Secondary Research based on Systematic Review on Application of Six Sigma and Quality Improvement Measures within Hospital and Healthcare set up.

A Capstone project submitted to

Johns Hopkins Bloomberg School of Public Health & IIHMR University

in partial fulfillment of the requirements for

the award of the degree of

Master of Public Health

by

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MPH - Cohort IV (2016-18)

Under the guidance of

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October 2017

Acknowledgement

The success of this Capstone Project required a lot of mentorship and assistance from many people which I feel I am privileged to enjoy and I would like to share the same. All my efforts secured this outcome only due to the supervision and assistance and I would like to thank my guides and mentors individually.

I owe my deep gratitude to my Capstone Guide, Mentor and Adviser Dr. Jagjeet Prasad Singh who took a keen interest in my project work and guided, me all along till the completion of work by providing all the necessary information for developing a good structure.

I would like to extend sincere gratitude and respect towards Dr. S.D. Gupta for providing me with an opportunity to do the Capstone work in IIHMR and giving me all the support and guidance which helped me to complete the project in due time.

I am extremely thankful to other faculty members for providing support and guidance, amidst their busy schedules at the institute in managing the academic and student affairs.

I heartily thank our Course Coordinator, Mr. Gowtamghosh B. Reddy for his guidance and suggestions throughout this Capstone work.

Last but not the least, I am fortunate enough to get constant encouragement and support from all my cohort members, especially my roommates, which also helped me to successfully complete the work.

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Executive Summary

Healthcare is a complex industry where numerous different stakeholders are involved at various stages of the care continuum and the end objective is to ensure the optimal care delivery for each end customer, that is, the patients. However, due to the multifaceted nature of healthcare delivery, maintaining efficiency and accuracy is an immense challenge. Over the past few decades, numerous studies have been conducted to streamline the various processes involved, in an attempt to reduce errors and improve performance. Many frameworks have been tested and "Lean Six Sigma" (LSS) is one of the best process improvement methods which has been tried and tested in other domains with reasonable degree of success. Application of LSS methodologies to healthcare business problems have been attempted on various occasions and it has proved promising indeed. In this paper, the focus is on how LSS can improve the care delivery process in a hospital environment. The "Lean and Six Sigma" concepts have been explored in detail to understand the basic philosophy and tools and techniques required for successful implementation. Post that a select group of case studies have been considered in depth to understand the problem scenarios, the application and the benefits obtained from the implementation. It has been observed in this study that in order to successfully implement the LSS methodology in a hospital setup, certain common success factors and roadblocks need to be considered and addressed properly. The conclusion from this paper is that further studies are required to strengthen the evidence in favor of LSS as a holistic framework for improving healthcare delivery efficiency.

Background and Introduction:

Countless management strategies have been established in the business world to improve the overall performances of institutions through enhancing the organizational processes. These strategies include a wide variety of frameworks as the ‘‘Lean and Six Sigma” or LSS methodologies, that aim to improve different processes through organized set of practices that facilitate better efficiency and greater outcomes, with some inefficient aspects as well (1). After an evolution from their earlier applications in the different manufacturing industries and units, these techniques and strategies have been increasingly used in other industries including various service-based sectors like financial services, software development, health care services, laboratory-based services and many others (1).

Implementation of strategies like “Lean Six Sigma” (LSS) in service related sectors like healthcare is both fascinating and challenging at the same time. Healthcare services usually contain many complex systems as well as processes involving various stakeholders who should perform their activities in terms of high clinical and administrative levels of quality standards. Since 2000s, LSS methodology has been gradually adopted within healthcare industries to minimize the medical errors and to enhance the quality of patient care. It also strives to improve the safety levels for both patients and healthcare workers (2).

The healthcare systems and services are being operated under extreme pressure which has increased a lot in the last decade due to many reasons like higher financial burden, growing as well as aging population, increased sophistication in the processes, and technical as well as managerial inefficiency (3). Unsurprisingly, healthcare vital sponsors like administrators and decision makers are always on the lookout for appropriate methods to better manage the above-mentioned

problems, streamline the system and as a result improve the outcomes and experience for the patient, and at the same time, optimize the escalating costs (4).

"Lean Six Sigma" is one of the ways to try to achieve this end goal through better process management, removing non-value add components from the system and making the healthcare delivery system defect free. It is a suitable methodology for application to healthcare settings as it requires attention to detail and can support and sustain the volume, speed and precision involved in various healthcare processes (5).

Objectives:

The objective of this review is to:

- Analyze the scope of "Six Sigma" and "Lean" with respect to the tools/techniques these methodologies use to improve different processes in healthcare delivery and optimizing cost of care Worldwide.
- Detail analysis of the actual implementation of "Lean Six Sigma" projects within healthcare domain to find the root of the problems that are affecting the healthcare industry these days and how attempts are being made to tackle them.
- Provide recommendations on applying these methodologies to improve certain healthcare processes which still need or will need attention in the future.

