2015

Analysis of Lean/Six Sigma Production Model in a Tertiary Care Asthma and Allergy Clinlic

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ANALYSIS OF LEAN/SIX SIGMA PRODUCTION MODEL IN A TERTIARY CARE ASTHMA AND ALLERGY CLINIC

A MASTER'S PROJECT
SUBMITTED TO THE GRADUATE FACULTY
GRADUATE SCHOOL
BETHEL UNIVERSITY

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IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF
MASTERS OF SCIENCE IN PHYSICIAN ASSISTANT

JULY 2015

BETHEL UNIVERSITY

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July 2015

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ABSTRACT

In response to demands on healthcare, systems have looked to refine current processes to use time, materials, and finances more efficiently. Lean/Six Sigma (L/SS) is a model that has been used to improve procedural efficiency in various settings. The purpose of this study was to implement L/SS into an outpatient private practice setting and to evaluate the effect on efficiency as measured in the length of individual patient visits who presented to that clinic for routine re-evaluation. In this study, the amount of time between a patient's entrance and exit from the clinic was documented for 878 patients before implementation of L/SS and for 319 patients after an 18 month implementation period. Statistical analysis of the variance was completed using ANOVA and found to have both a statistically significant ($P < .05$) and clinically significant change (eight minutes) in visit time between the two groups.

ACKNOWLEDGEMENTS

Advancements in Allergy and Asthma Care, LTD.

Christy Hanson and Don Hopper, Research Committee Chairs

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CHAPTER 1
INTRODUCTION

Background to the Problem

Demands on the current healthcare system in the United States have created a need to improve efficiency. This push for healthcare clinics and hospitals to become more efficient is motivated by the rising healthcare costs and increased demands. Clinics across the nation have elected to undergo methods of reform in order to improve efficiency.

Implementing efficiency measures can be a challenge for clinics. Often, increasing the number of patients seen in a workday decreases both patient satisfaction and the job satisfaction of the provider (Boffeli et al, 2012). The result is a challenging work environment for health care providers (Rosenburg, 2013). Thus, strategy must be employed when implementing efficiency measures in order to meet the individual demands of a specific clinic and eliminate non-value work.

A constant push from health care is to reach the "triple aim": best care, best experience, and lowest cost (Berwick, 2008). Providers find it a daunting task to see more patients in a day while keeping their patients happy and may feel that these two goals are mutually exclusive. Clinics are continuously attempting to find creative ways to increase clinic efficiency while maintaining or increasing patient satisfaction, although limited universal evidence-based strategies to achieve this goal have been published (Boffeli et al, 2012).

Observational studies on clinic behaviors can be extremely beneficial to the pursuit of increasing patient satisfaction and clinic efficiency. Such studies can identify certain behaviors that are common among providers who have excellent patient satisfaction as well as behaviors that are common among providers who work quickly (Boffeli et al, 2012).

The use of structured quality improvement methods is well established in the manufacturing industry. Total quality management (TQM)/continuous quality improvement (CQI), Six Sigma (SS), and Lean Production (L) are among some of the most popular of these methodologies (Kim, Spahlinger, Kin, Billi, 2006). Originally developed in the 1970‘s by Toyota Corporation, Lean Production has been utilized to improve performance in a variety of industries including aerospace and aluminum refining, financial services, insurance, and, most recently, the health care industry (Kim et al., 2006). The focus of Lean is to develop stable and standardized processes to provide optimal quality and efficiency through continual improvement of current processes and removal of “non-value added” activities/unnecessary steps (Lin, Gavney, Ishman, Cady-Reh, 2013). Six Sigma is a similar process that was pioneered by Motorola in the mid-1980s; this process utilizes rigorous statistical analysis to reduce defects and improve quality (Lin et al., 2013). The combination of the two methods (L/SS) focuses on assessing and eliminating errors and improving work-flow to be efficient and valuable (Lin et al., 2013).

By using these processes, health care teams have the opportunity to couple “evidence-based medicine” with “evidence-based management.” Since 1999, L/SS production has steadily gained popularity as a tool in the health care industry. According to a recent literature review, between 2000 to 2010, 177 articles were published on the use of L/SS in health care settings (DelliFraine, Langabeer, Nembhard, 2010). This trend continues to rise as health care industries respond to the need for increased efficiency and quality improvement; however, a majority of these studies have been performed in emergency department settings and do not necessarily reflect the unique needs and challenges of each specialty clinic (Capasso & Johnson, 2012). There is a lack of research done regarding implementation of these efficiency models within the

private practice setting. There is a need for exploration of the efficacy of large scale, proven methods in a smaller, private practice environment.

Purpose of the Study

The purpose of this study was to implement Lean/Six Sigma Production into a private practice setting and to evaluate its effect on clinic efficiency, as measured by length of re-evaluation patient visits.

Significance of the Study

Successful implementation of the Lean/Six Sigma Production within this clinic may have implications for other private practice clinics due to the personalized approach of that model. Private practice clinics could use the model to adapt to the current climate of healthcare, increasing patient flow and using resources more effectively. The model could allow private clinics to adapt in a time with the formation of larger healthcare groups that can effectively see more patients but lose the more personalized approach often achieved in a private practice setting. Thus, this model could have the ability to provide a low cost solution for various types of private practice clinics. These clinics could meet the need to see more patients without adding additional staff and maintaining the unique features of a particular clinic, all while improving satisfaction of patients and employees alike.

