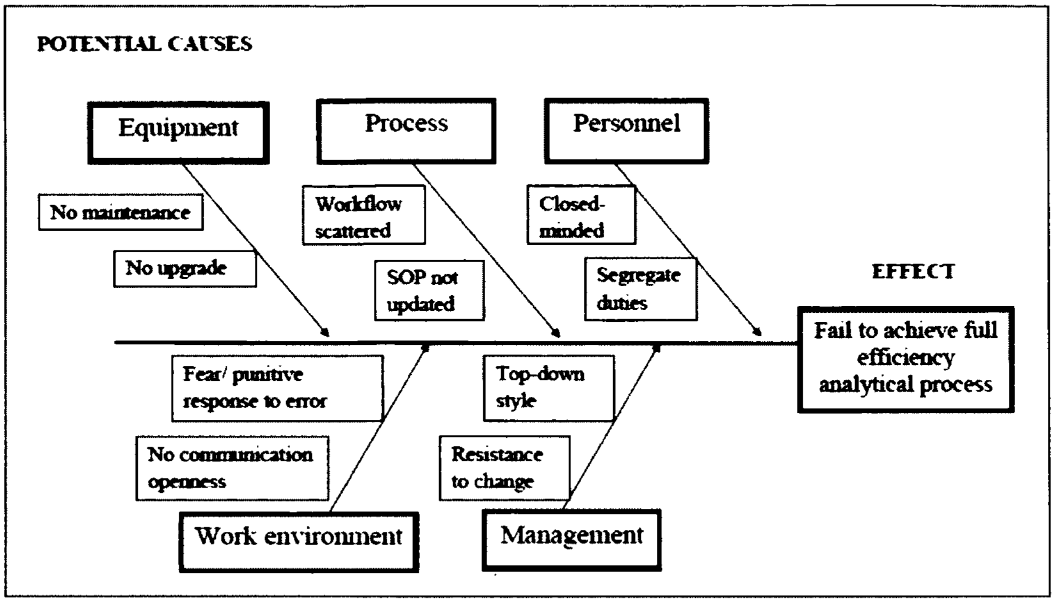


Figure 3. Fishbone diagram prior to redesigning the histology laboratory.

The fishbone diagram was utilized as an essential RCA tool to identify all possible contributing factors and areas where further investigation was required. As described in Figure 3, all aspects of the histology laboratory–starting with personnel and management, equipment, and work environment and processes–were interrelated with each other in contributing to the failure to achieve full efficiency in analytical processes. The Five Whys tool was added to support the fishbone diagram by asking questions for at least five times as described in Table 3. Based on this method, it was determined that the inefficient analytical process in the histology laboratory was due to a poor workflow design and disordered work environment.

Table 3

Five Whys Method in Identifying the Inefficient Workflow

Question	Answer
1. Why did the prior-redesigning analytical process fail to achieve its full efficiency?	1. Employees were not able to perform at their capacities.
2. Why employees could not perform productively?	2. Employees had to frequently move back and forth to accomplish one task.
3. Why were there excess movements for employees?	3. Analytical process was not set up at optimal level.
4. Why was the process suboptimal?	4. The workflow was not continuous flow.
5. Why was the workflow not continuous flow?	5. Poor workflow design such as the workstation arrangement was not in proper placed.

The PI project implemented in the histology laboratory was based on Lean principles with a focus on the elimination of waste in all forms, including waiting, overproduction, defects requiring rework, unnecessary movement of materials or people, excess inventory, and excess processing (Yu, 2013). According to Womack and Jones (2003), the key point of Lean thinking was "getting more done with less–less human effort, less equipment, less time, and less space" (p. 15).

After identifying the root cause of an inefficient workflow within the laboratory process, which was due to a poor workflow design, a *kaikaku* PI project was initiated. It was exemplified by the redesigning of the laboratory, which was conducted in 2012. Additionally, the *kaizen* PI projects that had been carried out was based on 5S–Sort (segregating and discarding waste or anything does not provide value), Straighten (rearranging the workplace to reduce excess motion, excess processing, excess movement of materials, defect correction, and inventory), Shine (conducting daily maintenance to keep workplace areas clean), Standardize (having job duty schedules in place), and

Sustain (repeating the first 4S as necessary to maintain the changed state). Applying the 5S method in the laboratory for improvement was not a one-time event; it was an ongoing effort.

In evaluating the workflow processes in the histology laboratory, data sets were collected during pre- and post-redesigning periods. Workflow processes during these periods were assessed by counting the number of steps an employee had to make per type of process performed in the histology laboratory (see Table 4 and Figure 4). The results showed lower numbers of steps for major staining procedures at the post-redesigning period, compared to the pre-redesigning period. The decreased numbers of steps with a lower bar height in Figure 4 represents a simplified workflow.

Table 4

Comparison of Step Count Per Staining: Pre- vs. Post-redesigning

	Pre-redesigning (2012)		Post-redesigning (2013)	
Type of Staining	**# of steps**	**95% CI**	**# of steps**	**95% CI**
Routine	123	[118,128]	85	[80,89]
Special	85	[81,87]	94	[92,96]
IHC	97	[95,99]	75	[69,81]
Cytology	59	[53,66]	57	[50,64]
Muscle	191	[186,195]	78	[75,81]

(95% CI = the lower and upper bounds of the 95^{th} percent Confidence Interval)

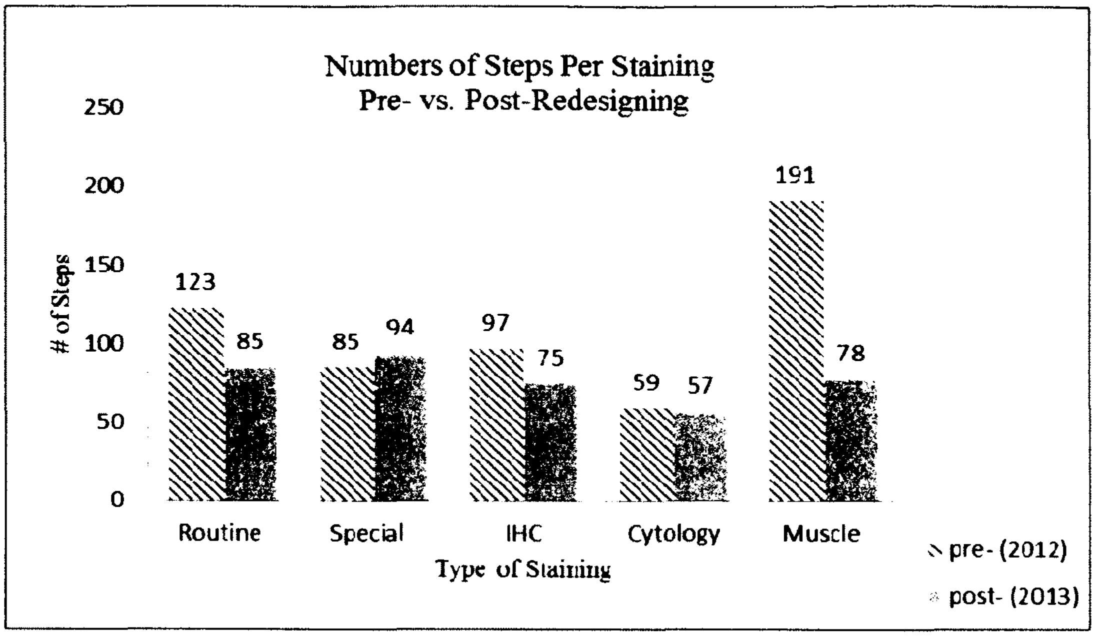


Figure 4. Histogram step count per staining in pre- vs. post-redesigning periods.