Methodology:

Relevant literature was retrieved through searching MEDLINE, EMBASE, PubMed, BioMed Central and Google scholar using different keywords related to "Lean Six Sigma" and healthcare

to understand the basics of the "Lean and Six Sigma" technique and its applicability to the field of healthcare. Further, the case studies have been selected from the American Society for Quality database of healthcare case studies for projects done in the USA. Couple of case studies have also been selected from an Irish hospital to preserve diversity in the array of examples. Additional documents and study reports from the web were also included to this study. These studies focus on the application of "Lean and Six Sigma" techniques in the hospital set up to identify process defects and improve them – leading to significant improvement in patient outcomes and satisfaction levels, while at the same time reducing costs. These aspects of care delivery, that is, patient outcomes, satisfaction levels and cost of care in healthcare set-ups around the world has been kept as an inclusion criteria as most of the healthcare authorities are looking for efficient ways to improve these parameters. Hence, lies the relevance of this study and why this particular set of studies have been short listed. These studies are just a small sample among the many such implementations of LSS methodology in a hospital environment and is representative of the success of LSS in healthcare in recent times. Then, the details of each of the "Six Sigma" and "Lean" methodologies were studied separately to understand the step by step approach, followed by the details of the combined "Lean Six Sigma" approach and its advantages. Then the next step is to try to see which specific techniques are more suited to be applied to which scenarios and why. Post the case study discussion, learnings from the individual cases studies were critically examined to understand the important success factors and roadblocks in the implementation – which is the actual analysis of this study.

Background and History of Lean:

Lean Thinking is an advanced methodology of managing an organization and its processes for improving the productivity, overall efficiency and the quality of its products or services. Management specialists from Japan and US developed the concepts, methods and procedures on the later half of the last century. These process improvement techniques have been successfully applied both in the aerospace industries like Boeing and in the automobile industries like Toyota with great results(6). In the manufacturing world, the concept is often described as "World Class manufacturing or High-Performance Manufacturing. Lean Thinking and is best illustrated using manufacturing example from manufacturing department" (6).

"Lean Manufacturing is derived from the methods of the successful Japanese automobile manufacturer, Toyota. Lean Manufacturing became internationally recognized as a result of the book, "*The Machine That Changed The World"*, by James Womack and Dan Jones(7)". As per the statements of Taiichi Ohno, the focus of such applications at Toyota was the "absolute elimination of waste, where waste is anything that prevents the value-added flow of material from raw material to finished goods" (7).

An organization's customers are the ultimate judges who can testify whether or not the organization was able to create certain values. The focus of the "Lean" approach leads the executives to improve the processes as well as performance of their respective organizations by eliminating any and all waste, defined by those activities which do not add any value to the end customer (Muda). "Lean" advocates to focus on improving the processes to control the flow of material or products on the factory or the shop floor. During the last few decades, these principles have been adapted to be effective in the services sector as well, to replicate the same levels of success as in manufacturing.

There are several Lean tools used in manufacturing, aimed at eliminating waste in the process flow, streamlining it and reducing cycle times, such as:

- Total Productive Maintenance (TPM)
- Value Stream Mapping
- "PDSA (plan, do, study, act)"
- Quick Changeover/Setup Reduction
- Pull/Kanban Systems(8)
- "Single Minutes Exchange of Dies" (SMED)
- "Kaizen"
- Cellular or Flow Manufacturing
- "Visual Workplace" or "5S Good Housekeeping" (6)

These are used as and when required to produce the targeted change in the system, depending on the business requirement. Organizations applying these "Lean" tools report significant improvements in the productivity as well as better effectiveness in their respective functions and departments.

Background and History of "Six Sigma":

"Six Sigma" like "Lean" is a strategy that is used in managing businesses, within an organization for improving the quality as well as the efficiency of the processes. While the focus of "Lean" is on exploring the effective ways to minimize waste and hence. streamline the operational processes. The primary aim of "Six Sigma" is to reducing variation in the processes and removing and reducing the defects by applying statistical methods of controlling the processes (1).

"Six Sigma" strategy was originally developed in "Motorola by Bill Smith in the year 1986" as a way of "eliminating defects in manufacturing process, where a defect is understood to be a product or process that is below the customers' expectations and recommended requirements. The name Six Sigma refers to a quality level defined as the almost flawless rate of defects as 3.4 defects per million opportunities (DPMO)" (1).

As a part of the strategies for process improvement, "Six Sigma" gained a lot of attention after its application in the General Electric under the leadership of its former CEO Dr. Jack Welch (1). As a part of the "Six Sigma" approach for identifying, assessing and improving processes, a variety of systematic methodologies have been developed.

The "Six Sigma" process improvement model is data intensive and relies on statistical techniques to identify defects and potential areas to focus on. The DMAIC model suggests the following steps for identifying and improving an operational process (9):

1. Defining the goals of a project and the requirements of both internal as well as external customers;
2. Measuring the organization's process and operation to assess the current performance;
3. Analyze, identification of the root cause(s) for the defects detected;
4. Improving the processes via elimination of identified root causes of the defects, and
5. Controlling the performance of the future operations and processes.

Another "Six Sigma" methodology named "Design for Six Sigma (DFSS) is being used to design new products and services in a systematic manner that meet or exceed customer expectations and can be produced at quality levels as suggested by Six Sigma" (9).

What is "Lean Six Sigma"? How are they combined?

A hybrid philosophy of "Lean Six Sigma" is in fact responsible for continuous improvement of the organizations as well as its processes. "Lean" aims at elimination of waste among the processes by creating a culture of dynamic improvement where people can learn powerful strategies and tools for solving real time problems. The continued improvement emphasizes on techniques like "visual management" and "standardization" that sustains the enhancement. On the other hand, "Six Sigma" methodology focuses at reducing variations within the processes to improve quality to meet or exceed expectations of the customers(10).

