Improving Lean Healthcare Effectiveness

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Abstract

To meet the quadruple aim, healthcare organizations must make improvements in quality and efficiency. Many have adopted Lean management principles as an improvement structure to successfully implement and sustain best practices. However, literature shows outcomes of Lean in healthcare are mixed. The purpose of this project is to improve the effectiveness of Lean as an improvement structure through the identification of perceived success factors that contributed to positive outcomes. An implementation framework, Promoting Action on Research Implementation in Health Services (PARiHS), aligns with current literature on Lean success factors. Therefore, the model's key constructs of evidence, context, and facilitation were used to guide inquiry and analysis. A mixed-methods study approach was used to gather qualitative and quantitative data on three Lean-based handover related projects. Key stakeholders for each project were included as the sample. Semi-structured interviews were conducted and content analysis was used to determine how well stakeholders identified constructs from the PARiHS framework. A survey was developed and six experts determined content validity of the instrument prior to survey administration. Data analysis included a Hierarchical Regression test with perceived project success as the outcome variable and evidence, context and facilitation as independent variables. Analysis showed a R Square Change of 0.64 ($p = 0.02$) meaning 64% of change in perceived project success is due to the combination of independent variables. Context was the only variable that made a significant unique contribution (t-value = 2.32; $p = 0.04$). Project findings suggest that context played a critical role in the perceived success of these three projects. Recommendations include additional use of the measurement tool in a wide range of settings to further determine validity and reliability.

Keywords: PARiHS framework, Lean management, Lean principles, success factors

Introduction to the Health System Problem

Problem Description

The right to access affordable and effective healthcare services is an ethical and foundational component of a healthy community. Yet, basic, cost effective healthcare remains out of reach for many United States (US) citizens. The need for healthcare delivery redesign in the US is critical as costs continue to increase beyond affordability without associated improved patient outcomes (Moraros, Lemstra & Nwankwo, 2016). In an effort to meet the Quadruple Aim, healthcare organizations internationally are adopting Lean management principles as a means to facilitate a continuous improvement culture, a reduction in waste within the health system and an overall increase of value to patients.

The ongoing outcome and cost challenges seen within healthcare is requiring healthcare systems to take a different process improvement approach than what has been done historically. Since the 1970's, healthcare across the globe has engaged in a multitude of management practice strategies to curtail healthcare spending and waste of precious resources; ultimately leading to no measurable impact in metrics (Radnor, Holweg, & Waring, 2012). With evidence supporting the need for a new direction, the Institute for Healthcare Improvement (IHI) published a white paper in 2005 on Lean management which stated rigorous implementation of Lean management practices in healthcare systems can lead to improved efficiency, decreased waste and value delivered to patients (IHI, 2005). However, despite the past four decades of organizational efforts including implementation of Lean management, healthcare reform continues to be laden with a host of challenges such as complexity of our care systems, contradictory expectations amongst political, regulatory and professional entities, and deeply rooted organizational cultures

resistant to change; all of which leading to skepticism amongst healthcare workers that Lean management is the silver bullet to meet the Quadruple Aim.

Current trends in the literature regarding Lean healthcare effectiveness does not reflect a clear picture of success. Individual studies implementing Lean management principles report improved metrics, but upon further systematic evaluation the study designs lack rigorous application of scientific method and statistical analysis (Andersen & Røvik, 2015; Moraros, Lemstra & Nwankwo, 2016). The absence of scientifically derived statistical evidence conflicting with organizational reports of Lean success has led to more questions than answers for healthcare systems when it comes to understanding if Lean can be successfully translated into healthcare contexts.

Extant literature also maintains a focus on success factors that have impact on the translation and success of Lean management in healthcare. Health systems can assist their learning and success through understanding their critical success factors, therefore leading to the most effective translation of Lean in their environment. Through this appreciative approach, continuous learning occurs and positive outcomes are observed more frequently.