In assessing the process workflow in the histology laboratory, process mapping could serve this purpose. Table 5 demonstrated the SIPOC as a cross-functional set of histology activities displaying every element involved in the process. The process started with clinicians, surgeons, specialists, or other institutions delivering specimens to the histology laboratory to be processed. The series of analytical processes performed by the histology team were intended to turn specimens into microscope slides for the pathologists to do patient diagnosis.

Table 5

SIPOC in the Histology Laboratory

Supplier	Input	Process	Process owners	Output	Customers
Clinicians, surgeons, specialists, other institutions	Specimens from small biopsy to tissue resection	Fixing, processing, embedding, sectioning, staining	Histology team	Microscope slides	Internal: pathologists End-users: patients

In viewing the workflow in more detail, process mapping for Routine staining was being constructed at the pre-redesigning period, as shown in Figure 5, and at the post-redesigning period, as shown in Figure 6. Counting the number of steps taken from one station to the next provided a breakdown of the estimated travel time for laboratory personnel to accomplish the Routine staining task. Walking through station by station allowed one to evaluate whether each step was necessary and whether extra travel steps or excess movements could be minimized. For example, there were approximately 20 or more steps taken in the pre-redesigning period for Routine staining, compared to those in post-redesigning. Counting numbers of steps per each staining type performed during pre- and post-redesigning was intended to evaluate the efficiency of the workflow in the histology laboratory.

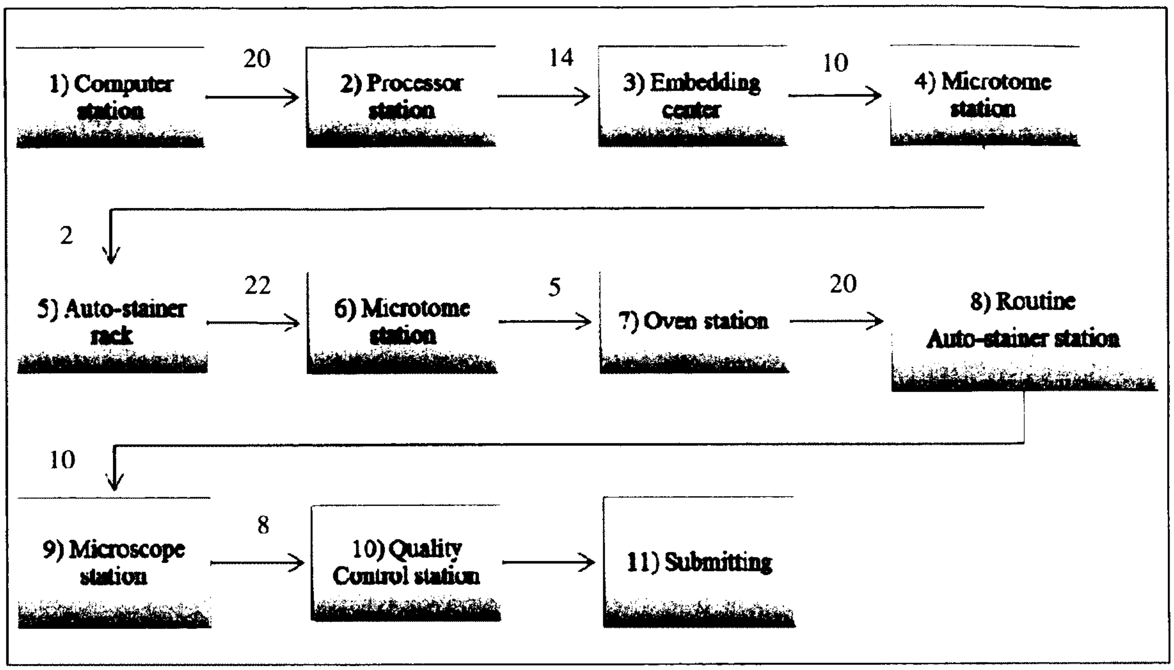


Figure 5. Process mapping of Routine staining at pre-redesigning.

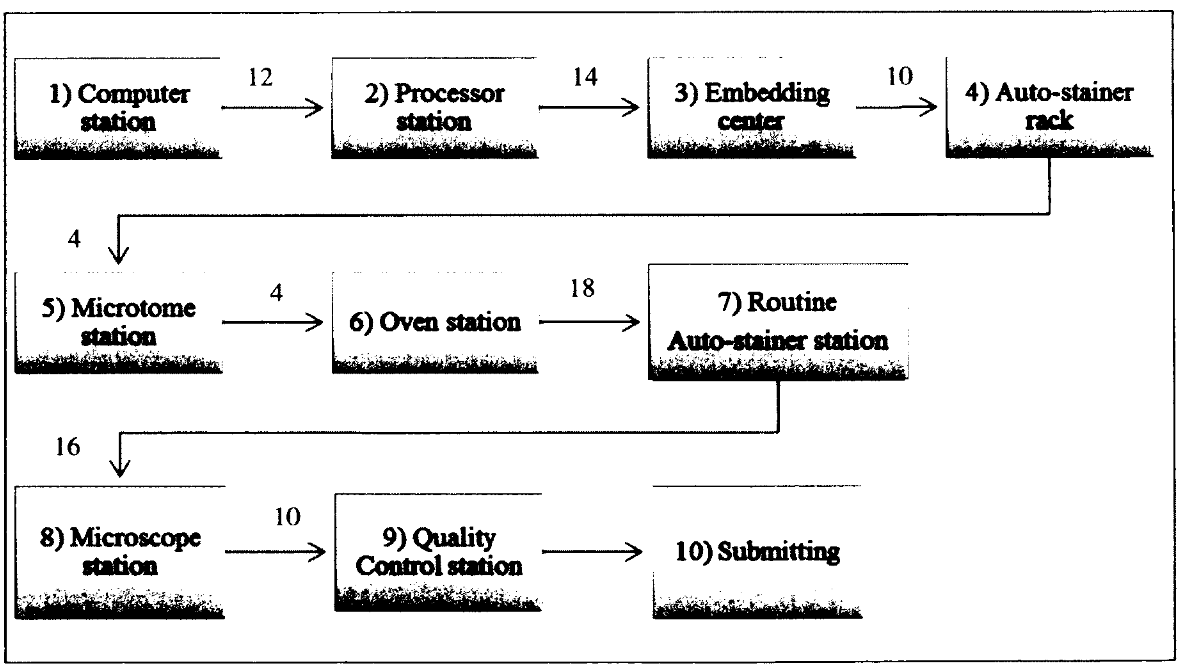


Figure 6. Process mapping of Routine staining at post-redesigning.

Prior to redesign, the laboratory operations were mostly split, based on routine laboratory work in the bigger area and other specialized requests, such as Immunohistochemistry (IHC) and Muscle staining, in smaller areas. The equipment was particularly arranged and divided, based on the need of laboratory staff performing Routine versus Special tasks. This segmented laboratory setting made the workflow cluttered, for it caused laboratory personnel to move back and forth to utilize shared equipment; therefore, it advantaged some staff members who performed Routine staining over others.

In streamlining the workflow of the analytical processes in the histology laboratory, it was profoundly important first to identify specifically where waste took place along the process. The unnecessary movement back and forth from one station to another station was considered excess motion. It was not only a waste of time but also was leading to ergonomic problems. By laying out the current workflow, laboratory personnel could determine how much distance was traveled from one station to another to accomplish one task. This gave them some insight when making an assessment for redesigning the process to be more efficient and effective. The *kaikaku* PI project included rearranging the shared equipment and stations more likely to be centralized in one area; this enabled personnel to minimize excessive motion when performing most staining procedures. All major instruments were placed close to one another, and microtomy workstations were arranged side by side in one big open area, leaving the cytology station, fridges, and freezer as well as reagent storages and waste containers in the smaller room. The streamlining in this project primarily focused on creating a continuous workflow with no interruptions and no waiting time.