The amalgamation of "Lean" with "Six Sigma" has come to be known as "Lean Six Sigma". Lean is used to reduce waste however, does not monitor the processes in order to determine whether in control or not. No usage of statistical tools in "Lean" to measure the processes' capabilities, for example, their ability to generate reproducible products or services meeting or exceeding customers' expectations. "Six Sigma" is "project-driven", because of which it is less flexible when it comes to addressing practical issues occurring daily. Issues such as "total preventive management (TPM)", changeover time, labor and efficiency of equipment, reduction in inventory, and overproduction are better managed using "Lean" techniques. An integration of "Lean Six Sigma" offers the opportunity in reducing defects through controlling variations in different processes and a reduction of waste using "Lean" techniques. "Lean Six Sigma" process improvements are conducted through "projects or Kaizen events while the project executions follow a rigorous pattern called the DMAIC as Define, Measure, Analyze, Improve, and Control. At every step in the DMAIC roadmap, specific tools are used to measure, analyze data, find root causes of problems, and determine the best options for their resolution" (10).

A wide variety of combinations of "Lean Six Sigma" techniques have been created, which frequently are termed as "Lean Six Sigma" approaches. The combined approach projects to the common process-centered as well as data-driven foundations of both "Lean and Six Sigma". Proponents of a combined approach assert that organizations can yield benefits from utilizing both the client-orientation and focus on eliminating the waste inherent in "Lean" along with the statistical tools and systematic defect-reduction strategies featured in "Six Sigma"(1).

"Lean Six Sigma" are just two of numerous approaches that are in use for systematically analyzing and improving process flow and efficiency within industries. Other similar approaches include "Business Process Modeling (BPM), Business Process Reengineering (BPR), and Workflow Mapping (WM), as well as a variety of TQM and CQI-oriented techniques such as management accounting systems, Kaizen, and Shewhart cycles that is PDCA or plan–do–check–adjust" (1). The selection of a particular process improvement approach will depend upon the specific circumstances and needs existing in a working environment, including the type of processes, the improvement objectives, the technical skills, industry specific knowledge, and operating resources available in that setting. For example, some approaches may be better suited to statistical analysis of defects that is Six Sigma, some to layout planning and product flow that is BPM and WM, and some to optimizing transitions between process steps for e.g., "Lean". "Lean Six Sigma" has been chosen as the primary focus in this study because of ample literature suggest their applicability to different healthcare delivery scenarios(11).

Data Analysis and other Quantitative Techniques used

"Lean" standard covers the entire organization value chain, while "Six Sigma" concentrates more closely on certain projects or processes within an organization. Such integration between "Lean

Six Sigma" as an improvement methodology brings many benefits to the organization including maximizing shareholder value, improving customer satisfaction and cost, quality and speed of processes(12).

"Lean Six Sigma" (LSS) combines both approaches and uses routines and tools from both methodologies, to derive the best from both methods, thus improving on speed and accuracy at the same time.

Any project conducted using the data-driven approach of LSS methodology will require the application of some data collection methods and relevant software. One of the most commonly used data analysis packages for statistical process control is "Minitab". To organize and analyze data most organizations use MS Excel which is equipped with a significant number of tools for descriptive statistics and calculating probability as well however, still lacking capabilities for more complex data analyses. A powerful statistical software suite is ""SigmaXL"" is which facilitates those capabilities to MS Excel and is both reliable and efficient to use. Since, these are integrated in Excel spreadsheets, it makes the data readily available for performing manipulation and analysis. Apart from evaluating data through statistical analysis, "SigmaXL" also makes the performance faster for routine data organization and manipulation using MS Excel where the various columns and rows are manipulated in a better way and pivot tables are created pretty fast(13). The scope of "SigmaXL" is beyond statistical analysis which contains tools that help analyze quality, Lean, and Six Sigma related issues much faster through its many templates. For Six Sigma Green Belts, Black Belts "SigmaXL" has gained popularity as a tool for quality, business managers, executives, engineers, technicians and other professionals around the globe(14).

"Minitab" software is a statistical analysis package which can handle large amounts of data and contains lot of tools for process control analysis that are required to track and contain process variability in a "Lean Six Sigma" project(15). Identifying areas of improvement and monitoring relevant metrics is the main purpose of the data analysis. "Minitab" can be used to check the following:

- Check the distribution of the data - whether it follows normal distribution or any other distribution
- Descriptive statistics of the process data (Mean, Median, Variance, Standard Deviation, Skewness, Kurtosis, etc.)
- Histogram chart for identifying the Shape, Central Tendency and Variation of data
- Box Plot for displaying the Variation and identifying quartiles and outliers
- Run Chart (on critical metric over time) to see process stability over time
- Scatter plots and Pareto Charts for identifying patterns in the data and correlations
- Control Charts to identify outliers and defects(15)

Use of "Lean Six Sigma" in Healthcare contexts

During the late 1980's, Healthcare organizations, particularly large health systems, began to study and adopt methods from industrial related quality management which included "TQM (Total Quality Management) and CQI (Continuous Quality Improvement)" approaches. Early applications focused primarily on establishing programs and infrastructure to measure quality and enhancing organizational culture surrounding quality issues. Some hospitals used TQM methods to implement process improvements and redesign both non-clinical and clinical work flows.