Oregon Health & Science University (OHSU) has been on their Lean journey for approximately seven years, using Lean management principles to facilitate a continuous improvement culture. Similar to the literature, OHSU implementation and sustainability of practice and process changes are not always successful; some initiatives showing positive outcomes and sustainability, while others reflecting no improvement. Failed change efforts have led to variation in practice, waste of resources, lack of improved outcomes, and broken trust within the healthcare community on Lean's effectiveness. Evaluation and analysis of Lean translation within OHSU may determine success factors contributing to successful initiatives.

Population Affected

The effectiveness of Lean principles within OHSU reaches far beyond those directly involved in a process improvement initiative. In fact, it touches all employees and clients who benefit from all three OHSU missions; teaching, healing and discovery. Those directly involved with this project only serve the healing mission, specifically the hospital inpatient setting; however, the results of this improvement project can feasible impact the whole organization.

Project Purpose

The purpose of this scholarly project is to improve the effectiveness of Lean as an improvement structure through the identification of perceived success factors that contributed to positive outcomes in prior Lean-based improvement projects. Knowledge gained through this project can then be incorporated in future initiatives to improve project outcomes.

Literature Review

Search Strategy

A literature search was conducted on the topic of success factors of Lean effectiveness in healthcare using the PubMed Central database located on the US National Library of Medicine, National Institutes of Health website and the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Academic Search Elite and Health Source databases through the OHSU online library system. The literature search used key affiliation words and MeSH terms; “Lean healthcare”, “Lean methodology”, “Lean management”, “Lean Six Sigma”, and “implementation science”, excluding all non-English articles and articles published prior to 2006. All key terms were combined using AND with the search term “success factors” to help further narrow the literature search and decrease large catchments of articles.

The literature search conducted returned 510 articles for review where the titles and abstracts were reviewed to assess relevance to healthcare and the main topic of Lean effectiveness. Of those initially reviewed, 37 were accessed via full-text or inter-library loan for further evaluation. Additionally, citation review of relevant articles added an additional five articles retrieved via on-line library resource. A review of three relevant articles from the IHI website were retrieved and evaluated as supportive content on the topic of interest.

Impact of Lean Healthcare Outcomes in the Literature

Contradictory to manufacturing, and as evidenced by the available literature, outcomes of Lean management implementation are less impressive in the healthcare sector. "On the surface, Lean thinking seems to be an approach that generates positive results. Yet, its application in healthcare has been controversial and its effectiveness questioned" (Moraros, Lemstra, & Nwankwo, pg 151, 2016). Available outcome literature demonstrates that studies continue to lack scientific methods and statistical analysis necessary to support validity of an author's results. Absence of scientifically derived evidence has led to biased report of results and conclusions of Lean's impact on healthcare systems; which typically is reported as favorable. Despite the growing literature on Lean management in healthcare systems, healthcare leaders are still left with no compelling outcome evidence to back implementation of Lean management. However, the IHI continues to recommend that organizations adopt Lean as a means to facilitate a continuous improvement culture necessitating a need to focus on facilitators that support Lean implementation and outcomes.

Success Factors of Lean Healthcare

Although Lean management in healthcare has had mixed outcomes, identifying and understanding the success factors of Lean implementation can provide benefit and future success

to healthcare systems. The implementation alone of "Lean tools" without consideration of how to integrate the necessary Lean principles related to organizational culture and behaviors will lead to an implementation gap and unsustainable change (van Rossum, Aij, Simons, van der Eng, & ten Have, 2016). Taking an appreciative approach to identify what leads to Lean management initiative successes will lay a foundation for organizations to build upon for their future Lean work. For ease of review and based on the systematic review by Andersen, Røvik and Ingebrigtsen (2014), success factors have been organized into four domains: context, content, application, outcome. Success factors that were identified most frequently in the literature are mentioned here.