The visual results illustrated in the spaghetti diagram provided a better visualization of the changes made after the PI project was implemented. The spaghetti diagram was not only used to demonstrate a visual workflow but also was used to help identify waste such as extra travel or excessive motion (see the appendices for the floor plan in spaghetti diagrams to show the specimen's route for each type of staining performed in the histology laboratory during the pre- and post-redesigning period).

Appendix A presents comparison spaghetti diagrams of Routine staining in the pre- and post-redesigning period. An evaluation of these diagrams resulted in less traveling back and forth within two separate rooms, showing more short U-shape routes in the main area after making the arrangement for specimen preparation that included storing the auto-stainer rack close to microtome stations and ovens. The rearrangement of reagent storage in the fridge created more straight-line traveling routes for the Special staining workflow at post-redesigning, compared to pre-redesigning settings (see Appendix B).

Similar to the result shown in Appendix A, the IHC staining's spaghetti diagrams at pre- and post-redesigning settings (see Appendix C) showed more short U-shape routes in the main redesigned area, for the workstation for this particular staining was completely moved and combined to resolve the segmented issue. Appendix D shows spaghetti diagrams for Cytology staining at pre- and post-redesigning settings. By switching that work area with the IHC setup, the Cytology staining workflow at the post-redesigning setting was clustered in the small room. By having a functional hood space next to the open counter, Muscle staining at the post-redesigning state was greatly improved by reducing more than half numbers of steps counted (see Appendix E). By comparing spaghetti diagrams between pre- and post-redesigning for five of the most commonly performed staining areas, the overall analytical laboratory process was visually analyzed and resulted in a continuous flow and, therefore, simplifying the workload of laboratory staff in most staining tasks performed.

In accordance with data described in Table 4 and Figure 4, the findings of the floor plan comparisons between pre- and post-redesigning, as presented in spaghetti diagrams (see Appendix A through Appendix E), showed it required less travel with simplified routes at post-redesigning settings as compared to those at pre-redesigning. The numbers of steps were reduced significantly in most staining procedures performed at post-redesigning settings. The comparison of step count data, process mapping, and spaghetti diagrams between pre- and post-redesigning could serve to measure the efficiency level of the PI project in streamlining the workflow process in a histology laboratory. With a more efficient workflow process obtained, customers could request and receive their orders JIT, which in turn could achieve higher customer satisfaction.

Part II

In examining the correlation study between employee and patient satisfaction related to the PI implemented in the histology laboratory, the hospital's culture survey adapted from the Senn-Delaney Survey and the patient safety survey could be utilized to indicate laboratory personnel's job satisfaction levels. Since the histology laboratory was a part of the hospital's Pathology and Laboratory Medicine Department, the data collected from that department could be utilized. Both surveys were initiated and distributed by an outside agency so that the confidentiality of the subjects was maintained. Data collected from the surveys were later compiled and archived in the hospital's Quality Improvement and Patient Safety Department. These surveys were conducted annually, and the scores for the year prior to the implementation of PI in 2012 and the year following re-designing in 2013 were collected and compared, as shown in Table 6.

Table 6

Comparison of Culture Survey Results in 2012 vs. 2013

Culture Survey Data --Pathology and Laboratory Medicine Department

Category	Score (%)		
	2012 (n=108)	2013 (n=174)	Difference
Change	54.4	55.4	1.00
We have two-way, frequent and open communications.	55.2	55	-0.20
There is great openness to change.	[redacted]	50.6	2.50
People are encouraged to innovate -- creativity is welcomed.	60	62.9	2.90
We have high levels of feedback and coaching.	54.3	53.2	-1.10
Collaborate	61.7	57.1	-4.60
Teamwork/ mutual support and cooperation is the norm.	65.1	61	-4.10
People are flexible/ fluid and empowered.	57.1	51.8	-5.30
There is a high level of trust and openness among people.	53.3	[redacted]	-4.20
Decisions are made for the greater good of the overall organization.	[redacted]	66.3	-4.90
Customer	[redacted]	[redacted]	1.80
There is a high level of awareness and focus on quality.	[redacted]	[redacted]	5.60
There is a high level of service consciousness or focus on customer.	[redacted]	[redacted]	-1.80

Scores represent percentage of respondents in agreement with survey statement.

Key:
Below 50% agree
50% - 69% agree
70% + agree

Three categories–Change, Collaborate, and Customer–were utilized for this study. In general, the average results from the culture survey were in the response range of agreement and above, with score range of 54.4% to 79.6% (in yellow and green highlights). The percentage score for each question in the category was listed in Table 6. In addition, Figure 7 illustrated the average mean of job satisfaction levels of laboratory personnel associated with Change, Collaborate, and Customer in the form of a histogram, comparing pre- and post-redesigning periods.

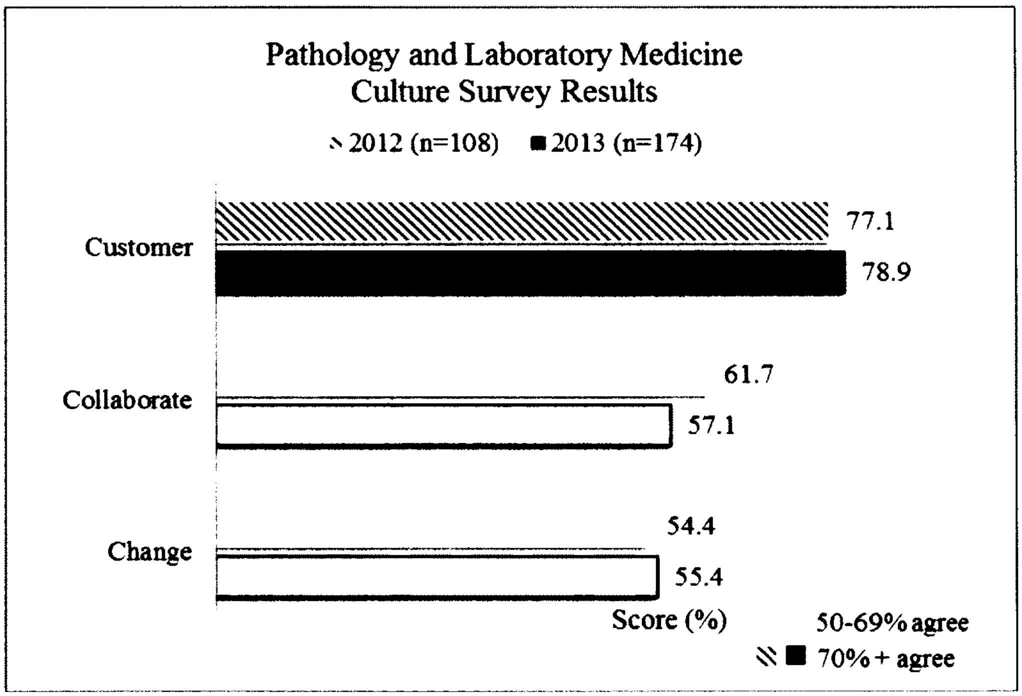


Figure 7. Histogram of culture survey results in 2012 vs. 2013.

The p-value for a paired t-Test for each category was calculated as presented in Table 7. In assessing the strength of evidence against the null hypothesis, it was stated that "the smaller p-value, the stronger the evidence against the null hypothesis" (Kirkwood & Sterne, 2003). Since the smallest p-value in the Collaborate category was less than 0.05 (p = 0.001), this showed that there was a significant level between the two means. Conversely, there was no statistical significance in the other two categories– Change (p = 0.376) and Customer (p = 0.698).

