TRANSFORMATIONAL PERFORMANCE IMPROVEMENT: WHY IS PROGRESS SO SLOW?

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ABSTRACT

In this chapter, we identify three distinct transformational performance improvement (TPI) approaches commonly used to redesign work processes in health care organizations. We describe the unique components or tools that each approach uses to improve the delivery of health services. We also summarize what is empirically known about the effectiveness of each TPI approach according to systematic reviews and recent studies published in the peer-reviewed literature. Based on examination of this research, we discuss what knowledge is still needed to strengthen the evidence for whole system transformation. This involves the use of conceptual frameworks to assess and guide implementation efforts, and facilitators and barriers to change as revealed in a recent evaluation of one major initiative, the Lean Enterprise Transformation (LET) at the Veterans Health Administration. The analysis suggests ways in which TPI facilitators can be developed and barriers reduced to improve the effectiveness and sustainability of quality initiatives. Finally, we discuss appropriate study designs to evaluate TPI interventions that may strengthen the evidence for their effectiveness in real world practice settings.

Keywords: Performance improvement; system transformation; work process redesign; lean management / lean six sigma; implementation science; evaluation study design

INTRODUCTION

In recent years, leaders and managers have begun to implement transformational performance improvement (TPI) initiatives to address challenges in health care.

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TPIs are intended to be whole system changes to work processes that result in significant improvements to the delivery of health services. Many of the various types of TPIs were developed in industry (e.g., manufacturing, aviation) prior to being adapted for use in medical settings. Despite the promise of such interventions, there has been slow progress in both actual improvements in the quality of care and reduction of variations in quality of care delivered in the United States (Institute of Medicine, 2001). A major reason for this may be the slow uptake of truly whole system TPI approaches, such as those to be addressed in this chapter.

We highlight three major TPI approaches commonly found in health care organizations: (1) lean management for performance improvement; (2) six sigma, including a popular variant when combined with lean, known as "lean six sigma"; and (3) high reliability organizations. Due to the particularly rapid rise of lean in health care over the last decade, we feature this approach to TPI in our review of the existing literature. We also describe frameworks from the field of implementation science and apply them to lean transformation initiatives. This is followed by examination of facilitators and barriers to TPI based on lessons learned from a recent system-wide change effort undertaken by the Veterans Health Administration. We conclude this chapter by suggesting alternative study designs for examining TPI interventions given the constraints of "real world" implementation approaches, timing of activities, and data availability in practice-based settings.

LEAN MANAGEMENT SYSTEM

First developed at Toyota in the 1980s (Ohno, 1988; Shingo, 2008), the lean management approach to operational performance improvement has scaled across numerous manufacturing and service industries worldwide and is increasingly being adopted to address many challenges facing US health care. This includes rising costs and insurance premiums, concerns about patient safety and medical errors, price variation, and wasted time and resources (Leite & Vieira, 2015; Liker, 2021; Jones & Womack, 2003). We define lean as an overall management or operating system based on a workforce culture that empowers staff with skills, tools, and resources to identify problems and implement changes leading to improved performance (Toussaint & Adams, 2015; Jones & Womack, 2003). When introduced as a "systems philosophy" or long-term way of thinking, lean provides a road map for maximizing value while minimizing waste, which is defined in health care as anything that does not provide value to patients. High-level principles for lean transformation are outlined as a five-stage process (Jones & Womack, 2003):

(1) Specify value from the standpoint of the end customer *(e.g., Patient)*
(2) Map all the steps in the 'Value stream' *(e.g., Care delivery process)*
(3) Make the value-creating steps flow toward the customer *(Patient-centered care)*

(4) Let customers pull value from each step of the process *(High service quality, Zero waste)*
(5) Pursue perfection through continuous improvement.

Components of a Lean Management System

Lean management (also known as Lean production, Lean enterprise, and Lean thinking) involves a set of principles, practices, and tools to assess and redesign operational processes to improve the performance of daily work processes (Radnor, Holweg, & Waring, 2012). A commonly used practice for addressing specific gaps in performance is A3 thinking, a structured approach to problem-solving in which a strategy to improve a particular problem is summarized on a single sheet of A3 paper, which is simply paper of size 11 × 17 inches. A3 reports typically include a problem definition, description of the current condition, a goal or target condition, root cause analysis, interventions or recommendations, and an implementation and sustainability plan. Other tools and practices include value stream mapping to identify unnecessary, wasteful steps and to plan for a more ideal flow of work; standardized work processes; visual tracking charts that show actual versus expected performance; plan-do-study-act (PDSA) rapid improvement cycles; and regular huddles among staff to discuss the status of operations, need for problem-solving, and to plan for the day. For the redesign of complex processes, staff from relevant departments may hold a kaizen event (*kaizen* is a Japanese term meaning "change for the better"), a short duration project typically lasting a few days with the intent of achieving improvement in the target area.