Context success factors. Context success factors are those facilitators that are directly related to the organization, situation and the environment in which implementation occurs of the Lean intervention (Andersen, & Røvik, 2015). Support and buy in of Lean management principles from leadership at all levels of the organization was one of the most common success factors cited amongst multiple articles. When an organizations leadership is fully engaged with Lean management principles they remove barriers to needed resources, support the implementation teams, and facilitate the necessary communication for success of the initiative (Abdallah, 2014; Andersen, Røvik, & Ingebrigtsen, 2014; Andersen, & Røvik, 2015; D'Andreamatteo, Ianni, Lega, & Sargiacomo, 2015; Stelson, Hille, Eseonu, & Doolen, 2017). Inculcation of Lean management within the leadership behaviors, where they fully live and breathe the principles, will build an environment fertile to grow a continuous improvement culture. Additional context facilitators include organizations who learn from their experiences (D'Andreamatteo et al., 2015) and have a vision that includes continual improvement (Andersen, & Røvik, 2015).

Content success factors. Content success factors are those facilitators that directly relate to the characteristics, development and decision making surrounding the identified problem and Lean interventions (Andersen, & Røvik, 2015). One of the key facilitators highlighted in the literature was the need to adapt or develop interventions that are appropriate for the intended environment (Andersen, Røvik, & Ingebrigtsen, 2014). Differences in the diverse environments will interact with the interventions differently, therefore needs to be considered during intervention development. Additionally, maintaining a patient centered focus throughout intervention development has been shown to facilitate successful outcomes (Andersen, Røvik, & Ingebrigtsen, 2014). Lastly, adequate training in Lean principles along with the associated tools that will be used during the intervention has been shown to be a facilitator of success (Abdallah, 2014; Andersen, Røvik, & Ingebrigtsen, 2014; Andersen, & Røvik, 2015). Without adequate training, interventions developed may not meet the needs of the problem to be solved or may focus only on the Lean tools versus building the engagement necessary for an intervention to be successful.

Application success factors. Application success factors are those facilitators that directly relate to how an intervention is implemented into the organizational or local environment (Andersen, & Røvik, 2015). The development of a cross-functional team consisting of members who may be impacted by the intervention has shown to be a strong facilitator of successful implementation in the literature (Abdallah, 2014; Andersen, Røvik, & Ingebrigtsen, 2014; Andersen, & Røvik, 2015; Stelson et al., 2017). Diversity of perspectives from those impacted by the change can help to identify pitfalls early in the process, allowing for a well-developed implementation plan. Additionally, the cross-functional team can help to influence, engage and create “buy in” with their colleagues which is critical for any successful change

initiative (Andersen, & Røvik, 2015; Stelson et al., 2017). Interestingly, internal consultants deemed experts in Lean have shown to help facilitate successful implementations of Lean initiatives, especially those who have a clinical background such as nurses (Abdallah, 2014; Andersen, & Røvik, 2015). This strengthens the evidence for organizations to build strong training programs, as noted earlier, to help build capacity within their organizations to have clinical staff lead implementation projects as internal consultants.

Outcome success factors. Outcome success factors are those facilitators that directly relate to the results of the intervention, including the sustainability phase (Andersen, & Røvik, 2015). Based on the literature, fewer success factors have been identified in this domain as compared to the other domains reviewed already. The main outcome success factor identified in the research is the need to build an organizational culture that supports and embraces long term continuous improvement as a part of their everyday work (Andersen, Røvik, & Ingebrigtsen, 2014; Andersen, & Røvik, 2015; D'Andreamatteo et al., 2015). Unless there is an underlying culture supporting continuous improvement, sustaining change while embarking on new initiatives will be at risk. For organizations who are still building the capacity of continuous improvement, one strategy identified by Andersen and Røvik's (2015) research demonstrated that focusing on quick wins and smaller projects can facilitate success in outcomes and sustainability.

Summary of success factors. The main identified success factors of Lean management do not differ widely from identified facilitators for change management. The literature identifies three main facilitators of change management: "commitment and participation of health care staff in the improvement process", "focus on developing people before developing organizations", and "support from all managers at all levels" (Poksinska, p. 325, 2010).