Table 7

Summary of Average Score, Difference, and p-Value

Culture Survey Data --Pathology and Laboratory Medicine department	2012 (n=108)	2013 (n=174)	Difference	p-value
Change	**54.4**	**55.4**	1.00	0.376
Collaborate	**61.7**	**57.1**	-4.60	0.001
Customer	[redacted]		1.80	0.698

The impact of PI on laboratory personnel's job satisfaction could be demonstrated by a paired t-Test, comparing the means of survey scores in the prior-redesigning and post-redesigning periods. Table 8 lists results of the ten survey questions in all three categories. In analyzing overall survey scores at the 0.05 significant level, the p-value of 0.393 indicated that there was no supportive evidence to reject the null hypothesis: "There is no difference in laboratory personnel job satisfaction levels between pre-redesigning in 2012 and post-redesigning in 2013."

Table 8

Comparison of a Paired t-Test for Culture Survey Scores in 2012 vs. 2013

t-Test: Paired Two Sample for Means	a	0.05	
	Pre- 2012 (n=108)	Post- 2013 (n=174)	
Mean	61.84	60.78	
Variance	106.93822	123.27956	
Observations	10	10	
Pearson Correlation	0.9416482		
Hypothesized Mean Difference	0		
df	9		
t Stat	0.896		
P(T<=t) one-tail	0.197		Cannot Reject Null Hypothesis because p > 0.05 (Means are the same)
T Critical one-tail	1.833		
P(T<=t) two-tail	0.393		Cannot Reject Null Hypothesis because p > 0.05 (Means are the same)
T Critical Two-tail	2.262		

In addition, based on the internal hospital survey on patient safety, three specific topics were examined:

- Overall Perception of Safety–How good is our error preventive system?
- Frequency of Events Reported–How often do we report our mistakes?
- Non-punitive Response to Error–Do we feel that event reports and mistakes that we make are held against us?

The perception of laboratory personnel on each topic in terms of positive, neutral, and negative responses to the internal hospital survey for both the pre- and post-redesigning periods is presented in Figure 8. In general, positive responses indicated laboratory personnel's awareness of patient safety. However, in comparing pre- and post-redesigning years, there was no statistical difference in the paired t-Test findings from the data collected, resulting in the "cannot reject the null hypothesis" conclusion, as shown in Table 9.

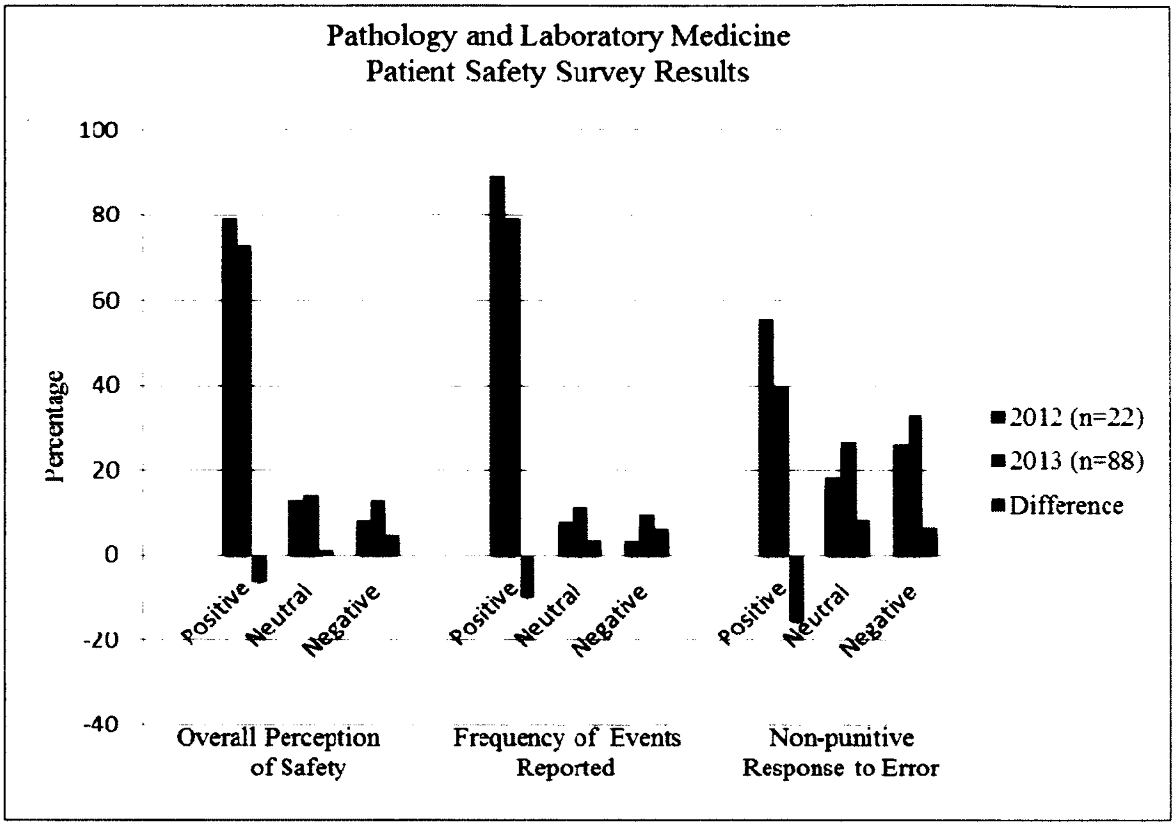


Figure 8. Histogram of patient safety survey results in 2012 vs. 2013.

Table 9

Comparison of a Paired t-Test for Patient Safety Survey Results in 2012 vs.2013

t-Test: Paired Two Sample for Means a 0.05

	Pre-2012 (n=22)	Post-2013 (n=88)	
Mean	33.344444	33.333333	
Variance	1069.1628	696.8475	
Observations	9	9	
Pearson Correlation	0.9817103		
Hypothesized Mean Difference	0		
df	8		
t Stat	0.004		
P(T<=t) one-tail	0.498		Cannot Reject Null Hypothesis because p > 0.05 (Means are the same)
T Critical one-tail	1.860		
P(T<=t) two-tail	0.997		Cannot Reject Null Hypothesis because p > 0.05 (Means are the same)
T Critical Two-tail	2.306		

In summary, the culture surveys given to laboratory personnel were based on the Senn-Delaney Survey and the hospital survey of patient safety. The comparative analysis of the data was grouped into four categories: (1) Change, (2) Collaborate, (3) Customer, and (4) Organizational Culture. These categories were selected as the key parameters in determining if the implemented PI project greatly impacted employee job satisfaction. Initiating the PI project required change and involvement from everyone involved at some point. During the project, collaboration among personnel was the key to success. More importantly, the main force behind the execution of the PI project was customer focus driven, which ultimately impacted patient satisfaction. In order to sustain the change, the processes could be integrated into the work environment and become organizational culture.

Change

Transformation at a clinical laboratory in this hospital setting started as a PI project. Senn-Delaney Survey questions in the Change category addressed how receptive employees were toward change–determining whether there was openness to change, how the communication was conveyed, whether communication for buy-in works, how leaders took their roles to promote change, and whether coaching was being conducted as a leadership style. The success of the PI project was dependent on everyone involved being flexible and receptive to change. Laboratory personnel who were resistant to change could negatively influence the success of implementing the redesigning proposal. Findings of the Senn-Delaney Culture Survey, presented in Table 6, showed that most laboratory personnel were receptive to change with an overall score of 54.4% in 2012 and 55.4% in 2013. Being open to change and encouraged to be creative during the change were essential starting points, and these two points in the survey showed a 2.5% and 2.9% positive influence in comparing pre- and post-redesigning.

Collaborate

The Senn-Delaney Survey questions rated the Collaborate category, based on some key components including teamwork, trust, and empowerment. In analyzing the data of the Collaborate category in the Senn-Delaney Culture Survey, there was a slight decrease from 61.7% to 57.1% when comparing post- to pre-redesigning period (as shown in Figure 7). The lower score in post-redesigning could point to both laboratory personnel and upper management not being ready to collaborate for the change. Without mutual support and trust, solid teamwork could not be developed for the redesign project. Teamwork was an essential ingredient to make change happen in no time.

