

IMPACT OF EARLY STAGE LEAN MANAGEMENT IMPLEMENTATION ON PATIENT
SAFETY CULTURE IN ACUTE CARE HOSPITAL UNITS

By

Laura E. Winner

A dissertation submitted to Johns Hopkins University in conformity with the requirements for
the degree of Doctorate of Public Health.

Baltimore, Maryland

January 31, 2019

© Laura E. Winner 2019

All Rights Reserved

Abstract

Healthcare is under intense pressure to reduce waste, provide better value at lower cost and eliminate preventable harm. Lean is a term used to describe operational improvement methods to eliminate waste and do more with less (1). Early application of Lean in healthcare focused on implementing Lean tools to achieve reduction in lead-time and cost in specific units or departments. Lean in healthcare has evolved over the past 15 years beyond implementation of tools alone to include implementation of Lean Management Systems.

Methods

A structured literature review of peer-reviewed articles on Lean Management in healthcare, published between 2000 and 2017, was conducted. The relationship between early stage Lean Management implementation and safety culture assessment at an acute care hospital was explored using difference in difference analysis of 2015 and 2017 scores. Face-to-face interviews with nurse managers involved in early stage implementation of Lean Management in an acute care hospital were conducted between July and September 2018.

Key results

Articles reporting on Lean Management implementation in healthcare suffer from weak pre-post designs lacking statistical analysis limiting understanding of the true impact of Lean Management implementation. In this study, analysis of the perceptions of local management, perceptions of senior management, and safety organizing scale questions of the safety culture assessment using the Difference in Difference approach showed no statistical difference for units exposed to early stage Lean Management compared to those not exposed.

Interviews of nurse managers revealed that introduction of the Lean management system, particularly the True North room, provided clarity on what was important to the organization. All nurse managers interviewed were well acquainted with True North noting alignment of unit metrics to organizational goals. Interviews also revealed tension between the executive level need for standardization of huddle boards and staff engagement. Nurse managers emphasized that, while unit huddle board metrics must align with organizational goals, they must also be meaningful to front line staff to achieve desired improvement.

Conclusions

Longer exposure times to Lean Management systems, stronger study designs, and rigorous statistical analysis are needed to evaluate the effectiveness of Lean Management implementation in healthcare.

Thesis Advisors:

Laura Morlock, PhD, Professor and Executive Vice Dean for Academic Affairs, Johns Hopkins Bloomberg School of Public Health

Cheryl Dennison-Himmelfarb, PhD, Professor, Johns Hopkins University School of Nursing

Jill Marsteller, PhD, Professor, Johns Hopkins Bloomberg School of Public Health

Peter Pronovost, MD, PhD, Adjunct Professor, Johns Hopkins University School of Medicine

Hanan Aboumatar, MD, MPH, Associate Professor Johns Hopkins University School of Medicine

Lilly Engineer, MD, DrPH, Assistant Professor, Johns Hopkins Bloomberg School of Public Health

Acknowledgements

I would like to thank the many people in my life that contributed to my success in completing the requirements for the degree of DrPH.

My advisor Dr. Laura Morlock whose positive encouragement along with steady and sound advice kept me on the path.

Committee members Cheryl Dennison-Himmelfarb, Jill Marsteller, Lilly Engineer, and Matt Stewart.

My colleagues Peter Pronovost, Hanan Aboumatar, Lori Paine, Amy Plotts, Eileen Kasda, Charlie Reuland, Maria Koszalka, Lisa Filbert and Erica Reinhardt.

And my family – my parents, Bernie and Dottie Winner, for instilling in me a deep appreciation of lifelong learning; my siblings Terri Winner Quinn and Dotsy Malone for helping me persevere through the tough times; and most of all my partner in life Chris Smith for unwavering love and support!

Table of Contents

Abstract	ii
Acknowledgements.....	iv
Key Terms.....	viii
Chapter 1 Introduction	1
Chapter 2 Background Lean and Lean Management	6
Chapter 3 Methods.....	11
Chapter 4 Results Aim 1.....	26
Chapter 5 Results Aim 2.....	48
Chapter 6 Results Aim 3	75
Chapter 7 Discussion	86
Appendix A – Unit Safety Culture Assessment Scores.....	98
Appendix B - Interview Guide.....	103
Appendix C – Lean Leadership Program Overview.....	106
Appendix D – Curriculum Vitae.....	110
References.....	117

List of Tables

Table 1: Safety Attitude Questionnaire Perception of Management Questions.....	9
Table 2: Safety Organizing Scale Items.....	10
Table 3: PRISM Elements and Lean Leadership Program Components	15
Table 4: Intervention and Comparison Units.....	18
Table 5: Variables and Measures.....	21
Table 6: Difference in Differences Equation.....	24
Table 7: Lean Management Definitions.....	26
Table 8: Articles by Country.....	28
Table 9 All Articles meeting inclusion Criteria.....	29
Table 10: Description of Articles Included.....	33
Table 11: Description of huddles in Articles.....	39
Table 12: Characteristics of huddles.....	68

Table 13: Safety Culture Assessment Response Rates.....	76.
Table 14: Difference in Difference Results: Perception of Management questions.....	77
Table 15: Difference in Difference Results: Perception of Management questions with active CUSP covariate.....	78
Table 16: Correlation between variables.....	79
Table 17: Difference in Difference Results: perception of Management domain with active CUSP, Turnover Rate, and Percent RNs < 35 years old.....	79
Table 18: Difference in Difference Results: perception of local management and perception of senior management domain average.....	81
Table 19: Difference in Difference Results: perception of local management and perception of senior management domain average with covariates CUSP, turnover rate and percent RNs < 35 years old.....	81
Table 20: Difference in Difference Results: Safety Organizing Scale questions.....	82
Table 21: Difference in Difference results for Safety Organizing Scale questions with active CUSP covariate.....	83
Table 22. Difference in difference with covariates active CUSP, turnover rate, and percent RNs < 35 years old.....	84
Table 23: Difference in Difference for Safety Organizing Scale domain average.....	85
Table 24: Difference in Difference for Safety Organizing Scale domain average with covariates active CUSP, turnover rate, and percent RNs < 35 years old.....	85

List of Figures

Figure 1: Lean Management System Flow.....	8
Figure 2: PRISMA Flow Diagram.....	12
Figure 3: PRISM Model.....	14
Figure 4: Logic Model.....	16
Figure 5: Study Sample Selection.....	25
Figure 6: Emergency Department Huddle Board December 2015.....	51
Figure 7: Medical X Huddle Board February 2016.....	52
Figure 8: Medical X Huddle Board October 2016.....	53
Figure 9: True North Room Patient Centered Care Strategic Priorities October 2016.....	53
Figure 10: Standard Work for True North Huddle.....	54

Figure 11: True North Room Metric Expansion.....	56
Figure 12: True North December 2017.....	56
Figure 13: True North Room with additional Visual Controls.....	57
Figure 14: True North outer wall and door removed to open the space August 2018...57	
Figure 15: ED Huddle Board Design Mock-up November 2016.....	58
Figure 16: Emergency Department Huddle Board December 2016.....	58
Figure 17: Emergency Department Huddle Board September 2018.....	59
Figure 18: Medical X Huddle Board March 2017.....	60
Figure 19: Medical Y Huddle Board July 2017.....	61
Figure 20: Medical Y Huddle Board July 2018.....	61
Figure 21: Medical Z Huddle Board June2017.....	62
Figure 23: Surgery Unit Huddle Board December 2017.....	63
Figure 24: Neuroscience Huddle Board March 2017.....	64
Figure 25: Neuroscience Huddle Board August 2017.....	64

Key terms

A3 tool– a single sheet of paper named for the A3 international size of paper, roughly 11" x 17", used to foster shared understanding of goals and scientific PDCA (plan, do, check, act) problem solving.

Daily accountability process – routine for monitoring performance to target and action to correct problems.

Discipline – self-control to perform desired behaviors such as standard work.

Gemba – Japanese term for where the action or work takes place

Huddle board – a type of visual control in the work area that displays key performance indicators, often incorporating barriers and problem solving to improve performance.

Lean – a term used to describe improvement operations at Toyota Motor Company to eliminate waste and do more with less.

Lean Leadership Program (LLP) – a 12-week unit-based, cohort approach educational program to create Lean management capabilities and culture in strategically selected clinical areas

Lean management system–integrated combination of approaches such as leader standard work, visual controls, daily accountability processes, and discipline used together to assess and improve daily operations.

Leader standard work – daily activities of leaders in the workplace that are structured and routine and place emphasis on managing their area of responsibility by process.

Lean tools –techniques used to identify and address waste (examples include waste walk, spaghetti diagram, value stream map, 5S, kaizen/rapid improvement events).

Model Cell - micro sites of Lean Management System implementation, which are held up as an example for others to emulate.

True North – an imagined line running in the direction of the earth's North Pole, perpendicular to the equator. Also strategic direction for an organization.

True North metrics –select key performance indicator targets that set the direction for organizational performance.

Visual controls – methods that make status of performance apparent at a glance.

Chapter 1

Introduction

Lean has gained popularity in healthcare over the last decade. Lean is a term coined by Krafcik(4) and made famous by Womack and Jones in 1990 to describe the Toyota Production System (1). Toyota has been held out as an example of operational excellence due to its domination in the automotive industry. Many have attempted to emulate Toyota's methods with the hope to achieve the same levels of operational excellence. Most fall short due to selective implementation of Lean tools that emphasize short-term gains with a quick return on investment. Spears in Learning to Lead at Toyota makes the important distinction that the success of the Toyota Production System lies not in tools but rather in applying principles (5). Lean management systems are built on principles such as a profound respect for people doing the work and empowering them to engage in daily improvement through direct observation, scientific thinking, and experimentation at the front line with managers coaching their staff in problem solving rather than solving problems for them.

Implementation of Lean management as a principle-based system is in its infancy in healthcare. Introduction of Lean in healthcare followed shortly after the landmark Institute of Medicine reports To Err is Human in 1999 and Crossing the Quality Chasm in 2001. To Err is Human highlighted the shortcomings of healthcare and shined a light on the magnitude of harm resulting from medical care, placing the estimate between 44,000 and at 98,000 lives lost to medical errors each year (6) . In Crossing the Quality Chasm, the IOM put forth the following six aims: patient care should be safe, timely, efficient, effective, patient-centered and equitable.

“Making environments safer means looking at processes of care to reduce defects in the process or departures from the way things should have been done. Ensuring patient safety, therefore,

involves the establishment of operational systems and processes that increase the reliability of patient care". Pg. 58 (6)

The early years of Lean implementation focused on proof of Lean's applicability to healthcare. Overwhelmingly the published peer reviewed literature has focused on application of Lean tools to achieve targeted gains in efficiency, particularly lead-time. (7) In contrast, Lean management systems focus intently on process with the goal of creating a learning organization conducting experiments daily to achieve continuous improvement. We hypothesize that when implemented as a set of principles, a Lean Management System with supporting tools will have an enhanced positive impact on organizational culture and performance.

Kristensen and colleagues demonstrated that quality management systems have a positive effect on perceptions of teamwork and safety climate in European hospitals (8). Behaviors of leaders that increase their visibility and accessibility to the front line such as Executive walk-rounds and Comprehensive Unit-based Safety Programs (CUSP) have been shown to be associated with improved safety climate (9). In a randomized study conducted in a tertiary care teaching hospital nurses who participated in Executive Walk Rounds had higher safety climate scores (72.9% positive) than nurses in the control group who did not participate in Executive Walk Rounds (52.5% positive) (10, 11). Additionally a study done in a Taiwan hospital demonstrated that perception of management leadership mediates patient safety climate (12). Because Lean management systems share some of the components of the management systems studied, it is of interest whether implementation of Lean management systems improves safety climate scores. Lean management pilot units at ThedaCare reported improvement from 2008 to 2009 on quality and safety drivers such as falls, Coumadin education, pain assessment, bed access, turnover, staff competency, delays in access, interactions within 4 days of discharge and medication errors (13).

This dissertation studies the impact of early stage implementation of Lean management components in an acute care hospital on safety climate.

Study Aims and Hypotheses

Aim 1 Explore through literature review what is known about implementation of Lean management in healthcare.

Research Question 1:

What is known about Lean management implementation in healthcare?

Aim 2 Explore experiences of nurse managers involved in the early stage implementation of Lean Management System components in nursing units at an acute care hospital

Aim 3 Examine the relationship between early stage Lean management implementation and safety culture assessment.

Research question 2

Is there an association between early stage Lean management implementation and changes in scores on safety culture assessments in acute care hospitals?

To address the research question, data from the safety culture assessment (SCA) conducted at an acute care hospital were analyzed. The safety culture assessment consists of validated domain questions from the Safety Attitudes Questionnaire, Hospital Survey on Patient Safety (HSOPS) and the Safety Organizing Scale (SOS). Units were categorized by exposure to Lean management implementation via the Lean Leadership Program. Change in unit mean domain scores during 2017 – 2015 were calculated and compared for statistical significance using difference in difference methods (14).

Hypothesis 1

Unit exposure to the Lean leadership program is associated with greater change in mean scores on perception of management questions on the safety culture assessment.

Hypothesis 2

Unit exposure to the Lean leadership program is associated with greater change in mean scores on safety organizing scale questions on the safety culture assessment.

Significance

Healthcare management in the United States has not kept pace with the rapid technological advances and evolving payment reforms. Toussaint, a physician who has studied hundreds of organizations over the last decade, concludes that healthcare management is stuck in the last century (15) inhibiting the advances so desperately needed. Hindering these advances is the western view that emphasizes short-term results with little patience for development of a culture that promotes long-term prosperity. At the core of the Toyota Production System is a long term vision (16). Short-term gains in outcome metrics are secondary to building the culture of respect for people and continuous improvement. This is at odds with the current “whack-a-mole” healthcare landscape where programs such as pay for performance and reimbursement schemes direct attention to selected metrics directly tied to financial incentives.

Lean management emphasizes management by process (3) in contrast to the more prevalent healthcare management by objective approach. This emphasis on process demands leaders spend time where the work takes place. Implementation of Lean management system components (such as leader standard work, visual management, and daily accountability in the gemba- a Japanese term for where the work

takes place, promote habits that engender behaviors consistent with principles of high reliability. The five principles of high reliability described by Weick and Sutcliffe are preoccupation with failure, reluctance to simplify, sensitivity to operations, commitment to resilience, and deference to expertise (17).

In summary, many organizations now employ Lean to improve value in healthcare. Yet reports of its effectiveness vary. This variation may be explained by the context in which Lean is implemented. Specifically, whether Lean is implemented as a tool or as a management system. This dissertation will deepen our understanding of Lean management systems in healthcare and identify factors that could improve its effectiveness.

Chapter 2

Background

Lean and Lean Management

Taichi Ohno, considered to be the father of the Toyota Production System (TPS), laid out the tools, systems and principles of TPS in his book "TOYOTA PRODUCTION SYSTEM: Beyond Large-Scale Production" (18). Krafcik(1) coined the term Lean to differentiate Toyota's approach from other automobile manufacturers. James Womack and Daniel Jones popularized the term Lean in their book "The Machine that Changed the World: The Story of Lean Production— Toyota's Secret Weapon in the Global Car Wars That is Now Revolutionizing World Industry."

According to Womack

"Lean production is "Lean" because it uses less of everything compared to mass production – half the human effort in the factory, half the manufacturing space, half the investment in tools, half the engineering hours to develop a new product in half the time." P. 13 (1)

Lean is now a common term in our vernacular. Most healthcare organizations seeking to implement Lean start with tools that identify and eliminate waste to demonstrate that Lean can bring about targeted point improvements in order to gain buy-in and broader support for Lean adoption. Lean is relatively new to healthcare. In a commentary in JAMA Internal Medicine Armstrong, Fox and Chapman point to the tendency of healthcare organizations to apply Lean in siloes, insular and tool based to achieve point improvements rather than improvement across patient centered value streams (19). Mazur, McCreery and Rothenberg also call out the tendency to implement tool vs. behavior Lean approaches (20). Liker emphasizes that many who are adopting Lean have missed the culture that is at the core of Toyota:

“Unfortunately, most companies throughout the world that are adopting Lean practices are going about it the wrong way. They often describe what they are doing as “adding tools to the toolkit”(p.27),(16).

Also noted by Gupta 2016:

“The lack of distinction between the system and its components further adds to the ambiguity in defining Lean; and hence many perceive Lean as just a tool box and, in doing so, miss the sensible philosophy behind it.” (p. 1026,(21)

David Mann, in the article “The Missing Link: Lean Leadership” asserts that the difference between Lean initiatives with fleeting success compared with those with enduring improvement lies in Lean management behaviors and structures and that full Lean implementation requires change in governance and behaviors at the leadership level (2). “Lean provides the templates and practices that enable leaders to learn and then look for, ask about, and reinforce the leadership behaviors that sustain the gains”-(pg. 26,(2) . Reinforcing leadership behaviors is a means of establishing new habits. Habit has been identified as a means of mindful organizing, a key to organizing for high reliability. (22)

Many healthcare organizations have yet to deploy Lean as a management system designed to embed and support Lean principles. This is a major shift for healthcare which has long favored the Alfred Sloan command and control style of leadership (3) A handful of healthcare organizations have reported on successful quality improvements following implementation of a Lean management system, among them are ThedaCare (23) and Virginia Mason (24). These organizations have matured in their Lean journey and view Lean as a management system, grounded on the philosophy of Lean developed at Toyota, which includes a profound respect for all and a commitment to continuously learn and improve. Following the approach of ThedaCare and Virginia Mason, other healthcare organizations are now beginning to implement Lean as a management system. According to Kaplan at Virginia Mason Medical Center in Seattle Washington:

“To successfully facilitate system transformation toward higher quality care at lower cost, Lean

tools must be part of a comprehensive management system, within a supportive institutional culture, and with committed leadership.” (25)

A Lean management system creates the mechanism by which integration and alignment occur on a daily basis. Front line staff working at the unit level feed information on unit performance up to their direct supervisors (26). This connects the workforce responsible for driving results with leadership and strategy. This allows Information to flow up to leadership and for help to flow down from leadership to the front line [see figure 3 (26, 27)]. The main components of a Lean management system include leader standard work, visual controls, daily accountability and discipline(28).

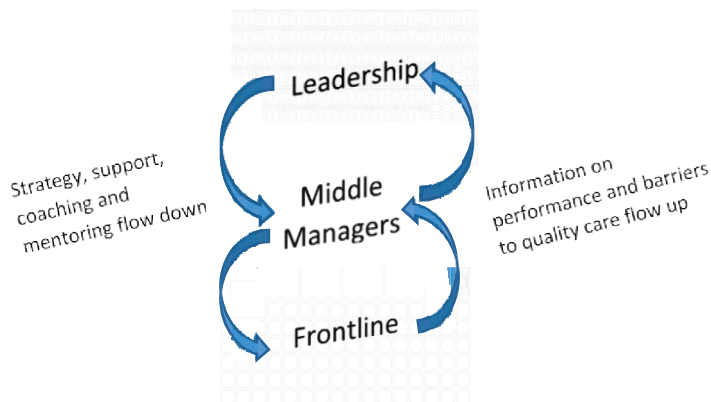


Figure1 Lean Management System Flow Adapted from “Andy & Me and the Hospital – Further Adventures on the Lean Journey” (27)

Behaviors at the leadership level have been shown to improve safety climate scores. Implementation of Leadership WalkRounds in both a community and academic acute care hospital resulted in an increase in safety climate scores (29). Implementation of a Lean management system requires that leaders spend time in the gemba (where the work takes place) supporting the efforts of front line staff, a behavior consistent with Leadership WalkRounds.

Safety Culture

Healthcare has developed a number of validated survey instruments to measure staff perceptions of safety culture. One of the most widely used tools for assessing safety climate in healthcare settings is The Safety Attitudes Questionnaire (SAQ). The SAQ was adapted from the Flight Management Attitudes Questionnaire (FMAQ) used in aviation to study safety climate and has been validated for use in healthcare (30).

The study hospital's Safety Culture Assessment (also referred to as SCA) combines the Safety Attitudes Questionnaire with HSOPS and the nine questions from the Safety Organizing Scale. The survey consists of seven domains: teamwork climate, safety climate, job satisfaction, stress recognition, perceptions of unit management, perceptions of department management, and working conditions.

The perception of management domain of the SAQ includes seven questions: three questions on perception of Local Management and four on perception of Senior Management (Table 1).

Table 1: Safety Attitudes Questionnaire Perception of Management Domain Questions.

SAQ Question	SAQ Domain focus
Local management (e.g. managers/supervisors) supports my daily efforts.	Local management
Local management (e.g. managers/supervisors) does not knowingly compromise patient safety.	Local management
I get adequate, timely info about events that might affect my work from local management (e.g. managers/supervisors).	Local management
Senior management (e.g. department leaders, chairpersons, executive leaders) supports my daily efforts.	Senior Management
Senior management (e.g. department leaders, chairpersons, executive leaders) does not knowingly compromise patient safety.	Senior Management
I get adequate, timely info about events that might affect my work from senior management (e.g. department leaders, chairpersons, executive leaders).	Senior Management
The staffing levels in this work setting are sufficient to handle the number of patients.	Senior Management

The Safety Organizing Scale (SOS) was developed and validated for use in hospital units (31). The SOS consists of 9 questions related to principles of high reliability: preoccupation with failure, reluctance to simplify, sensitivity to operations, commitment to resilience, and deference to expertise (17). The SOS uses a 7 point Likert scale with 1 =“not at all” and 7 = “to a very great extent”.

Table 2: Safety Organizing Scale Items

Q1 We have a good “map” of each other’s talents and skills
Q2 We talk about mistakes and ways to learn from them
Q3 We discuss our unique skills with each other so we know who on the unit has relevant specialized skills and knowledge.
Q4 We discuss alternatives as to how to go about our normal work activities.
Q5 When giving report to an oncoming nurse, we usually discuss what to look out for
Q6 When attempting to resolve a problem, we take advantage of the unique skills of our colleagues
Q7 We spend time identifying activities we do not want to go wrong
Q8 When errors happen we discuss how we could have prevented them
Q9 When a patient crisis occurs we rapidly pool our collective expertise to attempt to resolve it.

A literature review conducted by Mazur identified a need for research that studies Lean thinking and behaviors in hospitals of differing sizes and missions (32). Vest, following a review of the literature, made two recommendations for further research: better research methods and longer timelines. In particular, research that includes a comparison group would strengthen the evidence (33). This dissertation studied intervention and comparison groups over a two-year period in a 440 bed academic Level II trauma center.

Chapter 3

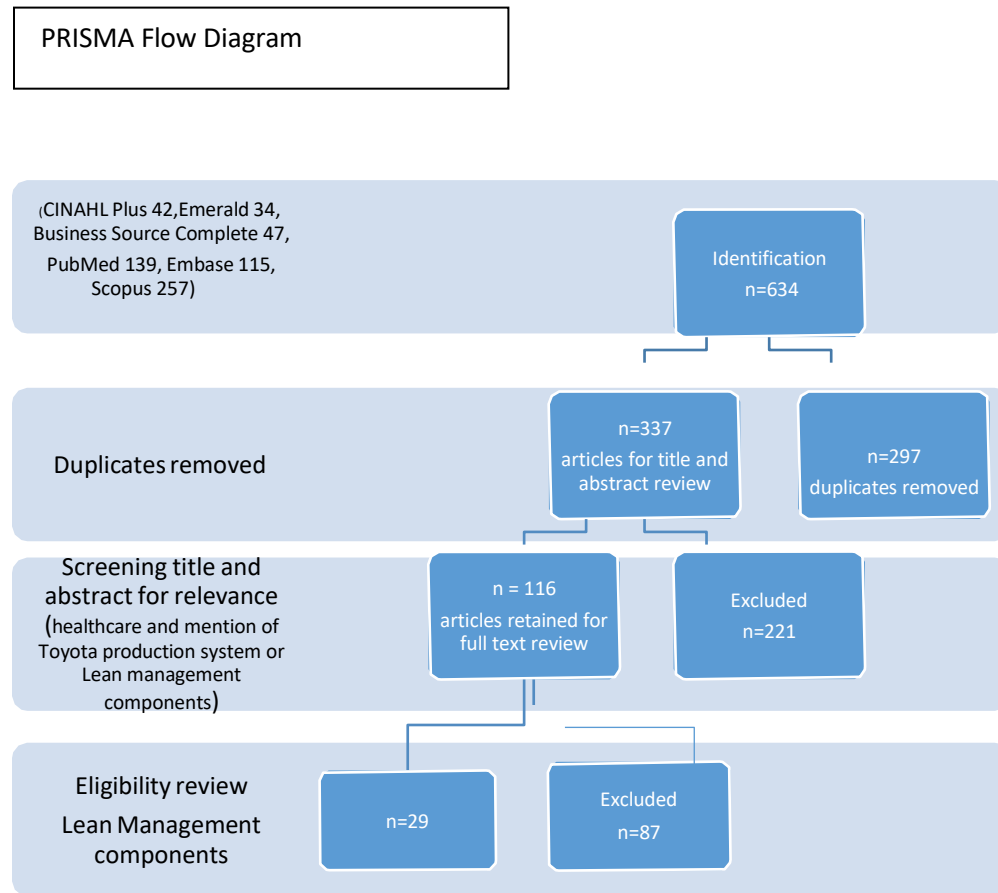
Methods

Methods - Aim 1

Explore through literature review what is known about Lean management systems in healthcare.