Leadership engagement from the executive team to the bedside practitioners is a critical context success factor necessary to build a supportive culture of Lean management. Additionally, providing a strong training program for staff at the bedside is a key content success factor that builds individual skills, thinking and associated responsibility to take on initiatives at the local level. Lastly, empowering staff as the experts to improve their work is a main application success factor, whereas actively engaging them in the process leads to success versus dictating their participation in a top-down initiative. Interestingly, these change management facilitators cover three of the four domains identified in the literature.

Literature Gaps and Limitations

Due to the strong interest in using Lean management in healthcare as a means for continuous improvement, Lean's body of literature is growing rapidly. However, despite such growth, gaps continue to exist, especially around outcome and process metrics. Based on the evidence evaluated, the majority of research is absent of rigorous scientific methodology and statistical analysis, leading to results that should be interpreted cautiously. Additionally, success factors associated with Lean project success were prominently found in the literature, however, with little focus on the potential barriers. At first glance, one may interpret this as an unconscientious effort for researchers to shed a favorable light on Lean management, but it is more likely a symptom of how difficult it is to actually scientifically study the complexity and socio-technical factors of Lean implementation in healthcare. Further research is recommended using strong scientific methodologies to create a solid foundation of evidence to truly evaluate if Lean healthcare is effective or not.

Relate the literature to the Organizational Problem

Literature shows Lean principles have been extremely effective in improving process and outcome metrics in manufacturing through engagement of leadership and staff and building a continuous improvement environment; however, Lean methodology as an improvement structure in the healthcare setting, including OHSU, has not been as fruitful. Lean effectiveness in healthcare is impacted by a host of factors; all of which must be assessed as to their impact on success. Lack of consistent success of OHSU's Lean-based projects leads to the belief that certain factors and their presence or absence may be having an impact on project outcomes. As supported by the evidence, success factors can positively impact outcomes of Lean and these success factors should be amplified and deemed critical for success.

Summary of Project

This project evaluated and analyzed three OHSU Lean-based projects associated to handoff and transitions of care to identify factors of success. The specific projects are: Intensive Care Unit to Acute Care Unit Handover Process, Emergency Department to Acute Care Handover Process and Post Anesthesia Care Unit to Acute Care Handover Process. Through the identification of OHSU success factors, followed by the integration of the success factors into future improvement projects, OHSU can then improve the effectiveness of Lean as an improvement structure.

Approaches to the Conduct of the Project

Setting

Project setting. Oregon Health & Science University is an academic medical center that provides quaternary care across the state of Oregon and southern Washington. The organization is on the seventh year of their Lean journey which was facilitated by a Lean consulting group for

the first two years. The Lean projects selected for review have been completed in the healthcare mission of the organization and focused on transitions of care from one setting to another.

Organizational readiness. Given the variation in outcome success and engagement in the differing OHSU Lean-based projects, there has been an appetite to better understand the "why", especially in the quality management department and those responsible for process improvement. Given recent changes in two members of the executive leadership team, one of which the director of quality reports too, there is considerable risk the current framework for process improvement, Lean principles, will be scrutinized. As described in the evidence, Lean healthcare is met frequently with skepticism, and that is particularly palpable now at OHSU.

Anticipated barriers or facilitators. As already described, there is a strong interest in better understanding what facilitates a successful Lean-based project so I anticipate support from the quality department. I anticipate two barriers. One, determination of clear, objective criteria for the identification of a successful project may prove difficult and will likely be a combination of outcome metrics and perceptions of those who were a part of the project. Not all projects had clear measurable goals that were not subjective in nature. Second, once Internal Review Board determination is complete, I anticipate barriers in interviewing and surveying multiple, diverse team members for each project due to project participant's availability or change in employment.

Participants

Inclusion and exclusion criteria. All interdisciplinary professionals and support team members who participated in the development or implementation of the improvement project would be considered for inclusion. However, individuals would be excluded if they were not employed by OHSU at the time of project development or implementation. Roles who could

participate would include providers, nursing, transportation staff and unit clerks. A project will be excluded if data cannot be collected from a diverse group of greater than two members.

Size and rationale. Three projects will be reviewed so there can be evaluation of trends in Lean success factors. Additionally, a minimum of one member will need to be interviewed for a project to be included so the perspective of each project is represented.