Customer

The Senn-Delaney Survey questions in the Customer category were developed to indicate the level of awareness and focus on quality and the level of service consciousness or customer focus (Senn-Delaney, 2013). These questions analyzed how employees evaluated their work performance in relation to their awareness to bring the highest possible quality in delivering service and having a customer-focused mindset. The finding of more than 70% agreement in this category showed that laboratory personnel do put patient care first. With the implemented PI project, the focus on quality went up by 5.6%, but the focus on customers slightly decreased by 1.8% prior to redesigning (as shown in Table 6).

Organizational Culture

The internal hospital survey on patient safety revealed the laboratory staff's perspective in regards to dealing with medical errors, including the overall perception of safety, frequency of events reported, and non-punitive response to error. From each question, the common dominator was the employees' responses in terms of fear. Based on the findings, in both the pre-redesigning year (2012) and post-redesigning year (2013), laboratory personnel demonstrated a high level of awareness regarding patient safety. Although there was no statistical difference in comparing the pre- and post-redesigning years as demonstrated in Table 9, laboratory personnel showed an overall positive response on how they perceived the laboratory error prevention system and how they felt about reporting mistakes and what actions needed to be taken. From this finding, it demonstrated that in general, laboratory personnel prioritized patient safety over fear.

CHAPTER 5

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

In today's health care reformation, patient satisfaction profoundly plays a critical role in improving patient care and safety. Patient satisfaction perceptions call for all personnel in the medical field to pay extra attention in order to attain a better quality in patient care. In order to improve patient satisfaction, it is essential to start by developing employee satisfaction.

During three years of process observations in the histology laboratory from a laboratory standpoint and utilizing RCA tools, including the fishbone diagram and Five Whys technique, the researcher for this study was able to identify the root cause of an ineffective workflow in the laboratory and design a PI project, based on Lean principles such as *kaikaku* and *kaizen*. In implementing the PI project, Lean tools, including process mapping and spaghetti diagrams, were developed to assess the effectiveness of the PI project, which resulted in a positive impact with more efficient workflow obtained in the post-redesigning setting.

From the employee satisfaction standpoint, it showed that in implementing PI, the positive response of laboratory personnel toward change greatly impacted the success of this project. Additionally, the success of the implemented PI project in redesigning the laboratory for streamlining the workflow depended on the collaboration of all team members. With a customer-focused mindset, laboratory personnel optimally delivered laboratory services to pathologists for patient diagnosis. Furthermore, laboratory personnel job satisfaction levels were associated with the work environment. The positive organizational culture that drove out fear and motivated employee engagement and empowerment had an impact on patient safety, particularly for non-punitive responses to errors and in creating an error-preventive system.

In summary, the collected PI project data analysis showed some improvement in workflow within the histology laboratory processes. However, the collected survey data for the Change, Collaborate, Customers, and Organizational Culture categories between pre- and post- redesigning periods demonstrated overall that no statistical significance was discovered to support the research hypothesis that "there is a difference in laboratory personnel job satisfaction levels between pre-redesigning in 2012 and post-redesigning in 2013." This indicated that the PI process conducted for a short period of time showed no significant difference in job satisfaction levels of laboratory personnel. From this study, it could be highlighted that PI was a continuous process over an extended period of time. As with many variables that could affect employees' job satisfaction level, a longer period of time of more than two years of study would be required in order to have more reliable measurement.

Due to the results of this project, an extensive study of several more years would be needed to increase the significance and persuasiveness of the findings. According to Lean experts, Womack and Jones (2003), it would require a minimum of a five-year commitment for a Lean project in which many *kaizen* projects were planned and executed. As the model laboratory continued with its *kaizen* projects, documenting and recording the year-to-year process observations and conducting data analysis would be extremely important in order to see changes being made.

REFERENCES

REFERENCES

Aiken, L., Sermeus, W., Heede, K., Sloane, D., Busse, R., Mckee, M., . . . Kutney-Lee, A. (2012). Patient safety, satisfaction, and quality of hospital care: Cross sectional surveys of nurses and patients in 12 countries in Europe and the United States. *BMJ,* 344. doi: http://dx.doi.org/10.1136/bmj.e1717

Allen, M., & ProPublica. (2013). *How many die from medical mistakes in U.S. hospitals?* Retrieved from http://www.scientificamerican.com/article.cfm?id=how-many-die-from-medical-mistakes-in-us-hospitals

Czarnecki, H., & Loyd, N. (2002). Simulation of lean assembly line for high volume manufacturing. Retrieved from: http://www.scs.org/confernc/hsc/hsc02/hsc /papers/hsc037.pdf

Daemmrich, A. (2011). U.S. healthcare reform and the pharmaceutical industry. *Harvard Business School.* Retrieved from http://www.hbs.edu/faculty/Publication %20Files/12-015.pdf

Deming, W. E. (1986). *Out of the crisis.* Cambridge, MA: Massachusetts Institute of Technology, Center for Advance Engineering Study.

Evan, R., & Lindsay, W. (2012). *Managing for quality and performance excellence.* Mason, OH: South-Western Cengage Learning, Inc.

Heskett, J., Sasser, W., Jr., & Schlesinger, L. (1997). *The service profit chain: How leading companies link profit and growth to loyalty, satisfaction, and value.* New York, NY: The Free Press.

Institute of Medicine (IOM). (1999). *To Err is human: Building a safer health system.* Washington, DC: National Academy Press. Retrieved from http://www.nap.edu/openbook.php?record_id=9728&page=R1

Institute of Medicine (IOM). (2001). *Crossing the quality chasm: A new health system for the 21st century.* Washington, DC: National Academy Press. Retrieved from https://www.iom.edu/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf

James, J. (2013). A New, Evidence-based estimate of patient harms associated with hospital care. *Journal of Patient Safety,* 9, 122-128. Retrieved from http://journals.lww.com/journalpatientsafety/Abstract/2013/09000/A_New,_Evidence_based_Estimate_of_Patient_Harms.2.aspx

Johnson, M., & Gustafsson, A. (2000). *Improving customer satisfaction, loyalty, and profit.* San Francisco, CA: John Wiley & Sons, Inc.

Juran, J. (1992). *Juran on quality by design: The new steps for planning quality into goods and services.* New York, NY: The Free Press, A Division of Macmillan, Inc.

Ketola, J., & Roberts, K. (2003). *Correct! Prevent! Improve! Driving improvement through problem solving and corrective and preventive action.* Milwaukee, WI: ASQ Quality Press.

Kirkwood, B., & Sterne, J. (2003). *Essential Medical Statistics* (2nd ed.). Malden, MA: Blackwell Science, Ltd.

Kizer, K., & Dudley, R. (2009). Extreme makeover: Transformation of the veterans health care system. *Annu Rev Public Health, 30*, 313-39. Abstract retrieved from *pubmed.gov*.