The literature search strategy was developed following consultation with a librarian and the database pulls were conducted on November 20, 2017. The search strategy included the following databases: PubMed (over 28 million citations from biomedical and health literature), Scopus (largest database of peer-reviewed literature), Emerald (full text access to over 200 journals in economics and business management), Embase (over 29 million citations from over 90 countries), CINAHL (Nursing and Allied Health Literature) and Business Source Complete (over 3,000 business and management publications). The following boolean search string was used: Lean management, Lean transformation, Lean implementation, Lean environment, Toyota Production System, AND healthcare, health care, hospital, hospitals. The date range for articles was 2000 to 2017 and restricted to English language. This search returned 634 publications across the six databases. Of the 634 returned, EndNote identified 297 duplicates, which were removed. The remaining 337 article titles and abstracts were then reviewed for relevance to the research topic. An additional 221 articles were removed at this stage.

Figure 2



The remaining 116 full text articles were further classified into tool and project based only or Lean management system based. Papers were included if they met the following selection criteria: 1) reported on a Lean management system or 2) reported on management system components as described by Mann (leader standard work, visual controls, daily accountability process, and discipline). Twenty-nine articles were selected for inclusion. An additional five articles were found through snowballing. The resulting 34 articles were imported into NVivo qualitative software. The articles were categorized by year, country, organization, research methodology, design, outcome of interest, presence of a comparison group, and

statistical analysis method. Articles were reviewed for themes related to Lean Management System component implementation.

Methods Aim 2

Assess attitudes and perceptions of nurse managers related to the implementation of Lean Management System components in hospital nursing units.

Realism is the theory that there is one absolute truth. Relativism on the other hand is the theory that there is not one truth, rather there are many perspectives shaped by context and culture. This researcher adopted relativism for this qualitative case study. Additionally the way knowledge was gained was using emic epistemology: the researcher interacted with the subjects. Semi-structured interviews were conducted in person following a protocol consisting of questions generated using David Mann's taxonomy (28) (Appendix B). Nurse Managers of units implementing Lean management were interviewed between July 20th and September 5th, 2018. There were seven interviewees from six units that implemented Lean management system components between 2015 and 2018 (one of the units had a change in nurse managers during the study period and both nurse managers were interviewed). Interviews were conducted over a one-hour period. All interviewees agreed to be recorded, reviewed the resulting transcription of the interview and provided feedback to aid transcription accuracy. After the fifth interview, no new information surfaced suggesting saturation. The transcripts were uploaded into NVivo software and coded for themes by a single coder using David Mann's taxonomy (28).

Methods - Aim 3

Examine the relationship between early stage Lean management implementation and safety culture assessment.

Theoretical Framework

This study will draw on implementation science, leveraging the Practical Robust Implementation and Sustainability Model (PRISM) framework (34).

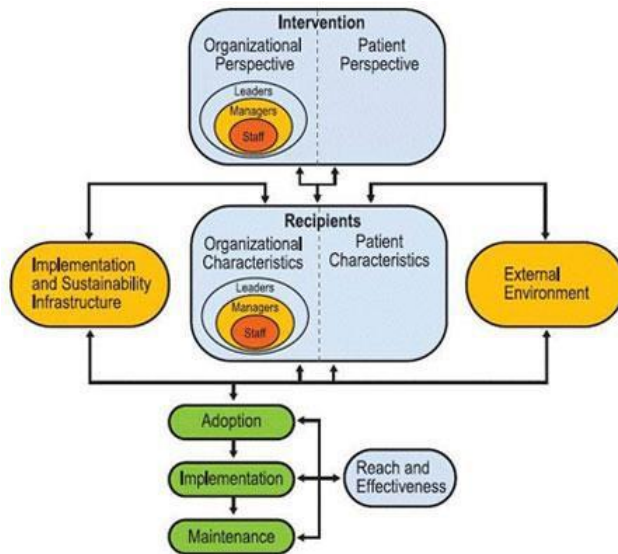


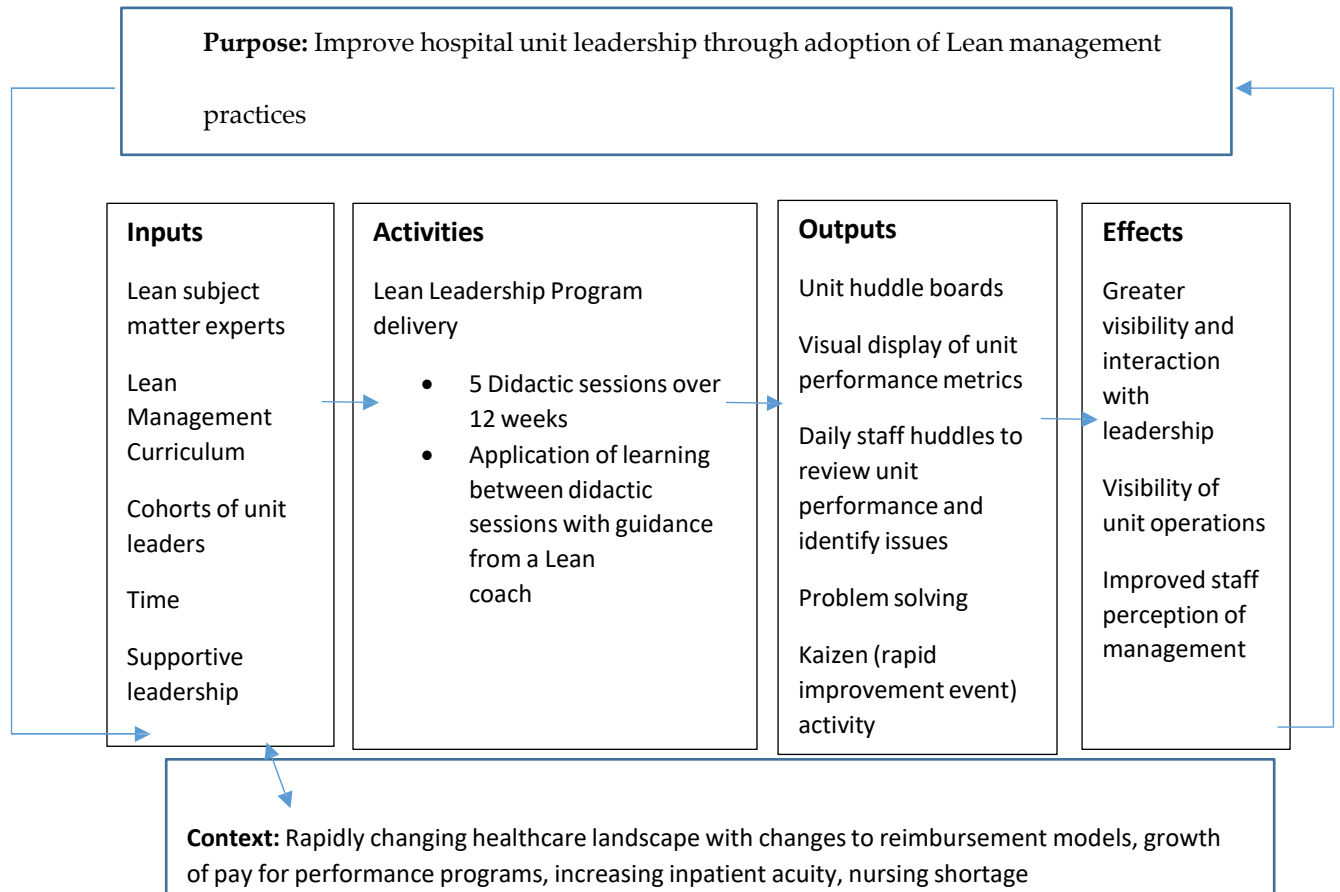
Figure 3 PRISM Model - Image downloaded from <https://www.fic.nih.gov/About/center-global-health-studies/neuroscience-implementation-toolkit/Pages/methodologies-frameworks.aspx>, accessed August 14, 2017

The design of the Lean Leadership Program leveraged several elements of the PRISM model influencing adoption, implementation and sustainability in the four intervention units (Emergency Department, Medical X, Medical Y, and Medical Z). Table 3 below maps specific Lean Leadership Program components to elements of the PRISM model identified by Feldstein and Glasgow.

Table 3 - PRISM elements and Lean Leadership Program components

	Elements within PRISM	Lean Leadership Program components
Program Organizational Characteristics	<ul style="list-style-type: none"> • Coordination across departments and specialties • Usability and adaptability • Trial ability and reversibility • Ability to observe results 	<ul style="list-style-type: none"> • Pairing upstream and downstream units • Iterative application of learning in the unit between didactic sessions with coaching/feedback • Selection of performance metrics to track on unit huddle boards
External Environment	<ul style="list-style-type: none"> • Payer satisfaction 	<ul style="list-style-type: none"> • Alignment to externally reported metrics (i.e. left without being seen, boarding time in ED)
Implementation and Sustainability Infrastructure	<ul style="list-style-type: none"> • Performance data • Dedicated team • Adopter training and support • Relationship and communication with adopters • Facilitation of sharing of best practices • Plan for sustainability 	<ul style="list-style-type: none"> • Selection of key metrics • Unit leadership cohort • Didactic sessions with accompanying implementation support in unit • Presentations to Lean Leadership Program cohort peers • Routine scheduled huddles
Recipients Organizational characteristics	<ul style="list-style-type: none"> • Management support and communication • Data and decision support 	<ul style="list-style-type: none"> • Gemba walks • Leadership Rounding

Figure 4: Logic Model



Study design

The study is a retrospective longitudinal cohort design. The study population is bedded hospital units at an acute care hospital in Baltimore, MD. The independent variable is Lean Management exposure through the Lean Leadership Program. The dependent variable is change in mean score on SCA domain questions. We categorized units into exposure and non-exposure to Lean management based on unit leader participation in the Lean Leadership Program. We used a Difference in Difference approach to

compare change over time in the intervention group compared to change over time in the comparison groups.

Exposure to Lean Leadership Program

Lean experts from the Armstrong Institute for Patient Safety and Quality provided training in Lean management via a 12-week Lean Leadership Program (LLP) consisting of both didactic classroom sessions and experiential learning applying Lean management in hospital units (Appendix B). The design of the program paired leaders from upstream and downstream units within a patient value stream. Upstream and downstream refers to units connected in a patient's journey during hospitalization. Upstream units receive patients early in the patient's care and the downstream unit receives the patient from the upstream unit as the patient progresses in their care. The first LLP cohort included a physician, nurse and administrator triad from the Emergency Department (upstream unit) and from Medicine B, (downstream medical unit). The second cohort included the Medical Intensive Care Unit (upstream unit) and Medicine A (downstream medical unit). Participants in the LLP attended five didactic Lean educational sessions held biweekly over a 12-week period. Sessions included introduction of Lean tools to identify and eliminate waste as well as key components of a Lean management system: (selection of key performance metrics, visual management approaches to making performance, defects and problem solving visible through huddle boards, standard work and discipline.(28). In the intervening weeks between didactic sessions participants implemented Lean management with the support of a Lean coach. Table 4 provides a list of unit types and numbers of beds for the intervention and comparison groups.

Table 4 - Intervention and Comparison Units

Respondent Group (de-identified)	Unit type	Licensed Beds
Intervention Units		
Emergency X	Emergency	0
Medical X	Medicine	36
Medical Y	Medicine	36
Medical Z	Medicine	12
Comparison Units		
Chronic X	Chronic	20
Chronic Y	Chronic	32
Chronic Z	Chronic	36
Maternal Child Health X	Maternal Child Health	24
Maternal Child Health Y	Maternal Child Health	0
Medical XX	Medicine	30
Medical XY	Medicine	18
Medical XYZ	Medicine	28
Medical XZ	Medicine	12
Neonatal X	Neonatal	25
Neurosciences X	Neurosciences	8
Neurosciences Y	Neurosciences	17
Pediatrics X	Pediatrics	5
Psychiatry X	Psychiatry	20
Surgery X	Surgery	38
Surgery XX	Surgery	10
Surgery XY	Surgery	10
Surgery Y	Surgery	10
Surgery Z	Surgery	10

The Lean transformation at this hospital began shortly after a visit by health system and hospital leaders in March 2015 to ThedaCare, a health system in Appleton, Wisconsin that has successfully implemented a Lean management system in their acute care hospitals. Participants in the ThedaCare visit included the

Chief Operating Officer, Vice President (VP) for Patient Care Services, VP Care Management Services, VP of Medical Affairs, Director of Collaborative Internal Medicine Service, Director of the Emergency Department, Senior Director of Support Services, and Lean sigma staff from the health system. The respective leadership teams discussed key takeaways and developed a plan for adoption of a Lean management system in their own hospitals.

Despite Lean application in healthcare over the past 15 years, there is little research on the impact of Lean implementation on safety climate. Weng and colleagues demonstrated that perceptions of management mediate safety climate scores (12), however that work did not include mechanisms by which perceptions of management can be improved. This study will analyze changes in safety survey scores following early stage implementation of Lean management at an acute care hospital.

Sources of data

Quantitative data

The Armstrong Institute in Patient Safety and Quality facilitates administration of a safety culture assessment utilizing the Safety Attitudes Questionnaire (SAQ) and the Safety Organizing Scale (SOS) across the health system every 2 years. The survey vendor Pascal Metrics® administered the survey electronically to hospital staff in 2015 and again in 2017. Supervisors, managers and directors assigned hospital staff to their home units in advance of the survey. Pascal Metrics® compiled the results and supplied them to the Armstrong Institute in Patient Safety and Quality staff in Excel spreadsheet format. The spreadsheet contained response rates as well as responses to survey questions recorded at the unit level and by role on the unit.

Secondary hospital unit level SAQ data from 2015 and 2017 were obtained from the Armstrong Institute for Patient Safety and Quality in Excel spreadsheet format. The field “respondent group” represented unit survey responses. Filtering of the spreadsheet was used to identify and exclude ambulatory units

indicated by respondent groups receiving the MOSOPS (Medical Office Survey on Patient Safety Culture) or ASCSPS (Ambulatory Surgery Center Survey on Patient Safety) to reduce the data to inpatient units only. Because three units changed names between the 2015 and 2017 surveys, data cleaning included matching the SAQ unit respondent group names used in 2015 to the SAQ unit respondent group names used in 2017, then updating the 2015 unit name to match the 2017 unit name for comparison. Nursing data (such as names and types of units, number of licensed beds, vacancy rate, turnover rate, CUSP status of units, and change in Nurse manager from 2015 to 2017) was provided by hospital nursing administration in several excel spreadsheets. Dummy variables for Time and CUSP status were created. The “respondent group” field and a dummy variable for LLP status were added to the nursing unit data spreadsheets for both 2015 and 2017. The SAQ data spreadsheet for 2015 was then merged with the formatted 2015 unit variables spreadsheet using the field labeled “respondent group” as the unique key. This process was repeated to merge the 2017 SAQ spreadsheet and 2017 unit variable spreadsheet. The 2015 merged spreadsheet was then imported into Stata. Using the append command in Stata; data from 2017 were then combined with the 2015 data in long form for analysis.

Instrument

The perception of management questions come from the Safety Attitudes Questionnaire, a widely used tool to measure safety culture in healthcare. Sexton and colleagues derived the SAQ from the Intensive Care Unit Management Attitudes Questionnaire, which was derived from the earlier Flight Management Attitudes Questionnaire (FMAQ) (30). Reliability of the SAQ scale was shown in a sample of 203 healthcare sites including inpatient units with 10,843 questionnaires (67% return rate) across the US, UK and New Zealand (29). The six domains in the SAQ include teamwork climate, overall safety climate, perceptions of management, job satisfaction, working conditions and stress recognition.

Variables and measures

Research Q2:

Is there an association between early Lean management implementation and scores on the safety culture assessment?

Table 5: Variables and Measures

	Independent variables	Dependent
<p>Research Q2, Hypothesis 1</p> <p><i>Unit Lean leadership program exposure is associated with greater change in perception of management domain mean scores compared to units not exposed.</i></p>	<ul style="list-style-type: none"> Lean Leadership Program participation (binary) 	<ul style="list-style-type: none"> Change in mean Perception of Management domain score (continuous)
<p>Research Q2, Hypothesis 2</p> <p><i>Unit Lean leadership program exposure is associated with greater change in unit safety organizing scale domain mean scores compared to units not exposed.</i></p>	<ul style="list-style-type: none"> Lean Leadership Program participation (binary) 	<ul style="list-style-type: none"> Change in mean Safety Organizing Scale Domain score (continuous)

Study variables

Lean leadership program exposure:

Definition: Unit exposure to Lean management through the Lean Leadership Program (LLP)

0 = no unit participation in LLP, 1= unit participation in LLP

Time

Definition: Year of survey administration

0 = 2015, 1=2017

CUSP (Comprehensive Unit Based Safety Program) dummy variables:

Definition: Unit CUSP activity level status

CUSP Active

0 = no, 1= yes

Change in mean SCA domain score:

Definition: calculated difference in mean score for each specific SCA domain from 2015 to 2017.

Analysis plan

Exploratory analysis was performed to provide descriptive statistics for 2015 and 2017 on unit type, overall response rate, and composition of respondents for units by role. Safety culture assessment survey mean domain scores for 2017 were compared with mean domain scores for 2015. The 2015 scores represented pre-exposure and 2017 scores represented post-exposure. Research has suggested that Lean Management takes 6-18 months to have an effect (35).

Difference in Differences (DID) Method

Difference in Differences (DID) operates under the parallel trend assumption that the intervention and comparison groups have a similar trend over time. When there is no randomization and therefore potential for variables other than the treatment to be influencing the outcome of interest for both groups the DID approach isolates the treatment effect by “double differencing” (difference between the intervention and comparison before and after difference). A dichotomous indicator variable for LLP exposure was created with $LLP = 1$ for units that participated in the LLP, and $LLP = 0$ for comparison units that did not participate in LLP. A dichotomous indicator variable for Time was created with $Time = 0$ for 2015 and $Time = 1$ for 2017.

Equation

Diff in Diff model

$$Y_{it} = \beta_0 + \beta_1(LLP_{it}) + \beta_2(Time)_{it} + \beta_3 (LLP_{it}*Time_{it}) + \epsilon_{it}$$

Y_{it} represents the independent outcome variable “change in mean survey score” for the i^{th} unit at time t .

β_0 represents the value of Y when both LLP and Time are zero.

β_1 is the regression coefficient for the effect of LLP on the mean change in score holding all other variables constant.

LLP_i represents a dummy or indicator variable for participation in the LLP with LLP units = 1 and comparison units = 0,

β_2 is the regression coefficient for the effect of time on the mean change in score holding all other variables constant.

Time represents a dummy variable for time with Time = 0 for 2015 and Time = 1 for 2017, (LLP_{it}*Time_{it}) represents the interaction term for the interaction of LLP and time for the ith unit at time t. ϵ_{it} represents the error term.

Table 6 – Difference in Difference Equation

	Pre	Post	Difference
LLP	$\beta_0 + \beta_1$	$\beta_0 + \beta_1 + \beta_2 + \beta_3$	$\beta_2 + \beta_3$
Comparison	β_0	$\beta_0 + \beta_2$	β_2
Difference	β_1	$\beta_1 + \beta_3$	β_3

$$\text{Diff in Diff} = \beta_3$$

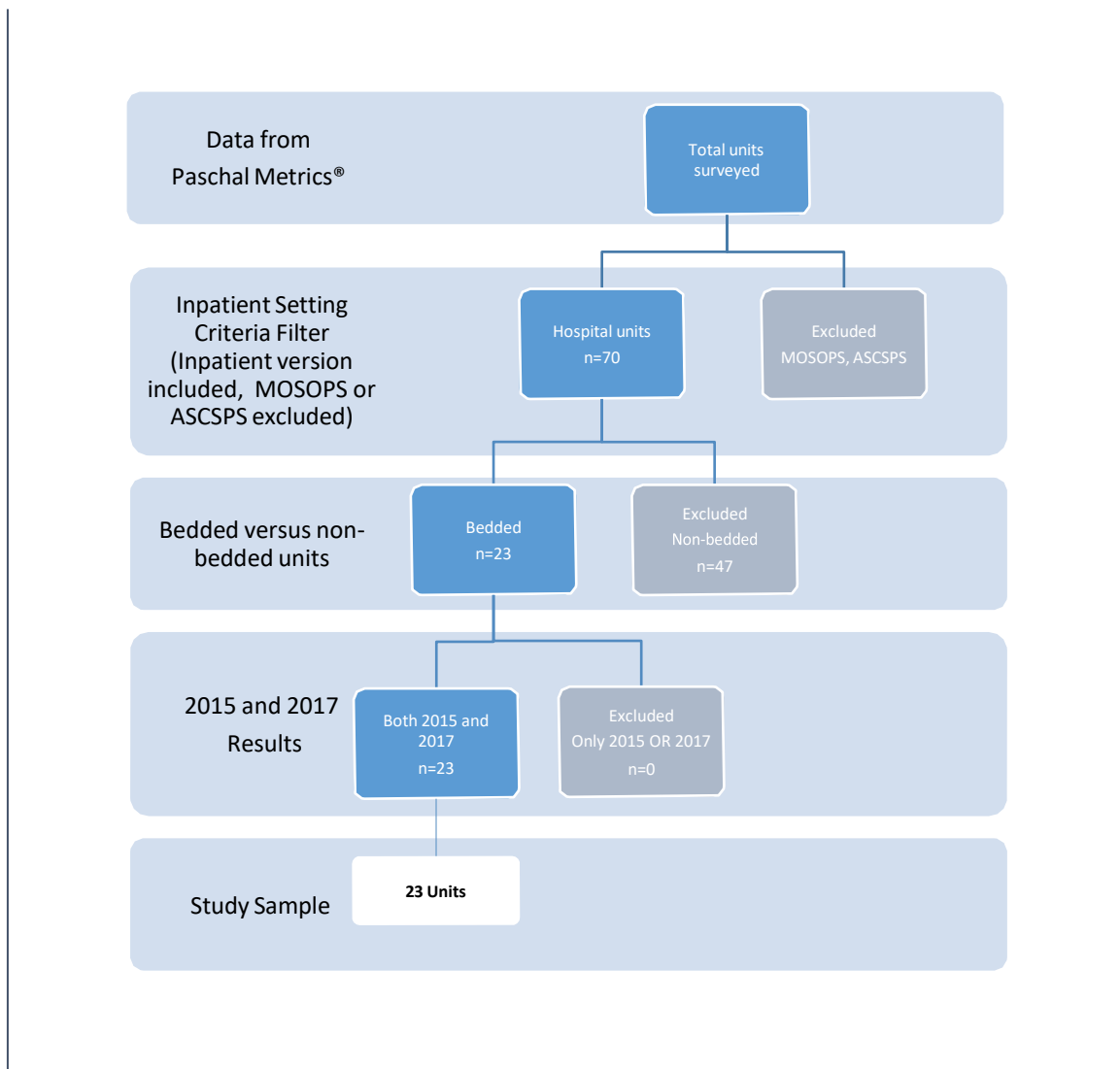
Inclusion Criteria

All hospital inpatient bedded units with survey results in both 2015 and 2017 were included in the analysis. The data export from Paschal Metrics® combines all safety culture assessment results across inpatient and ambulatory settings. The data were provided in separate spreadsheets for 2015 and 2017. Respondent groups were assessed further to determine which units had data for both 2015 and 2017 surveys.

Exclusion Criteria

Ambulatory respondent groups receiving the MOSOPS (Medical Office Survey on Patient Safety Culture) or ASCSPS (Ambulatory Surgery Center Survey on Patient Safety) were excluded from the analyses. It also was intended to exclude inpatient bedded units for which there were not both 2015 and 2017 survey results. However, review of the data set indicated no units were missing survey results for 2015 or 2017.

Figure 5 - Study sample selection



Chapter 4

Aim 1 Results

Aim 1

What is known about Lean management systems in healthcare?

Lean Management descriptions/definitions

David Mann's description of Lean Management System components in the table below serves as the definitions for this study. Within the articles meeting inclusion criteria, additional descriptions were offered which may be helpful.