Recruitment process. Solicitation of all project participants will occur using a standardized email that will include project purpose, means of data collection, and an ethical conduct statement. Sponsors, process owners, stakeholders and process improvement consultants will qualify for invitation to participate in the interview portion of the project. All identified stakeholders will have the opportunity to participate in the survey. Internal Review Board application was submitted during the month of November, 2017 and was considered exempt by the board.

Protection of participants. All results of the project did not include names or roles. Specific projects were identified along with associated success factors at a construct level.

Actual Implementation and Outcome Evaluation

Implementation

Implementation of the project occurred after IRB determination and started with solicitation of project members to participate in a qualitative semi-structured interview. Semi-structured interviews occurred in March of 2018 with five of the six stakeholders invited to participate. The quantitative survey was sent to 31 participants in early May of 2018 and 18 (58%) responded.

Measures and data collection sources, process, procedures

Measures and Data collection. A mixed-methods design was used to carry out this improvement project. Seventeen qualitative semi-structured questions were administered and recorded via in-person interview. Interview length varied from 37 to 51 minutes. The purpose of the interviews were to solicit a stakeholder's perceptions on project outcomes, success factors and barriers regarding the Lean-based project in which they participated. Additionally, a quantitative survey was developed and was informed by the PARiHS framework constructs, evidence, context and facilitation. The survey included a total of 26 questions and used a five point likert scale. The survey included seven questions per construct, three outcome questions, one demographic question, and a question to identify the handover project the survey respondent participated in. Content validity of the instrument was determined by six experts. As illustrated in Appendix A, Table A2., each survey question was rated in three areas: clarity, comprehension and content. A rating of five meant it fully met the criteria and a one would be the lowest score. Feedback was requested for any score of three or less. Edits were made based on feedback received and the final survey was administered via an online survey tool.

Analysis methods. Semi-structured interviews were conducted and directed content analysis was performed using developed codes based on the PARiHS framework. After analysis, counting of codes in each construct helped to determine how often the stakeholders perceived aspects of the PARiHS framework and if it was mentioned as a success factor or barrier. After survey administration, the qualitative data was analyzed using the Statistical Package for the Social Sciences (SPSS) to see if certain factors contributed differently to project success. During these analyses, perceived project success was considered the dependent variable and evidence, context and facilitation were the independent variables. Data analysis included two tests, an

Analysis of Variance (ANOVA) and Hierarchical Regression. The ANOVA test was performed to explore if there were differences within the groups means. The Hierarchical Regression was performed to test if one or more of the independent variables have a relationship with the dependent variable, meaning do any of the PARiHS constructs impact the project outcome.

Desired outcomes. Strong recommendations to the organization that is supported by data as to the success factors that can influence the successful launch, completion and sustainability of a Lean-based project. A recommendation could take the form of a checklist inclusive of necessary success factors as a part of project implementation, enhanced training opportunities for clinical staff, greater development of internal clinical consultants, or increased engagement of leadership.

Use of information systems and technology. Survey monkey was used for administration of the quantitative survey, Outlook email was used to invite participants to take part in a survey or interview, Microsoft excel was used as a way to organize data and export data into SPSS, and SPSS was used for analysis of data.

Ethical Considerations. I did not anticipate nor encounter any ethical concerns at this point. A concern starting the project was around the risk for a low number of participants leading to minimal data; however this risk was included in the recruitment email proactively.

Implementation of Project

Evolution of Project

After the project proposal submission and IRB waiver, the implementation of the improvement project stalled. Though the literature on Lean success factors could be interpreted into four content areas, the literature did not lay a foundation to further guide inquiry and

analysis. In essence, there were no standardized tools or a designed path to follow. Upon assessment, the project needed an established framework to further direct implementation.