Maxfield, D., Grenny, J., McMillan, R., Patterson, K., & Switzler, A. (2005). *Silence kills: The seven crucial conversations for healthcare*. Retrieved from http://www.aacn.org/WD/practice/docs/publicpolicy/silencekills.pdf

Obamacarefacts. (2013). *ObamaCare facts: Facts on the Affordable Care Act*. Retrieved from http://obamacarefacts.com/obamacare-facts.php

Otto, C., & Pendergraph, G. (2013). Medical error prevention: Patient safety. *MediaLab, Inc*. Retrieved from http://www.medialabinc.net/pdf/archive_courseprintpdf-medical_error_prevention_patient_safety-9668-0012-student.pdf

Rosenstein, A. H., & O'Daniel, M. (2008). A survey of the impact of disruptive behaviors and communication defects on patient safety. *The Joint Commission Journal on Quality and Patient Safety*, 34, 8, 464-471. Retrieved from http://www.mc.vanderbilt.edu/root/pdfs/nursing/ppb_article_on_disruptive.pdf

Senn-Delaney Leadership Consulting Group. (2013). *Senn-Delaney survey*. Huntington Beach, CA: Author. Retrieved from http://www.senndelaney.com

Weaver, J. (2014). Understanding and utilizing Lean and Six Sigma in histology laboratory. *MediaLab Inc*. Retrieved from https://www.medialabinc.net/pdf/ archive_courseprintPDFUnderstanding_and_Utilizing_Lean_and_Six_Sigma_in_ the_Histology_Laboratory-26939-0012-student.pdf

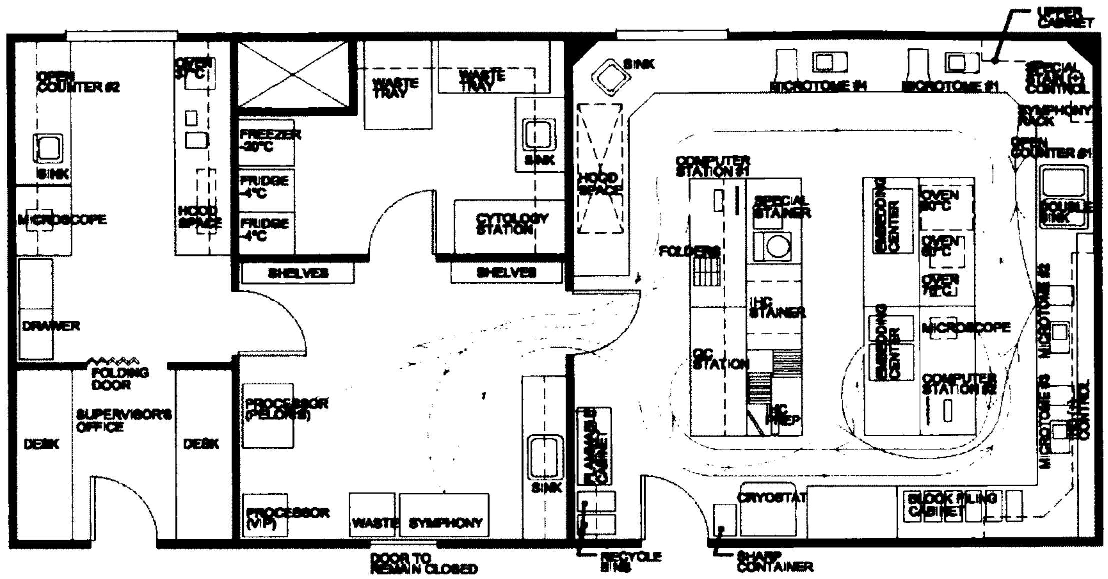
Womack, J., & Jones, D. (2003). *Lean thinking: Banish waste and create wealth in your corporation*. New York, NY: Free Press of Simon & Schuster, Inc.

Yu, M. (2013). Basics of Lean and Six Sigma for the Laboratory. *MediaLab, Inc.* Retrieved from https://www.medialabinc.net/pdf/archive_courseprintPDF-Basics_of_Lean_and_Six_Sigma_for_the_Laboratory-18207-0012-student.pdf

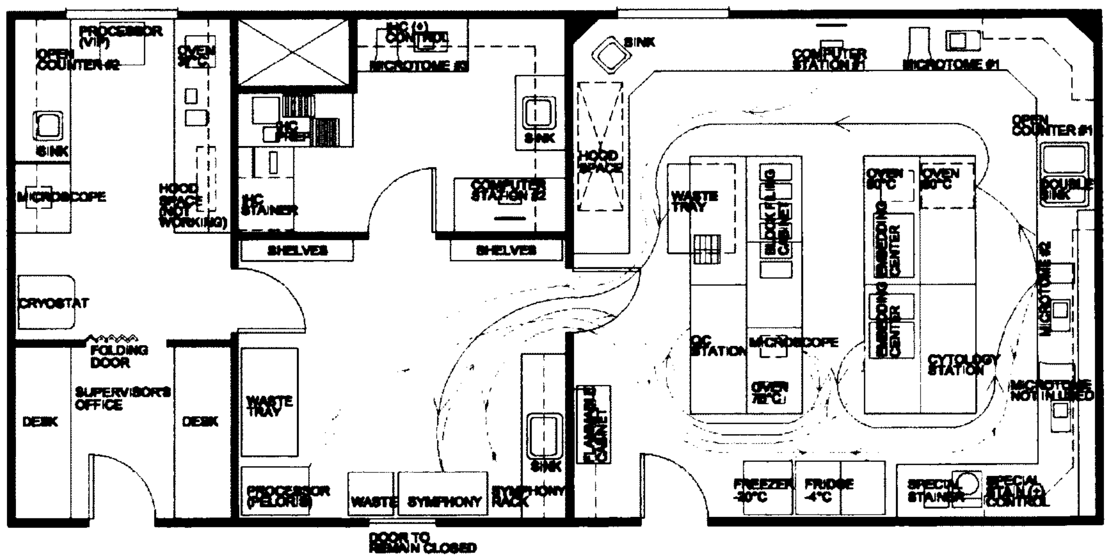
APPENDICES

APPENDIX A

SPAGHETTI DIAGRAMS OF ROUTINE STAINING



ROUTINE STAINING
(POST-REDESIGNING)
SCALE: 1/8"=1'-0"

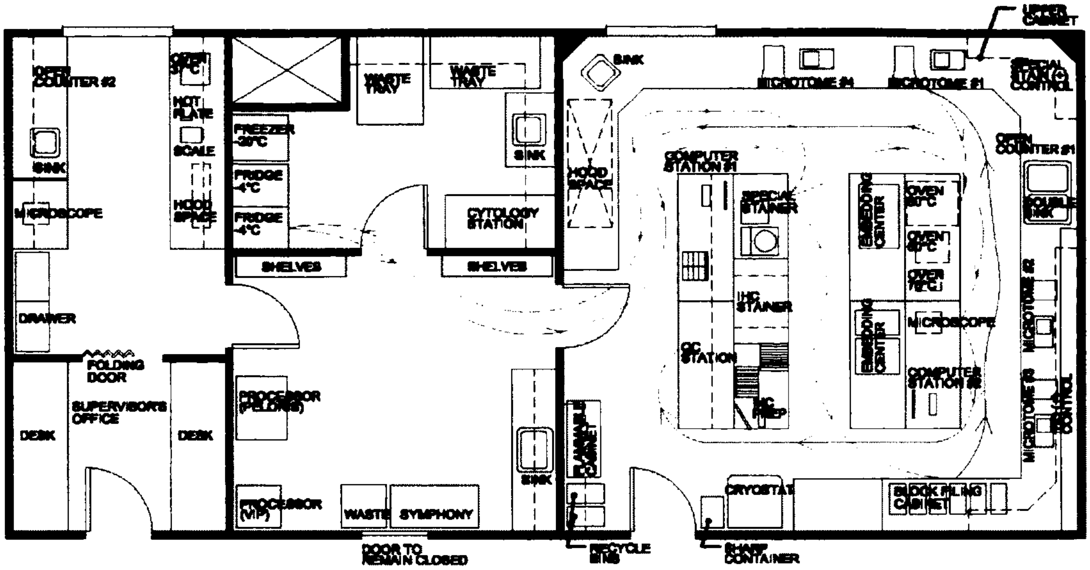


ROUTINE STAINING
(PRE-REDESIGNING)
SCALE: 1/8"=1'-0"