Table 7 - Lean Management definitions

Author/ Year	Term	Definition
Mann 2005 (28)	Lean Management System	Comprised of 4 elements: leader standard work, visual controls, daily accountability process and discipline.
Steed 2012(36)	Lean system in healthcare	The relentless elimination of waste in every area of operations with the aim of reducing inventory, cycle times, and costs, so that delivering higher-quality patient services can be provided in the most efficient, effective, and responsive manner.
Toussaint 2013	Lean management	Six principles that constitute the essential dynamic of Lean management: attitude of continuous improvement, value creation, unity of purpose, respect for front-line workers, visual tracking, and flexible regimentation.
Crema 2016	Health Lean Management(HLM)	A management philosophy to develop a hospital culture characterized by increased patient and other stakeholder satisfaction through continuous

		Improvements in which all employees (managers, physicians, nurses, laboratory people, technicians, office people etc.) actively participate in identifying and reducing non-value-adding activities (waste).
Verbano 2017	Health Lean Management(HLM)	A managerial approach that, through the development of a Continuous Improvement (CI) culture, permits elimination of waste in all the hospital areas and actively involves all of the employees in identifying and reducing non-value-adding activities.

Lean Management System Naming Conventions

Early adopters of Lean management systems adopted and adapted the naming conventions from the Toyota Production System. Virginia Mason Medical Center and Henry Ford Hospital replaced the name Toyota with the name of their own organization resulting in the names Virginia Mason Production System and the Henry Ford Production System. Other healthcare organizations implementing Lean management system components incorporated the word system but created their own name for their system such as the Business Performance System at ThedaCare and, at Stanford, the Stanford Operating System. Additional terms such as “daily management system” or “daily engagement system” were used to describe the sub-systems within Lean Management Systems. (37), (38, 39)

The article inclusion criteria utilized in the study were reporting on implementation of one or more Lean management components (leadership standard work, visual controls, daily accountability and discipline). This approach yielded 29 articles. An additional five articles were found through snowballing. Of the 34 articles that met inclusion criteria, 56% originated from North America with 18 from the United States (USA) and 2 from Canada. The breakdown of the remaining 14 are as follows: five from Scandinavia (Denmark, Finland and Sweden), five from Italy, one each from the Netherlands,

France, Ireland/ UK, and Australia. The settings included academic medical centers, community hospitals and ambulatory care settings and included both adult and pediatric patient populations. Only six of the articles returned from the search and meeting inclusion criteria were published before 2013, and five of those six originated from North America (Table 8).

Table 8 - Articles by country

Country	Number of articles	Earliest publication
United States	18	2010
Italy	5	2013
Sweden	3	2013
Canada	2	2011
France	1	2007
Denmark	1	2011
Ireland/UK	1	2013
Netherlands	1	2013
Australia	1	2015
Finland	1	2017

Of the 18 articles published from the U.S., one involved eight hospitals across the country including hospitals from the west coast, east coast, mid-west and south. Of the remaining 17 articles, seven were from organizations on the west coast (Washington, Oregon and California), six from the mid-west (Wisconsin, Michigan, Minnesota), one from the west south central region(Texas) and the remaining three from the east coast, (Pennsylvania, North Carolina, and Florida). A chronological list of all of the articles meeting inclusion criteria is included in Table 9 below.

Table 9 - Articles meeting inclusion criteria

Author	Country	Type of organization	Methods	Design	Outcome of interest	Comparison Group	Statistical analysis
Early years 2010-2012							
Ballé (40)	France	Hospital	Qualitative	Case study	None	None	None
Rutledge (39)	USA	Seattle Children's Hospital Laboratory affiliated with Univ. of Washington	Quantitative	Quasi-experimental pre-post design	Process metric: Lab test turnaround time	None	None
Barnas (41)	USA	2 Community hospitals in Wisconsin	Quantitative	Quasi-experimental pre-post	Process metrics: Productivity, quality safety, engagement	None	None
Culig (42)	USA	Ed Dardanel Heart and Vascular Center (HVC) within Forbes Regional Hospital, Pennsylvania	Qualitative	Case study	Outcome metric: Risk-adjusted mortality rate, Risk-adjusted rate of complications	Benchmarking group from Society of Thoracic Surgeons National Adult Cardiac Surgery Database.	descriptive statistics only
Deans (43)	Canada	Holland Bloorview Kid's Rehabilitation Hospital, Toronto	Mixed methods	Case study and pre-post design	Process metric: Access to care	None	None
Karstoft (44)	Denmark	Odense University Hospital academic medical center	Quantitative	Quasi-experimental pre-post design	Process metrics: Number of radiology exams, waiting time	None	None
Steed (36)	USA	US hospitals	Qualitative	Survey and questionnaire	Attributes of successful Lean leaders	None	None
2013-2017							

Crema (45)	Italy	N/A	Qualitative	N/A - Discussion of healthcare performance management	Thematic Analysis	None	None
Crema (46)	Italy	N/A	Qualitative	Systematic Literature review	Guidelines for successful implementation of management practices (HLM, CRM)	None	None
Faulkner (37)	USA	Lucille Packard Children's Hospital, CA	Quantitative	Quasi-experimental pre-post design	Process metrics: Time to retrieve supplies, time to MD, bundle compliance	None	None
Toussaint (47)	USA	N/A	Qualitative	Narrative	Framework for Lean implementation assessment	None	None
Poksinska(48)	Sweden	N/A	Qualitative	Case study	(1) developing and maintaining relationships; (2) getting and giving information; (3) making decisions; and (4) influencing people	None	None
Donnelly (49)	USA	Children's hospital, Florida	Qualitative	Case study	None	None	None
Kaplan (25)	USA	Virginia Mason Medical Center, Washington	Qualitative	N/A – Opinion piece	None	None	None
Ljungblom (50)	Sweden	N/A	Qualitative	Literature review and qualitative	Evidence of ethics	None	None
Mannon (51)	USA	ThedaCare, Wisconsin	Qualitative	Narrative	None	None	None
Aij(52)	USA	Nine hospitals	Qualitative	Survey	Manager traits	3 groups of hospitals: Lean, low performing, and high performing	Nonparametric Kruskal-Wallis chi-squared exact test and

							Wilcoxon 2 sample test
Aij(53)	Netherlands	Teaching hospital	Qualitative	Case study, Interviews, leader self-report	Thematic analysis	None	None
Crema(54)	Italy	N/A	Qualitative	Systematic Literature review	Connections and overlaps between health Lean management (HLM) and clinical risk management (CRM)	None	None
Hung(38)	USA	Primary care	Qualitative	Survey	Process metrics facilitators and barriers of Lean management implementation	None	None
Kane(55)	USA	Emergency Department, academic medical center, CA	Quantitative	Quasi-experimental pre-post design	Process metrics: LOS, process efficiency, patient satisfaction	None	None
O'Brien (56)	Australia	Hospital	Qualitative	Case study, survey	Staff perceptions of visual management interventions	None	None
Robinson (57)	USA	Oregon Health and Sciences University	Qualitative	Descriptive	Attributes Characteristics of Lean leadership	None	None
Ulhassan (58)	Sweden	Danderyd Hospital	Qualitative	Case study	Thematic analysis	Two cardiac inpatient units	None
White(59)	Ireland/UK	N/A	Qualitative	Literature review	Thematic Analysis	None	None
Zarbo(60)	USA	Henry Ford Hospital, Michigan	Qualitative	Case study	Outcome and Process metrics: Quality, inventory, time, productivity, safety	None	None
Crema(61)	Italy	Hospital in Florence Province	Qualitative	Case study	Safety improvements from Lean project implementation	None	None

Halvorson(62)	USA	Academic tertiary care hospital, Oregon	Mixed methods	Case study and pre-post design	Process metrics: Percent of patient transfers from ICU to acute care unit within 120 minutes, survey responses related to quality of hand-off communication	None	Kruskal-Wallis one-way analysis of variance and test of two proportions.
Roszell (63)	USA	Academic medical center, North Carolina	Qualitative	Instrument creation, validation and psychometric properties analysis	Validity, Reliability		Cronbach's Alpha, Interitem correlation, k and Pearson's r
Schultz (64)	USA	N/A	Qualitative	Literature review of Lean management systems in healthcare	Review of literature	None	None
Donnelly (65)	USA	Children's hospital , Texas	Qualitative	Case study	None	None	None
Hihnala (66)	Finland	University Hospital	Qualitative	Interviews	Health managers experience with Lean management	None	None
Simon(67)	Canada	Alberta Health Services	Mixed methods	Case study and pre-post design	Process metrics: Reduction in wait times for cardiac arrhythmia service program (Electrophysiology)	None	None
Verbano (68)	Italy	Galliera Hospital	Qualitative	Interviews	Percent of admitted patients with LOS > 30 days	None	None

The earliest article returned from the search and meeting inclusion criteria was a 2010 article describing Lean management system implementation in a laboratory at Seattle Children’s Hospital in the northwestern US (39). An earlier article by Ballé (40) describing Lean management behaviors in a hospital ward in Paris was found through snowballing. Five articles on Lean management in healthcare were identified through snowballing; four of those five were published after 2010. This is consistent with the notion that application of Lean in healthcare prior to 2010 was largely limited to application of Lean tools.

All five of the quantitative studies meeting inclusion criteria had a quasi-experimental pre-post design lacking a comparison group (Table 10). Three mixed method case studies also reported on pre-post designs. This finding is consistent with Vest’s reporting of the problem of weak study designs in a literature review of Lean Sigma, Lean, and the Studer Group’s Hardwiring Excellence research literature (33). According to Vest, two recommendations that would improve research designs are inclusion of comparison groups and statistical analysis. The majority of the articles meeting inclusion criteria (20/29) reported on qualitative methods only.

Table 10 – Description of articles included

Research method	Study Design	Count	Comparison group	Statistical analysis
Quantitative	Quasi-experimental pre-post design	5	None	None
Qualitative	Case study, surveys, literature reviews, narratives	26	3	3
Mixed Methods	Case study and pre-post design	3	3	1

Qualitative Methods Design

Themes found in the 20 qualitative articles are organized below by the four components of a Lean management system described by Mann: leader standard work, visual controls, daily accountability and discipline (28).

Leader Standard Work

Leader standard work is defined as routine practices that put the focus on both results and the processes used to achieve the results (28). The purpose of leader standard work is to align the organization around strategic priorities, and minimize unwanted variation in management practices. The management system does not depend on the individual style of the manager—instead it is process dependent. (2)

Barnas described ThedaCare’s leader standard work as a structured management reporting system. A rapid improvement event approach, which had been the foundation of their early Lean efforts, was used to develop their Business Performance System® (BPS). They renamed leader standard work to leadership standard work. ThedaCare’s BPS was created in 2 phases, with the first phase focused on what they referred to as “learning to see” during which a “No Meeting Zone” (41) was created providing protected time for the new work of leaders. The No Meeting Zone, scheduled at the beginning of the day, was a 2-hour block of time during which no other meetings could occur. A “daily stat sheet” (a form that helps leaders plan their conversations with direct reports), a “daily performance and defect review huddle” that brings the unit staff and unit leaders together to review and discuss performance to targets, and a “unit based leadership team” are all subcomponents of leadership standard work created in the learning to see phase (41). The unit based leadership team brings together the unit leaders, and their unit leadership team, along with finance on a monthly basis to evaluate performance.

In the second phase of developing the BPS, the problem-solving phase, additional activities were added to help with the improvement work. During this phase, additional standard work included auditing standard work, visual tracking on the unit, and A3 thinking. Auditing of standard work was

noted as not only a means of determining whether work was done, it also surfaced when standard work was done but results were not achieved which prompted evaluation of the effectiveness of the standard work.

“Unit leaders now have a structured management reporting system to reduce variation in their management styles. Leaders all now follow leadership standard work, and their daily work is now consistently aligned with the hospital and system strategy.” (41, p 387)

Leadership presence in the workplace was seen as the best way for leaders to be visible and show support to staff (55),(57)}. Kaplan, describing the Virginia Mason Production System (VMPS) goes further.

“VMPS also requires leaders to move from the ‘hero mentality’ of problem solvers to being coaches who build learning teams that use VMPS for long-term improvement.” (25)p. 972

Leader standard work in the Department of Pathology and Lab Medicine at Henry Ford Hospital included reviewing performance metrics during daily gemba walks. Part of the expectation of leaders is to coach staff and the daily gemba walks provide a regular opportunity for leaders to better understand the work, which improved their ability to coach for better performance (60).

The change in leadership practice is emphasized as critical to the success and sustainment of Lean.

Virginia Mason requires executive leaders and members of the board to travel to Japan and participate in what they refer to as “deep training” in their management system to prepare them for their new role and behaviors (25)

Lean daily management requires significant behavioral changes for many leaders. The expectation is that leaders will spend time in the gemba where the work takes place on a regular basis. In addition to

rearranging their schedules to allow time for visits to units, leaders also need to view their role differently.

“In order for the business management system to succeed and grow, leaders (VPs) must fully engage in the process first so they can learn to mentor, support, and teach their teams. A developmental team must support their learning”. (41) p. 392

Perhaps the most difficult change for leaders to make in a Lean management system is the change from being a problem solver to becoming a coach and mentor to help staff become problem solvers. Simon quotes Krefle “it is not the role of leadership to solve the problems, but rather know the questions to ask to drive the problem solving process” (67).

Aij, reporting on his own experiences implementing Lean leadership in a Dutch university medical center, observed that the frequent leadership visits to the units provided the leadership team with opportunities to see problems and areas in need of improvement firsthand. The case study interviews revealed that while most of the leaders embraced the gemba visits as opportunities to improve alignment to goals some did not see the need for gemba visits to “talk about the same issues all over again” (69, page 124).

Visual Controls

Visual controls are methods that make a process observable and can take many forms. Visual display of performance data is a key visual control method used in Lean management systems. In healthcare, these visual displays are frequently referred to as huddle boards.

The visual display most often takes the form of a magnetic dry erase whiteboard (huddle board) located on a wall in the unit or area where the work takes place. The huddle board displays key performance data that are relevant to staff and leadership, and makes unit performance visible at a glance. Different from a bulletin board, the huddle board is dynamic (47) and allows for interaction and discussion ideally

on a daily or even shift-by-shift basis.

However other names used for the visual displays in the articles included visibility walls (55), extended kaizen boards ((44) daily management or daily engagement system (38), visual KPI management board (70), and Lean display board (Hihnala).

“The 2nd management function, and key to staff engagement, is data sharing through the use of visibility walls. Visibility walls are used for tracking clinical metrics and are posted in prominent accessible areas. This provides easy access to performance data, allows staff to see the results of their changes, and maintains active real-time engagement.”(55 p. 432)

Along with variability in the naming of visual controls there is also a difference in implementation with some taking a very rigid standardized top down design while others allow more customization at the local level. The Department of Pathology and Laboratory Medicine at Henry Ford Hospital was very prescriptive in their design, specifying 5 columns and rows for the visual display and dictating what should be displayed in each column and row, and the resulting standardized design of columns formed the acronym QTIPS (Quality, Time Inventory, Productivity, and Safety)(60). Other organizations allow for local customization based on the space constraints and/or a desire for staff to create their own visual management board to ensure the board is meaningful to staff. Aij shares his experience, indicating a leadership and front line disconnect.

“There was a big gap between how I thought it would be and what I heard from my employees. I thought that there would be daily measurement of performance indicators, which would be visually managed on the work floor. In fact, only two managers had actually implemented Lean and some visual management boards were still unused.” (53 p. 123)

Ulhassan, contrasting 2 cardiology wards with very different adoption of visual management boards, echoes the importance of customizing at the local level so that “staff find them relevant and useful”(58)p.227. Boards can also include sections for staff to post and discuss improvement ideas (51).

Daily Accountability

Accountability is enhanced through frequent real-time data driven feedback on performance. More mature Lean Management System implementations such as Henry Ford, Virginia Mason ThedaCare, Stanford, and Nemours describe a daily management system (DMS). Interviews conducted with managers in the ambulatory practices at Stanford revealed that eight of twelve managers believed that connecting frontline performance metrics in the daily management system was key for sustaining process improvements. (38).

A common approach used in healthcare to achieve daily accountability is the huddle. The huddle brings staff together and provides a mechanism for bidirectional information flow between front line and managers in a structured disciplined way. Various ways in which the huddle is enacted were described, all with a predictable cadence that promotes alignment and flow of information and support. Some unit huddles occur daily or several times a day while others may occur less frequently. The length of the huddle in the literature varied from 5 minutes to 30 minutes, with most describing a 10-15 minute huddle (Barnas, Culig, Deans, Karstoft, Wade). Culig describes “daily, rigidly orchestrated 10 minute huddles during which all participants stand”. (Culig p.395) Barnas describes the BPS daily huddle as a “10 to 15 minute daily review in which unit leadership and staff focus on process improvement to identify current work-flow defects, create assignments, and establish the discipline of daily follow-through as a team” (41, p 391).

Frequency of huddles may vary based on organization level as well. Tiered huddles refer to sequenced huddles occurring among the different levels of the organization to promote alignment from the front line to the top leadership. Tier 2 and 3 (tier is a term used to describe the level of the organization) may occur less frequently such as weekly. Purpose of the huddles described varies from reviewing key performance indicators and problem solving to idea generation (Table 11).

Table 11 - Description of Huddles in the Included Articles

<u>Author</u>	<u>Frequency</u>	<u>Duration</u>	<u>Purpose</u>	<u>Location</u>	<u>Attendees</u>
Barnas (41)	Daily	10-15 minutes	Identify defects Assign follow-up	Unit board	Unit leadership and staff
Kane (55)	3 times per day	10 minutes,	Identify improvement opportunities and patient care concerns	At visibility wall	Managers and staff
Culig (42)	Daily	10 minutes	Problems from past 24 hours	At visibility wall in meeting room	Caregivers
Deans (43)	Daily	15 minutes	Review outcome measures and performance targets, identify improvement projects	Not provided	Primary lead and team
Kaplan (25)	Daily	Not provided	Bidirectional feedback	On the work floor	Leaders and team
Karstoft (44)	Weekly	15 minutes		Extended kaizen boards	All teams in the department, members and department heads
Rutledge (39)	Daily	30 minutes	Theoretical goals	Audit board	Lean team and administrators and medical directors of the laboratory
Simon (67)	Daily	15 minutes	Identify problems and track problem solving process	Unit visual KPI management board	“team”

The daily management system (DMS) at Stanford referred to as the Stanford Operating System or SOS “makes problems and improvements a visible and active part of daily work and culture” (37). The microsystem local improvement team described by Faulkner closely resembles Krafcik’s description of Lean production teams in the automobile industry. Krafcik described formation of small local teams and

highlighted that the Lean production plants had moved away from relying on industrial engineers to standardize and improve processes and instead made that a job expectation of plant workers (4). An article describing implementation of the Daily Management System (DMS) of the Henry Ford Production System in the Lab reported on number of metrics tracked and number of improvements. They consider their DMS an accountability subsystem. This publication described the methodology used for selecting metrics for improvement and retiring metrics when targets were achieved and sustained over time, with some being monitored from 1-6 months and others monitored greater than 6 months.

Discipline

Mann lists discipline as one of the four elements of a Lean management system (28). Barnas explicitly refers to discipline when describing ThedaCare's "10 to 15 minute daily review in which unit leadership and staff focus on process improvement to identify current work-flow defects, create assignments, and establish the discipline of daily follow-through as a team." (41)

Implementation

As Ljungblom stated, "some authors observed that the term Lean management has often been misunderstood in health care organizations, and during implementation, the organization missed the cultural and structural provisions" (50). Crema explicitly points out that there is no roadmap for implementation of Lean management systems in healthcare and that this is an area in need of future research (Crema 2016).

Adopting a Lean management system requires a significant cultural shift for most healthcare organizations. Among the organizations reported on in the articles, some have favored a top down, rigid prescriptive approach while others a blended top down and bottom up approach. Aij asserts that implementing Lean requires a combination of commitment from the top along with bottom-up efforts.

((69) Zarbo describes a blending of top down standardization of design components of the huddle board

while permitting autonomy at the local level to choose meaningful metrics. (60).

While most referred to their daily management system as a subsystem of the larger management system,

Halvorson referred to it as a Lean tool used in a project.

“DMS, a Lean tool, was critical in quickly identifying and addressing problems, and regular stakeholder meetings allowed for rapid modification of the standard work and tools to ensure ongoing momentum and accountability for this project”.(62, p.619)

Model Cell

“Model cell” is a term used in Lean production to describe micro sites of Lean management system implementation.(65) The intent of a model cell is to provide proof of concept on a small scale, ideally through achievement of breakthrough improvement. These model cells then become the exemplar for other business units. Model cells within the hospital setting described in the articles include individual inpatient units (41) and individual ancillary services such as the laboratory (60) or radiology (65). Views differ on whether a model cell or system wide implementation is preferred. The majority of authors support establishing a model cell, arguing that model cell success is critical to achieving needed leadership support and that the model cell serves as the impetus for system wide implementation through spread to other parts of the organization ((55), (67)). Crema contends that the model cell approach is inadequate because it does not achieve a shared culture across the organization (45).

People development

Ballé in an article describing Lean as a “learning” management system focused on the oft-overlooked key to Toyota culture, which is people development.

“As the Toyota veterans are fond of saying, Lean is about “making people before making parts,” or in the wards’ context, developing nurses before delivering care.” (40)(14)

An area of strong agreement among the articles was that the role of leader in a Lean management system is to coach, mentor and support teams (37, 41, 57, 60, 70). Leaders and managers develop people by going

to the gemba and asking questions to help them hone their problem solving skills. Culig emphasized the importance of problem solving at the front line in creating a sense of ownership among nurses: Staff worked through problems that had occurred over the past 24 hours and captured their learning on a problem-solving sheet using the five whys. The authors reported 923 problem-solving sheets over a 2-year period (42). Zarbo reported more than 1,000 process improvements per year across 4 hospitals and 26 medical centers (60). While the amount of problem solving in an organization may be a signal of a continuous improvement culture, Simon suggests that problem solving must move from random efforts to more strategic improvements to achieve meaningful system change. (70)

A distinctive, unique article by Ljungblom studied whether healthcare organizations implementing Lean management in Sweden consider ethics. Ljungblom cites Phillipson describing the division of ethics into two approaches: a minimalistic approach and a maximalistic approach (50). The minimalist approach focuses on actions that are to be avoided. Implementations focused on efficiency only for instance are minimalistic. Again citing Philipson, Ljunblom describes maximalistic ethics as “a set of ideals/values that describe the correct way, like guiding stars, to clearly create a vision, set goals, motivate managers and co-workers, promote joy of work and increase the organization’s credibility.” (71). An example of a maximalistic approach to Lean management implementation in the United States is ThedaCare’s True North placing the patient, referred to as Lori to personalize the patient voice, at the center (51). Ljungblom concludes that ethics is not a consideration in healthcare organizations implementing Lean management in Sweden and that adopting a maximalistic approach to implementation would improve the likelihood of success. (50).

Safety

A safety theme was evident in the articles from Italy and came from one main source, the Department of Management and Engineering at Padova, Vicenza Italy. Crema and Verbano account for

all five of the articles and used the term “health Lean management” which they abbreviated to HLM.

Crema and Verbano studied the overlap and synergies of HLM with clinical risk management (CRM) and identified a need for further research on whether and how HLM can help advance safety.

Quantitative Study Designs

Among the quantitative studies, the application of a Lean management system was limited to specific departments or units (emergency department, labor and delivery, core laboratory, radiology, and select inpatient units). All five quantitative articles had weak quasi-experimental pre-post study designs and lacked randomization. Only one article had a comparison group and only one included statistical analysis (Table 2). All five reported on implementations in select pilot units or departments. None reported on an organization wide deployment.

Rutledge 2010 reported on implementation of Lean management in laboratory medicine at Seattle Children’s Hospital in Seattle, Washington. Rutledge reported a 50% reduction in lab turnaround time with a 20% volume increase over a four-month period (39). The article described tool applications such as 5S, spaghetti diagramming and line layout to achieve performance improvement, as well as management system components such as visual controls and daily huddles promoting accountability to sustain the improvements over a 4-year period. No statistical analysis was provided and there was no comparison group.

Barnas’s 2011 article reported on the implementation of ThedaCare’s Business Performance System™ at two community hospitals in Wisconsin (Appleton Medical Center and ThedaClark Medical Center) in 2008. Implementation occurred in 3 phases referred to as an alpha pilot, a beta pilot, and

cohort 3. The alpha pilot was launched in six units (obstetrics, radiology, cardiovascular, med/surg. unit, neuro/surg. and inpatient oncology) and included leader standard work in the form of daily stat sheets, daily defect review huddles, and monthly unit-leadership team meetings. Metrics for the six alpha pilot units included productivity as well as quality and safety improvement metrics (falls, Coumadin education, pain assessment, first-call bed access, turnover, staff competency, delays in access, interaction within four days of discharge, and medication errors). Increases in productivity between 2008 and 2009 were reported in the alpha pilot units ranging from one to 11% in all but the obstetrics unit, and all alpha pilot units improved on selected quality and safety metrics. Percent improvements in employee-opinion survey scores from 2008 to 2009 for the six alpha pilot units and three non-alpha pilot units were provided in graphical form, but no statistical analysis was provided. Following the launch of the alpha, beta and cohort 3 groups, improvement was also reported to have occurred from 2009 to 2010 in 36 of 54 metrics comprised of quality, safety, satisfaction, employee engagement and financial metrics (41). The amount of the improvement of those 36 metrics was not reported, there was no comparison group, and no statistical analysis provided.