Research Question

Therefore, this study sought to answer the question: is the Lean/Six Sigma Production model effective in improving the efficiency of a private allergy and asthma clinic in terms of the amount of time a patient spends in clinic? In order to answer this question in the context of this particular clinic, the amount of time patients spent in clinic was first measured according to current operational procedures and measured again according to the procedural changes

developed according to the Lean/Six Sigma model. Changes in the amount of time a patient spent in clinic was statistically analyzed to determine the efficacy of this model in a private practice clinic.

Definitions

Efficiency: A measure of productivity, with the goal being to maximum productivity with minimum wasted effort or expense (iSixSigma, 2015). For the purpose of this study, the measurement used to assess productivity was limited to patient visit time.

CHAPTER 2
LITERATURE REVIEW

Introduction

This chapter contains a brief overview regarding the state of healthcare in the United States, the pressures current healthcare organizations are facing, methods that have been used to respond to these pressures, and a discussion on the quality improvement tools relevant to this study: Lean/Six Sigma (L/SS).

Healthcare in the United States

The United States healthcare delivery system is commonly described as inconsistent, expensive, and inefficient (Mergener, 2012). Healthcare costs have continued to increase, reaching $2.6 trillion in 2010, which is 17.6% of the gross domestic product with a projected rise to $4.7 trillion by 2020 (Nordal, 2012). Even with these staggering costs, the United States healthcare system often fails to meet the goals of providing safe, effective, patient-centered, timely, efficient, and equitable care (Crossing the Quality Chasm, 2001; Mergener, 2012).

For example, prior to implementation of the Patient Protection and Affordable Care Act, 32 million Americans were without health insurance, thus limiting access to healthcare within that population (Nordal, 2012). Additionally, public health in the United States has changed. Life expectancy has increased leading to an increase in chronic conditions of the aging population and an inability for the current healthcare system to keep up with the health needs of the elderly (Nordal 2012; Crossing the Quality Chasm, 2001). Also, the current methods of healthcare delivery are not organized in a manner that can seamlessly manage a patient's various chronic conditions (Mergener, 2012). Many times, the route to proper care requires that a patient follow a confusing path of "handoffs" between various providers which results in slowing care, limiting

communication between healthcare providers, and decreasing patient safety (Mergener, 2012; Crossing the Quality Chasm, 2001).

In response to this collection of challenges facing healthcare, the United States government has shown a commitment to continual health care reform. This has been evident within the past few decades with legislation such as the State Children's Health Insurance Program in 1997, the Medicare Prescription Drug Improvement and Modernization Act of 2003, and most recently the Patient Protection and Affordable Care Act (ACA) of 2010. The ACA was passed with the goals of increasing access to healthcare, improving patient outcomes and overall public health, and reducing the amount of money spent on healthcare (Mergener, 2012; Nordal, 2012).

Current Pressures on the United States Healthcare Delivery System

While most can come to a consensus on the need for improvement within the healthcare system, implementation of the ACA undoubtedly places new pressures on the healthcare system (Nordal, 2012). The Patient Protection and Affordable Care Act provides an extensive legal framework to attain the goals for United States healthcare that comes with increased demand of 32 million newly insured Americans, decreased reimbursement for services, and new quality measures that must be met (Mergener, 2012; Nordal, 2012).

Reimbursements for services will likely decrease for multiple reasons with the implementation of the Affordable Care Act. Under section 3134 of the Affordable Care Act, the Secretary of Health and Human Services possesses the authority to review various billing codes that are currently used to obtain reimbursement for services and adjust codes that are deemed "misvalued" (Mergener, 2012). Adjusting the codes may limit the ability of providers to obtain reimbursement for various services provided (Mergener, 2012). Additionally, Section 3403 of

the ACA includes the formation of an Independent Payment Advisory Board (IPAB) who will make recommendations to decrease Medicare costs without eliminating benefits, limiting care, or increasing premiums (Mergener, 2012; Battistella, 2013). Thus, provider salaries are the most probable area to receive cuts; it is estimated that 40% of the projected savings will be due to decreased provider reimbursement (Battistella, 2013). Decreased payments are meant to motivate providers to become more strategic when determining care and ordering tests with the goal to reduce healthcare costs without impacting the quality of care (Battistella, 2013). When similar changes were made to the Medicaid program, an increased reimbursement gap resulted in providers who limited participation in the program or withdrew altogether in response to negative economic effects on their practices (Battistella, 2013).

Many studies have highlighted the inconsistency of the quality of healthcare in the United States (Mergener, 2012). In an attempt to rectify the inconsistencies, the Affordable Care Act contains incentives for providers who are willing to provide performance data to Medicare's Physician Quality Reporting System (PQRS) through 2014 (Mergener, 2012). However, penalties will be implemented in 2015 for those unwilling to participate (Mergener, 2012). Through performance data reports, patients can assess the quality of care offered by various providers; motivating providers to increase ratings and patient care (Mergener, 2012).