After a thorough evaluation process, inclusive of cross mapping Lean success factors found in the literature to established implementation models, the decision was made to adopt the PARiHS framework to lead inquiry and analysis (See Appendix A, Table A1). As noted in its title, the PARiHS framework is used in the health services adding further support to its use in guiding the projects exploration. The PARiHS framework is made up of three constructs: evidence, context and facilitation. These constructs were then used to guide the development of the projects measurement tools, the semi-structured interview questions and likert-scale survey. Adoption of this framework was a crucial turning point in the project finally moving forward.

Unintended consequences

A mixed-methods study can be extremely resource intensive and that was not fully appreciated at the time of project design. The benefit of a mixed-methods approach is to allow for the richness of the qualitative data collected on a sparse topic such as Lean success factors to then inform a larger quantitative data collection. The original project design had the qualitative data informing the creation of qualitative survey questions; however, due to the extensive time it took to complete the qualitative data analysis this plan was revised. Time to complete interviews, transcription of those interviews and subsequent content analysis spanned over multiple months and ended in only three of five interviews being analyzed.

At the time of project implementation, the lack of a standardized quantitative measurement tool was also not fully appreciated. Though the adoption of the PARiHS framework was critical to the project, the framework did not bring with it a standardized tool. Creation of a measurement tool requires a validation process to ensure it measures what the tool

was intended to measure adding additional steps and time to the project that was unbudgeted. Though this delayed administration of the survey, this unintended consequence was determined to be positive surprise. Not only was the exercise of going through a content validity exercise educational, the measurement tool can now be further tested in other studies.

Data and Key Findings

Directed content analysis of three interviews showed that the PARiHS framework constructs were mentioned frequently. The constructs of context and facilitation were coded most often, 32 and 36 times respectively. Codes were included if the individual perceived the presence or the absence of a specific code. The evidence construct was coded less frequently, 16 times, and all comments coded were stating the presence of the specific item, not the absence of it. No new codes were developed outside of the 3 PARiHS constructs.

The quantitative survey administered had a 58% (n=18) response rate. Twenty-four of the 26 questions made up the four subscales that were analyzed: evidence, context, facilitation, and outcome. Analysis included basic descriptive statistics which can be found in Table 1.

Table 1. ***Descriptive Statistics***

	Mean	Std. Deviation	N
Outcome Subscale Mean	2.96	1.10	18
Context Subscale Mean	3.62	.64	18
Facilitation Subscale Mean	3.60	.53	18
Evidence Subscale Mean	3.47	.56	18

The analysis of variance showed that three of four measures (evidence, context, outcome) showed significant differences between variables, 0.02, 0.05, and 0.00 respectively (Table 2). A Hierarchical Regression analysis was conducted with perceived project success as the outcome variable and evidence, context and facilitation as independent variables. This analysis revealed a

R Square Change of 0.64 (p=0.02) meaning 64% of the change in perceived project success is due to the combination of independent variables (Table 3). The only variable that made a significant unique contribution is the context variable (t value =2.32; p =0.04) (Table 4). Project findings suggest that context played a critical role in the perceived success of these three projects.

Table 2. ***Analysis of Variance***

		Sum of Squares	df	Mean Square	F	Sig.
Evidence Subscale Mean	Between Groups	2.33	2	1.17	5.66	.02
	Within Groups	3.09	15	.21		
	Total	5.42	17			
Context Subscale Mean	Between Groups	2.24	2	1.12	3.58	.05
	Within Groups	4.70	15	.31		
	Total	6.94	17			
Facilitation Subscale Mean	Between Groups	1.40	2	.70	3.10	.08
	Within Groups	3.39	15	.23		
	Total	4.79	17			
Outcome Subscale Mean	Between Groups	12.57	2	6.28	11.66	.00
	Within Groups	8.08	15	.54		
	Total	20.64	17			

Table 3. ***Hierarchical Regression Model Summary***

					Change Statistics				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change
1	.801[a]	.642	.565	.72637	.642	8.375	3	14	.002

a. Predictors: (Constant), Facilitation Subscale Mean, Evidence Subscale Mean, Context Subscale Mean

Table 4. ***Hierarchical Coefficients***[a]