Faulkner described the daily management system (DMS) at Lucille Packard Children's Hospital at Stanford as consisting of the macro-system at the executive leadership level, the mesosystem at the middle management level and the microsystem at the local unit level. The work of a local improvement team (LIT) at the microsystem level to improve the process of care for obstetric patients experiencing post-partum hemorrhage is detailed. The LIT leveraged A3 thinking with PDSA cycles, standard work, visual controls and the acronym MESS (Methods, Equipment, Supplies and Staff). The MESS acronym on the visual control board acted as a prompt for staff to identify and document on the board abnormal conditions and to anticipate potential performance issues. Because the focus of the LIT was to improve care processes for patients experiencing a rare life-threatening condition in-situ simulations were used to mimic the process. The LIT team reported dramatic reductions in process cycle times of the newly

designed process compared to baseline (from 12 minutes to 18 seconds for nurses gathering supplies and from 5 minutes to 57 seconds for MD response time) during in situ simulations (37). Performance audits were implemented for accountability to sustain the improved process.

Kane described use of the Lean management system for daily operations in the Emergency Department at Stanford from 2012 to 2013. The daily operating system is referred to as the Stanford Operating System (SOS). Kane refers to the Lean management system activities within the SOS as Active Daily Management (ADM). ADM consists of leaders going to the gemba, use of visibility walls to make performance visual and daily huddles for information sharing. Results reported from implementing ADM in the ED were a 17% reduction in median LOS, 73% decrease in door to doctor time, reduction from 2% to 0.65% in left without being seen (LWBS) and for admitted patients a 15% reduction in time from disposition to transfer(55). No comparison group and no statistical analysis were reported.

Halvorson, at Oregon Health and Sciences University in Portland, Oregon, described a daily accountability process used in Lean work to improve hand-off during patient transfers from Intensive Care Units to Acute Care Units. The daily accountability process that was implemented, which they refer to as the daily management system or DMS(62), consisted of daily audits of hand-offs, daily huddles to discuss the handoff audit performance, and visual controls through posting performance on the unit bulletin board. Compliance with the hand-off standard work was reported to be 100%. The percent of patients with hand-off completed within 120 minutes improved from 47.25 % at baseline to 64.95 % at 12 months and communication of information needed to care for the patient improved from 84.85 % to 94.9% (both statistically significant at $p < 0.05$) (62).

Karstoft reported on an implementation of Lean management in the radiology department at Odense University Hospital in Denmark. Visual management, which they refer to as “extended kaizen boards”, were used to display performance metrics and goals (44, p271),. Improvements reported

included reduction of in-room time, which resulted in reduction in waiting time and approximately 900 additional CT exams per year. No comparison group and no statistical analysis were provided.

Simon reported on implementation of a Lean management model cell to reduce wait time for the Arrhythmia Service Program at Alberta Health Services, Cardiac Sciences in Alberta, Canada. Daily huddles and “visual KPI (key performance indicator) management boards” were implemented and percent of patient wait times for urgent procedures meeting the 3-day benchmark improved to 98 % from a baseline of 46%.(67) No comparison group and no statistical analysis were provided.

Culig, describing the Toyota Production System based approach in the new Cardiac Surgery program in Forbes Regional Hospital in Monroeville, Pennsylvania referred to the implementation as operational excellence or OE. Benchmarking data were used to determine lower mortality and complication rates compared to regional rates (61% lower mortality and 57 % lower complication rate)(42). Statistical analysis was not provided.

Mixed Methods Design

Deans reported on Lean management implementation in a pediatric Neuromotor Developmental Pediatric Outpatient Clinic in Canada. The main management system component implemented was daily accountability process with huddles lasting 15 minutes during which performance on key performance indicators was reviewed and countermeasures identified. The targeted process metric of wait time for pediatric neuromotor outpatient clinic appointment for 80 % of the patients was reduced from 238 days to 192 days (43). However, no comparison group and no statistical analysis were provided.

Future research

As Schultz expressed in 2016, the literature on Lean management system implementation is sparse and more research is needed to evaluate the effectiveness of a Lean management system in healthcare (64). Crema and Verbano point out specific opportunities for future research. Case studies in particular studying the synergy of safety and Lean projects with a goal of providing guidance on implementation success factors are recommended (45). Also needed is a consensus on the definition of Lean management and Lean management system to allow comparisons. More robust study designs are needed to gain knowledge regarding the effectiveness of Lean Management System implementation to improve quality and safety of healthcare. Studies of full system Lean management implementation with a proper comparison group are also needed.

Chapter 5

Aim 2 Results

Aim 2. *Through a case study approach explore the experience of nurse managers implementing Lean Management System components in nursing units at an academic hospital.*

Background

The setting for this study is an academic hospital serving a community in east Baltimore. The hospital is one of six hospitals in a larger health system. Prior to 2015, a subset of hospital staff were exposed to Lean tools through Lean and Lean Sigma course offerings as well as through participation in kaizen events. In March 2015, the hospital's Chief Operating Officer, Vice President for Medical Affairs and Vice President for Care Management, along with peer leaders across the health system, visited ThedaCare in Appleton, Wisconsin to see application of a Lean Management System in health care. The site visit included an overview of ThedaCare's True North room by past CEO John Toussaint, MD. In addition to the tour of the True North room, the leadership team toured inpatient units to witness other components of the management system including unit huddle boards displaying key outcome metrics along with process metrics. ThedaCare unit staff were on-hand to present the unit huddle boards, provide a description of their standard work, and answer questions. The ThedaCare site visit concluded with a one hour facilitated wrap-up session among the system leadership to reflect on the visit and engage in conversation about applicability of a Lean Management System to their respective entities. Materials from the visit were available to participants for download from an on-line source and attendees were permitted to take pictures and video during the visit.

Conversations about Lean management implementation at the hospital considered that the approach would not be a pure Lean transformation. One hospital leader described Lean transformation as a singular approach to improvement likening it to "carrot soup", consisting of a single ingredient, and

suggested that the hospital “might put more carrots in our minestrone” rather than go with a pure Lean transformation. The hospital uses many approaches to improvement including Lean, six sigma, implementation science, human factors, design thinking and others, aka “minestrone” soup. This is an important distinction when adapting the approach to the needs of a particular organization such as an academic medical center. These conversations continued over the summer months. A follow-on visit to ThedaCare was arranged in August of 2015 for additional hospital leadership staff including the Vice President for Patient Care Services, Senior Director of Support Services Operations, physician leaders from the Emergency Department and the Hospitalist service, and additional Armstrong Institute for Patient Safety and Quality (AI) Lean staff members.

Following the second visit to ThedaCare the hospital’s Lean steering committee (consisting of the VP of Patient Care services, VP of Care Management, Chief of Staff, and Armstrong Institute Lean staff) had ongoing discussions on how to implement Lean daily management. These conversations included how to create a True North visual display. Leadership had expressed concern over the aesthetics, particularly with the Board meetings occurring in a conference room nearby. Initial steering committee conversations proposed various ways to make the display aesthetically pleasing and allow for concealing the display when desired.

In October of 2015, the Armstrong Institute for Patient Safety and Quality Lean Leadership Program (LLP) began, which combined didactic classroom instruction with opportunities to implement Lean tools and management system components in intervening weeks (Appendix C). Units were invited to participate in the LLP by the Chief Operating Officer and VP of Patient Services. As part of the LLP, a Lean coach assisted participants in implementing and trialing the interventions on their units. One of the deliverables at the end of the LLP was an active unit huddle board and unit huddles. The huddle board is a visual management tool in the area where the work takes place (most often a dry erase whiteboard)

designed to promote alignment of unit activities to strategic priorities of the organization as well as promote dialogue and engage front line staff in daily performance improvement. LLP participating units were educated on the purpose of visual management huddle boards and huddles and asked to design a huddle board to meet their unit's needs. The approach was an organic bottom-up approach to implementing Lean management system components at the unit level. The hospital leadership had not yet committed to implementing a full Lean Management System.

Cohort 1 of the LLP included staff from two units connected in the patient journey: the hospital Emergency Department and Medical X inpatient unit (a medicine unit that admitted patients from the ED).

The ED focused on improving their safety and efficiency metrics: left without being seen (LWBS) and time from registration to seen by a physician. Lean tools were used to conduct a mini-kaizen (a rapid improvement event) to optimize screening at triage and improve time from registration to seen by MD. This was a key tactic to reduce the percent of patients who left without being seen. The LWBS metric was posted on the huddle board daily. One of the early iterations of the huddle board was to display the KPIs in red or green font based on performance to target. Posting the numbers in red or green font allowed people to see at a glance how the unit had performed the prior day.

The Emergency Department initially located their huddle board in the back of the unit outside a break room. This location was convenient for nursing staff who convened there for change of shift. However, it was difficult for other disciplines to access the huddle board. The board was relocated to a more central location in the main treatment area to allow participation by various disciplines. After the huddle board was relocated, there was more interdisciplinary participation in the huddles. The content of the ED huddle board also evolved. Early versions of the ED huddle board displayed performance

metrics, pareto charts, improvement ideas, a pick chart for prioritization of improvement ideas, and action plan status (Figure 6).



Figure 6 - Emergency Department Huddle Board, December 2015

Medical X also launched its initial huddle board in early 2016. The huddle board was located on a wall in the nursing station at the front of the unit. Improvement efforts focused on improving efficiency of the discharge process to reduce waiting time for patients admitted through the Emergency Department as that had become an issue for the organization. As part of that effort, a color-coded key to National Emergency Department Overcrowding (NEDOC) scores was posted on the huddle board (Figure 7). The NEDOC score is a nationally accepted measure of emergency department occupancy with thresholds set to help indicate when ED overcrowding is a threat to patient safety and patient experience. Medical X requested the NEDOC score from the ED at key times throughout the day and recorded the score on the huddle board. The Med Unit X huddle script included sharing the NEDOC score with staff to communicate urgency for making inpatient beds available for patients waiting in the Emergency Department.

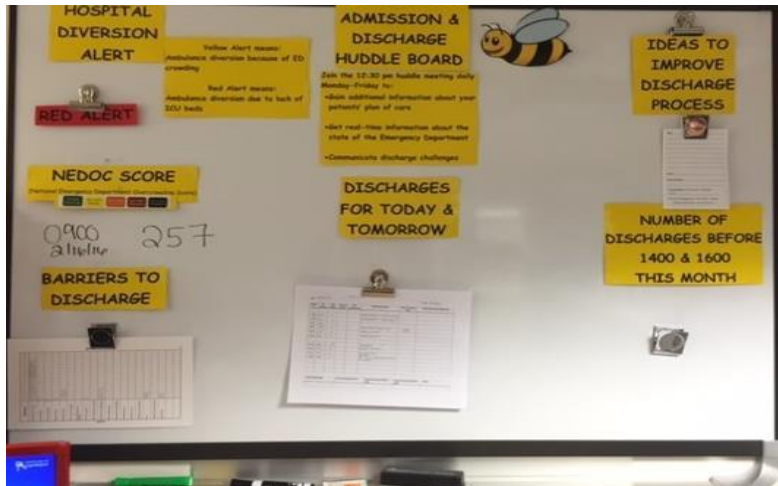


Figure7 - Medical X Huddle Board February 2016

The LLP program was offered again in April 2016. Cohort 2 included nurse managers from Medical Y and Medical Z. Many Medical Z patients transfer to a stepdown medical unit during their hospital stay and Medical Y is one such unit that is a downstream unit in the Medical Z patient journey. The Medical Y team included the nurse manager as well as leaders from environmental services. The key performance indicator (KPI) chosen for the Medical Y huddle board was room cleaning turnaround time. This KPI was critical to making beds available for Medical Z patients ready to move to a lower level of care.

Cohort 1 unit Medical X continued to iterate on their huddle board over the next 7-8 months and added quality and safety KPI's such as falls and hand hygiene performance (Fig 8).

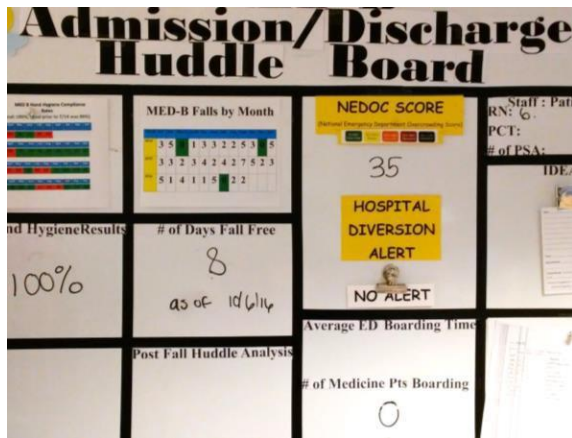


Figure 8 - Medical X Huddle Board October 2016

In October of 2016, the decision was made to convert an underutilized office just outside of the boardroom into the “True North Room”. Utilizing an office space with a door provided the option to close and lock the door when desired. An added advantage was the location of the office on the same floor with the leadership team offices. The Chief of Staff led the conversion of the room and arranged for placement of magnetic strips on one wall of the room. True North metrics were initially limited to the Patient Centered Care strategic priority (Figure 9). The key performance indicators posted included quality and safety, patient flow, and patient experience metrics.



Figure 9 - True North room Patient Centered Care Strategic Priorities - October 2016

A True North huddle was introduced and was held every Friday from 10 to 10:30 am. Standard work was created (Figure 10) and this new behavior was added as part of an existing Executive Council meeting that had begun at 10 a.m. in the nearby boardroom. Combining the True North huddle with the existing leadership Executive Council Meeting made adoption of the new habit easier and was a contributing factor to the success of adoption of the True North huddle. The Executive Council members would gather in the True North room during the TN huddle and then proceed to the boardroom following the huddle for the remainder of the Executive Council meeting.

Figure 10 - Standard work for True North Huddle

Standard Work: True North Huddle	
PURPOSE: <ul style="list-style-type: none"> • IDENTIFY EXECUTIVE LEADERSHIP PRIORITIES • ALIGN STRATEGIC AND MANAGEMENT OBJECTIVES • BUILD A CULTURE OF CONTINUOUS IMPROVEMENT 	PROCESS: TRUE NORTH HUDDLE
REVISION # AND DATE: 3, 10/28/2016	DOCUMENT OWNER: CHIEF OF STAFF

	Step	Description	Key Point / Reason	Who	Time
Pre-Huddle	1	Update metric data.	Understand current performance	Designated Staff	Prior to huddle
	2	Post new project ideas on white board.	Encourage spirit of continuous improvement	All senior leadership	
Huddle	3	Gather around huddle board.	Engage all staff	All senior leadership	Fridays, 10:00-10:30

	Step	Description	Key Point / Reason	Who	Time
	4	Review current metrics: <ol style="list-style-type: none"> 1. People 2. PFCC 3. Performance 4. Integration 5. Discovery 6. E 	Understand current performance	Designated senior leader; will rotate through all leaders	am
	5	Highlight Focus Areas for the month. Review Focus Areas 1 & 2 on white board by (these require A3's and drill down data): <ol style="list-style-type: none"> 1. Brainstorming improvements 2. Delegating responsibilities 	Encourage improvement.	All staff	
	6	Review new project/improvement ideas. <ol style="list-style-type: none"> 1. Ask, "Does this help us achieve our True North?" (pick chart) 2. Move "just do it" ideas to Work in Progress 	Prioritization of efforts.	Designated senior leader	
	7	Review parking lot items as appropriate.	Prioritization of efforts	Designated senior leader	
Post-Huddle	8	Regularly review metrics for appropriateness. Change metrics if performance	Ensure continuous improvement.	Senior leadership	Quarterly
	9	Rounds at Huddle Boards on the units: <ul style="list-style-type: none"> • Celebrate successes 	Ensure continuous improvement.	Senior leadership	Regularly

Shortly after the introduction of the True North Room, there was a desire to expand the number of strategic priorities posted in True North. The strategic priorities of Performance, People, and Integration were added (Figure 11).



Figure 11 - True North Room Metric Expansion

By December of 2017, all four walls of the True North room displayed strategic priorities of the organization (Figure 12). A dry erase board was added to capture the focus for that week.



Figure 12 - True North Room December 2017

Because there were so many metrics now displayed, additional visual management techniques were introduced such as yellow stars and bright green frames to bring attention to specific metrics. Standard work for the huddle was updated to incorporate reviewing metrics with bright green frame.



Figure 13 – True North Room with additional visual controls

The True North huddle on Friday at 10 a.m. was so well attended that the decision was made in August of 2018 to take down the outer wall and remove the door to open up the space (Figure 14). This was a major breakthrough in cultivating transparency.



Figure 14 – Wall and door removed to open the space August 2018

In November of 2016, the Emergency Department X huddle board was moved to a more central location in the patient care area of the Emergency Department X adjacent to the trauma rooms and ambulance entrance. The team mocked up a new design for the huddle board (Figure 15).



Figure 15 – Emergency Department X Huddle Board Design Mock-up November 2016

During 2016, Emergency Department X experienced turnover in the nurse manager position. The newly hired nurse manager had prior experience working in a hospital that had implemented Lean management and had experience using the A3 problem-solving tool. Later iterations included use of visual controls of red, yellow, green based on performance to target along with display of A3 improvement work on the bottom of the board (Figure 14)

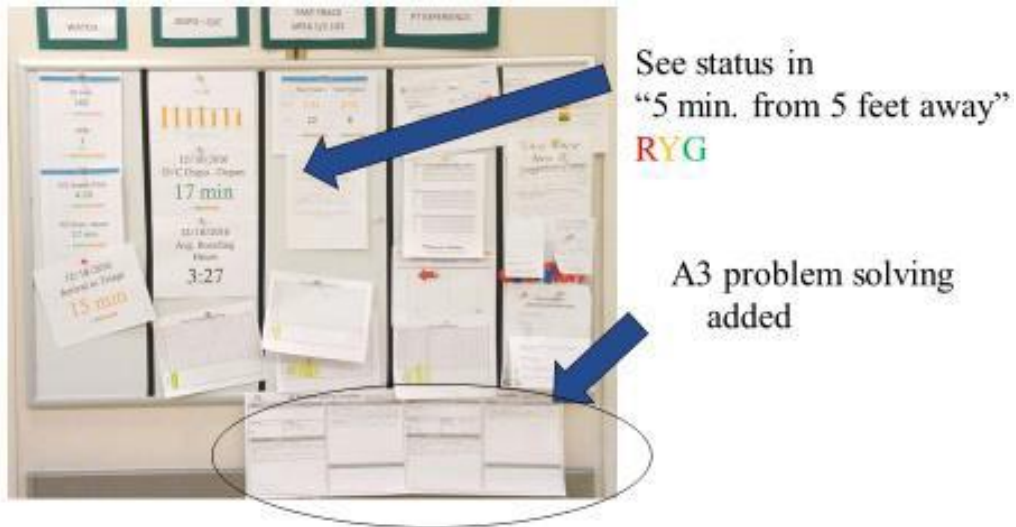


Figure 16 - Emergency Department X Huddle Board December 2016

The Emergency Department X huddle board continued to evolve and the department experienced turnover in the nurse manager position again in July 2018. By September of 2018, the design of the board had changed again (Figure 17).

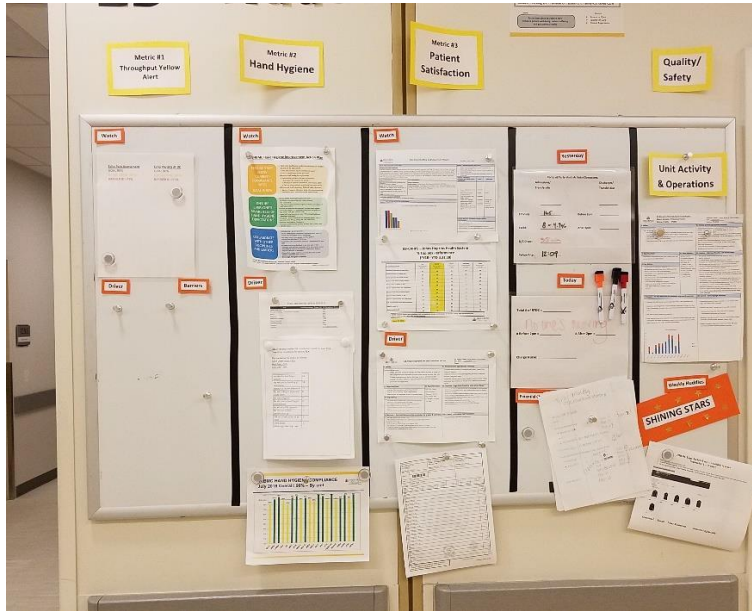


Figure 17 – Emergency Department X Huddle Board September 2018

The Medical X huddle board also continued to evolve over time using more visual means for communicating information such as red and green to indicate performance to target. In addition, a section of the board was devoted to investigating the causes of falls and problem solving (Figure 18).



Figure 18 - Medical X Huddle Board March 2017

The biggest change to any of the huddle boards was the change in the Medical X huddle board from a magnetic dry erase white board to an electronic format via an LCD mounted on a wall in July 2017. This change came at the request of Medical X unit nursing staff (51% under 35 years old) who according to the nurse manager wanted to use the technology available to “bring the unit up to the 21st century”. A large LCD display was mounted on the wall in the area where the prior huddle board had been. The nurse manager and charge nurses created a PowerPoint file displaying graphs of unit performance. The file was updated with real-time data on key performance indicators.

The second LLP cohort launched in March of 2016 included Medical Y and Medical Z. As previously mentioned, Medical Y focused their unit huddle board on improving timely bed availability by improving room cleaning turnaround time. Environmental services (EVS) staff attended the training with Medical Y staff and together they agreed to track performance to target for room cleaning turnaround time. Improving room cleaning turnaround time was chosen to improve bed availability and thereby reduce boarding time in the ED. The board displayed the NEDOC score, indicating how busy the ED was, to communicate urgency for Medical Y and EVS staff (Figure 19).

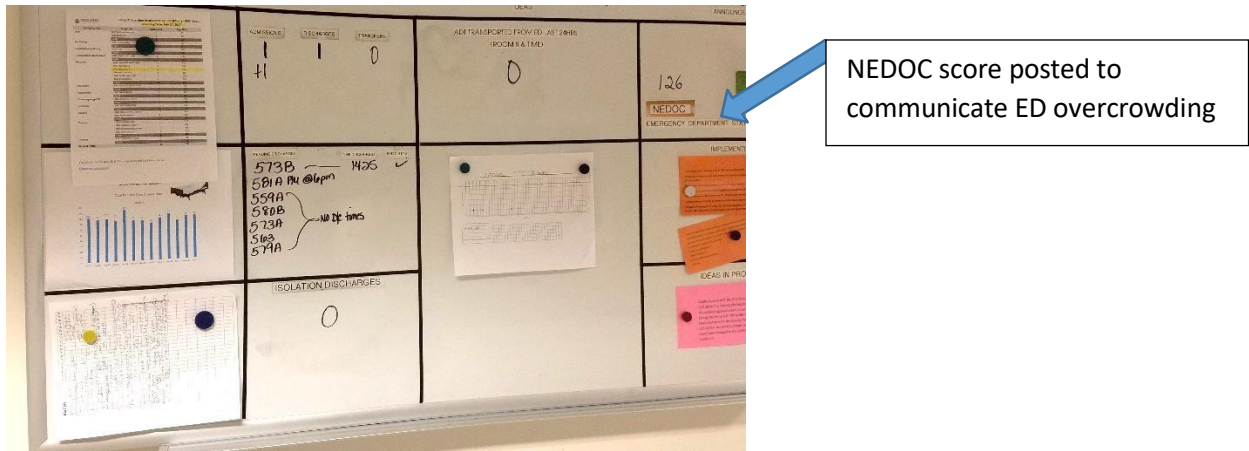


Fig 19 - Medical Y Huddle Board July 2017

Nursing and environmental services staff huddle at 3 pm daily to review efficiency of bed cleaning. Bed cleaning turnaround time performance to target is posted on the huddle board daily. Medical Y and EVS found the design and functionality of the huddle board helpful and there were little to no changes made over time (Figure 20).