Another example of guidelines intended to improve healthcare quality is the use of electronic health records (EHR). The purpose of EHR use is to provide coordinated care and improve documentation methods (Stusser and Dickey, 2013). The need for quality healthcare is not disputed, but the requirements for improvements do not come without an investment of time and money. For example, practices that switch to certified electronic health records and comply with "meaningful use" have an incentive of $44,000, but estimates indicate that it costs a

minimum of $35,000 per physician to switch to an EHR (Mergener, 2012). This cost does not take into account the decreased productivity during the implementation phase nor the estimated annual cost of $15,000 to maintain EHR use (Mergener, 2012). As important as quality improvement measures are, the cost associated with them cannot be discounted when assessing the impact on the current pressure in healthcare.

Effects on Independent Practices

In addition to the predictable changes within healthcare throughout the next few years, unknown effects must be considered as well. The unknown has caused providers to "seek shelter" in the uncertain environment (Merenger, 2012). This mindset is especially apparent within the realm of private practice. As business costs and regulations increase with simultaneous reimbursement decrease, providers are experiencing increased anxiety regarding the direction of the healthcare delivery system (Beach & McIntyre, 2013). One potential consequence is providers abandoning private practice in exchange for larger groups with more security (Beach & McIntyre, 2013). The number of independent practices within the United States has been decreasing by two-percent annually for the past 25 years; the Affordable Care Act has accelerated this rate (Mergener, 2012). The current uncertainty regarding the future of healthcare leads providers currently in independent practice to contemplate if they can survive in light of the impending changes or if it would be wiser for them to become a member of a large integrated health system (Merenger, 2012).

Independent practices choosing to weather the uncertainty will logically seek to improve efficiency measures to effectively respond to the current pressures on the healthcare system. These pressures include the need to improve the individual patient experience through quality measures, improve public health, and adhere to governmental regulations. Private practices must

accomplish all of these tasks while decreasing costs when reimbursement is not as robust.

Strategies for Efficiency Improvement

In response to increased demand on providers, hospitals, and clinics to improve efficiency, a variety of methods have been developed. Several of these strategies including adjustments with staffing, scheduling, and task management will be briefly discussed in this section of the literature review. Some clinics have toyed with creative patient scheduling in order to decrease patient wait times (Cayirli and Veral E 2003). Medical scribes have been implemented in a variety of emergency department, hospital, and clinic settings in order to decrease tasks placed on the healthcare provider (Bank A. J, Obetz, C., Konrardy, A., Pillai, K.M., McKinley, B.J., Kenney, W.O., 2013). Other clinics have created a care model, giving specific job assignments for staff to eliminate interruptions (Kalisch B.J., and Aebersold, M., 2010). Specific cases containing these prospective solutions will be reviewed in this section.

Clinics have tried altering patient scheduling to reduce patient wait time and reduce provider idle time. The Park Nicollet Medical Center in Minneapolis, Minnesota was able to effectively decrease patient wait time by scheduling appointments in 10 minute intervals to achieve a continuous flow of patient appointments (Varkey et al, 2008). Although single-block continuous flow scheduling model worked well for Park Nicollet Medical Center, many outpatient clinics find that multiple-block scheduling as opposed to single-block systems substantially decrease patient waiting time as well as provider idle time (Cayirli et al, 2003). Integrated scheduling is another scheduling strategy that includes scheduling all low variance, shorter appointments earlier in the clinic day and reserving higher-variance, longer appointments for later in the clinic day. Literature states that a number of outpatient clinics have utilized this method to increase efficiency and effectively reduce overall patient waiting time (White et al,

2011). However, review of the literature suggests that there is no one-size-fits-all scheduling pattern that will work for every clinic. Thus to maximize efficiency, clinics must tailor scheduling patterns to fit the individual needs of each individual provider at each individual clinic (Cayirli et al, 2003).

The use of medical scribes has been documented to improve efficiency and increase revenue in the specialty clinic settings (Bank et al, 2013). Medical scribes are typically pre-medical or pre-PA students hired to assist with clerical aspects of patient care, specifically with documentation and EHR (Bank et al, 2013). One example of improved efficiency after scribe utilization is with the United Heart and Vascular Clinic, an outpatient cardiology clinic in St. Paul, Minnesota (Bank et al, 2013). This clinic experienced a 59% growth in patients seen per hour and a 57% increase in relative value units (RVU) per hour by implementing medical scribes into the practice (Bank et al, 2013). Over a 65-hour workweek, the use of scribes allowed this cardiology clinic to see an additional 81 patients, leading to $205,740 of increased revenue (Bank et al, 2013).