APPENDIX B

SPAGHETTI DIAGRAMS OF

SPECIAL STAINING



SPECIAL STAINING
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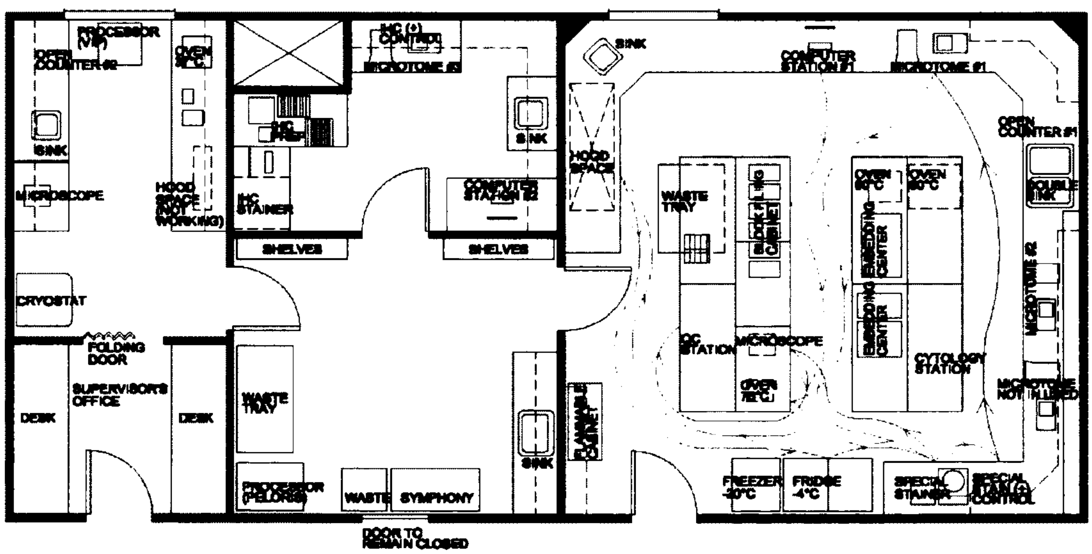

SPECIAL STAINING
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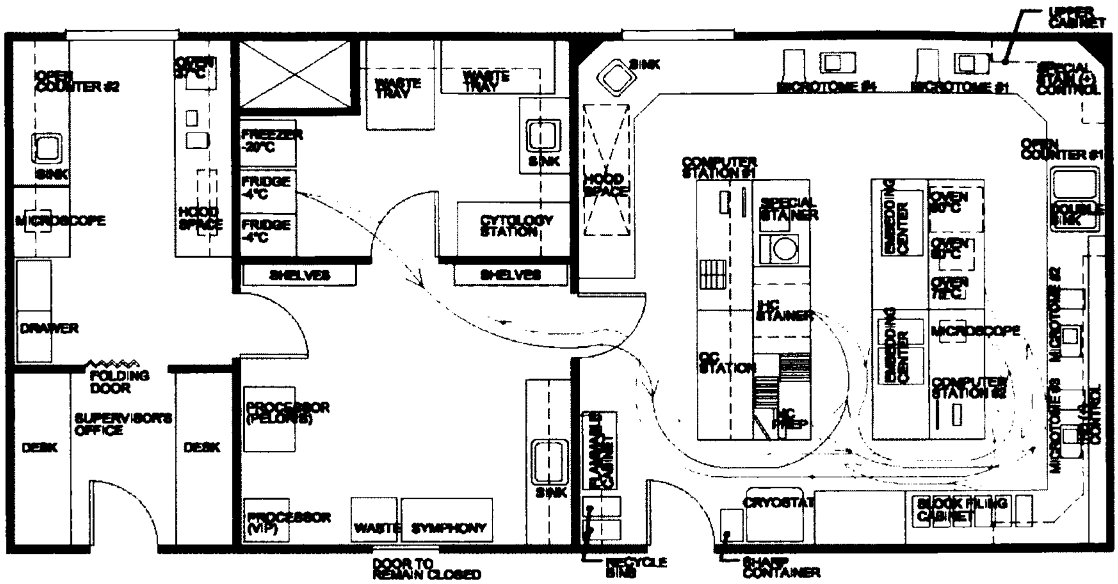
SCALE: 1/8"=1'-0"

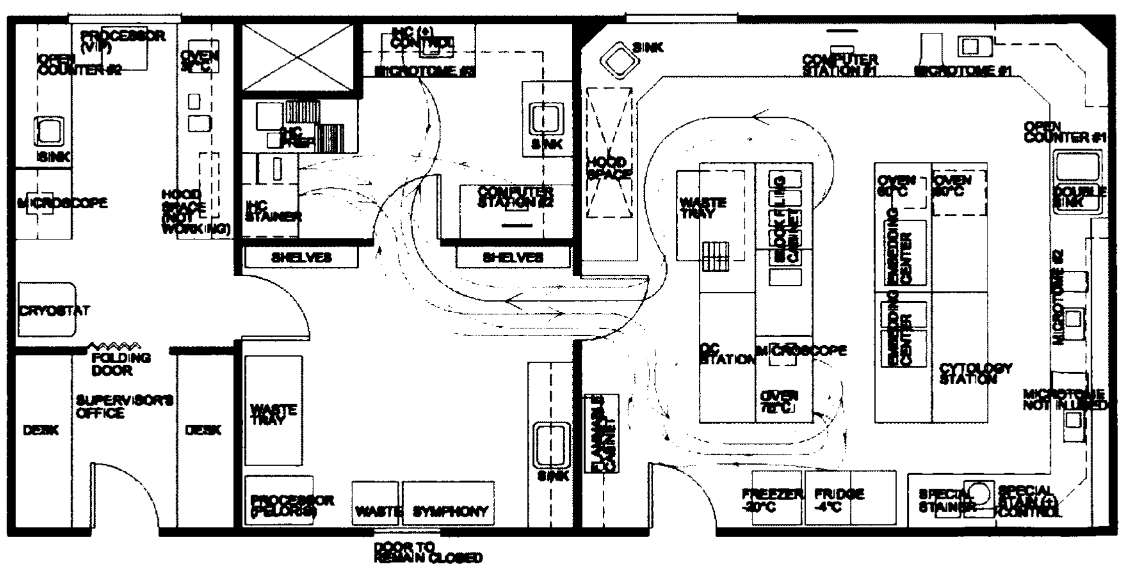
APPENDIX C

SPAGHETTI DIAGRAMS OF

IHC STAINING



IHC STAINING
(POST-REDESIGNING)
SCALE: 1/8"=1'-0"

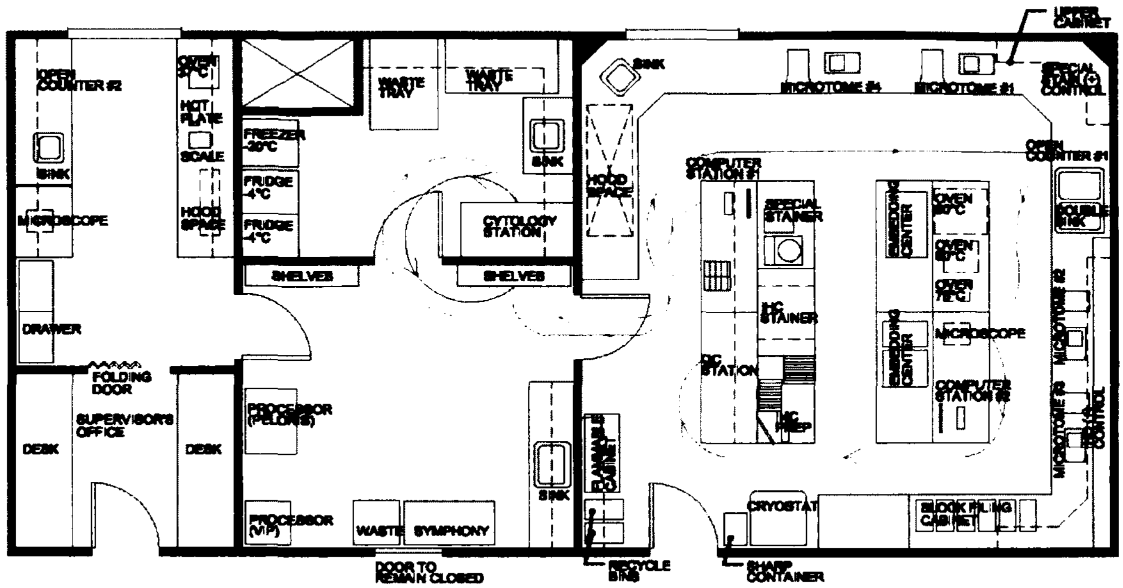


IHC STAINING
(PRE-REDESIGNING)
SCALE: 1/8"=1'-0"