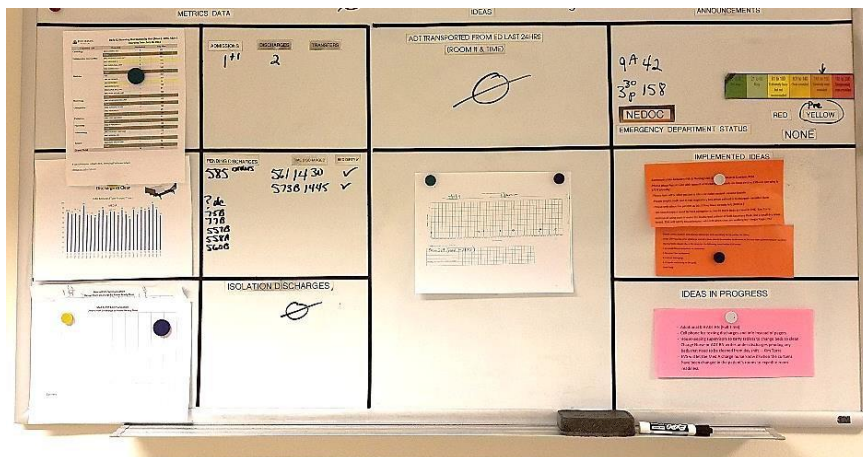


Figure 20 - Medical Y Huddle Board July 2018

Medical Z had limited wall space and had difficulty finding adequate space for the huddle board. For that reason, the Medical Z huddle board was smaller than the other huddle boards. The patient flow

metric chosen was average ED boarding time for patients admitted to the Medical Z from the ED (Figure 21).

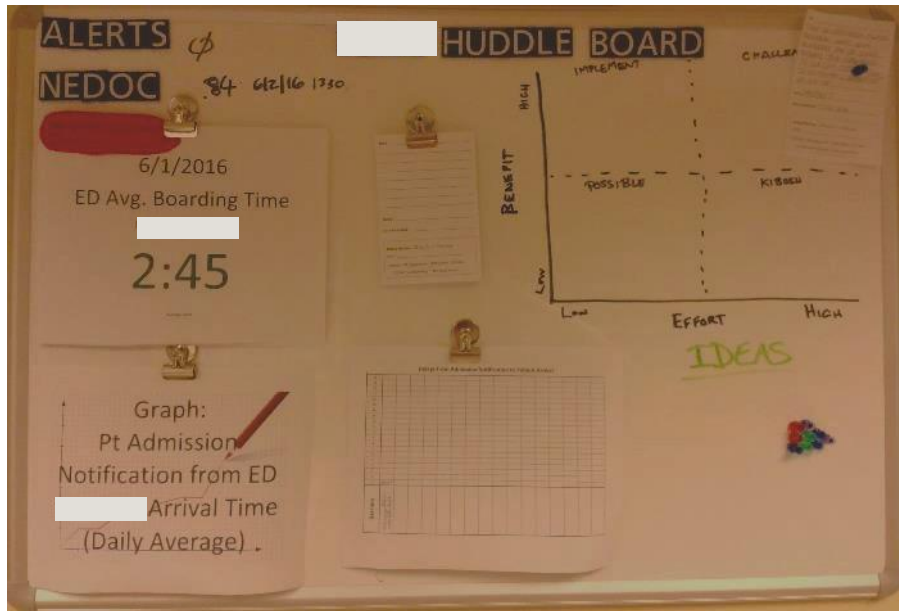


Figure 21 Medical Z Huddle Board June 2016

The Medical Z huddle board was later revised with the key performance metric changed to focus on early mobility for Medical Z patients (Figure 22).

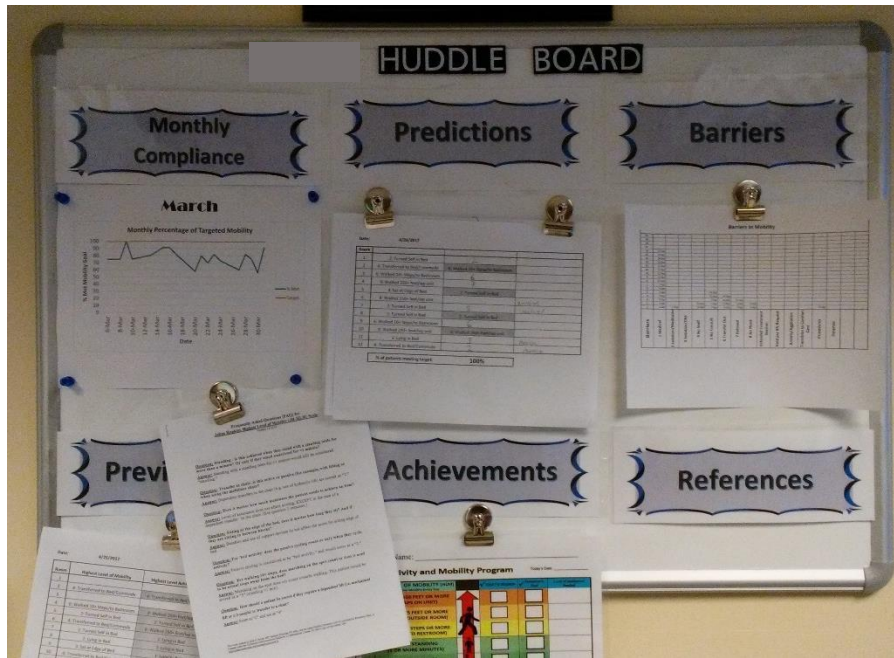


Figure 22 – Medical Z Huddle Board April 2017

LLP Cohort 3 consisted of a surgical inpatient unit and a neuroscience unit. The nurse manager for the surgery unit had worked at another health system hospital, a community hospital that had also been implementing unit huddle boards and huddles, which informed the layout of the surgery unit huddle board (Figure 23).



Figure 23 - Surgery X Huddle Board December 2017

The initial Neurosciences Y unit huddle board posted nine improvement focus areas (Figure 24).

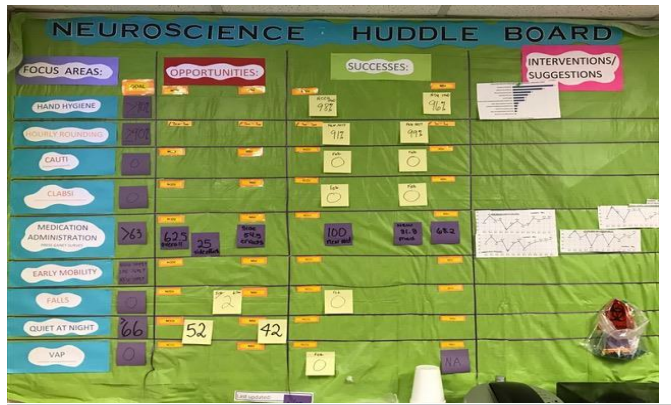


Figure 24 – Neurosciences Y Huddle Board March 2017

Later iterations reduced the number of focus metrics to four and included a horizontal row to capture barriers and improvement efforts. The lower part of the board provided a section for watch metrics – metrics that were important to monitor but were not focus metrics (Figure 25).

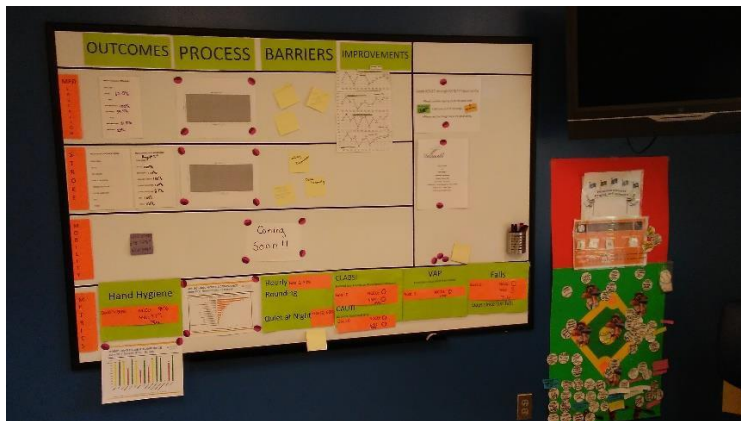


Figure 25 Neurosciences Y Huddle Board August 2017

Leadership noticed the variation in the huddle board designs while rounding on units and requested that the design of the huddle boards be standardized. A kaizen event was held in February of 2018 to engage nurse managers in creating a unit huddle board standard. The Medical X Nurse Manager participated in the kaizen; however, Medical X was exempted from standardizing their board to allow the

electronic huddle board pilot to continue. Work to implement a standard huddle board layout is underway on Medical Y as a pilot unit.

Nurse Manager Interviews

The Investigational Review Board acknowledged this study as exempt (Appendix B) from the written consent process and participation in the interviews served as consent. All of the interviews were conducted in-person on the hospital campus between July 20th and September 5th, 2018. All interviewees agreed to audio recording of their interviews and all received a copy of the interview transcript for review and editing.

Seven nursing unit management staff from hospital units implementing Lean Management System components were interviewed using the interview protocol provided in Appendix B. The hospital's Lean management system included implementation of the True North room, huddle boards, and huddles. Experience at the hospital among the interviewees ranged from 2 years to 40 years. One individual had 2 years of experience, three had 8 to 15 years, two had 16 to 25 years, and one had 40 years of experience. Three of the seven interviewed had prior experience with Lean. One nurse manager commented that Lean was required in their last two organizations. Only one reported experience with Lean daily management and huddle boards.

All interviewees were familiar with True North. When asked what True North means the interviewees had the following responses:

“The strategic initiatives that provide direction for the hospital, they are displayed in (the Executive suite) and in the Director of Nursing office.” – Nurse Manager 1

“I know what it means. It means that True North (TN) is the direction in which the institution is going and we need to be aligned to make sure we are aligned with the strategic goals of the institution.” – Nurse Manager 2

“I am aware of the True North room over in administration and in the Department of Nursing...that is what the goal of the hospital is supposed to be...but I do not know how much more they (staff) could tell you about it.” – Nurse Manager 5

“I think of the Executive Room, they’re doing a great job I was just over there last week looking at it...I like that it’s really coming from the top down, they’re doing it, we’re doing it, I like that.” - Nurse Manager 4

A consistent theme throughout the interviews was that True North provided more clarity for staff on what was important and provided an opportunity for nurse managers to share with staff how their work ties to priorities for the organization. There was variability in how much direct exposure unit staff have had to the True North room. One nurse manager had already taken charge nurses to the True North room while others planned to do so.

“I have taken all the charge nurses over to True North to educate them what we do over here matters. What your opinions and all the interventions you guys... have done.....to show them what they do here, how it feeds to the capacity management committee and how this committee effects True North...your daily work goes to this committee and how this committee feeds into True North to show the whole process. It was kind of funny, while we were all over there during a charge nurse meeting over there and (the hospital president) said “Oh you’re at True North!” It was kind of nice.” – Nurse Manager 2

“I think it’s a part of what we do now. I don’t think it’s really foreign to many people.” –Nurse Manager 6

“I am hoping to be able to take my charge nurses over and walk them through True North and really kind of show them directly how this ties up and how this is just a piece and how your piece has a direct impact. “ – Nurse Manager 3

“I have tried to explain it to the staff before but I don’t think anybody’s really been over there to see it although I have encouraged my leadership team to go see it. They have heard about the strategic initiatives and different times through the year when we talk about particularly what’s going on with that. “- Nurse Manager 5

Huddle board and huddles

When asked about the huddle board, nurse managers described a tension between fostering local ownership by engaging front line staff in the design of the board with leadership's desire to standardize huddle boards across the hospital. Information shared at the huddle must be timely and relevant in order for the staff to value this new behavior of interrupting their work to convene for a 5 to 10 minute huddle. Further, nurse managers noted tension between what staff might see as valuable and what the nurse manager viewed as valuable. Some nurse managers viewed additions to the board suggested by staff necessary to increase staff engagement. Units that were early adopters of huddle boards and huddles were given the opportunity to design their huddle board to meet unit needs and were later requested to comply to a newly created hospital standard at a time when "staff were already using their board and were happy with the layout they had." Nurse Manager 1

All of the unit huddle boards were nursing driven.

"I love the huddle board concept but again it's not multidisciplinary as it was designed to be at all. Again, it is another nursing initiative. And that is so disappointing. At some point in my career, I want to work somewhere where it is true collaboration with the provider group and nursing is not working in a silo. This is definitely nursing focused." –Nurse Manager 4

In the three units that had interdisciplinary attendance at huddles, there were issues with attendance by all disciplines.

"The level of provider engagement is waning. It's really difficult when we don't have provider presence on a daily basis. That is something I have talked to the chair about. You have to be present. You have to model the behavior and accountability. Same for our administrator, you have to be present in the unit." – Nurse Manager 2

Purpose of the huddle

Nurse managers varied in their response to the purpose of the huddle with some expressing the purpose to be very specific to improving targeted performance metrics while others expressed the purpose more

broadly to include engaging front-line staff in improving their work, communication, staff recognition and an opportunity to provide support to staff mid-way through the shift:

“Staff recognition, sharing of knowledge, engagement and giving staff support midway through the shift. My engaged people really like it, the non-engaged view it as one more thing we have to do. - Nurse Manager 4

Additionally in units where there were multiple huddles per day, some huddles were referred to as operational and some as a situational update. The operational huddle occurred at shift change and the situational update mid-shift. The exact timing of the mid-shift huddle varied based on what worked for each individual unit. Frequency of huddles varied with three of the five units huddling multiple times a day across 24 hours and the remaining two huddling once a day at a consistent time Monday through Friday only (Table 12).

Table 12 – Characteristics of huddles

Unit	Frequency of huddles	Huddle lead	Participation
Emergency Department X	Three times per day (7a, 10:45a, 7p)	Charge nurses	Interdisciplinary
Medical X	Once a day (M-F only at 12:30)	Charge nurses	Nurses and techs
Medical Y	Once a day (3p)	Nurse Manager	Interdisciplinary (Nursing, environmental services)
Medical Z	Once a day (M-F only at 2 pm)	Coordinator	Interdisciplinary (Nursing, Physical Therapy, Occupational Therapy)
Surgery X	Four times a day (7a, 1p, 7p, 1a)	Charge nurses	Nurses and techs

The three units that adopted the practice of charge nurses leading the huddles were able to implement huddles across multiple shifts. Engaging charge nurses in leading huddles across multiple shifts exposed more unit staff to the huddle board and huddles. The remaining two units had a single huddle on the day shift Monday through Friday only, and had a single individual responsible for leading the daily huddle – either the patient care manager or a dedicated coordinator resource.

When asked whether the huddles are helpful nurse managers had varying responses with some considering the huddles very helpful.

“We would be lost without the huddle, no one would know quality improvement, no one would know what metrics we are working on, and they would not have any of that information.” - Nurse Manager 7

“Oh I think they are very helpful, very helpful.” – Nurse Manager 4

“I consider it the greatest accomplishment of my leadership career.” Nurse Manager 3

One nurse manager commented that the huddles are helpful

“When it’s interactive and we discuss barriers and how to solve with 2-way communication.”
Nurse Manager 2

Another nurse manager had less favorable views stating that the huddles were

“Not helpful because we did not have things we could physically take hold of”. – Nurse Manager 5

The nurse manager explained that huddles were considered helpful when the metric of focus was one that the unit staff felt they had direct control over such as tracking actions by staff to promote early mobility for patients.

When asked what their staff would say about the huddles nurse manager responses were mixed.

“The staff like it too. I think they are proud of it.” – Nurse Manager 1

“They would say the same thing (valuable). It is that conversation. If I covered the board with a sheet, they would still want to meet and just have the discussion. It’s their way to connect with us too” - Nurse manager 3

“I don’t have time to pay attention to it. I’m just being real. At least half would say that, the other half would say it’s ok. The only time they have time to pay attention is when CMS or Joint Commission is here, and they are looking for an answer and they will say oh it’s right there. It’s a good guide. I don’t know how meaningful it translates to them when they are just trying to do their job especially days like today when it is super busy and they are just trying to get through the day. When it solves a problem or issue then it’s meaningful to them.” –Nurse Manager 2

“I kind of think they would say that is wasn’t beneficial.” Nurse Manager 5

These mixed responses from nurse managers underscores the importance of implementation approaches.

When the huddle board was focused on a metric that was important to senior leadership but not front line staff the huddle tended to be viewed as not as valuable by front line staff.

Leadership visibility

All nurse managers reported that leadership visits the unit with six of seven reporting that leadership visits monthly. Consistent across the managers was the notion that leadership spoke with staff when visiting the unit. One nurse manager commented that the leadership visits to the unit to see the huddle board and huddles helps.

“One it’s repetition for the staff, they hear over and over again what it is we are doing, how it works, why we are doing it. It also shows them it has the attention of other people, it is important to other people, so maybe we really should take some pride in the work we are doing.” - Nurse manager 3

Adoption

A common challenge expressed by the interviewees implementing huddle boards and huddles was the challenge inherent in adopting any new behavior. One nurse manager commented

“Staff engagement when you are doing something new and different, it is always a challenge getting people on board and getting them to show up and get them engaged in the process.-
Nurse Manager 6

Another described their approach to overcoming the challenge implementing the huddles:

“The biggest piece is persistence. In the beginning, I literally hunted people down. I would lock arms or hold their hand and escort them to the room. We did that for weeks.” – Nurse Manager 3

Data

Data was another challenge reported by nurse managers. Issues included relying on someone outside of the unit to update performance data and that updates to data were infrequent. Some of the KPIs required data mining and statistical analysis by administrators.

Lean Leadership Program Training

The Lean Leadership Program launched in the fall of 2015. One of the nurse managers who participated in the LLP reported initially being resentful that the learning sessions would be eight full days held on Fridays, and felt participation was not really a choice commenting:

“It felt like this is just one more thing I have to do. As it progressed I really saw it as beneficial.”
– Nurse Manager 4

Sustainability

Managers that expressed that the huddle was helpful have sustained their huddle board and huddles over a three-year period. Key to the sustainability was not relying on a single resource to update the huddle board and run the huddle. Units that engaged charge nurses from all shifts including weekends sustained their huddle boards and huddles. One unit discontinued use of the huddle board entirely, expressing constraints related to space in the unit, resource limitations due to maternity leave, and a desire to wait and see what the new standard for huddle boards would be going forward.

Standardization of the huddle board

In response to questions about standardization:

“I think it’s good because now we all know what’s important...so over my time here before I would kind of guess what I thought was important and that’s what we would put up. Now it’s clear this is important that the staff need to know about and we’re going to send you the data.” – Nurse Manager 4

Units were given freedom to create the huddle board as they wished only to later be asked to conform to a new standard design.

Use of A3 for problem solving

Only one unit posted A3s on their huddle board and the nurse manager, who had prior experience with A3s at another institution, drafted those A3’s. When asked about their experience with A3 the nurse managers expressed discomfort with the tool.

“We never had an A3 class.”- Nurse Manager 3

“Is there really a difference between A3 and SBAR? Because the nurses and techs understand it (SBAR). The A3 is a little more overwhelming for me looking at it as a front-line staff. – Nurse Manager 7

SBAR is a tool that originated in the Navy to provide clear and concise communication in an emergency and is now in use in healthcare. SBAR stands for Situation, Background, Assessment and Recommendation. When nurse managers identified a problem, the VP for Patient Care Services would request they present it in an SBAR format. Use of SBAR and A3 led to some confusion and concern that A3 was just another fad.

“We have the A3 for the No Pass Zone. Again, to me it almost seems like flavor of the year. We used to do SBARS. We still do SBARS but not at the rate we were doing them.” – Nurse Manager 4

Another theme was viewing the drafting of an A3 in some situations as excessive and non-value added.

“I think doing an A3 just because you are working on a project is redundant. But if it’s a big process or operation absolutely. Doing an A3 just to do an A3 is just work. I think some people get carried away with doing A3s. I don’t think they are necessary for every aspect of your job. I’m just going to say that. Sometimes it’s not value added. Some people will say, “Did you do an A3 for that?” No, I didn’t because I didn’t think I needed to. I like A3 when it is going to be a long project and you are going to do monitoring of the project for data, especially if it is complex.–Nurse Manager 2

In one unit a four step problem solving approach was used on the huddle board itself, a variation on Plan-Do-Study-Act relabeled as “Gap -Why -Try- Reflect”, an approach used at another health system hospital. The problem solving process is recorded on the whiteboard itself.

“I do think there is an opportunity in an A3 – I hope we stabilize and reach a point of homeostasis with A3s because we have gone overboard. I couldn’t be sucked up in creating an A3 for everything. To me that huddle board is a giant working A3 in and of itself so I have never thought to add A3’s to it.” - Nurse Manager 3

Key findings

Implementation of Lean Management System components in the inpatient units at the hospital began in advance of leadership committing to a Lean Management System. Cohort 1 and Cohort 2 were directed to focus on patient flow metrics on their huddle boards and in huddles as that was an organizational priority at the time. This created a tension between huddle board metrics that align to True North metrics for the organization and huddle board metrics that are meaningful to the managers and the front line staff.

Implementing the huddles required nurse manager persistence in reinforcing the new habits of huddling. This can be particularly challenging when introducing a concept that the nurse managers themselves have little experience with and requires nurse managers to trust in the process without personal experience.

Nurse managers all had familiarity with True North. They were able to articulate that True North is the direction the organization is going in, and what is most important to the organization. They were also able to describe how their unit metrics aligned with True North.

The Lean leadership program provided education on many Lean tools to assist improvement work including A3 problem solving (Appendix C, week 3), however nurse managers expressed a lack of experience and competence with the A3. Additionally they expressed confusion between a prior tool introduced to surface problems (SBAR) and the A3.

Chapter 6. Aim 3 Results

Aim 3 *Examine the relationship between early stage Lean management implementation and safety culture assessment.*

Research question 3

Is there an association between early stage Lean management implementation and changes in unit safety culture scores in acute care hospitals?

Despite application of Lean in healthcare over the past 15 years, little is known about the impact of Lean implementation on safety climate. Weng and colleagues demonstrated that perceptions of management mediate safety climate scores (12) however that work did not include mechanisms by which perceptions of management can be improved. This dissertation studies changes in safety survey domain scores following early stage implementation of Lean management at an academic hospital in Baltimore, MD.

Data from the hospital's safety culture assessment (SCA) survey were analyzed. The safety culture assessment consists of validated domain questions from the Safety Attitudes Questionnaire, Hospital Survey on Patient Safety (HSOPS) and the Safety Organizing Scale (SOS). Units were categorized by exposure to Lean management implementation via the Lean Leadership Program and a dummy variable was created with LLP = 0 no exposure and LLP = 1 Exposure. Safety Culture Assessment mean response rates for respondent groups are listed in Table 13 below.

Table 13 Safety Culture Assessment Response Rates

Respondent Group	Response Rate 2015	Response Rate 2017	Change 2015 - 2017
Comparison	66%	100%	0.34
Comparison	47%*	81%	0.34
Comparison	64%	73%	0.09
Comparison	80%	55%*	-0.25
Comparison	100%	100%	0.00
Comparison	54%*	80%	0.26
Comparison	50%*	73%	0.23
Comparison	81%	74%	-0.07
Comparison	64%	82%	0.18
Comparison	78%	79%	0.01
Comparison	69%	70%	0.01
Comparison	43%*	78%	0.35
Comparison	69%	88%	0.19
Intervention	46%*	60%	0.14
Comparison	67%	83%	0.16
Intervention	54%*	81%	0.27
Intervention	90%	96%	0.06
Intervention	55%*	80%	0.25
Comparison	50%*	81%	0.31
Comparison	65%	81%	0.16
Comparison	69%	78%	0.09
Comparison	100%	65%	-0.35
Comparison	80%	70%	-0.10
Total Overall	67%	79%	0.12

*Units with response rate below 60%, **Intervention units in bold font.**

Hypothesis 1

Unit exposure to the Lean leadership program is associated with greater change in mean perception of management domain scores.

Unit perception of management question scores for intervention and comparison units in 2015 and 2017 were analyzed using difference in differences with the *diff* command in Stata 15® Statistics Data Analysis software. None of the *difference in differences* p values were significant at the 0.1 level with low R square values (less than 15 % of the variation explained). (Table 14).

Table 14 -Difference in Difference results: perception of management questions

SAQ question	Diff in Diff	St. Err	[t]	P>[t]	R square
Perception of local management 1 Local management (e.g. managers/supervisors) supports my daily efforts.	0.077	0.309	0.25	0.805	0.11
Perception of local management 2 Local management (e.g. managers/supervisors) does not knowingly compromise patient safety.	0.160	0.294	0.54	0.590	0.11
Perception of local management 3 I get adequate, timely info about events that might affect my work from local management (e.g. managers/supervisors).	-0.143	0.314	0.46	0.651	0.02
Perception of senior management 1 Senior management (e.g. department leaders, chairpersons, executive leaders) supports my daily efforts.	0.046	0.329	0.14	0.888	0.07
Perceptions of senior management 2 Senior management (e.g. department leaders, chairpersons, executive leaders) does not knowingly compromise patient safety.	0.199	0.286	0.69	0.492	0.07
Perceptions of senior management 3 I get adequate, timely info about events that might affect my work from senior management (e.g. department leaders, chairpersons, executive leaders).	-0.012	0.304	0.04	0.968	0.05

Perceptions of senior management 4 The staffing levels in this work setting are sufficient to handle the number of patients.	0.201	0.606	0.33	0.742	0.12
--	-------	-------	------	-------	------

Many factors influence a unit safety culture and perceptions of management. The Comprehensive Unit-based Safety Program (CUSP) has been shown to improve perception of management safety culture scores(72). The difference in differences was run again with active CUSP as a covariate generating similar results with high p values lacking statistical significance at the 0.1 and low R square values (Table 15).