Another method some healthcare settings have used to increase efficiency is the implementation of a "care model." A care model is used to create specific roles of care providers in order to minimize interruptions and associated errors by separating tasks based on predictability (Kowinskey et al, 2012). This particular model was initially created in response to nursing staff being pulled away from assigned and predictable tasks (Kowinskey et al, 2012). Predictable tasks are defined as work that happens repetitively and reliably and that can be scheduled (Kowinksey et al, 2012). Unpredictable work is defined as tasks that are not scheduled and that occur randomly (Kowinskey et al, 2012). Frequent interruptions in the typical healthcare environment decrease efficiency as well as the job satisfaction of providers and nursing staff

(Kalisch et al, 2010). These interruptions can lead to errors, which would create more work for the provider and healthcare team (Kalisch et al, 2010). By assigning nurses to either predictable work or to unpredictable work, those assigned to predictable work were able to stay on task and maintain flow (Kowinksey et al, 2012). A one-year study done at the University of Pittsburgh Medical Center demonstrated that implementing such a care model increased efficiency of nursing tasks without increased expenses (Kowinskey et al, 2012).

In summary, a variety of methods to increase efficiency have been implemented by healthcare organizations to respond to increased demands. The literature outlines improved efficiency by adjusting patient scheduling models, staffing strategies, and task management. All of these approaches to increase efficiency have proved valuable within different settings. However, universal success of any of these approaches has not been shown due to the wide diversity of individual needs of various clinics.

Basics of Quality Improvement Tools

Operations research techniques are used in a variety of manufacturing contexts for quality improvement. Health care management has been shaped tremendously by the growing popularity of these quality improvement tools in the past two decades (Kim et al, 2006; DelliFraine et al, 2010). Two tools, Lean (L) and Six Sigma (SS), are the leading quality improvement tools, often used together (L/SS), in manufacturing industries and are gaining popularity in the healthcare sector (Kim et al, 2006; DelliFraine et al, 2010). According to a recent literature review, from the initial application of L/SS to the healthcare industry in 2000 to the end of their study in 2010, 177 relevant articles were published (DelliFraine et al, 2010). Financial pressures and healthcare reform have created an economic environment where healthcare organizations have to prioritize efficiency (Kim et al, 2006). The development of quality improvement tools, such as L/SS,

provides a systematic approach for the development of individualized solutions that fit specific settings (Kim et al, 2006).

Lean Production

Initially developed by Toyota, Lean Production principles have been embraced for decades in the industrial arena to improve productivity, reduce variation, and achieve lower defect rates (Warner et al, 2013). The focus of Lean is to "create standardized and stable processes" that provide the best quality of service/product, in the most efficient way possible (DelliFraine et al, 2010, p. 212). Quality and efficiency measures are attained by removing waste and unnecessary steps from processes, or "non-value added work" (Kim et al, 2006; DelliFraine et al, 2010). For example, redundancies in the flow of operations are eliminated in favor of more direct pathways (Kim et al, 2006; DelliFraine et al, 2010).

The first step of Lean is to understand value as defined by "the customers" (patients, families, physicians, PAs, other health care providers, staff, etc.) (Kim et al, 2006). Secondly, observations need to demonstrate how the processes currently operate by working with a team to identify areas of waste, delay, and inefficiency (Kim et al, 2006). As a team, an "ideal process" is developed and a subsequent plan of action is determined (Kim et al, 2006). The implementation phase that follows encourages employees to work toward creative solutions for continual revision of the "ideal process" (Kim et al, 2006). The fifth step, which is often the most difficult, is a shift of the culture, a commitment to the process of improvement and waste elimination on a permanent basis (Kim et al, 2006; DelliFraine et al, 2010).

Six Sigma

Six Sigma was developed by Motorola in the mid-1980s in order to reduce variability, and thereby errors, by establishing "aggressive goals for quality" (DelliFraine et al, 2010, pg 3).

Quality is measured by Six Sigma in terms of defect rates; for example, the target error rate is no less than 3.4 defects per million opportunities or six standard deviations from the process mean (DelliFraine et al, 2010). Variability is reduced by creating and adhering to a well-thought out and tightly controlled process (DelliFraine et al, 2010).

The process is developed through a 5-step methodology: define, measure, analyze, improve, and control (DMAIC) (Warner et al, 2013; DelliFraine et al, 2010). First, a problem is defined. Next, data is collected and statistically analyzed to determine sources of variation/error and to identify opportunities for improvement. Adjustments are made to the current process, and subsequent data is collected and analyzed to assess and promote sustained improvements in error rates (Warner et al, 2013; DelliFraine et al, 2010). The final step, control, necessitates a cultural shift in the way organizations are run (Antony & Banuelas, 2002).

Six Sigma and Lean

The end goals of both Six Sigma and Lean are very similar and it can be difficult to differentiate one from the other. To summarize the difference according to DelliFraine et al (2010), "Lean focuses on *doing the right things* (value-added activities) and Six Sigma focuses on *doing things right* (with no errors)" [emphasis added]. The methodology of improvement is similar as well; however, where Six Sigma focuses more on analytical techniques and error rates, the focus of Lean is on process and cultural change (DelliFraine et al, 2010).

Despite conceptual differences, both tools eliminate waste and redundancy in operational processes. Thus, they are seen as complementary and are often used in conjunction with each other in process improvement projects (DelliFraine et al, 2010). When used together, organizations can create processes that add "value" to their systems and quantify effectiveness using statistical analysis (DelliFraine et al, 2010).