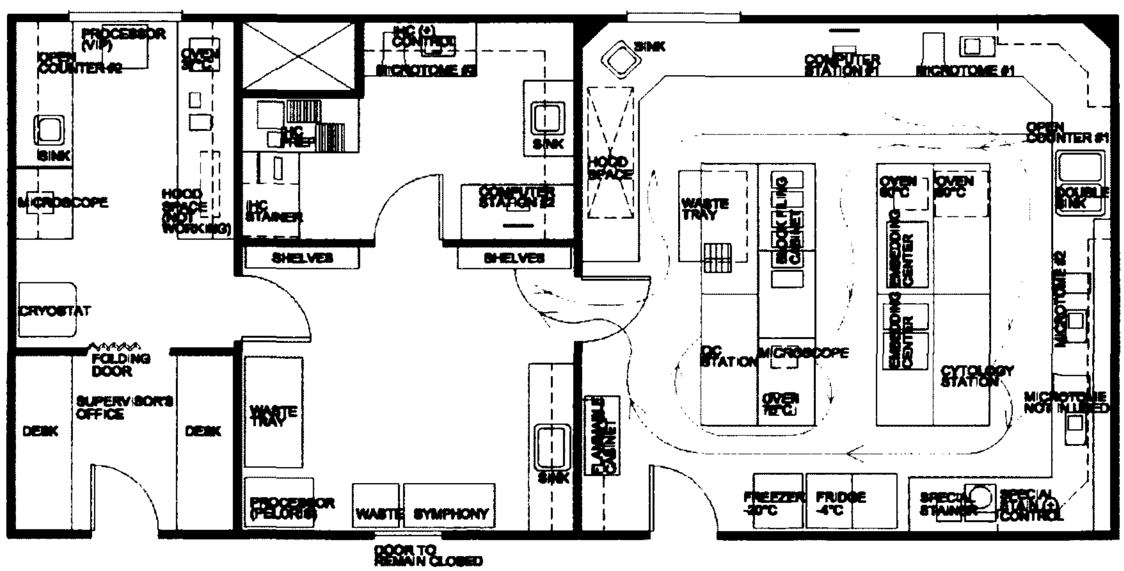
APPENDIX D

SPAGHETTI DIAGRAMS OF

CYTOLOGY STAINING



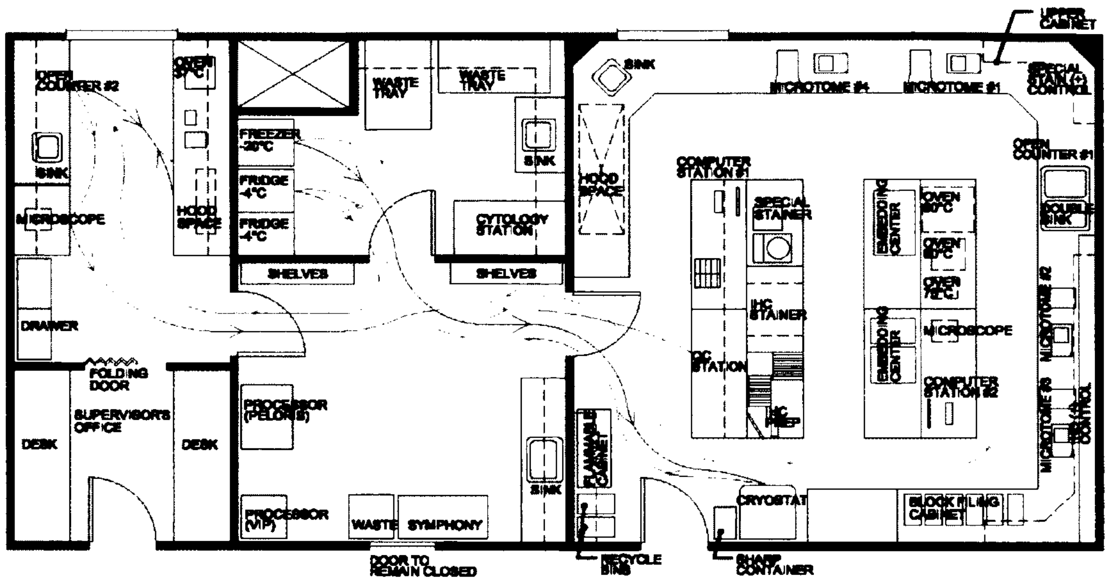
CYTOLOGY STAINING
(POST-REDESIGNING)
SCALE: 1/8"=1'-0"



CYTOLOGY STAINING
(PRE-REDESIGNING)
SCALE: 1/8"=1'-0"

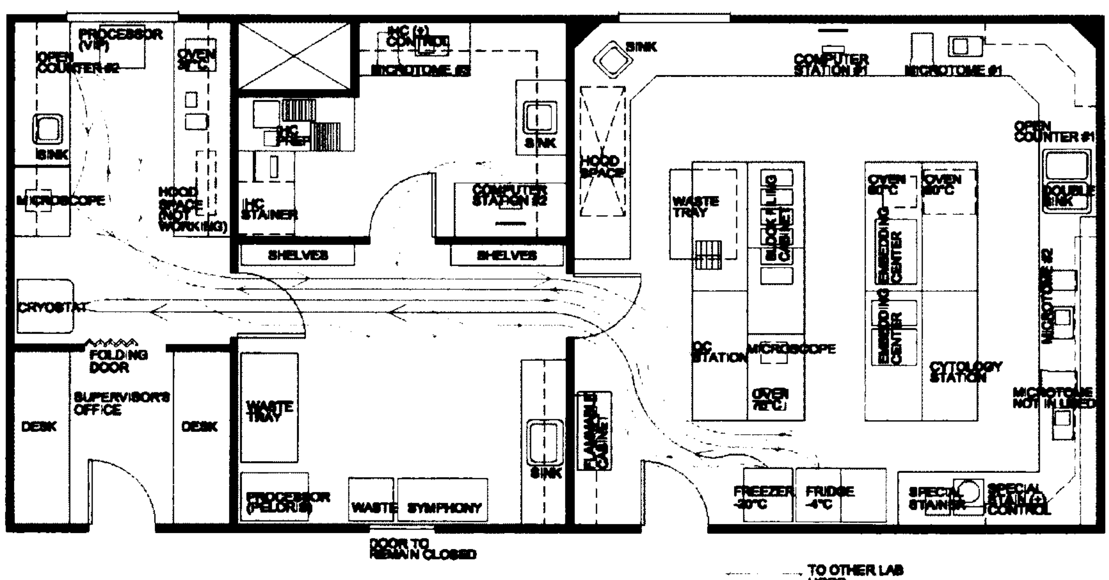
APPENDIX E

SPAGHETTI DIAGRAMS OF MUSCLE STAINING



MUSCLE STAINING (POST-REDESIGNING)

SCALE: 1/8"=1'-0"



MUSCLE STAINING (PRE-REDESIGNING)

SCALE: 1/8"=1'-0"