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
1	(Constant)	-1.99	1.23		-1.63	.13
	Evidence Subscale Mean	.24	.61	.12	.39	.70
	Context Subscale Mean	1.35	.58	.78	2.32	.04
	Facilitation Subscale Mean	-.21	.67	-.10	-.31	.76

a. Dependent Variable: Outcome Subscale Mean

Outcomes

Comparison of findings to the literature

As evidenced by this projects findings, contextual factors play a significant role in the outcome of a Lean-based improvement. This finding aligns with already established literature supporting that context factors are relevant to Lean implementation and translation. Lean management principles are translated by the healthcare system through the interpretation of the local environment producing contextually unique versions of Lean and leading to different outcomes (Andersen & Røvik, 2015; Ulhassan et al., 2013). In a study to identify critical success factors of Lean implementation, Andersen & Røvik (2015) showed that two thirds of the facilitators were local and derived by the hospital system context. Similarly, the findings in this improvement project revealed that 64% of the change in perceived project success is due to a combination of independent variables, with only the context variables having a significant contribution. Findings of this nature support the need to consider contextual factors within an organization and the departments of the organization when implementing Lean as an improvement structure.

Differences between expected and observed results

Given the current literature and lived personal experience, a directional hypothesis was established; the strength of context and facilitation factors in Lean-based improvements positively impacts the project's success. Based on the project findings, context was the only factor that was a significant contributor. Interestingly, facilitation was the only subscale that did not show a significant difference in the means between the different projects which may have impacted overall outcomes. Continued testing of the measurement tool would be beneficial to confirm these initial findings and allow for broader application.

Impact on the system

Knowing the importance that contextual factors positively impact Lean-based improvement project outcomes provides an opportunity for the organization to improve Lean healthcare effectiveness. If this new knowledge is strategically implemented project outcomes could drastically improve. In addition, improvement of Lean-based project outcomes could positively impact attitudes around Lean in healthcare creating additional buy in from stakeholders and organizational leaders. This secondary benefit could strengthen the organizational context leading to further Lean-based project success. The key to success will be in ensuring that context is incorporated up front in every project and considered a hard stop to project implementation until appropriately addressed.

From a broader perspective of healthcare, the identification of success factors to Lean effectiveness could have an enormous impact on healthcare delivery. The right to access affordable and effective healthcare services is an ethical and foundational component of a healthy community. Yet, basic, cost effective healthcare remains out of reach for many United States (US) citizens. Identification and implementation of critical success factors can positively

impact efficiency, cost and quality of care in healthcare systems that desperately need improvement.

Practice Related Implications/Recommendations/Limitations

Lean principles have been adopted in healthcare organizations globally and has been supported by respected organizations such as the IHI. As the improvement structure of choice by many organizations, it is critical that there is stronger evidence and recommendations to guide Lean implementation. This project was a step in improving the evidence available to support improvement of Lean healthcare effectiveness and has shown the importance of addressing contextual factors in Lean-based improvement projects.

This improvement study had a number of limitations that may have impacted the study's results. The measurement tool used to capture quantitative data was newly developed and had minimal validity testing. Another limitation was the age of the projects evaluated in this study. One project was implemented over five years ago so there was risk for recall bias potentially impacting ones perceptions and responses to the administered survey. Recommendations would include further testing of the tool on a broader range of Lean-based projects, old and new, to further determine validity and reliability.

Conclusion

In the absence of strong outcome evidence in the literature supporting Lean as the solution for healthcare reform, researchers are focusing on success factors which may impact and influence the effectiveness of Lean management in healthcare systems. As defined in the evidence reviewed, the majority of success factors identified relate to the cultural and contextual components within an organization. This is where Lean implementation strategies are typically lacking.

Evaluation of three different OHSU Lean-based initiatives around handoff and transitions of care revealed that context factors are critical to the success of Lean-based projects within the organization. Through this project, OHSU is now better informed and could strategically implement Lean-based projects in the future based on identified success factors. This strategic approach would lead to increased success of Lean management practices and would facilitate a continuous improvement culture, a reduction in waste within the value stream and an overall increase of value to patients.