Critiques of L/SS

In the midst of the growing popularity of Lean/Six Sigma, some researchers have expressed concern with the level of evidence for their widespread use in the healthcare setting (Vest, 2009; DelliFraine, 2010). Some critics classify the level of evidence supporting L/SS improvement as weak due to methodological limitations undermining validity of results (Vest, 2009; DelliFraine, 2010). These limitations include weak study designs, inappropriate analysis, failure to rule out alternative hypothesis, and failure to note changes in organizational culture or substantial evidence of lasting effects from these efforts (Vest, 2009; DelliFraine, 2010). Articles that focus more narrowly on targeted areas with in depth analysis were able to present stronger evidence that L/SS can improve processes of care (Vest, 2009). Additionally, researchers point out gaps in the current literature regarding the use of SS/L to improve clinical outcomes and the cost effectiveness of the models (DelliFraine, 2010). Researchers have identified the need for more studies with rigorous design and analysis with exacting evaluation to ensure validity of conclusions, demonstrate sustainability, and effectively guide healthcare leaders who desire to transform their organizations (Vest, 2009; DelliFraine, 2010).

Previous Studies

The successful application of Lean/Six Sigma principles in quality improvement efforts has been demonstrated in a variety of healthcare settings. L/SS provides both framework and flexibility that can easily be adapted to new settings. L/SS can provide a tool for healthcare organizations to develop systematic yet individualized solutions to the challenge to increase quality efficiently. The most commonly published process-improvement projects in the healthcare industry include improving operating room and emergency department patient flow,

reducing medication and non-medical errors, following best practices of care, and reducing patient waiting and other turnaround times (DelliFraine et al, 2010).

An example of implementation of the L/SS method was performed in an observational study by Lin et al (2013). Lean/Six Sigma quality-improvement strategies were put in place to improve efficiency of patient flow in a tertiary care otolaryngology clinic (Lin et al, 2013). The goals of this project were to decrease the overall lead time from patient arrival to patient-provider interaction, to improve on-time starts of patient visits, and to decrease excess staff/patient motion (Lin et al, 2013). The study was conducted for five days using time stamps in order to identify patient flow constraints and areas for potential improvements (Lin et al, 2013). Specific interventions were developed by the team of people directly involved in the process. A six month transition and implementation period was allowed before a second observational study was undertaken where once again lead time, on-time starts, and staff/patient motion were assessed (Lin et al, 2013). The use of Lean Six Sigma principles in this clinic led to statistically significant decreased patient wait time and improvements in on-time patient exam start time (Lin et al, 2013).

Conclusion

The current state of the United States healthcare system has created an environment that is challenging to healthcare organizations. In an attempt to survive in the face of these challenges, organizations have looked to efficiency improvements within their system. This literature review briefly summarizes some of the methods by which healthcare organizations have responded to these pressures, including a discussion of the Lean/Six Sigma method to evaluate and improve efficiency.

CHAPTER 3
METHODOLOGY

Introduction

This study aimed to assess the ability of Lean/Six Sigma Production (L/SS) to improve clinic efficiency of a private practice clinic that specializes in asthma and allergic conditions. Improving efficiency during a patient visit was desirable as a first step in the clinic's attempt to increase revenue, decrease cost, and improve provider job satisfaction. The efficiency of clinic procedures was evaluated by documenting total patient visit times. This chapter describes the participants, the materials used, study design size and duration, procedures, and statistical methods.

Population

This study occurred at a private practice allergy and asthma clinic in Minnetonka, a suburb of Minneapolis, Minnesota. The focus of this study was on procedural efficiency and thus did not distinguish patients by age, gender, socioeconomic status, or ethnicity. Patients were selected in a sequential manner over a period of three months prior to procedural implementation and two months following procedural changes. Patient population was limited to previously established patients presenting for routine re-evaluation to reduce the variation between visit types and due to the nature of these visits and the highest potential for reduction in visit length.

The healthcare team included five providers: one physician, three physician assistants, and one nurse practitioner. Clinical staff members consisted of registered nurses, medical assistants, and medical scribes. The administrative team consisted of receptionists, transcriptionists, and business office managers. For the development of procedural changes according to the L/SS model, a team from Fairview's Network Clinical Systems department was consulted.

Materials Used

Receptionists used stop watches to measure, in minutes, the length of patient visits. The time was documented when the patient enters and exits the clinic. The time stamps were initially recorded on paper and then entered into an Excel spreadsheet.

Study Design, Size, and Duration

In order to assess the ability of L/SS to improve clinic efficiency, a quantitative, experimental study was performed. Procedural changes were developed by the clinic in partnership with Fairview's Network Clinical Systems department in accordance with the L/SS model. Clinic workflow and patient wait times were recorded before procedural changes (procedure one) and after the implementation of the procedural changes (procedure two). Comparisons were made between non-equivalent patient groups at the clinic.

The independent variable was the procedure and the time spent in the clinic was the dependent variable. Initial data collection took place over a span of three months, followed by procedural implementation process of 18 months. The final data collection took place over the subsequent two months. The sample size for the first set of data collection was 878 re-evaluation patients and 319 re-evaluation patients for the second set of data following the procedural changes.