Table 15 -Difference in Difference results: Perceptions of Management questions with active CUSP covariate

SAQ question	Diff in Diff	St. Err	[t]	P>[t]	R square
Perception of local management 1 Local management (e.g. managers/supervisors) supports my daily efforts.	0.069	0.307	0.22	0.824	0.14
Perception of local management 2 Local management (e.g. managers/supervisors) does not knowingly compromise patient safety.	0.151	0.292	0.52	0.606	0.15
Perception of local management 3 I get adequate, timely info about events that might affect my work from local management (e.g. managers/supervisors).	-0.154	0.307	0.50	0.617	0.09
Perception of senior management 1 Senior management (e.g. department leaders, chairpersons, executive leaders) supports my daily efforts.	0.056	0.326	0.17	0.865	0.11
Perceptions of senior management 2 Senior management (e.g. department leaders, chairpersons, executive leaders)	0.208	0.282	0.74	0.465	0.12

does not knowingly compromise patient safety.					
Perceptions of senior management 3 I get adequate, timely info about events that might affect my work from senior management (e.g. department leaders, chairpersons, executive leaders).	-0.008	0.306	0.03	0.980	0.06
Perceptions of senior management 4 The staffing levels in this work setting are sufficient to handle the number of patients.	0.205	0.613	0.33	0.740	0.13

Specific leadership behaviors of individual nurse managers have been associated with enhanced retention(73). Available data on unit variables such as turnover rate, vacancy rate and percent of RNs under 35 years of age were tested for correlations, generating the results in Table 16 below which show a moderate positive correlation between turnover rate and vacancy rate. Turnover rate was included as a covariate and vacancy rate was dropped from further analysis.

Table 16 Correlation between variables

	% RNs under 35 y.o.	Turnover Rate	Vacancy Rate
% RNs under 35 y.o.	1.00		
Turnover Rate	-0.0943	1.00	
Vacancy Rate	-0.1027	0.3823	1.00

The diff in diff analysis was run again with active CUSP, turnover rate and percent RNs under 35 year old. R square values increased ranging from 0.14 to 0.26, however the p values remained >0.1 showing no statistical significance (Table 17).

Table 17 Difference in difference results: Perception of Management question scores with covariates of active CUSP, turnover rate, and percent RNs < 35 years old

SAQ question	Diff in Diff	St. Err	[t]	P>[t]	R square
Perception of local management 1 Local management (e.g. managers/supervisors) supports my daily efforts.	0.045	0.298	0.15	0.881	0.26
Perception of local management 2 Local management (e.g. managers/supervisors) does not knowingly compromise patient safety.	0.143	0.294	0.49	0.630	0.20
Perception of local management 3 I get adequate, timely info about events that might affect my work from local management (e.g. managers/supervisors).	-0.139	0.298	0.47	0.642	0.21
Perception of senior management 1 Senior management (e.g. department leaders, chairpersons, executive leaders) supports my daily efforts.	0.015	0.325	0.05	0.964	0.19
Perceptions of senior management 2 Senior management (e.g. department leaders, chairpersons, executive leaders) does not knowingly compromise patient safety.	0.186	0.283	0.66	0.513	0.19
Perceptions of senior management 3 I get adequate, timely info about events that might affect my work from senior management (e.g. department leaders, chairpersons, executive leaders).	-0.066	0.302	0.22	0.828	0.16
Perceptions of senior management 4 The staffing levels in this work setting are sufficient to handle the number of patients.	0.146	0.635	0.23	0.819	0.14

Table 18 - Difference in Difference results for perception of local management and perception of senior management domain average.

	Diff in Diff	St. Err	[t]	P>[t]	R square
Perception of local management domain average	0.023	0.275	0.08	0.934	0.08
Perception of senior management domain average	0.0-75	0.332	0.23	0.823	0.10

Table 19 - Difference in difference results for perception of local management and perception of senior management domain average with covariates CUSP, turnover rate and percent RNs under 35 years old

	Diff in Diff	St. Err	[t]	P>[t]	R square
Perception of local management domain average	0.08	0.261	0.03	0.976	0.25
Perception of senior management domain average	0.040	0.334	0.12	0.905	0.18

Hypothesis 2

Unit exposure to the Lean leadership program is associated with greater change in mean safety organizing scale domain scores.

Safety organizing scale domain question scores for intervention and comparison units in 2015 and 2017 were analyzed using difference in differences with the *diff* command in Stata 15® Statistics Data Analysis software. None of the *difference in differences* p values were significant at the 0.1 level, with low R square values (less than 15 % of the variation explained). (Table 17)

Table 20 - Difference in Difference results for Safety Organizing Scale questions

Safety Organizing Scale Question	Diff in Diff	St. Err	[t]	P>[t]	R square
SOS1 We have a good “map” of each other’s talents and skills	0.064	0.407	0.16	0.875	0.08
SOS2 We talk about mistakes and ways to learn from them	-0.089	0.402	0.22	0.825	0.04
SOS3 We discuss our unique skills with each other so we know who on the unit has relevant specialized skills and knowledge.	-0.075	0.449	0.17	0.869	0.11
SOS4 We discuss alternatives as to how to go about our normal work activities.	-0.118	0.411	0.29	0.775	0.08
SOS5 When giving report to an oncoming nurse, we usually discuss what to look out for	-0.145	0.330	0.44	0.662	0.03
SOS6 When attempting to resolve a problem, we take advantage of the unique skills of our colleagues	-0.306	0.394	0.78	0.442	0.06
SOS7 We spend time identifying activities we do not want to go wrong	-0.406	0.394	1.03	0.308	0.10
SOS 8 When errors happen we discuss how we could have prevented them	-0.118	0.393	0.30	0.765	0.08
SOS 9 When a patient crisis occurs we rapidly pool our collective expertise to attempt to resolve it.	-0.160	0.350	0.46	0.649	0.04

The difference in difference approach was also used to run the model with active CUSP included as a covariate, which also showed no significant differences for the safety organizing scale questions and low R square values (Table 21).

Table 21 - Difference in Difference results for Safety Organizing Scale questions with active CUSP covariate

Safety Organizing Scale Question	Diff in Diff	St. Err	[t]	P>[t]	R square
SOS1 We have a good “map” of each other’s talents and skills	0.066	0.411	0.16	0.873	0.08
SOS2 We talk about mistakes and ways to learn from them	-0.092	0.406	0.23	0.821	0.05
SOS3 We discuss our unique skills with each other so we know who on the unit has relevant specialized skills and knowledge.	-0.075	0.454	0.17	0.869	0.11
SOS4 We discuss alternatives as to how to go about our normal work activities.	-0.115	0.416	0.28	0.784	0.08
SOS5 When giving report to an oncoming nurse, we usually discuss what to look out for	-0.151	0.332	0.45	0.652	0.04
SOS6 When attempting to resolve a problem, we take advantage of the unique skills of our colleagues	-0.315	0.394	0.80	0.429	0.08
SOS7 We spend time identifying activities we do not want to go wrong	-0.408	0.398	1.03	0.311	0.11
SOS 8 When errors happen we discuss how we could have prevented them	-0.119	0.398	0.30	0.767	0.08
SOS 9 When a patient crisis occurs we rapidly pool our collective expertise to attempt to resolve it.	-0.163	0.354	0.46	0.648	0.04

Adding turnover rate and percent RNs under 35 years old increased the R square values (0.17 to 0.37), but the p values remained high >>0.1 showing no statistical significance. (Table 22)

Table 22. Difference in difference with active CUSP, turnover rate, and percent RNs < 35 years old

Safety Organizing Scale Question	Diff in Diff	St. Err	[t]	P>[t]	R square
SOS1 We have a good “map” of each other’s talents and skills	0.037	0.384	0.10	0.923	0.26
SOS2 We talk about mistakes and ways to learn from them	-0.116	0.394	0.29	0.770	0.18
SOS3 We discuss our unique skills with each other so we know who on the unit has relevant specialized skills and knowledge.	-0.052	0.401	0.13	0.898	0.36
SOS4 We discuss alternatives as to how to go about our normal work activities.	-0.178	0.386	0.46	0.647	0.28
SOS5 When giving report to an oncoming nurse, we usually discuss what to look out for	-0.226	0.322	0.70	0.487	0.17
SOS6 When attempting to resolve a problem, we take advantage of the unique skills of our colleagues	-0.344	0.370	0.93	0.359	0.25
SOS7 We spend time identifying activities we do not want to go wrong	-0.444	0.348	1.27	0.210	0.37
SOS 8 When errors happen we discuss how we could have prevented them	-0.160	0.359	0.45	0.658	0.31
SOS 9 When a patient crisis occurs we rapidly pool our collective expertise to attempt to resolve it.	-0.139	0.322	0.43	0.668	0.27

Table 23 - Difference in Difference for Safety Organizing Scale domain average scores

	Diff in Diff	St. Err	[t]	P>[t]	R square
Safety organizing scale domain average	-0.144	0.349	0.41	0.682	0.07

Table 24 - Difference in differences for mean SOS Domain average score with covariates active CUSP, turnover rate, and percent RNs under 35 years old

	Diff in Diff	St. Err	[t]	P>[t]	R square
Safety organizing scale domain average	-0.173	0.317	0.55	0.588	0.31

This study was an exploratory study not powered to detect statistical significance. Due to the early stage of Lean management implementation at the hospital and time limitations for this study, larger sample sizes were not possible. In order to answer the question whether early stage Lean management implementation has an impact on safety culture assessment perceptions of management and safety organizing scale domains, larger sample sizes are required.

Chapter 7

Discussion

Key findings

Implementation of Lean management is in the exploratory stage in health care. There is not currently one agreed upon definition of Lean management. Some refer to Lean management as managing operations that apply Lean tools with little change in management practices. Others refer to implementation of a Lean management system that includes visibility walls with True North metrics and huddle boards and huddles at the unit level. Articles on Lean Management System implementation using David Mann's taxonomy had weak pre-post quasi-experimental study designs that were insufficient to evaluate the comparative effectiveness of Lean management over traditional management approaches in improving operations.

Additionally the articles report on partial implementation in particular units or departments that have similarities to manufacturing such as the laboratory that processes and produces results of tests on blood and tissue specimens, or radiology that produces images for interpretation by radiologists, or the emergency department that has production time pressures tracking patient flow efficiency metrics. None of the articles described a hospital wide deployment thus limiting knowledge gained to partial deployment only.

Safety culture assessment responses (from perceptions of local management, perceptions of senior management and safety organizing scale domains) of hospital units exposed to Lean management components through the Lean Leadership program compared to comparison units using a Difference in Differences methodology, showed no statistically significant difference even after controlling for covariates. Difference in Differences analysis was run again comparing domain averages for perception of local management, perception of senior management and safety organizing scale domains of hospital

units exposed to Lean management components to control units. The diff in diff comparing domain averages for perception of local management, perception of senior management and safety organizing scale domains showed no statistically significant differences at the 0.1 significance level (p values > 0.5 for all three domains).

This study was exploratory and no sample size calculations were performed, introducing the possibility that the sample size was not sufficient to detect significant differences. The low response rates of less than 60% at baseline compared to 80% or better in three out of four intervention units, introduce the possibility that the baseline scores were a less representative sample for intervention units than the 2017 scores. The short implementation exposure time of ten months for LLP cohort 1 and 7 months for cohort 2 between LLP exposure and 2017 SCA administration may have been insufficient exposure time. It is also possible that the LLP is not an effective means for implementing Lean management system components at the unit level.

The case study of hospital units implementing Lean management system components following the LLP provided insight into the experience of nurse managers. The LLP was designed to engage nurse managers in identifying a key performance metric to track on the huddle board. The LLP did not require that unit huddle boards share a standard design. The bottom-up design of the huddle boards increased front-line engagement, however this also created tension when leaders began rounding on the huddle boards and desired a standard design.

The role of the nurse manager is a pivotal one in gaining front line staff buy-in and behavior change and bridging the gap between leadership and the front-line. Nurse managers described the importance of their commitment and persistence to achieving successful behavior change. According to nurse managers, the huddle board was embraced when the metrics and information displayed were important to front-line staff. If staff did not see the huddle board metric as meaningful or the information displayed

as useful the huddle was viewed as just one more thing staff was required to do, taking them away from patient care duties. This is an important aspect of Lean Management System implementation. Even in the bottom-up unit based approach busy front line nurses needed to be won-over to see this as valuable. Ongoing dialogue between the nurse manager and front line to understand what is important to them and iterating on the huddle board content helped with engagement.

While not part of the LLP, nurse managers acknowledge establishment of the True North component of the Lean management system as providing clarity on what was important to the organization. Prior to the True North room there were a plethora of improvement initiatives and prioritization of those initiatives was not clear to nurse managers. Leadership visibility was acknowledged with three of four intervention units describing the frequency of those visits as at least monthly and sometimes twice a month.

Lean management systems cannot rely on any one individual. Developing a culture that embraces standard work, visual management and an accountability process requires leadership group buy-in and importantly commitment. Sustainability of huddle boards and huddles by involving all staff across all shifts in the behavior promotes a more consistent culture across shifts.

Limitations

Aim 1--Literature review

The intent of the literature search was to cast a wide net with search terms to include all that is known about Lean management in healthcare. Currently there is no single agreed upon definition for Lean management. The selection of David Mann's definition for a Lean management system for inclusion criteria restricted the literature review to organizations implementing Lean management system components of leader standard work, visual management, accountability process and the discipline to do the former three components. The criteria for inclusion and exclusion were applied to the resulting

literature by a single investigator introducing potential researcher bias. The same single researcher reviewed articles for inclusion criteria, introducing the potential for researcher selection bias. The study was limited to peer-reviewed articles.

Aim 2

Case study interviews

Internal validity

Because the case study interviews were conducted in 2018, the study may suffer from recall bias regarding staff experiences implementing Lean management components over the prior two and a half year period.

Participant researcher bias could influence the coding of the interviews and potentially bias the responses of those interviewed. While this researcher was not directly involved in the unit level implementation, the nurse manager awareness of the role of this researcher in development and implementation of the True North portion of the Lean Management System at the hospital may have influenced their responses. While this researcher was not directly involved in teaching the LLP or coaching the patient care managers, the knowledge of this researcher's role in the health system may have influenced responses.

Aim 3--Study design

Internal validity

Quasi-experimental design with lack of randomization is a limitation. Without randomization, the groups are non-equivalent, subject to participant assignment bias and omitted variable bias.

Characteristics of the units selected for the LLP intervention such as need for improvement or likelihood of success may have influenced selection introducing selection bias. If extreme groups (high or low

performing units) were chosen to participate this may also introduce the possibility of regression to the mean.

It was not possible to blind the participants, introducing the possibility of the Hawthorne effect.

Contamination is a concern because changes in leadership behavior over time during leader rounds could affect non-intervention units as well.

The inability to blind the researcher introduces researcher bias.

History is a threat since two years elapsed between administration of the safety culture assessment, introducing the possibility of other interventions occurring between 2015 and 2017; however, use of the difference in differences approach helps address omitted variable bias.

Small sample size was a major limitation of the study. Key findings of the quantitative portion of the difference in differences analysis may be obscured by the small sample size, particularly for intervention units. This study was an exploratory case study and no sample size calculations were performed. The low p values may be due to insufficient power to detect a difference.

External validity

This study was performed at a single academic hospital located in Baltimore, Maryland and may not be generalizable to other academic hospitals or to community hospitals in Baltimore or in other regions.

Further research using larger sample sizes and studies conducted in other hospitals is needed.

The SAQ survey sample is considered to be more representative of the target population when response rates are 60% or greater. According to Pronovost and Sexton, "When response rates fall below 60%, the data represent opinions rather than culture and the results should be used with caution(74). There were eight units with SCA response rates below 60% for 2015 survey administration, and 1 unit had a response rate below 60% for 2017.

External validity

This study, conducted at a single academic medical center in Baltimore, MD, may not be generalizable to academic medical centers in other regions. Additionally the study may not be generalizable to community hospitals.

The implementation of Lean Management System components was a grass roots implementation by nurse managers and unit staff and may not be generalizable to other types of Lean Management System implementation, particularly top-down system-wide implementation.

Policy implications

There is ever increasing pressure to deliver better value at lower cost. Consumers of healthcare, both patients as well as payers, have access to a variety of performance data provided by groups such as Leapfrog and Healthgrades. This increasing transparency puts additional pressure on organizations to improve processes. Specific performance metrics tied to financial incentives create additional motivation for organizations to pursue operational excellence. Payment reform such as global budget revenue limits the ability of an organization to generate revenue and thereby refocuses attention on cost reduction as a means of generating a profit margin. Additional pressures in healthcare include cyclical shortages of healthcare professionals, in particular nurses. High turnover rates in hospitals make the adoption of standard work a logical strategy for avoiding errors and complications. Lean management provides a structure for achieving standard work and operational excellence yet better and more research is needed on the best way to implement a Lean management system to achieve operational excellence. A major gap is the paucity of strong research designs. Better research designs are needed, incorporating appropriate comparison groups with statistical analysis of study results.

The Joint Commission has recognized the importance of creating a culture of safety that encourages reporting of unsafe conditions for promoting high reliability. The Joint Commission now requires that healthcare organizations regularly assess safety culture. There is also an opportunity to better leverage Lean management system components to promote habits of high reliability. Some Lean management system implementations such as Nemours Children's Health System include a readiness huddle that promotes principles of high reliability such as sensitivity to operations and preoccupation with failure (65). Without strong evidence of the effectiveness of a Lean management system to improve patient outcomes there is no basis for a policy mandate or financial incentive for Lean Management System implementation. Stronger study designs with meaningful outcome metrics are needed to influence policy.

Implications for future research

This study of early Lean management implementation establishes a foundation for future research.

The literature review identified the need for stronger study designs when evaluating the impact of a Lean management system. As more organizations deploy Lean management systems the opportunity exists to develop an agreed upon definition of Lean management systems in healthcare and design statistically rigorous studies involving a larger sample size.

The Safety Culture Assessment includes questions that evaluate perceptions of local and senior management that are key to effective Lean management implementation. Although not originally designed to evaluate Lean management implementation, the Safety Culture Assessment questions focus on staff perceptions of both local and senior management providing a means for assessing ideal Lean leader behaviors. This study also guides future implementation strategies to target the desirable behaviors for safety organizing.

References:

1. Womack JP, Jones DT, Roos D. Machine that changed the world: Simon and Schuster; 1990.
2. Mann D. The missing link: Lean leadership. *Frontiers of health services management*. 2009;26(1):15-26.
3. Toussaint J, Adams E. Management on the mend: The healthcare executive guide to system transformation 2015.
4. Krafcik JF. Triumph of the lean production system. . *Sloan Management Review*. 1988;30(1).
5. Spear SJ. Learning to Lead at Toyota. *Harvard business review*. 2004;82(5):78-86.
6. Donaldson MS, Corrigan JM, Kohn LT. To err is human: building a safer health system: National Academies Press; 2000.
7. Moraros J, Lemstra M, Nwankwo C. Lean interventions in healthcare: do they actually work? A systematic literature review. *Int J Qual Health Care*. 2016;28(2):150-65.
8. Kristensen S, Hammer A, Bartels P, Sunol R, Groene O, Thompson CA, et al. Quality management and perceptions of teamwork and safety climate in European hospitals. *International journal for quality in health care : journal of the International Society for Quality in Health Care*. 2015;27(6):499-506.
9. Weaver SJ, Lubomksi LH, Wilson RF, Pfoh ER, Martinez KA, Dy SM. Promoting a culture of safety as a patient safety strategy: a systematic review. *Annals of Internal Medicine*. 2013;158(5 Pt 2):369-74.
10. Thomas EJ, Sexton JB, Neilands TB, Frankel A, Helmreich RL. The effect of executive walk rounds on nurse safety climate attitudes: a randomized trial of clinical units[ISRCTN85147255] [corrected]. *BMC Health Serv Res*. 2005;5(1):28.
11. Kristensen S, Christensen KB, Jaquet A, Møller Beck C, Sabroe S, Bartels P, et al. Strengthening leadership as a catalyst for enhanced patient safety culture: a repeated cross-sectional experimental study. *BMJ Open*. 2016;6(5):e010180.
12. Weng SJ, Kim SH, Wu CL. Underlying influence of perception of management leadership on patient safety climate in healthcare organizations - A mediation analysis approach. *International journal for quality in health care : journal of the International Society for Quality in Health Care*. 2016.
13. Barnas K. ThedaCare's Business Performance System: Sustaining Continuous Daily Improvement Through Hospital Management in a Lean Environment. *The Joint Commission Journal on Quality and Patient Safety*. 2011;37(9):387-AP8.
14. Villa JM. diff: Simplifying the estimation of difference-in-differences treatment effects. *Stata Journal*. 2016;16(1):52-71.
15. Toussaint JS. Healthcare improvement can't happen without better management. *Healthcare*. 2016;4(3):127-8.
16. Liker JK, Hoseus M, Center for Quality P, Organizations. *Toyota culture : the heart and soul of the Toyota way*. New York: McGraw-Hill; 2008. 562 p.
17. Weick KE, Sutcliffe KM. *Managing the unexpected: sustained performance in a complex world*: John Wiley & Sons; 2015.
18. Ohno T. *Toyota production system: beyond large-scale production*: crc Press; 1988.
19. Armstrong S, Fox E, Chapman W. To meet health care's triple aim, lean management must be applied across the value stream. *JAMA internal medicine*. 2013;173(8):692-4.
20. Mazur L, McCreery J, Rothenberg L. Facilitating Lean Learning and Behaviors in Hospitals During the Early Stages of Lean Implementation. *Engineering Management Journal*. 2012;24(1):11-22.
21. Gupta S, Sharma M, Sunder M V. Lean services: a systematic review. *International Journal of Productivity & Performance Management*. 2016;65(8):1025-56.
22. Vogus TJ, Hilligoss B. The underappreciated role of habit in highly reliable healthcare. *BMJ quality & safety*. 2016;25(3):141-6.

23. Barnas K. ThedaCare's business performance system: sustaining continuous daily improvement through hospital management in a lean environment. *Joint Commission journal on quality and patient safety*. 2011;37(9):387-99.
24. Phillips J, Hebish LJ, Mann S, Ching JM, Blackmore CC. Engaging Frontline Leaders and Staff in Real-Time Improvement. *Joint Commission journal on quality and patient safety*. 2016;42(4):170-83.
25. Kaplan GS, Patterson SH, Ching JM, Blackmore CC. Why Lean doesn't work for everyone. *BMJ quality & safety*. 2014;23(12):970-3.
26. Dennis P. *Getting the right things done: a leader's guide to planning and execution*: Lean Enterprise Institute; 2007.
27. Dennis P. *Andy & Me and the Hospital: Further Adventures on the Lean Journey*: CRC Press; 2016.
28. Mann D. *Creating a lean culture*. Volume I. 2005.
29. Frankel A, Grillo SP, Pittman M, Thomas EJ, Horowitz L, Page M, et al. Revealing and Resolving Patient Safety Defects: The Impact of Leadership WalkRounds on Frontline Caregiver Assessments of Patient Safety. *Health services research*. 2008;43(6):2050-66.
30. Sexton JB, Helmreich RL, Neilands TB, Rowan K, Vella K, Boyden J, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. *BMC health services research*. 2006;6:44.
31. Vogus TJ, Sutcliffe KM. The Safety Organizing Scale: development and validation of a behavioral measure of safety culture in hospital nursing units. *Medical care*. 2007;45(1):46-54.
32. Mazur L, McCreery J, Rothenberg L. Facilitating lean learning and behaviors in hospitals during the early stages of lean implementation. *EMJ - Engineering Management Journal*. 2012;24(1):11-22.
33. Vest JR, Gamm LD. A critical review of the research literature on Six Sigma, Lean and StuderGroup's Hardwiring Excellence in the United States: the need to demonstrate and communicate the effectiveness of transformation strategies in healthcare. *Implementation science : IS*. 2009;4:35.
34. Feldstein AC, Glasgow RE. A Practical, Robust Implementation and Sustainability Model (PRISM) for Integrating Research Findings into Practice. *The Joint Commission Journal on Quality and Patient Safety*. 2008;34(4):228-43.
35. de Koeijer RJ, Paauwe J, Huijsman R. Toward a conceptual framework for exploring multilevel relationships between Lean Management and Six Sigma, enabling HRM, strategic climate and outcomes in healthcare. *The International Journal of Human Resource Management*. 2014;25(21):2911-25.
36. Steed A. An Exploration of the Leadership Attributes and Methods Associated With Successful Lean System Deployments in Acute Care Hospitals. *Quality management in health care*. 2012;21(1):48-58.
37. Faulkner B. Applying lean management principles to the creation of a postpartum hemorrhage care bundle. *Nursing for women's health*. 2013;17(5):400-11.
38. Hung D, Martinez M, Yakir M, Gray C. Implementing a Lean Management System in Primary Care: Facilitators and Barriers From the Front Lines. *Quality management in health care*. 2015;24(3):103-8.
39. Rutledge J, Xu M, Simpson J. Application of the Toyota Production System improves core laboratory operations. *American Journal of Clinical Pathology*. 2010;133(1):24-31.
40. Ballé M, Régnier A. Lean as a learning system in a hospital ward. *Leadership in health services (Bradford, England)*. 2007;20(1):33-41.
41. Barnas K. ThedaCare's business performance system: sustaining continuous daily improvement through hospital management in a lean environment. *Joint Commission journal on quality and patient safety*. 2011;37(9):387-99.