Examples of specific TQM interventions included "the development of cross-disciplinary teams to examine and improve work processes, training employees to identify quality improvement opportunities, and the use and application of statistical methods for process improvement"(1). Under the banner of TQM and CQI, health care institutions began to evaluate and make changes to a variety of care practices. For example, selected service functions such as basic laboratory, pharmacy, admitting and discharge, medical records, housekeeping, and material support services were relocated to patient care areas to improve organizational efficiency. Applying TQM principles, hospitals restructured processes to make care more patient focused. In one TQM application, "the turnaround of radiology reports was improved by revising work flow to feature electronic signature by radiologists, elimination of a trainee signature requirement, accelerated transcription, structured reports, faster film delivery to reading desks, and training about the importance of radiology reports for clinical decision making"(1).

Many health care organizations, inspired by TQM, established broader and more customer-focused quality measurement systems including patient questionnaires, quality and appropriateness reviews, performance appraisals, patient monitoring reports, infection rate surveillance, and other quality-oriented metrics.

"Black and Revere (2006)" describes, "Lean and Six Sigma emerged from the fertile environment created by TQM. Recent applications of Lean Six Sigma in health care attempt to improve on previous experiences with TQM by making project deliverables more discrete and measurable, retaining a strong customer/patient rather than organizational focus, quantifying results, and attempting to deliver specific quality improvements within a designated time frame"(16).

A wide variety of projects since the beginning of 2000, have been applying "Lean Six Sigma" strategies to health care quality improvement. For instance, pilot programs utilized the "Lean" approaches and methods at Intermountain Healthcare which resulted in substantially reduced "turn-around time or TAT" for pathologist reports from the histological pathology laboratory. Other Lean-facilitated developments at Intermountain Healthcare included numerous examples which included reduction in I.V. backlog in the pharmacy, the time needed to perform glucose tests on patients reduced, decreasing the time to enter new medication orders and timely completion of medical charts and entries, and rearrangement of the electronic methods of payment for merchant accounts.

"Six Sigma methods are perfectly suited to the healthcare sector due to their zero tolerance for faults and Six Sigma's immense potential for reducing medical errors" (14)**.** "Lean" tools are also appropriate for application to a wide variety of processes in healthcare, and are capable of addressing critical challenges like medication errors, mounting costs and staffing deficiencies(17). Together, the LSS methodologies have the same potential to improve the performance across the healthcare industry as compared to the manufacturing and automotive industries (18).

Applications of different LSS tools in various Hospital scenarios

One of the foremost healthcare organizations to implement Six Sigma methods to their processes was the Commonwealth Health Corporation in Massachusetts, USA, which was done in 1998(19)**.** The execution was done by consultants from the company GE General Electric and gave great results – "a net 33% increase in radiology department performance and a 21.5 % reduction in operating costs" (14). Following these exemplary results, other US healthcare establishments have also tried to replicate similar success: "Charleston Area Medical Center in West Virginia, Mount Carmel Health System in Ohio, and Thibodaux Regional Medical Center in Louisiana. Benedetto,

in a publication in 2003 has demonstrated the Six Sigma approach at the University of Texas MD Anderson Cancer Center, while Elsberry (2000) has defined how the same institute increased the number of completed examinations by 45 % without adding any resources"(20).

Outside the US, the first healthcare establishment on record to implement "Six Sigma" was the "Red Cross Hospital in Beverwijk, Netherlands, with assistance from the Institute for Business and Industrial Statistics at the Amsterdam University reported total savings of $1.2M was generated post three years of operation under the Six Sigma framework"(20).

"The National Health Service (NHS)" in the UK successfully applied both Six Sigma and "Lean" where "Lean" presently captures the center of attention for the NHS with many of the "Lean" philosophies contained within the new "Productive Ward" initiative. NHS conducted a study using "Lean Six Sigma" implementation conducted by "Proudlove et al (2008)", where it was demonstrated that there are a lot of difficulties in identifying the different processes for different customers in healthcare settings; emphasis was also put on the importance of using clear and correct jargon, and it was underscored that there is sufficient opportunities for a more comprehensive framework of process improvement strategies with appropriate evidences(20).

Since then, the use of "Lean Six Sigma" techniques in different healthcare settings has expanded to a lot of different contexts and problem scenarios. Success stories comprise of a wide range of situations like, streamlining the healthcare delivery process, improving claims reimbursement(21), and reducing inventory size for surgical apparatus and related operational costs(22)(23). Projects have also been executed in different products or service settings including customer facing departments for example, Radiology or X-ray department, A&E or emergency room, client based services like inpatient and outpatient diagnostics, administrative back offices for example, billing, clinical coding, medical records, cross-departmental projects for example, medical and medication

errors and in overall hospital improvements such as reduction of operational costs, improving bed availability and employee retention(24). While application of "Lean Six Sigma" methods in healthcare processes meets barriers that are similar to those for other industries, two challenges are specific to healthcare: measurement and workforce psychology. In context of healthcare, it is often difficult to identify processes which can be measured in terms of defects(25). It is also vital to avoid business terminologies when communicating with healthcare providers ad professionals to improve chances of acceptance(14).