Procedure

For this study, the clinic defined value as reducing the amount of time a patient spent in clinic. This goal came directly from the desire to reduce operational costs, increase revenue by seeing more patients, and improve job satisfaction, without sacrificing patient satisfaction. After determining the values and goals of the clinic, current operations were documented and observed. This was first done by value stream mapping in which providers described each

process within a patient visit while identifying opportunities for improvement within current processes. Once a map was created to reflect current procedures, the team from Fairview followed sequential patients on a particular day through the entirety of an appointment. The amount of time each patient spent on various tasks, such as checking in for an appointment, participating in diagnostic tests, and waiting for a provider, was documented for the purposes of identifying areas for procedural improvement. In addition to data collected by Fairview, receptionists employed by the clinic also collected data over a three-month period pertaining only to the amount of time spent in the clinic by a patient, not including the allotment of time within each visit. No names or personal information was recorded.

After clinic visit data was collected for three months, clinical administration and healthcare providers reviewed the findings. In light of the values of reducing the length of patient appointments to reduce cost, increase revenue, and improve job satisfaction, areas with potential for process improvement were identified. The opportunities for procedural improvement included tardiness of patients, cumbersome pre-visit planning, interruptions and errors while organizing discharge summaries, and staff members venturing outside of defined roles resulting in disjointed workflow. Using that information, the group of providers and administrators constructed a plan that modified the processes to align with the values of the clinic and the goal toward improved efficiency through the Lean/Six Sigma process. Procedural changes were implemented for an 18 month period and included (a) informing patients that the appointment time was fifteen minutes prior to the time on the provider's schedule to reduce effect of patient tardiness on clinic flow; (b) creating health reminders and a flowsheet of updated patient statistics to streamline pre-visit planning on the part of the provider; (c) requiring staff members to stay in the exam room with the patient until all paperwork was completed for discharge to

reduce workflow interruptions; (d) encouraging staff to adhere to assigned roles instead of disrupting workflow to complete tasks not included in his or her job description Following the implementation phase, receptionists gathered data regarding the amount of time each patient spent in clinic for the following two months. Comparison of the amount of time each patient spent in clinic prior to and following procedural changes was then assessed and data analysis was completed.

Informed consent was not required, given no patient identifiers or demographics were collected or evaluated and this study did not affect the patient. The data regarding the length of patient visits was gathered in a sequential manner and were independent of individual patient identity. This study did not interfere with the patient's visit nor was any treatment or testing performed on them.

Validity and Reliability

Procedural design and data collection were completed in collaboration with a team from the Network Clinical Systems department of Fairview, a large healthcare organization, that has overseen similar efficiency reviews with other clinics and physician groups. Working with experienced professionals with prior success in similar endeavors provided this project with validity by ensuring sound methodology.

The same group of individuals collected the data from the two procedures, preventing potential inconsistency in the process of data collection. Additionally, both procedure one and procedure two data was collected at the same private practice clinic, evaluating the same five providers, ensuring difference in visit times was not attributable to variance of work paces of different providers or variances between clinics. It is possible that providers were motivated to work faster when they knew they were being timed, however, as the same providers and the

same timing methods were used in both procedure one and procedure two, this potential bias was normalized over the two procedures.

Reliability in the timing was determined by providing a defined start and stop point for the timing of the re-evaluation patient visits. The time for a patient was started as soon as the patient enters the clinic waiting room. A visit was considered complete once the patient exits the clinic.

Only established patients presenting for re-evaluation were included in the study. Considering that new patient visits were significantly longer than re-evaluations, consistency with the type of visit was essential for validity of the results.

CHAPTER 4
DATA ANALYSIS

Data was collected from 878 and 319 re-evaluation patient visit times prior to and following procedural changes, respectively. The difference in the number of the sample size (878 versus 319 patients) prior to and following the procedural change was simply due to the ability of the clinic to collect data and the amount of re-evaluation visits that could be accounted for during that time period.

A one to two minute change in clinic visit time per patient was considered clinically significant because it would allow providers to see an additional patient in a 30 minute time slot per nine hour work day as illustrated in Equation 1.

$$\underset{\text{in patient visit}}{2\ \text{minute reduction}} * \frac{15\ appointments}{day} = \frac{30\ minutes}{day} = 1\ appointment\ time\ slot$$

Equation 1. Determination of clinically significant reduction in length of patient visit.

Based on a 30 minute time slot scheduled for re-evaluation patients, with a standard deviation of 15 minutes, a sample size of 878 patients will provide a greater than 95% confidence level to detect a 2.5 minute difference in the two procedure methods (with 80% power and an alpha level of . 05). Analysis of variance in the data collected was completed with Excel using a single factor ANOVA test and is displayed in Table 1. The null hypothesis was that there would be no difference between the average amount of time for a patient re-evaluation visit prior to and following procedural changes. The alternative hypothesis was that there was a statistical difference between procedure one and procedure two, prior to and following procedural change.

Analysis of Variance of Re-evaluation Appointments

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	14761.14	1	14761.14	10.48992	0.001233296*	3.849252
Within Groups	1681572	1195	1407.173			
Total	1696333	1196				

*Data is significant at $p<0.05$.

Table1. Analysis of variance of re-evaluation patient visits.