42. Culig MH, Kunkle RF, Frndak DC, Grunden N, Maher Jr TD, Magovern Jr GJ. Improving patient care in cardiac surgery using toyota production system based methodology. *Annals of Thoracic Surgery*. 2011;91(2):394-9.
43. Deans R, Wade S. Finding a balance between "value added" and feeling valued: revising models of care. The human factor of implementing a quality improvement initiative using Lean methodology within the healthcare sector. *Healthcare quarterly (Toronto, Ont)*. 2011;14 Spec No 3:58-61.
44. Karstoft J, Tarp L. Is Lean Management implementable in a department of radiology? *Insights into imaging*. 2011;2(3):267-73.
45. Crema M, Verbano C. Future developments in health care performance management. *Journal of multidisciplinary healthcare*. 2013;6:415-21.
46. Crema M, Verbano C. Guidelines for overcoming hospital managerial challenges: a systematic literature review. *Therapeutics and clinical risk management*. 2013;9:427-41.
47. Toussaint JS, Berry LL. The promise of Lean in health care. *Mayo Clinic proceedings*. 2013;88(1):74-82.
48. Poksinska B, Swartling D, Drotz E. The daily work of Lean leaders – lessons from manufacturing and healthcare. *Total Quality Management & Business Excellence*. 2013;24(7/8):886-98.
49. Donnelly LF. Daily management systems in medicine. *Radiographics : a review publication of the Radiological Society of North America, Inc*. 2014;34(2):549-55.
50. Ljungblom M. Ethics and lean management - a paradox? *International Journal of Quality and Service Sciences*. 2014;6(2-3):191-202.
51. Mannon M. Lean Healthcare and Quality Management: The Experience of ThedaCare. *Quality Management Journal*. 2014;21(1):7-10.
52. Aij KH, Aernoudts RL, Joosten G. Manager traits and quality-of-care performance in hospitals. *Leadership in health services (Bradford, England)*. 2015;28(3):200-15.
53. Aij KH, Visse M, Widdershoven GAM. Lean leadership: An ethnographic study. *Leadership in Health Services*. 2015;28(2):119-34.
54. Crema M, Verbano C. Investigating the connections between health lean management and clinical risk management. *International journal of health care quality assurance*. 2015;28(8):791-811.
55. Kane M, Chui K, Rimicci J, Callagy P, Hereford J, Shen S, et al. Lean manufacturing improves emergency department throughput and patient satisfaction. *Journal of Nursing Administration*. 2015;45(9):429-34.
56. O'Brien L, Bassham J, Lewis M. Whiteboards and discharge traffic lights: visual management in acute care. *Aust Health Rev*. 2015;39(2):160-4.
57. Robinson ST, Kirsch JR. Lean Strategies in the Operating Room. *Anesthesiology clinics*. 2015;33(4):713-30.
58. Ulhassan W, Von Thiele Schwarz U, Westerlund H, Sandahl C, Thor J. How visual management for continuous improvement might guide and affect hospital staff: A case study. *Quality Management in Health Care*. 2015;24(4):222-8.
59. White M, Wells JS, Butterworth T. The Productive Ward: releasing Time to Care()--what we can learn from the literature for implementation. *Journal of nursing management*. 2014;22(7):914-23.
60. Zarbo RJ, Varney RC, Copeland JR, D'Angelo R, Sharma G. Daily Management System of the Henry Ford Production System: QTIPS to Focus Continuous Improvements at the Level of the Work. *American journal of clinical pathology*. 2015;144(1):122-36.
61. Crema M, Verbano C. Safety improvements from health lean management implementation: Evidences from three cases. *International Journal of Quality and Reliability Management*. 2016;33(8):1150-78.

62. Halvorson S, Wheeler B, Willis M, Watters J, Eastman J, O'Donnell R, et al. A multidisciplinary initiative to standardize intensive care to acute care transitions. *International Journal for Quality in Health Care*. 2016;28(5):615-25.
63. Roszell SS, Lynn MR. A Measure of Lean Quality Improvement for Hospital Staff Nurses. *Journal of nursing care quality*. 2016;31(4):373-9.
64. Schultz SR, Ruter RL, Tibor LC. Lean Management Systems in Radiology: Elements for Success. *Radiology management*. 2016;38(2):23-30; quiz 2.
65. Donnelly LF. Daily Readiness Huddles in Radiology-Improving Communication, Coordination, and Problem-Solving Reliability. *Curr Probl Diagn Radiol*. 2017;46(2):86-90.
66. Hihnala S, Kettunen L, Suhonen M, Tiirinki H. The Finnish healthcare services lean management. *Leadership in health services (Bradford, England)*. 2018;31(1):17-32.
67. Simon J, Houle M. Translating improvement methodology into healthcare culture. *Business Process Management Journal*. 2017;23(4):769-78.
68. Verbano C, Crema M, Nicosia F. Visual management system to improve care planning and controlling: the case of intensive care unit. *Production Planning & Control*. 2017;28(15):1212-22.
69. Kjeld Harald A, René LMCA, Gepke J. Manager traits and quality-of-care performance in hospitals. *Leadership in Health Services*. 2015;28(3):200-15.
70. Simons P, Backes H, Bergs J, Emans D, Johannesma M, Jacobs M, et al. The effects of a lean transition on process times, patients and employees. *Int J Health Care Qual Assur*. 2017;30(2):103-18.
71. Mia L. Ethics and Lean Management – a paradox? *International Journal of Quality and Service Sciences*. 2014;6(2/3):191-202.
72. Timmel J, Kent PS, Holzmueller CG, Paine L, Schulick RD, Pronovost PJ. Impact of the Comprehensive Unit-based Safety Program (CUSP) on safety culture in a surgical inpatient unit. *Jt Comm J Qual Patient Saf*. 2010;36(6):252-60.
73. Force MV. The relationship between effective nurse managers and nursing retention. *The Journal of nursing administration*. 2005;35(7-8):336-41.
74. Pronovost P, Sexton B. Assessing safety culture: guidelines and recommendations. *Quality and Safety in Health Care*. 2005;14(4):231-3.

Appendix A

Table A1 – Change in unit perceptions of local management (plm) mean scores 2015 v. 2017

	2015	2017		2015	2017		2015	2017	
Respondent Group	plm1_	plm1_	Change	plm2_	plm2_	Change	plm3_	plm3_	Change
	mean	mean		_mean	_mean		mean	mean	
LLP Exposure									
Emergency Room X	2.95	3.27	0.32	3.3	3.72	0.42	3.26	3.34	0.08
Medical Z	3.77	3.39	-0.38	3.77	3.67	-0.1	4.06	3.69	-0.37
Medical Y	3.36	4	0.64	3.63	3.69	0.06	3.94	4	0.06
Medical X	3.77	3.78	0.01	3.71	3.56	-0.15	3.95	3.8	-0.15
Comparison									
Surgery X	3	4.1	1.1	3.17	3.7	0.53	3.5	3.76	0.26
Neurosciences Y	3.64	3.69	0.05	3.79	3.76	-0.03	3.62	3.88	0.26
Maternal Child Health X	3.72	3.95	0.23	4	4.14	0.14	3.83	4.05	0.22
Psychiatry X	4.22	4.13	-0.09	4.67	4.25	-0.42	4.13	3.93	-0.2
Surgery XX	4.16	4.69	0.53	3.25	4.56	1.31	4.15	4.75	0.6
Surgery XY	3.91	3.63	-0.28	4.14	3.67	-0.47	4	3.58	-0.42
Surgery Y	4.75	3	-1.75	5	3.36	-1.64	4.75	3.45	-1.3
Chronic X	4.29	4.06	-0.23	4.21	3.71	-0.5	4.5	3.53	-0.97
Chronic Y	3.86	3.94	0.08	3.8	3.72	-0.08	3.95	3.87	-0.08
Chronic Z	3.52	3.5	-0.02	4	3.4	-0.6	3.44	3.64	0.2
Medical XZ	4	3.76	-0.24	4.44	3.97	-0.47	4.18	4.07	-0.11
Medical XX	3.81	3.85	0.04	3.74	3.62	-0.12	3.58	3.6	0.02
Medical XY	4.38	4.5	0.12	4.38	3.83	-0.55	4.5	4.71	0.21
Maternal Child Health Y	4	3.63	-0.37	4.14	4.02	-0.12	4.17	3.9	-0.27
Neurosciences X	3.16	4.09	0.93	4.35	4	-0.35	3.1	4.18	1.08
Neonatal X	3.89	3.91	0.02	4.35	4.23	-0.12	3.69	3.93	0.24
Medical XYZ	3.46	4.08	0.62	3.89	3.77	-0.12	3.57	4.12	0.55
Pediatrics X	3.27	3.67	0.4	3.6	4.08	0.48	3	3.5	0.5
Surgery Z	3.78	3.97	0.19	4.04	4.1	0.06	3.81	3.8	-0.01

	2015	2017	Δ	2015	2017	Δ	2015	2017	Δ	2015	2017	Δ
Respondent Group	psm1_mean	psm1_mean		psm2_mean	psm2_mean		psm3_mean	psm3_mean		psm4_mean	psm4_mean	
LLP Exposure												
Emergency Room	2.77	3.03	0.26	3.41	3.69	0.28	2.89	3.25	0.36	1.89	2	0.11
Medical Z	2.75	2.8	0.05	2.76	3.4	0.64	3.19	3.14	-0.05	1.88	1.94	0.06
Medical Y	3.46	3.77	0.31	3.66	3.58	-0.08	3.58	3.85	0.27	2.09	2.45	0.36
Medical X	3.3	3.43	0.13	3.57	3.35	-0.22	3.67	3.49	-0.18	1.73	1.72	-0.01
Comparison												
Surgery X	3.11	3.33	0.22	3.3	3.02	-0.28	3.19	3.38	0.19	2.03	1.92	-0.11
Neurosciences Y	3.14	3.21	0.07	3.43	3.29	-0.14	3.77	3.48	-0.29	1.5	2.38	0.88
Maternal Child Health X	3.39	2.86	-0.53	3.56	3.41	-0.15	3.38	3.24	-0.14	2.53	2.23	-0.3
Psychiatry X	3.71	4.33	0.62	4.42	4.47	0.05	3.92	4.44	0.52	4	3.81	-0.19
Surgery XX	3.83	4.44	0.61	3.31	4.07	0.76	3.85	4.38	0.53	2.14	3.44	1.3
Surgery XY	3.19	2.79	-0.4	3.79	3.35	-0.44	2.84	2.96	0.12	1.83	1.92	0.09
Surgery Y	3.86	3.18	-0.68	4	3.73	-0.27	3.71	3.45	-0.26	3.67	2.55	-1.12
Chronic X	3.81	3.47	-0.34	4.06	3.65	-0.41	3.86	3.53	-0.33	2.94	1.71	-1.23
Chronic Y	3.57	3.68	0.11	3.84	3.57	-0.27	3.84	3.53	-0.31	2.52	2.26	-0.26
Chronic Z	3.13	3.28	0.15	3.41	3.62	0.21	3.26	3.64	0.38	2.33	1.65	-0.68
Medical XZ	3.17	3.34	0.17	3.69	3.59	-0.1	3.59	3.62	0.03	3.94	3.83	-0.11
Medical XX	3.39	3.54	0.15	4	3.53	-0.47	3.55	3.59	0.04	2.69	2.18	-0.51
Medical XY	3.75	4.04	0.29	4.33	3.79	-0.54	4.38	4.28	-0.1	4.78	3.83	-0.95
Maternal Child Health Y	3.25	2.74	-0.51	3.72	3.47	-0.25	3.53	3.33	-0.2	2.51	1.79	-0.72
Neurosciences X	2.6	3.06	0.46	2.95	3.24	0.29	2.85	3.41	0.56	1.7	2.88	1.18
Neonatal X	3.37	3.48	0.11	4.17	4.14	-0.03	3.33	3.61	0.28	3.84	3.52	-0.32
Medical XYZ	3.03	3.66	0.63	3.54	3.75	0.21	3.5	3.85	0.35	2.59	3.02	0.43
Pediatrics X	2.87	3.54	0.67	3.53	3.96	0.43	2.8	3.33	0.53	2.67	2.78	0.11

Surgery Z	2.56	3.38	0.82	3.04	3.68	0.64	3.19	3.54	0.35	1.68	2.83	1.15
-----------	------	------	-------------	------	------	-------------	------	------	-------------	------	------	-------------

Table A2 – Change in unit perception of senior management (psm) mean scores 2015 v. 2017

Δ = Change

Table A3 Change in unit sos1 – sos3 mean scores 2015 – 2017

	2015	2017		2015	2017		2015	2017	
	sos1_ mean	sos1_ mean	Change	sos2_ mean	sos2_ mean	Change	sos3_ mean	sos3_ mean	Change
Respondent Group									
LLP Exposure									
Emergency Room X	4.14	3.97	-0.17	4.00	3.82	-0.18	3.39	3.38	-0.01
Medical Z	3.82	4.42	0.6	4.5	4.47	-0.03	3.53	4.11	0.58
Medical Y	4.36	4.68	0.32	4.28	4.64	0.36	4.31	4.53	0.22
Medical X	4.11	4.4	0.29	4.65	4.72	0.07	4.19	4.35	0.16
Control									
Surgery X	3.84	4.3	0.46	3.97	4.67	0.7	3.27	3.92	0.65
Neurosciences Y	4.07	4.23	0.16	4	4.07	0.07	3.71	3.64	-0.07
Maternal Child Health X	4.06	4.36	0.3	4.11	4.64	0.53	3.89	4.77	0.88
Psychiatry X	5	5.25	0.25	5.04	5.56	0.52	4.71	5.06	0.35
Surgery XX	4.36	5.56	1.2	5.43	5.5	0.07	5	5.5	0.5
Surgery XY	4	4.67	0.67	3.85	3.75	-0.1	3.75	4.38	0.63
Surgery Y	5.63	3.64	-1.99	5.38	4.09	-1.29	5.25	3.64	-1.61
Chronic X	4.06	4.24	0.18	4.82	5.53	0.71	3.81	4.94	1.13
Chronic Y	5.14	5.32	0.18	5.1	5.28	0.18	4.71	6.16	1.45
Chronic Z	3.8	3.92	0.12	4.44	4.15	-0.29	3.52	3.5	-0.02
Medical XZ	3.83	4.71	0.88	4	4.28	0.28	3.44	4.34	0.9
Medical XX	3.97	4.2	0.23	4.47	4.73	0.26	4.17	4.5	0.33
Medical XY	5.44	4.88	-0.56	4.89	4.88	-0.01	5.33	4.68	-0.65
Maternal Child Health Y	4.65	4.44	-0.21	5.27	4.74	-0.53	4.57	4.23	-0.34
Neurosciences X	4	4.29	0.29	3.63	4.15	0.52	3.74	4.32	0.58
Neonatal X	5.27	5.23	-0.04	4.67	4.93	0.26	4.43	4.84	0.41
Medical XYZ	4.65	4.46	-0.19	4.65	4.62	-0.03	4.15	4.14	-0.01
Pediatrics X	4.2	4.92	0.72	4.13	4.71	0.58	3.6	4.58	0.98
Surgery Z	4.04	4.87	0.83	4.21	4.53	0.32	3.5	4.32	0.82

Table A4 Change in unit sos4-sos6 mean scores 2015 – 2017

	2015	2017		2015	2017		2015	2017	
	sos4_ mean	sos4_ mean	Change	sos5_ mean	sos5_ mean	Change	sos6_ mean	sos6_ mean	Change
Respondent Group									
LLP Exposure									
Emergency Room X	3.71	3.5	-0.21	5.11	4.75	-0.36	4.46	4.23	-0.23
Medical Z	3.59	4.06	0.47	5.47	5.37	-0.1	4.88	5	0.12
Medical Y	4.33	4.64	0.31	5.5	5.5	0	5.25	5.13	-0.12
Medical X	4.24	4.31	0.07	5.31	5.24	-0.07	4.82	4.85	0.03
Comparison Group									
Surgery X	3.51	4.4	0.89	4.81	5.2	0.39	4.11	4.9	0.79
Neurosciences Y	3.64	3.65	0.01	5.43	5.23	-0.2	4.14	4.35	0.21
Maternal Child Health X	4.18	4.23	0.05	4.39	5.23	0.84	4.06	5.27	1.21
Psychiatry X	4.5	5.25	0.75	6.13	5.75	-0.38	4.88	5.56	0.68
Surgery XX	4.93	5.25	0.32	5.71	6	0.29	4.85	5.38	0.53
Surgery XY	3.6	3.96	0.36	5.15	5.25	0.1	4.6	4.75	0.15
Surgery Y	5.38	3.73	-1.65	6.63	4.82	-1.81	6.13	4.27	-1.86
Chronic X	4.47	5	0.53	5.71	5.71	0	4.53	5.12	0.59
Chronic Y	4.52	5.06	0.54	5.67	5.84	0.17	5.38	5.63	0.25
Chronic Z	3.8	3.69	-0.11	5.32	5.08	-0.24	4	4.15	0.15
Medical XZ	3.39	4	0.61	5.24	5.48	0.24	4.11	5.18	1.07
Medical XX	3.83	4.35	0.52	5.25	5.69	0.44	4.6	4.98	0.38
Medical XY	5.11	4.68	-0.43	5.89	5.22	-0.67	6.11	4.96	-1.15
Maternal Child Health Y	4.22	4.16	-0.06	5.83	5.42	-0.41	5.03	4.95	-0.08
Neurosciences X	3.37	4.24	0.87	5	5.5	0.5	4.42	4.91	0.49
Neonatal X	4.08	4.73	0.65	5.68	5.91	0.23	4.86	5.36	0.5
Medical XYZ	3.95	4.12	0.17	5.85	5.46	-0.39	5.13	4.96	-0.17
Pediatrics X	3.67	4.58	0.91	5.73	5.21	-0.52	4.43	4.79	0.36
Surgery Z	3.93	4.23	0.3	4.89	5.59	0.7	4.36	5.13	0.77

Table A5 Change in sos7-sos9 mean scores 2015 – 2017

	2015	2017		2015	2017		2015	2017	
	sos7_ mean	sos7_ mean	Change	sos8_ mean	sos8_ mean	Change	sos9_ mean	sos9_ mean	Change
Respondent Group									
LLP Exposure									
Emergency Room	3.92	3.89	-0.03	4.29	4.27	-0.02	5.11	5.16	0.05
Medical Z	5	4.31	-0.69	4.59	4.42	-0.17	5.06	5.36	0.3
Medical Y	4.56	5.02	0.46	4.72	5.34	0.62	5.64	5.61	-0.03
Medical X	4.73	4.76	0.03	4.91	4.89	-0.02	5.75	5.26	-0.49
Comparison Group									
Surgery X	3.81	4.66	0.85	4.39	4.94	0.55	5.03	5.38	0.35
Neurosciences Y	4.14	4.08	-0.06	4.5	4.15	-0.35	5.21	5.04	-0.17
Maternal Child Health X	3.72	4.82	1.1	4.56	5.55	0.99	5.28	5.77	0.49
Psychiatry X	5.33	5.13	-0.2	5.04	5.47	0.43	5.96	6	0.04
Surgery XX	4.54	5.81	1.27	5.21	5.87	0.66	5.64	6	0.36
Surgery XY	4.3	4.42	0.12	4.05	4.42	0.37	5.45	5.54	0.09
Surgery Y	5.25	3.82	-1.43	6	4.09	-1.91	6.88	5.1	-1.78
Chronic X	4.31	5.24	0.93	4.65	5.88	1.23	5.12	6.06	0.94
Chronic Y	4.95	5.22	0.27	5.43	5.42	-0.01	5.29	6.03	0.74
Chronic Z	3.8	4.27	0.47	4.8	4.8	0	4.68	5.08	0.4
Medical XZ	3.44	4.57	1.13	4.44	4.61	0.17	5.11	5.32	0.21
Medical XX	4.43	4.68	0.25	4.92	5.1	0.18	5.39	5.56	0.17
Medical XY	5.44	4.92	-0.52	5.33	5.13	-0.2	6.11	5.79	-0.32
Maternal Child Health Y	4.81	5.05	0.24	5.78	5.4	-0.38	6.22	5.84	-0.38
Neurosciences X	4.21	4.85	0.64	4	4.79	0.79	5.11	5.44	0.33
Neonatal X	4.65	5.25	0.6	4.78	5.2	0.42	6.08	6.21	0.13
Medical XYZ	4.7	4.92	0.22	4.68	5.06	0.38	5.85	5.27	-0.58
Pediatrics X	4.57	4.88	0.31	4.64	5.08	0.44	4.93	5.63	0.7
Surgery Z	4.14	4.68	0.54	4.36	4.77	0.41	4.93	5.43	0.5

Appendix B

Interview Guide

Case Study Interviews for Lean Management Implementation study
Describing Lean management implementation in an acute care hospital

Introduction

Thank you for your time today. My name is Laura Winner. I am a Doctoral candidate in the Department of Health Policy Management at the Johns Hopkins Bloomberg School of Public Health.

I would like to ask you about your experience with Lean daily management on your unit.

The purpose of this interview is to gain insight into the experience of hospital nurses and other staff when implementing Lean daily management. Your completion of this interview will serve as your consent to be in this research study. Before we start, I also want to ask your permission to audio-record this interview. This would allow me to go back, listen carefully to our conversation, and get all the important details to inform this study. Would that be ok with you? If not we can proceed without the audio-recording.

Turn recorder on

.

Date _____ Time _____

Interviewee # _____ Interviewee Role _____

- How long have you worked at this hospital? _____
 - How long on this unit? _____

Think about the past 3 years on the unit.

- Can you tell me about improvement initiatives that have occurred on your unit over the past 3 years? _____
- What has your experience been with Lean?

Domain: Leader standard work

- What can you tell me about huddles on your unit?
Probes:
 - a. How often do huddles occur?
 - b. When do they occur?
 - c. What is the purpose of the huddle(s)?
 - d. Who participates in the huddle?
 - e. Who leads the huddles?
- How are people prepared to lead the huddle?
- Describe what is discussed at the huddle.
- What happens when a problem or issue surfaces at the huddle
- From your perspective how helpful are the huddles?
- What do others on the unit think about the huddles?

Domain: Alignment

- How were the huddle board metrics decided?
- What does the term “True North” mean to you?
- How does the work on your unit connect (with True North)?
- How often do leaders (directors and above) visit your unit?
- Can you describe what is discussed when leaders visit your unit? With whom do they speak?

Domain: Visual management

- How do you know if the unit is performing well?
- What are some examples of visual management on your unit?
- Describe how you use your huddle board to communicate progress to staff and others

Domain: Daily Accountability

- Do you have targets for key performance indicators?
- How often is performance to target discussed and with whom?
- What happens if performance is not at target?

Domain: Problem solving

- Who is involved in improvement work on this unit?
- How does the unit identify root causes of problems?
- Are there documents you use to capture improvement work on your unit?
- Tell me about your familiarity with the A3.
- What has your experience been like using the A3?
- Who participates in the improvement work described on the A3?
- How often is the A3 reviewed and updated?
- Where is the A3 kept?

Coaching/mentoring by Lean coach

- Tell me about your interactions with your Lean coach.
- How often did you meet with your Lean coach during the Lean leadership program?
- How often was your Lean coach on your unit?
- What did you and your coach discuss?
- Any suggestions to improve mentoring/coaching along the way?

Closing

- **Is there anything else you would like to share about your experience?**

I will write up this interview and provide you an opportunity to review and suggest edits.

You will not be identified as the respondent. I will be compiling the information I receive from you and other respondents and will be happy to share that with you if you are interested.

Appendix C

Lean Leadership Program Overview

The Lean Leadership Program (LLP) is a 12-week program offered by the Armstrong Institute for Patient Safety and Quality.