Case Study 1

"To achieve zero percent error rate in Administration of Antibiotic and Eliminating Surgical Sentinel Events at Columbus Children Hospital" (14)

1. **Institution and the Business Problem: "**Nationwide Children's Hospital in Columbus, Ohio is the primary pediatric healthcare provider for 37 counties in Ohio that has more than 800 medical staff members and 4500 employees". The business problem was that an internal evaluation conducted in the hospital in 2004 found, "only 64% patients with acute appendicitis received the correct antibiotic at the correct time, as per clinical guidelines" (14). This was the starting problem, but eventually to manage all types of errors linked to surgical procedures as the project was expanded.
2. **Project Goals:** There were two primary goals of the project as follows:
   - "To achieve zero percent antibiotic administration rate errors
   - To achieve less or no sentinel events (errors) in surgeries" (14)
3. **Details of the Project:** Columbus Children's Hospital adopted a systems approach for identifying the problem and doing a root cause analysis. As per the classical model, a

prescription error is viewed as the result of an individual mistake by the nurse, technician or physician; the solution in this mode is to identify the concerned person and work with him to correct the error. In contrast, a systems approach interprets an individual's error as rooted in the way the system is functioning and potential solutions to avoiding similar errors in future, lie in altering the system. For example, if a nurse makes a medication error, the root cause analysis may identify that the reason behind the error as she was the only nurse on the floor at the time, responsible for caring for the patients, distributing medications, as well doing some administrative work. If she can focus on her work, the chances of error would automatically be reduced. (14)

To address the root causes CCH developed a program called Operation Take-Off which consisted of:

- Standardization of patient verification and timeout process
- Policy revision requiring site marking on all cases involving laterality
- Redesigning the checklist for surgical site verification
- Timeout placards usage in sets of instruments used
- Adopting large scale marketing and education campaign within hospital

4. **Tools and techniques:** Diverse set of tools and techniques were used to address the root causes as follows:
   - Benchmarking Techniques
   - Pareto Analysis using parent chart
   - Root Cause Analysis
   - Quality Improvement in Surgery team of the hospital used brainstorming technique
   - Reliability Analysis

After a lot of formal meetings and training sessions, it was possible to bring all the nurses and surgeons on board.

5. **Results:** In the first year of Operation Takeoff, in 2006, the percentage of acute appendicitis patients getting correct antibiotics on time increased from 64% to 98.2 %, that is the error rate reduced from 36% to 1.8% (a 20-fold reduction). In terms of surgical errors (sentinel events), there were only 2 cases of near misses (14).
6. **Monitoring over time:** Some very effective measures are applied to ensure the processes are monitored for continuous improvement.
   - Near miss events are unplanned events that are subjected to root cause analysis in same ways as the sentinel events. The Project Director monitors each case near-miss events personally and an analysis is completed within 24 hours, to capture accurate information leading to the event.
   - Designated nurses were appointed, not identified to the staff on duty, to monitor the compliance to adopted policies.

Case Study 2

"Increasing the Percentage of Heart Failure Patients Receiving Heart Failure Discharge Instruction from 45.3% to at least 90%" (14)

1. **Institution and the Business Problem:** This case study is from a non-profit healthcare system, where internal audit found that adherence to clinical quality related observed metrics for inpatient heart failure discharge instruction was consistently below national standards. For the year 2006, the mean rate of compliance was 45.3 percent. Non-compliance could result in penalties with reimbursements from the Centers for Medicare and Medicaid Services

(CMS), besides additional costs because of the potential harmful events, like readmissions, and also a decrease in patient satisfaction (14).

2. **Project Goals:** The goal of the project was to increase observed rate of compliance for inpatients receiving heart failure discharge instruction from 45.3% to at least 90% by 2 years (January 2008). Heart failure discharge instruction included written instructions or educational materials addressing a patient's activity level, diet, discharge medications, potential follow-up appointments, body weight monitoring, what to do if symptoms reappeared or worsened at home and also explaining to patient and care givers at the time of discharge from the hospital (14).

3. **Details of the Project:** Analysis of the situation and looking into root causes revealed the following issues with the Healthcare System:

   - There was no proper discharge planning and no Heart Failure form was available
   - Multiple discharge processes with no standardization or accountable person
   - Physicians not abiding by proper discharge care instructions
   - At the time of discharge an incomplete medication reconciliation
   - Ownership for process compliance missing

   Pareto analysis revealed the top few reasons which contribute to the problem as follows:

   - The nursing team was discharging the patients
   - The hospital employees' knowledge of the six elements of discharge- "Activity level, Diet, Discharge medications, Follow-up, Weight monitoring, what to do if symptoms worsened", all these were pretty low
   - Outdated discharge forms which did not have all the information

4. **Techniques used:** The tools used for this analysis included the following –
    a. Six Sigma DMAIC
    b. Root Cause Analysis
    c. Pareto Analysis
    d. Critical to Quality Matrix design

    Using the above tools, the quality team developed a set of strategies to improve the operational processes by "standardizing discharge process across nursing units, discharge instructions, improve knowledge level of heart failures staff and standardizing the whole process of discharge" (14).

5. **Results:** The project could reach a compliance rate of 90% with heart failure related discharge instructions being provided to patient and care givers, within 3 months of a pilot. The implementation of building standardization into segmentation of the process resulted in improvements for the process as a whole that was included in the standardization of processes. There were, "the discharge of patients in nursing units, finding the most effective type of discharge instruction, improving the overall knowledge of staff through training of heart to failure instruction, and, finally, simplifying the heart failure discharge instruction process" (14).

6. **Monitoring over time:** The ongoing monitoring was done using the tools like Critical to Quality matrix and Pareto analysis at regular intervals. Each of the areas identified through the root cause analysis were monitored on an ongoing basis to see that they are addressed and improved upon continuously.