Prior to procedural change, the average amount of a time for a re-evaluation patient visit was 69 minutes, with a standard deviation of 42 minutes. Following the implementation of procedural changes, the average length of a re-evaluation patient visit was 61 minutes, with a standard deviation of 21 minutes. Thus, an average change in eight minutes was achieved and a reduction in standard deviation of 21 minutes. Using a single factor ANOVA test of the data, the p value was found to be 0.00123 for re-evaluation patient visit times. With a p value less than the alpha of 0.05, the change in re-evaluation patient visit times can be considered statistically significant. Thus, the null hypothesis can be rejected and the alternative hypothesis accepted that there was a significant change between the two groups at a statistical level. An eight minute change in visit times surpasses the one to two minute threshold needed to achieve clinical significance, as previously discussed and illustrated in Equation 1. Thus, this change is also considered to be clinically significant.

Equation 2 demonstrates the potential impact of this change on number of patient appointments per day based on a 30 minute visit time and nine hour work day.

$$\frac{8\ minute\ reduction}{in\ patient\ visit} * \frac{15\ appointments}{day} = \frac{120\ minutes}{day} = 4\ appointment\ time\ slot$$

Equation 2. Projected increase in number of patient appointments following procedural changes.

As demonstrated in Equation 2, with a reduction in re-evaluation visit times of eight minutes after procedural changes, there is a potential for a single provider to see an additional four patients per nine hour work day based on a 30 minute visit time. Based on the data that was gathered, one confounding factor in this analysis is that patient visit times often stretch out beyond their 30 minute appointment slot. The average visit time after procedural changes for re-evaluation patients was 61 minutes. Thus, the real impact of an eight minute change in patient visit times may be less than Equation 2 projects. If appointment slots are reconsidered to be 60 minutes, the reduction in eight minutes per re-evaluation appointments still has the potential to add two re-evaluation patients per day.

Sub-analysis

Although this study was limited to the evaluation of change in visit times of re-evaluation patients, time stamp data was initially collected for all appointment types. Appointment types included skin tests, new patients, etc. ANOVA testing was completed for these visits as well, but the p value was greater than 0.05 and the null hypothesis was accepted that there was no significant change between appointment times prior to and following procedural change. There was a notable reduction in time for some types of visits prior to and following procedural change, but due to the much smaller data set collected for these appointments, they could not be considered statistically significant. A summary of the calculated p values for the various appointment types is located in Table 3 in Appendix C.

CHAPTER 5
CONCLUSION

Summary

The Lean/Six Sigma model was implemented into a private practice asthma and allergy clinic in Minnetonka, MN. The clinic determined that a reduction in the length of patient appointments and improved efficiency was their "value" as defined by the Lean/Six Sigma process. The length of time for a re-evaluation appointment was first recorded for 878 patients, followed by an 18 month period of procedural changes in the clinic, and concluded with recording the length of appointment time for 319 patients following procedural changes. The average amount of time spent in clinic prior to and following procedural changes was 69 and 61 minutes, respectively. Analysis of variance was completed with ANOVA testing with a p value of less than 0.05 considered significant. Analysis of re-evaluation appointments revealed a p value of 0.00123 denoting statistical significance between the appointments prior to and following procedural changes and the success of the clinic to reduce the length of appointments in a significant way.

Limitations

The patients in this study were selected in a sequential method and not selected based on personal identity or specific health concerns. Thus, the primary limitation of this study design was variability between the patient groups, both before and after procedural change. This method of patient selection introduced a potential inconsistency due to differences between the patient populations in procedure one and procedure two. Additionally, the type of patient visits that analyzed were limited to re-evaluation patients. Therefore, conclusions regarding increased clinic efficiency must be limited to re-evaluation patients and cannot be generalized to other visit types. Another limitation is generalizability due to the fact that data collection was performed at a

single private practice, tertiary care, asthma and allergy clinic. The results may not be applicable to all healthcare settings, including primary care, other specialty clinics, and inpatient medicine.

Further Research

This study was focused on the initial implementation of the Lean/Six Sigma process improvement tool and analysis was limited to a select group of visit types. As such, there are several areas that are open for further exploration. These areas include analysis of additional visit types, change and sustainability of change over time, as well as exploring impact of change fiscally and socially.

As mentioned in the limitations section, this study focused only on re-evaluation patient visits. Additional analysis could focus on other appointment types (ie new patients, skin tests, office calls etc.). This would lead to increased ability to generalize results of the process.

Lean/Six Sigma is a process improvement tool that is founded in the concept of continual quality improvement over time. As such, there is a focus on change in mindset in order to create a culture that is continually seeking ways to improve processes. Several specific process changes were implemented in this study leading to increased efficiency in re-evaluation patient visits. However, it is not yet known whether these changes are sustainable over time or if there has been enough of a cultural change to prompt continual implementation of process improvement. Future study could repeat collection of time stamp data for re-evaluation patients at a later date. If there is further reduction in patient visit times, this would suggest that a cultural shift toward continual process improvement over time has taken place.

The goal of this study was to determine whether or not the Lean/Six Sigma production model was effective in improving the efficiency of a private allergy and asthma clinic and to quantify the change in visit times. However, this quantified and statistically significant change has yet to be translated into real life application. The assumed impacts of reduced cost, increased

revenue, and improved job satisfaction were not explored or quantified. Further research could address these applications to demonstrate the fiscal and social benefits or harms of implementation of this model.