Summary and Next Steps

Lean healthcare effectiveness will be critical in supporting organizations in meeting the quadruple aim. Continued research on factors of success for Lean-based projects will further add evidence to guide organizations in implementation. Results of this study will allow OHSU to start the conversation on strategies to improve their Lean healthcare effectiveness through attention to context. However, the study should not end here. Next steps should include additional quantitative data collection in a broader array of projects and departments. Further data collection will only confirm current results and strengthen the importance to attending to the contextual factors in every project.

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Appendix A

Table A1. ***PARiHS Framework and Lean Success Factors Cross Mapping***

PARiHS Framework (3) **1. Evidence** **2. Context** **3. Facilitation**	**Lean Success Factors in the Literature (4)** **1. Context** **2. Content** **3. Application** **4. Outcome**
Evidence • Assessment of evidence and potential of implementation • Adaption to local context • Inclusion of local decision makers • Consideration of organizational culture	**Content** • Adapt or develop interventions for intended environment • Maintaining patient-centered focus during intervention development • Decision making surrounding identified problem
Context • Allocation of adequate resources for implementation • Engagement of leadership • Implementation strategies with a multi-disciplinary focus • Organization approach to measurement • Understanding of the prevailing organizational culture	**Context** • Engagement and visibility of leadership • Removal of barriers and allocation of resources • Organization that learns from their experiences **Application** • Development of cross-functional teams **Outcome** • Support of a learning culture that embraces continuous improvement
Facilitation • Help people understand what to change and how to change • Enabling individuals or teams to analyze, reflect and change their behaviors and attitudes • Development of skills for the facilitator through experiential learning and acquiring skills	**Content** • Adequate training in Lean methods so focus is less on tools and more on engagement **Application** • Internal experts in Lean, preferably with clinical backgrounds

Table A2. ***Quantitative Survey Questions Validity Scoring***

Construct	Question	Clarity	Comprehension	Content
Evidence	The process was created by stakeholders who participate in the activity at the point of care.	4	4.2	4.6
Evidence	The process is patient-centered.	4.6	4.4	4.8
Evidence	The decision to adopt the new process was made by the stakeholder group.	4.4	4.2	4.4
Evidence	The decision to change the old process was made by the stakeholder group.	4.6	4.2	4.4
Evidence	There was an assessment of readiness for change in the areas impacted by the new process.	4.4	4.6	4.4
Evidence	The new process was created to improve outcomes for patients	4.8	4.6	4.8
Evidence	The stakeholder group considered best practices when designing the new process.	4.2	4.2	4.4
Context	Leadership supported the stakeholder group's improvement efforts.	4.2	4.4	4
Context	Leadership assisted in removing barriers when barriers were identified.	4.8	4.8	4.2
Context	Adequate resources were allocated to the project.	4.4	4.8	4.4
Context	Continuous learning is a part of the organizational culture.	4.2	4.6	4.4
Context	The process was monitored after implementation.	4.4	4.6	4.4
Context	The stakeholder group included roles involved in the process.	4	4.2	4.4
Context	Implementation strategies included all roles involved in the process.	4	4.4	4.4
Facilitation	Facilitator(s) was/were skilled to help the stakeholder team identify the need for change.	4.4	4.4	4.4
Facilitation	Facilitator(s) engaged the stakeholder group in creating a future state process.	4.2	4	4.4
Facilitation	The stakeholder group was provided training pertinent to the improvement process.	4.6	4	4.4
Facilitation	Evaluation of process metrics was facilitated post implementation.	4.2	4.2	4.6
Facilitation	Opportunity was provided to analyze outcomes.	4.4	4.4	4.6
Facilitation	Attitudes around the process changed.	4.4	4.6	4
Facilitation	The need for changing the process was clear.	4.2	4.6	4.6
Outcome	The handover process obtained the outcomes it was intended to obtain.	4.6	4.6	4
Outcome	The handover process was successfully implemented	4	4.2	4.2
Outcome	The implemented handover process remains in daily practice	4.2	4.4	4.2