Case Study 3

"To reduce the Length of Stay for patients suffering from Heart Failure & Shock (DRG127) and are admitted to a Medium-Sized Hospital" (14)

1. **Institution and the Business Problem:** A medium sized acute care hospital has been chosen in the following case study which was trying to reduce the time that patients suffering from heart failure were spending on care. The Avg. (Average) length of stay (ALOS) of a hospital for these selections of heart failure patients (with shock) was 5.18 days and it was 1 full day more than the geometric mean. Only 57% of the patients were discharged before 4.1 days and the process variability was very high, as denoted by the sigma rate of 1.68(14). This lack of efficiency in delivering quality care was adversely affecting the patient outcomes and was also proving to be costlier to the healthcare system.

2. **Project Goals:** Goals were set up to achieve higher efficiency of patient care process, improved patient outcomes and reduced unnecessary costs.
    - Increase percentage of discharges by 4.1 days to 95% from 57%
    - Improve process sigma level to 3.18, from current value of 1.68
    - Decrease the mean LOS of heart failure patients from 5.18 to less than 4.1 days(14)
3. **Details of the Techniques used:** The usual gamut of six sigma tools were used to identify the reasons behind the high length of stay for the selected group of heart failure patients. These are as follow:
    a. Six Sigma DMAIC
    b. Pareto Charts
    c. Statistical Process Control Charts

d. Root Cause Analysis frameworks

Using these tools and after extensive data analysis it was identified that 7 out of 18 hypothetical root causes were significantly impacting the length of stay for heart failure patients and driving high costs and poorer outcomes. These were as follows:

- Congestive Standard orders were not used for evaluation and treatment
- The stay of a patient in the hospital also included a weekend which resulted in increasing the length of stay
- There was a delay in the time between the discharge order given and patient actually leaving the hospital
- Patient becomes deconditioned due to prolonged bed ridden
- Some patients were held back even after meeting InterQual discharge criteria
- Treatment processes were not based on Gold Standards
- Inpatient holding process not standardized

A possible solution strategy was defined for each vital root causes, as given below:

Heart Failure standard orders – To reduce variation by developing a set of order in healthcare practices, educating physicians and hospital staff to use these orders and developing interdisciplinary pathway.

Delay in discharge order in leaving the floor – Developing a better communication processes by anticipating the next or upcoming discharge date/needs from day one of admission.

Weekend stays – To develop proper staffing plan and resource allocation plan in order to support standard order of CHF and a channel which should include scripting to facilitate

use and discharge. Team-based communication and handoff to be improved for weekend stays. Implementation of standardized usage of inter-disciplinary channel-based contingency DC orders.

Likewise, the other root causes were also analyzed and appropriate measures were adopted to counter them.

4. **Results:** The return of investment from the efforts made on the project was good, as noted from the observed results.
    - The average length of stay for heart failure was reduced from 5.18 to around 2.6 days, which is an improvement of close to 50%.
    - "91% of patients discharged within 4.1 days or less, that was basically an increase of 34% from 57% the original figure" (14).
5. **Monitoring over time:**

    The control plan included the following key elements for sustaining the improvements and long-term gain:

    "Control subjects—length of stay, readmission rate, and proven Xs (drivers of LOS)

    Measurements—sensor/metric, frequency, sample size

    Actions—criteria for taking action, responsibilities

    Most control subjects were monitored every two weeks, with criteria for action based on performance relative to specifications and statistical process control charts" (14).

Case Study 4

"To reduce the Incidence of Hospital-Acquired Pressure Ulcers in a Medium-Sized Not-for-Profit Hospital" (14)

1. **Institution and the Business Problem**

   This institution was a medium sized not for profit hospital which was trying to reduce the incidence of hospital associated adverse conditions among admitted patients. The pressure ulcers which develop in patients who are bedridden for a long period of time was one such condition which was targeted. Compared to the national benchmark of 7%, the incidence of pressure sores among the hospital's patients was 18%, which was not only proving to be costly but was also leading to worse patient outcomes(14).

2. **Project Goals**

   The goal for the project was "to reduce incidence rate of hospital-acquired pressure ulcers from the current rate of 18% to 5%, two percentage points below the national average.

This rate of 5% was to be achieved by one year from the start of the project in July 2007" (14).

3. **Details of the Techniques used**

   Some specific metrics were used in this case like Braden Score and Pressure Ulcer Incidence rate. After analyzing a representative sample of the historical cases using the standard Six Sigma toolset some important drivers of pressure sores were identified as the root causes of the problem.

   - "Braden Score": This is a risk score for predicting pressure sores in admitted patients. This score needs to be completed within 8 hours of admission. This was not done regularly.

- Nurses' awareness about preventing pressure sores were limited.
- Pillows and props availability limited, position not changed regularly
- Limited availability of skin care products when needed
- Pressure Sore development depended on length of care
- Documentation of nursing care plan to track required care

Each of these individual drivers were studied to identify the appropriate rectification measure. Some examples are as follows:

- Assessment of skin condition was made mandatory within 8 hours of admission and on every shift
- "Braden scores" documentation and implementation of "visual identifiers" for at risk patients and their corresponding scores
- Assistance for chair bound patients and limitations on time on chair
- Adequate pillows and props for position change, for every room
- New mattresses having the technology of "pressure redistribution"
- "Wound care order" standardized for prevention and treatment of pressure sore
- Abolition of diapers as they increase the risk of pressure sores on selected areas(14).