Conclusion

The purpose of this study was to implement the Lean/Six Sigma model into an outpatient private practice setting and to evaluate the effect on efficiency as measured in the length of individual patient visits who present to that clinic for routine re-evaluation. The amount of time between a patient entering and exiting the clinic was recorded for 878 patients prior to procedural change and 319 patients following procedural change. Statistical analysis of the variance was calculated using ANOVA and it was determined that the eight minute average reduction in re-evaluation appointment was statistically significant, with a p value < 0.05. Thus, it can be concluded that the Lean/Six Sigma production model effectively reduced the amount of time required for re-evaluation and improving clinic efficiency.

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APPENDIX A
ANALYSIS OF DATA COMPARING DATA PRIOR TO AND FOLLOWING PROCEDURAL IMPROVEMENT

	June 2013-September 2013			April 2015-May 2015		
	BEFORE CHANGES			**AFTER CHANGES**		
Visit Type	Average (minutes)	Std. Dev. (minutes)	Number of Patients	Average (minutes)	Std. Dev. (minutes)	Number of Patients
Asthma Review/Skin Test	138	39	9	112	6	2
Follow Up	62	21	139	63	22	90
New Patient	122	60	242	124	41	177
Office Call	74	25	132	69	24	107
Office Call New Pt.	100	32	115	94	38	30
Re-evaluation	69	42	881	61	21	319
Skin Test	134	110	102	108	35	29

Table 2. Summary of data prior to and following procedural changes

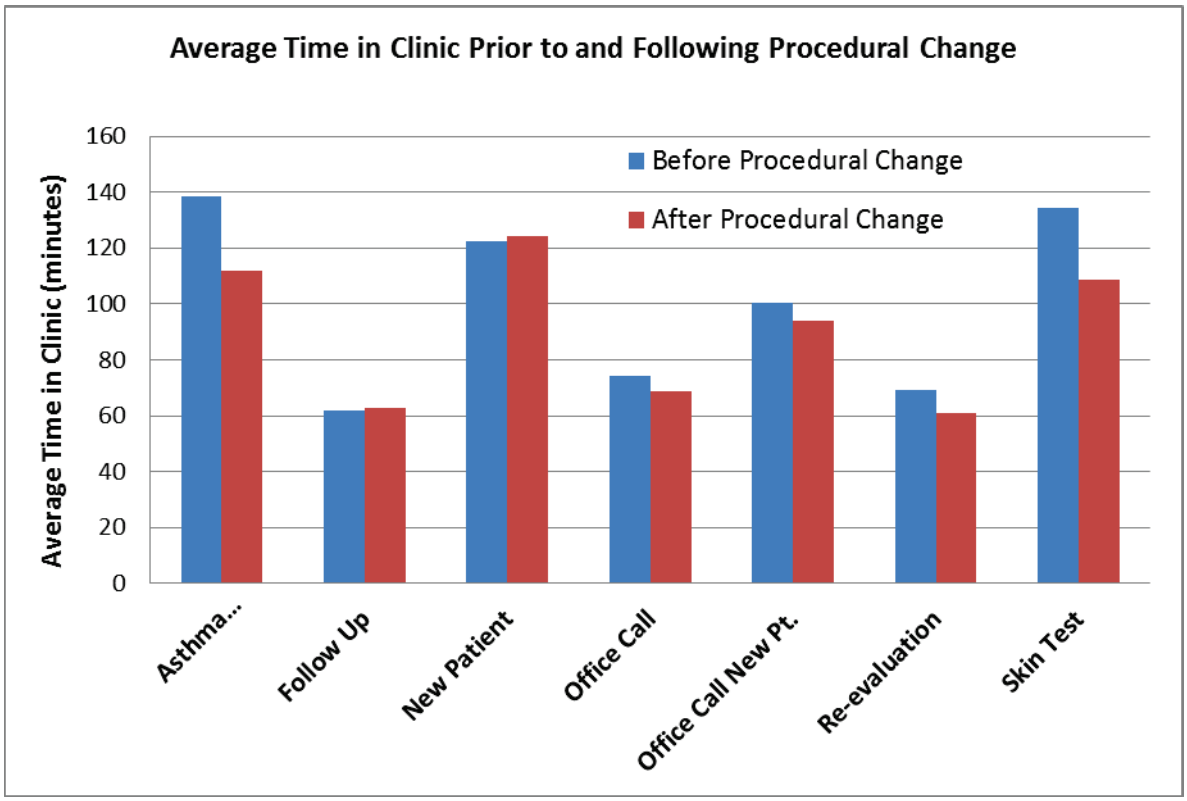

Figure 1. Graphical display of appointment length prior to and following procedural change

Visit Type	p value from ANOVA test
Asthma Review with Skin Test	0.404
Follow Up	0.779
Re-evaluation	0.00123
Skin Test	0.215
Office Call	0.0801
Office Call New Pt	0.215
New Pt	0.739

Table 3. Summary of calculated p values for each appointment type