The Lean Leadership Program (LLP) is a unit-based, cohort approach to create Lean capabilities and culture in strategically selected clinical areas. Rather than focus on a project as the training deliverable, the concept is to create “model line” areas that will become self-sustaining process improvement teams. The combination of training, application, and structure spread over the 12-weeks of the cohort, expect multiple process improvement interventions.

All learning sessions are scheduled on alternating Fridays and selected to minimize conflicts with the normal holidays.

Program Participants

This course is designed for health care professionals interested in or tasked with increasing efficiency in care delivery, including:

- executive leadership
- department administrators
- physicians
- mid-level providers
- nurses
- hospital and medical office administration staff
- facility and clinical engineers
- laboratory, imaging and specialized health care services staff
- clinical support staff
- pharmaceutical staff

Course Objectives

Explore and apply Lean and Six Sigma tools in health care. After taking this course, the participants will be able to:

- Apply the Lean Management concepts learned to a healthcare unit/area, its processes and its staff
- Practice sound data collection, data analysis and implementation techniques
- Organize and lead staff and an on-going culture of Lean continuous improvement

Course Agenda of Session Topics & Objectives

Participants are expected to be ready to start each class day at 9:00 am. Attendance is expected for all modules so Participants should notify the trainers if there are conflicts that will possibly prevent their presence. Detailed agendas for each day is as follows:

WEEK 1:

- Welcome and Introductions
- Lean Leadership Program Overview
- Session #1 Training
 - Introduction to Lean
 - Team Leadership
 - True North (Hoshin Kanri)
 - Process of “Change”
 - Process Mapping
 - Value Stream Mapping (VSM)
 - Lead Time, Cycle Time, TPCT
 - “Huddle Boards”
- Objectives through Homework Assignments
 - Create a VSM of your area
 - Performs observations in your area to determine: Lead time (LT), and Cycle times (CT) of each VSM step (if possible)
 - Perform a “waste walk” in your area and tabulate and summarize your findings
 - Collect data on all personnel in your area and all resource work schedules
 - Visit a “Huddle Board”

WEEK 2:

- Team Homework Report-Outs (10 minutes each)
- Session #2 Training
 - Advanced Lean Metrics (Takt Time, Dynamic Lead Time)
 - SIPOC
 - Muda, Mura, Muri
 - Aligned Unit Metrics
 - Histogram/Pareto Charts, Fishbone Diagrams, Spaghetti Diagrams, Trending
 - 7 Flows of Healthcare
- Objectives through Homework Assignments
 - Complete the SIPOC you started today.
 - Calculate Takt Time at a “peak demand time”.
 - Identify & implement one “quick hit” from your last Waste Walk.
 - Identify any “Unbalancing” and “Over-Burdening” situations in your area
 - Select a Problem/Bottleneck/Constraint and start collecting its data on a Living Histogram or Trending Bar Chart
 - Define one set of “Aligned Unit Metrics” in your area.
 - Share your progress and findings with your area staff

WEEK 3:

- Team Homework Report-Outs (10 minutes each)
- Session #3 Training
 - 5S
 - Value vs. Non-Value Added Work
 - Direct vs. Indirect Effort
 - One-Piece Flow
 - 5-Whys
 - Idea Boards
 - P-I-C-K Charts
 - A3 Problem Solving
- Objectives through Homework Assignments
 - Scope and schedule a 5S event in your area
 - Perform a “Gemba Walk” in search of “batching”
 - Using one of your constraint steps, analyze it for VA/NVA/NNVA, or Direct/In-Direct Work
 - Use one of your problems that you started “Histogramming” to perform a Brainstorming/ 5-Why session and PICK chart with some of your front line staff

WEEK 4:

- Team Homework Report-Outs (10 minutes each)
- Session #4 Training
 - Standard Work
 - Signals & Communication
 - Pull & Flex
 - Line Layout
 - Huddle Boards
- Objectives through Homework Assignments
 - Select and create a “Standard Work” in your area
 - Look for current “Kanban”s in your area
 - Implement a new “Kanban” in your area to improve a communication link
 - Design your area’s “Huddle Action Board” with Aligned Unit Metrics
 - Determine the best standard huddle time(s) with your staff and schedule a huddle board “kick-off”

WEEK 5:

- Team Homework Report-Outs (10 minutes each)
- Session #5 Training
 - Kaizens / Rapid Improvement Events (RIEs)
 - Operational Methods Sheets (OMS)
 - Mistake Proofing (Poke-Yoke)
 - Control Plans
 - Management Systems
 - Huddle Board Standard Work
- Objectives through Homework Assignments
 - Create Huddle Board Standard Work
 - Complete Huddle Board

- Develop & post How to Huddle document
- Lead Huddle Board Kick-off
- Build final report-out ppt (20 min)

FINAL PRESENTATION & GRADUATION

Appendix D

CURRICULUM VITAE

The Johns Hopkins University School of Medicine

Laura E. Winner, DrPH_(c), M.B.A., B.S.N., B.A.

DEMOGRAPHIC AND PERSONAL INFORMATION

Current Appointments

- 2011-present Johns Hopkins University School of Medicine, Armstrong Institute for Patient Safety and Quality
- 2005 – Present Joint Appointment, Johns Hopkins University School of Nursing, Baltimore, MD Joint Appointment Johns Hopkins University School of Nursing, Baltimore, MD

Personal Data

Senior Director, Lean Sigma Deployment
Armstrong Institute for Patient Safety and Quality
Johns Hopkins School of Medicine,
750 East Pratt Street, Baltimore, MD 21202
Office phone: 410-637-4378/ lwinner@jhmi.edu

Education

- 1985 Bachelor of Arts: Biology, McDaniel College (formerly Western Maryland College), Westminster, MD
- 1990 Bachelor of Science: Nursing
Johns Hopkins University, Baltimore, MD
- 2001 Master of Business Administration, Concentration: Medical Services Management, Carey Business School (formerly school of Professional Business and Education) Johns Hopkins University, Baltimore, MD
- 2018 Doctoral candidate, Doctor of Public Health, Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health
Baltimore, Maryland. Expected graduation May 2019

PROFESSIONAL EXPERIENCE

- 1990-1994 Clinical Nurse, Triage Nurse and Charge Nurse roles
Adult Emergency Department and Level I Trauma Center,
The Johns Hopkins Hospital, Baltimore, MD
- 1994-2002 Department of Medicine/Cardiology, The Johns Hopkins Hospital
Dobutamine Stress, Metabolic Stress, and Transesophageal
Echocardiography Diagnostic Laboratory Baltimore, MD
- 2002 – 2004 Quality and Innovation Coach, Center for Innovation in Quality Patient
Care, Johns Hopkins University School of Medicine, Baltimore, MD

- 2004 – 2009 Manager, Lean Sigma Deployment Leader Center for Innovation in Quality Patient Care, Johns Hopkins University School of Medicine, Baltimore, MD
- 2009 – 2011 Director, Lean Sigma Deployment, Johns Hopkins University School of Medicine, Center for Innovation in Quality Patient Care, Baltimore, MD
- 2011 – 2017 Director, Lean Sigma Deployment
Armstrong Institute for Patient Safety and Quality, Johns Hopkins University School of Medicine, Baltimore, MD 21202
- 2017- Present Senior Director, Lean Sigma Deployment, Armstrong Institute for Patient Safety and Quality, Johns Hopkins University School of Medicine, Baltimore, MD

Specialized Training

- 2000 Six Sigma Greenbelt Training
General Electric
Instructor: Gary Helton, GE Master Black Belt
- 2000 Managing Clinical Outcomes Program
The Johns Hopkins Hospital
Instructor: Marie T. Nolan, DNSc, RN
- 2003 Six Sigma Black Belt Training and Certification
Motorola University, Fort Worth, TX
Instructor: Jamie Crichton, GE Master Black Belt Instructor

2004 Lean Six Sigma Black Belt Training
 Medtronic Inc
 Instructor: Greg Johnson, Medtronic Master Black Belt Instructor

PUBLICATIONS:

PEER REVIEWED PUBLICATIONS:

1. Pronovost P, Holzmueller CG, Needham DM, Sexton JB, Miller M, Berenholtz S, Wu AW, Perl TM, Davis R, Baker D, **Winner L**, Morlock L. How will we know patients are safer? An organization-wide approach to measuring and improving safety. Crit Care Med. 2006 Jul;34(7):1988-95.
2. McKee C, Berkowitz I, Cosgrove SE, Bradley K, Beers C, Perl TM, **Winner L**, Pronovost PJ, Miller MR. Reduction of catheter-associated bloodstream infections in pediatric patients: experimentation and reality. Pediatr Crit Care Med. 2008 Jan;9(1):40-6.
3. Aboumater HJ, **Winner LE**, Davis RO, Trovitch PB, Berg MM, Violette KM, Messersmith WA, Maylor KK, Lehmann CU. No time to waste: decreasing patient wait times for chemotherapy administration using automated prioritization in an oncology pharmacy system. Am J Manag Care. 2008 May;14(5):309-16.

4. Aboumatar HJ, **Winner L**, Davis R, Peterson A, Hill R, Frank S, Almuete V, Leung TV, Trovitch P, Farmer D. Applying Lean Sigma solutions to mistake-proof the chemotherapy preparation process. *Jt Comm J Qual Patient Saf.* 2010 Feb;36(2):79-86.
5. Martinez EA, Chavez-Valdez R, Holt NF, Grogan KL, Khalifeh KW, Slater T, **Winner LE**, Moyer J, Lehmann CU. Successful implementation of a perioperative glycemic control protocol in cardiac surgery: barrier analysis and intervention using Lean six sigma. *Anesthesiol Res Pract.* 2011;2011:565069. doi: 10.1155/2011/565069. Epub 2011 Sep 6.
6. Pronovost PJ, Demski R, Callender T, **Winner L**, Miller MR, Austin JM, Berenholtz SM; National Leadership Core Measures Work Groups. Demonstrating high reliability on accountability measures at the Johns Hopkins Hospital. *Jt Comm J Qual Patient Saf.* 2013 Dec;39(12):531-44.
7. Pronovost PJ, Armstrong CM, Demski R, Callender T, **Winner L**, Miller MR, Austin JM, Berenholtz SM, Yang T, Peterson RR, Reitz JA, Bennett RG, Broccolino VA, Davis RO, Gagnolati BA, Green GE, Rothman PB. Creating a high-reliability health care system: improving performance on core processes of care at Johns Hopkins Medicine. *Acad Med.* 2015 Feb;90(2):165-72.
8. Gould LJ, Wachter PA, Aboumatar H, Blanding RJ, Brotman DJ, Bullard J, Gilmore MM, Golden SH, Howell E, Ishii L, Lee KH, Paul MG, Rotello LC, Satin AJ, Wick EC, **Winner L**, Zenilman ME, Pronovost PJ. Clinical Communities at Johns Hopkins Medicine: An Emerging Approach to Quality Improvement. *Jt Comm J Qual Patient*

Saf. 2015 Sep;41(9):387-95.

9. Pronovost PJ, Holzmueller CG, Molello NE, Paine L, **Winner L**, Marsteller JA, Berenholtz SM, Aboumatar HJ, Demski R, Armstrong CM; Armstrong Institute for Patient Safety and Quality Team. The Armstrong Institute: An Academic Institute for Patient Safety and Quality Improvement, Research, Training, and Practice. *Acad Med.* 2015 Oct;90(10):1331-9.

10. Pronovost PJ, Holzmueller CG, Callender T, Demski R, **Winner L**, Day R, Austin JM, Berenholtz SM, Miller MR. Sustaining Reliability on Accountability Measures at The Johns Hopkins Hospital. *Jt Comm J Qual Patient Saf.* 2016 Feb;42(2):51-60.

11. Johnson AE, **Winner L**, Simmons T, Eid SM, Hody R, Sampedro A, Augustine S, Sylvester C, Parakh K. Using Innovative Methodologies From Technology and Manufacturing Companies to Reduce Heart Failure Readmissions. *Am J Med Qual.* 2016 May;31(3):272-8. doi: 10.1177/1062860614562627. Epub 2014 Dec 15.

12. **Winner LE**, Burroughs TJ, Cady-Reh JA, Hill R, Hody RE, Powers RL, Callender T, Demski R, Pronovost PJ. Use of Cascading A3s to Drive Systemwide Improvement. *Jt Comm J Qual Patient Saf.* 2017 Aug;43(8):422-428.

Book Chapters

1. Winner, L. and Hill, R. (2016). How to Select and Scope a Project. In Levi (Levan) Atanelov(ED.), *Resident's Handbook of Medical Quality and Safety*. Switzerland: Springer International Publishing.

Innovation

SPECIAL PROJECTS

Spring 2002
operations

Dobutamine Stress Testing moved from IRB research into clinical

Adult Exercise Stress Testing Supervised by a Registered Nurse Protocol

Collaborated on innovative protocol to allow registered nurses to supervise exercise stress tests

Spring 2002

Cardiovascular Diagnostic Lab (CVDL) Nursing Chart Audit Endoscopy Unit Nursing Chart Audit

Created tool for data collection using the palm pilot to review charting practices of nurses in the prep, procedure and recovery areas of the CVDL and Endoscopy units, allowing synchronization of data to an Access database and exporting of data collected to SPSS for statistical analysis

2007

Creation and launch of Lean Sigma Prescription for Healthcare training program for healthcare

Other Publications:

Media Releases or Interviews

March 2008 Schmidt, Elaine. (2008, March 12). 5 Tips for Applying Six Sigma from ThreeTopHospitals.*iSixSigma.com*. Retrieved April 29, 2008, from <http://healthcare.isixsigma.com/library/content/c080312b.asp>

June 2011 **State of the Art:** Hospitals Engage Technology to Improve Hand Hygiene, Part 1 of 2 The Joint Commission Perspectives on Patient Safety June 2011, Volume 11, Issue 6.

July 2011 **State of the Art:** Hospitals Engage Technology to Improve Hand Hygiene, Part 2 of 2 The Joint Commission Perspectives on Patient Safety July 2011, Volume 11, Issue 7.

Other Media

Introduction to Lean Sigma Video, Armstrong Institute Website

https://www.hopkinsmedicine.org/armstrong_institute/training_services/workshops/lean_sigma_training/index.html

INTRAMURAL Funding

Previous

2001 Fellow in Outcomes Management
Department of Nursing, The Johns Hopkins Hospital

Certifications

1990 - Present Registered Nurse, Maryland State Board of Nursing

1993

Certified Emergency Nurses

EDUCATIONAL ACTIVITIES

Educational Focus: *Applying robust process improvement methodologies such as Lean and Six Sigma to address errors and inefficiencies in healthcare, to eliminate preventable harm, and improve patient outcomes.*

Classroom instruction

IHMI/Regional

- 2004 – 2010 Guest lecturer, Six Sigma Methodology, Helene Fuld Leadership Program for the Advancement of Patient Safety and Quality, The Johns Hopkins University School of Nursing, Baltimore, MD
- 2007 - ongoing Faculty, Lean Sigma Prescription for Healthcaresm course
- 2010 Faculty, “Achieving Competence Today” (ACT) program, Educating Learners in the Pursuit of Quality - a Robert Wood Johnson Foundation national program for medical residents and nursing students, teaching practice based learning, systems based learning and quality improvement based practice, The Johns Hopkins Hospital, Baltimore, Maryland
- January 2011 Guest lecturer: Masters in Health Administration Program
Johns Hopkins Bloomberg School of Public Health,
Lean Sigma One-Day Workshop
- August 2016 Quality and Safety in Clinical Settings, “Applying the Lean A3 Thinking Approach”, Institute for Excellence in Education Summer Teaching Camp

Sept 29, 2016 LEAD course, All Children's Hospital, St. Petersburg, Florida

February 2017 Guest lecturer: TIME Patient Safety course, *Healthcare Quality Assessment and Improvement: Lean Six Sigma in Healthcare*, winter intersession,
Johns Hopkins University Medical School

January 2018 Guest lecturer: TIME Patient Safety course, *Healthcare Quality Assessment and Improvement: Lean Six Sigma in Healthcare*, winter intersession,
Johns Hopkins University Medical School

Clinical instruction

2001 - 2003 Advanced Cardiac Life Support (ACLS) Instructor and
Cardiopulmonary Resuscitation (CPR) Instructor, Johns Hopkins
Hospital

Workshops /seminars

JHMI/Regional

December, 2009 "Conducting Safe and Effective Kaizen Events in a Clinical Setting"
Center for Innovation in Quality Patient Care Webinar, Baltimore, MD

Mentoring

Pre-doctoral Advisees /Mentees

2009 - 2018 Fuld Scholarship Fellow, Johns Hopkins University School of Nursing
 Andrew Horton
 Marlon Benjamin – Evaluation of Radio Frequency Identification as a means for measuring hand hygiene compliance
 Nisha Williams - Improving the Quality of Post-Partum Discharge Instructions
 Mary Vess - Identifying and reducing nuisance alarms in the Pediatric Emergency Department, The Johns Hopkins Hospital
 External to Johns Hopkins University mentee: Dr. David Chand from Akron Children’s hospital, “Observational study using the tools of Lean Six Sigma to improve the efficiency of the resident rounding process” *Journal of Graduate Medical Education*. June 2011 issue

Educational Program Building / Leadership

2007 – present Faculty, Curriculum Design - Lean Sigma Prescription for Healthcare™
 Lean and Lean Sigma courses designed specifically for healthcare professionals.

2010 IDEO Human Centered Design, one-week immersion training at IDEO headquarters, Palo Alto, California

Fall 2017 Lecturer, Coursera Massive Open On-line Course Patient Safety Specialization, “Planning a Patient Safety or Quality Improvement Project”, Johns Hopkins University School of Medicine

Fall 2018 Guest lecturer, Quality Improvement Tools On-line Course, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Trademarks/Serviceemarks

Lean Sigma “Prescription for Healthcare”sm, awarded July 2008

Other peer review activities

2015 Reviewed submission for Joint Commission Journal of Patient Safety and Quality Journal

Professional Networks

2008 – Present Catalysis Healthcare Value Network

2008 - Present Joint Commission Center for Transforming Healthcare

2018 – Present Press Ganey Performance Improvement Advisory Group

RECOGNITION

Awards, Honors

1985 Beta Beta Beta Biology Honor Society

1990 Sigma Theta Tau Nursing Honor Society

OTHER PROFESSIONAL ACCOMPLISHMENTS

POSTER PRESENTATIONS

- March 2006 Association of Operating Room Nurses 53rd Congress
“Got Instruments? Applying Lean Sigma Techniques to Improve Instrument Availability” And “Promoting a Culture of Safety in the Neurosurgical Operating Room Utilizing the CUSP Framework”, Washington, DC
- May, 2007 34th Society for Gastroenterology Nurses and Associates
Charting the Lean Sigma Course towards Efficiency, Baltimore, MD
- April 2011 Association of Peri-Operative Registered Nurses Congress 2011
Poster Surgical Specimen Labeling Defect Reduction, Philadelphia, PA

Invited talks

Regional

- Dec 2004 Implementing a Vision of Quality in Healthcare Delivery
Six Sigma Lecture
Windham Hotel, Baltimore, Md
- May 2004 The Future is Here: Managing Change in Clinical Care
Seminar for International Health Leaders
Johns Hopkins Medical Campus, Baltimore, Md
- Sept 2010 “Applying Lean Sigma to Hand Hygiene”

Delmarva Webinar

- Jan 2011 "Error Proofing", Johns Hopkins Medicine Patient Safety Invitational Course, Baltimore, MD
- Dec 2011 Grand Rounds, Lean Sigma, St. Joseph's Hospital
Baltimore, MD
- May 2014 "Focus on A3 Problem Solving and Health System Level A3"
Maryland Association for Healthcare Quality
Anne Arundel Medical Center

National

- Sept 2002 Cardiology Services Innovations: A Partnered Approach to Reducing Costs for Patients Admitted with Chest Pain, presented at ACI, San Francisco, CA
- March 2007 The 5th Annual Conference on Successfully Implementing Six Sigma in Healthcare, Johns Hopkins Lean Sigma Journey: Applying Lean and Six Sigma in a Variety of Clinical Settings
Las Vegas, NV
- May, 2007 American Heart Association Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke Conference
"How to use Business Approaches and Methods to Improve Quality and Safety" Washington, DC

July 2007	<p>University of Maryland School of Nursing</p> <p>17th Annual Summer Institute in Nursing Informatics</p> <p>Lean Kaizen: A Tool for Redesigning Work Flow – The Hopkins Experience, Baltimore, MD</p>
August 2007	<p>Deploying the Toyota Production System</p> <p>& Lean Healthcare in Hospitals “Lean Kaizen: Sparking a Culture of Continuous Improvement through Rapid Results”, San Diego, CA</p>
October 2007	<p>The World Congress Leadership Summit on Driving Process and Performance Excellence, “Applying Six Sigma, Lean and Baldrige Methodologies to Healthcare” Chicago, Illinois</p>
November 2007	<p>MCIC Vermont, Inc</p> <p>“Methods and Tools to Improve Patient Safety and Quality”</p> <p>New York, New York</p>
September 2008	<p>International Quality and Productivity Centre’s Fourth Annual Voice of the Customer Lean Six Sigma Improvement Week, speaker Track C, Chicago Illinois</p>
September 2009	<p>“Excellence in Hand Hygiene: Applying Lean Sigma to Hand Hygiene” The Joint Commission Annual Conference on Quality and Patient Safety, Explore, Enhance, and Energize: Leadership for the Future, Rosemont, Illinois</p>
December 2009	<p>“Using Lean Sigma to Improve Quality and Efficiency in Healthcare”</p>

Webinar, Johns Hopkins Center for Innovation in Quality Patient Care, Johns Hopkins School of Medicine, Baltimore, MD.

January 2011 “Error Proofing”, Workshop for Aintree University Hospitals NHS Foundation Trust Quality Safety Champions, Baltimore, MD

June 2011 “Error Proofing”, Second Annual Patient Safety Summit Johns Hopkins University School of Medicine, Baltimore, MD

January 2014 Panel Speaker, Hand-off Communication, Patient Safety, Science & Technology Summit, Patient Safety Movement
Laguna Niguel, CA

September 2014 Panel member, Continuous Process Improvement Forum, panel discussion covering key issues relevant to H.R. 5064, hosted by National Academy of Public Administration on Capital Hill, Washington, D.C.

May 2018 Moderator Track , Lean Business Transformation and Operational Excellence in Healthcare World Summit, New Orleans, Louisiana.

International

October 2004 Lean Sigma in Healthcare lecture Expo Calidad,
Mexico City, Mexico

October 2007 Johns Hopkins Medicine International “Leading Quality and Safety” Training, Delivered to key staff for the Secretary of Health
Campeche, Mexico

- November 2007 Healthcare Operations Management
 Implementing World-Class Healthcare Operations to Deliver
 Optimal Patient Care: Utilizing Lean Management Techniques to
 Boost Healthcare Productivity
 Singapore
- October 2009 Lean Sigma Overview, "Health Care Executive Leadership"
 Johns Hopkins International Partners Forum, Santiago, Chile

TEACHING AND MENTORING

- 2007 - Present Faculty Lean Sigma "Prescription for Healthcare"SM Program
 Armstrong Institute for Patient Safety and Quality
 The Johns Hopkins University, Baltimore, MD
- Feb 2014 Guest Lecturer "Organizational Characteristics and Outcomes:
 Translating Evidence into Practice"; Introduction to Healthcare Quality
 and Patient Safety – A Management Perspective. Department of Health
 Policy and Management, Johns Hopkins University Bloomberg School of
 Public Health, Baltimore, MD
- 2015-18 Guest Lecturer "Lean Sigma", Medical resident education TIME
 course in Patient Safety and Quality, winter intersessions, Johns
 Hopkins University Medical School
- 2018 Lecturer, Coursera Massive Online Open Course (MOOC)
 Course 3, Planning a Patient Safety or Quality Improvement
 Project, Patient Safety Specialization,

- Fall 2018 Instructor; Quality Improvement Tools on-line course,
Johns Hopkins Bloomberg School of Public Health
- Nov 2018 Guest lecturer; “Early-stage Lean Management System
Implementation”, Armstrong Institute at Johns Hopkins Bayview
Medical Center, Johns Hopkins Bayview Medical Center Campus

JHMI Committee Participation

- 2000-2002 Performance Improvement Committee – Medical Nursing
- 2002 – 2011 Center for Innovation in Quality Patient Care Steering Committee
- 2011 – Present The Johns Hopkins Medicine Patient Safety and Quality Council
- 2014 –Present Johns Hopkins Bayview Medical Center Lean Steering Committee
- Johns Hopkins Bayview Medical Center Patient Safety Committee
- The Johns Hopkins Hospital Pro-active Risk Assessment Group
- Senior Executive Champion, Pediatric Emergency Department
- Comprehensive Unit-based Safety Program, The Johns Hopkins Hospital

Consultancies

- September 2018 High Reliability Assessor, Hospital Moinhos De Vento, Porto Alegre,
Brazil.