4. Results

The results of the full implementation of this project was outstanding as evidenced by drastic reduction in pressure sores by 13 percentage points in 18 months.

The cost reduction due to efficient prevention of pressure/bed sores was also substantial ($1.85 M, 72%) and the process was successful in decreasing the annual costs of operating the hospital and also in increasing the patient outcomes and satisfactions at the same time(14).

5. **Monitoring over time**

The project team had also implemented a specific plan for control through continuous monitoring that included a communications and training plan and a revision of relevant policies and procedures. At the end of 18 months on to the project, the rate of incidence was maintained at 5% and was further reduced to 4.9 % in the subsequent months (14). This makes the project an excellent example of how much improvement can be done by implementing discipline and systematic structure around simple tasks in patient care.

Case Study 5

"Improving the availability of medical records in an Irish Multispecialty Hospital using DMAIC" (14)

1. **Institution and the Business Problem**

This project example is taken from an Irish hospital where it was noted that there was significant delay in elective surgical procedures due to non-availability of medical records at the right place and time. Medical records are known to hold most of the important patient details and are frequently consulted by physicians and healthcare providers during the treatment. Assuring that the relevant medical data and official records are accessible at the required time and place is vital for the efficient management of a hospital. The project team identified a frequently encountered problem related to medical data or records in the hospital: scheduled elective surgical procedures very often experienced interruption including possible cancellation and a lot of activities that are non-value adding like looking for the correct documentation and details of treatment.

2. **Project Goals**

"The defect rate associated with availability of proper medical records when needed was just more than 30% at the start of the project and the target was to reduce to less than 10 % by the end of the pilot" (14).

3. **Details of the Techniques used**

Standard DMAIC methodology was used to identify the defects and understand the causes leading to the defects. For Define stage, the theory of constraints was used to identify bottlenecks in the existing process. During the Measure stage, the project team defined a new metric to measure process failure (based on availability of medical records at the time scheduled for surgery) and measured the as-is efficiency of the process. The financial cost of errors/faults was also estimated by the project team. In the Analysis stage, the logic trees methodology was adopted to identify root causes for the absence of the medical records and then a cause-effect matrix was created based on the information. This stage also identified added vital process input as well as output variables. The implementation authority may well zero-in on an insignificant number of "CTQ or Critical to Quality metrics". In the "Improve stage" team developed checklists and follow-up measures to ensure that the medical data/ records are made available at the correct place and time.

4. **Results**

The Six Sigma project was able to demonstrate definitive and quantifiable improvements to the existing medical records system that provided direct advantage in terms of cost savings and improved efficiency to both the medical records department and the surgery operating rooms. Prior to the implementation of the LSS processes, defects have been

recorded at “28 out of 90 that is around 32%”. Defect rate after the project implementation was completed was measured at ‘5 out of 220’. This is equivalent to a defect rate of 2% and a big improvement beyond the expectations at the start of the project (14).

5. **Monitoring over time**

   In the Control stage of the project, the new process was documented along with the points of process bottle-necks with control and communications procedures established in accordance with the pertinent stakeholders and the concerned departments.

Case Study 6

Improving cycle time for written communication using Lean in a Psychiatry clinic(14)

1. **Institution and the Business Problem**

   This project is again from the same multi-specialty hospital in Ireland as mentioned above. It assessed the effectiveness of the written or printed communication on various patient-care plans between a psychiatric clinic inside the hospital and its wide variety of outside stakeholders that include mental health teams at the community level, GPs general physicians, and the patient care teams.

   The focus of this study was Clozapine an antipsychotic medicine which is very effective in treating schizophrenia that can also pose a number of serious as well as potentially life-threatening drug related adverse effects. The application of Clozapine is strictly controlled and this process includes several mistake-proofing measures as- “the patients must be registered with the Clozapine Patient Monitoring System and the medication can

be prescribed and dispensed only by the psychiatrists and pharmacists who are registered with the system" (14).

2. **Project Goals**

The objective was to reduce the lead time of written communication between the psychiatric clinic and its outside/community and primary care stakeholders significantly, from 'as is' 15 days to less than 3 days (14).

3. **Details of the Techniques used**

The project utilized the Lean methodology as the core approach and used Value Stream Mapping (VSM) to study the written communications process in detail. VSM (sometimes called process mapping) is a system in which the steps in a process are identified and drawn on a map, similar to drawing a process flowchart. After this process mapping is complete, each component is examined critically to identify the non-value add components that can be removed and the time needed for that step is also saved.

The value stream mapping of the project identified quite a few activities which were increasing the process time without adding any value to the end user; for instance, the printing of the letter drafts, which was not required. The project team identified several redundant steps, like waiting until the next 'Clozapine clinic', to review and approve the draft letters. The "as-is" process was restructured and redrawn to give a clear idea about the future state. In the re-design, all activities that are redundant and don't add values such as printing drafts and manually making corrections of the draft letters were eliminated, waiting during periods between clinics was deleted, and the IT infrastructure was reformed to permit direct editing of draft versions of the letters on the clinic's server

4. **Results**

The immediate benefit that came out of the implementation was that the cycle time for written communication between hospital and satellite centers was reduced from 15 days to 3 days, and that too, at minimal added resources/cost (14).

The significant decrease in the lead time allowed the overall care team outside the hospital and clinic to have full knowledge of the patients' care plans almost two weeks earlier compared to previous state. They could plan the individual activities better and this in turn resulted in providing better care on time. It also reduced the number of questions being asked by patients and their family members to the clinic personnel, also reduced the queries coming from primary care physicians and community mental health care providers. The new process also freed up clinic staff time as several redundant steps, for e.g. correcting draft letters, were eliminated. This additional free time actually generated positive results when they were used in other value-add activities, like for psychiatrists, it meant spending more time with other patients and reduce waiting times at clinic.

5. **Monitoring over time**

Once the new value stream map is implemented and its validity verified by the results achieved, it was the new standardized process and all that was needed is to make sure that the new process is followed strictly for some period of time. After that once the system and the staff are accustomed to the new process, that is the new normal and almost no monitoring is needed.

Discussion and Inference – Success Factors and Roadblocks

All these above-mentioned case studies point towards some common factors which determine the best outcomes from implementation of quality improvement measures. The business objective is to improve the efficiency of the processes for any quality initiative and in the case of hospitals it is also linked to achieving better clinical outcomes and higher patient satisfaction levels at lower costs. So, the metrics for a hospital should be carefully chosen to reflect those objectives. The case studies discussed above highlight this fact that the chosen metrics are linked to better patient experience and health outcomes.

It is significant to understand that simple application of "Lean or Six Sigma" techniques is usually not enough to ensure a highly successful project that can achieve desired process improvement in the clinical or health care setting. Achieving better efficiency and process flow requires the following as well:

- An organizational climate which is receptive where all the stakeholders understand the importance of achieving the best possible outcomes for patients at optimal cost and resources.
- Active management support and engagement: the hospital's leadership is the most important stakeholder who can help motivate the team members to sustain the momentum of change for the better.
- Sufficient financial and other resources: Proper budget and resource planning must be done in the beginning of the project so that quality improvement effort does not get dent the overall finances and resources get optimally utilized.

- Clear and achievable goal setting: The improvement targets should be realistic and should be targeted step by step to ensure that each of the root causes are targeted properly and the improvements are sustainable.
- Clear communications channels: All the team members within the organization should be aware of the details of the process change. Buy-in from all team members is important and can be easily obtained if they understand the necessity and recognize the importance of universal participation and the role of each individual.
- Education and awareness of staff: It may be required that all the concerned team members and staff be taken through properly designed sessions that explain the basics of the process and the logic behind important components of the program(27).

  "Deming" and many more management theorists have already pointed "implementing a truly transformative change takes time and shifts in organizational behavior that establish a foundation for process improvements to be accepted and fully integrated into the organizations routine operations and expectations. The softer side of organizational behavior in process change is a critical component and recognizing the importance of the same for a Lean or Six Sigma project to succeed, becomes more important in the healthcare setting since there is so much personal touch involved in the delivery of care inside the hospital" (28)(29).

These process improvement projects discussed above illustrate many of the essential steps that are typically involved in "Lean Six Sigma" analyses. The analysis actually started with systematic evaluation of each process in detailed manner, determining the hospital needs, then identifying the potential sources of inefficiency as well as waste, while also assessing structure, management and culture of the organization. The analysis was also informed by acquisition of process data like

relating to load of the patients, nurse-staffing needs, and protocol related requirements. On-site observations were also included in the assessment. Some specific roadblocks may be applicable for hospitals as follows:

- Physicians and other medical personnel are specialists and sometimes, in the big hospital, they are experts in their areas. They might resist the quality improvement initiatives if they are not sure that these measures will improve overall patient outcomes.
- The hospital often has different independent units and departments like pharmacies, imaging departments, laboratories and also the different specialty departments. When an activity is dependent on different departments, it is important to ensure that all the departments can communicate with each other effectively(30).
- Unpredictability is very common in hospital situations and there are many variables which impact the condition of a patient at a particular moment. So, to minimize the chances of an adverse outcome impacting the progress of the project, the patients and the parameters who are part of the pilot, should be carefully chosen.
- "Lean Six Sigma" consultants who are employed by the hospital need to have adequate exposure to the healthcare and more specifically the hospital environment, otherwise it will be difficult for them to take into account the complex interplay of different protocols which might be already present in the hospital to guide patient management(1).

Conclusion – Learnings and Next steps

In comparison to manufacturing and other service industries the application of "Lean Six Sigma" is at a growing phase till now if we consider healthcare delivery.

Most of the countries in the world are facing high burden of growing and aging population with increasing healthcare activities despite of scarcity of human and financial resources. This statement is relevant for both developed and developing countries. To mitigate such healthcare challenges, the application of "Lean Six Sigma" offers to improve the operational processes without compromising the workload or demanding higher healthcare budgets. The case studies discussed in this paper demonstrate that, implementing "Lean Six Sigma" in healthcare can facilitate to achieve improved operational efficiency, better quality of health products or services and improved cost-effectiveness of the interventions. Previous successes of simple projects can aspire future directions to undertake larger and more complicated projects in healthcare which create positive improvement cycles within the healthcare organizations as well as the entire health system in a broader scale.

As of now the application of LSS methodology in the hospital sector has been done in piecemeal till now, taking one problem at a time. More work needs to be done to develop a scientific methodology that can be applied to improve the healthcare processes in a holistic manner. No paper has attempted to develop a unified LSS framework for healthcare till now and there is a lot of scope in this sector for research. If an all-inclusive framework can be developed based on successful applications in other industries, the benefits of LSS methodology can be fully realized at the hospital or health center. This study is an attempt to provide the initial directions for further research towards that end.

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