Leaders and managers also make frequent visits to the workplace (*gemba*) to gain an understanding of the work being done and problems that staff are encountering, and to coach staff on how to identify and remedy work-related problems. This leader activity is a distinguishing feature of a lean management system. In these ways, lean management attempts to establish a culture and operating system that equips staff to generate continuous improvement through what are often incremental but regular enhancements to their work (KaiNexus, 2019).

What Do We Know About Lean in Health Care?

Systematic Reviews of Lean Research

One of the first systematic reviews by D'Andreamatteo, Ianni, Lega, and Sargiacomo (2015) included both empirical and theoretical articles on lean in health care. This review documented that more than 90% of the empirical studies were conducted in hospitals, with a few exceptions in primary care settings. Only a few studies addressed an entire organizational approach to lean management. Rather, research reports tended to focus on projects implemented within a single hospital unit or involving one organizational process. Positive associations with lean were most frequently reported for reducing various categories of waste, increasing

patient safety, and improving financial performance. Three articles documented an increase in staff satisfaction, and two articles demonstrated an improvement in staff safety.

Moraros, Lemstra, and Nwankwo (2016) assessed the effect of lean on worker and patient satisfaction, health and process outcomes, and financial costs. The authors found the most benefit on process indicators (e.g., patient flow, safety), no significant associations with patient satisfaction and health outcomes, and a negative association with financial costs and worker satisfaction. The authors concluded that evidence was lacking regarding these outcomes and that more rigorous research methods are needed to elucidate the full impact of lean. Notably, most studies appearing in these and similar reviews (Isfahani, Tourani, & Seyedin, 2019a, 2019b; Souza et al., 2021; Tlapa et al., 2020; Zepeda-Lugo et al., 2020) were conducted in hospital subunits, such as the emergency department, operating room, pharmacy, or medical/surgical patient care unit, rather than across entire organizations undergoing lean transformation. Additionally, studies often used small samples and pre-post designs with limited ability to assess confounding factors or alternative explanations.

Finally, a more recent systematic review included studies conducted in hospitals over the period 2000–2015 (Isfahani et al., 2019a, 2019b). The most frequently assessed performance measures were time indicators (e.g., first service provision time, waiting time, length of stay, turnover time), which largely improved after lean implementation. This focus on time is likely due to lean's attention to operational processes and reduction of waste (*muda*), a common form of waste in health care being time delays. Moreover, most evaluations have focused on identifying the benefits of lean, but not the associated costs of implementation or return on investment. Meta-analysis of existing systematic reviews can help summarize and clarify the net effectiveness of lean interventions in health care.

Research on Lean and Hospital-Wide Performance

Several published studies report associations between lean implementation and hospital-wide performance measures. Using survey data from 1,222 US hospitals on the use of lean and its related TPI systems, Shortell and colleagues (Shortell, Blodgett, Rundall, & Kralovec, 2018) report that, as of 2017, approximately two-thirds of hospitals were using either lean management, lean six sigma, which adds a focus on variance reduction, or robust process improvement, which adds a structured change management component (Chassin & Loeb, 2013). Analyses of these data revealed that measures of lean maturity, leadership commitment, use of a lean daily management system, and extent of lean training were each positively associated with hospital performance.

A related study using the same US hospital data (Shortell, Rundall, & Blodgett, 2021) examined relationships among the extent of lean implementation in the human resources, finance, and information technology functions of hospitals and self-reported impact. The analyses revealed that all functions were associated with positive reports of performance. Subsequent study linking the

same lean survey of 1,222 hospitals to national data sources such as Centers for Medicare and Medicaid Hospital Compare (Shortell, Blodgett, Rundall, Henke, & Reponen, 2021) found that hospitals with more extensive lean practices (i.e., throughout most departments and outpatient clinics) performed better than nonlean hospitals in terms of lower adjusted inpatient expense per discharge, better patient experience as measured by Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores, lower 30-day readmission rates, and more appropriate use of imaging, but not on measures such as risk-adjusted mortality rates.

Lee, McFadden, & Gowen III (2018) collected survey data from 215 US hospitals, assessing the relationship between hospital leaders' self-report of the extent of both lean management and lean six sigma implementation, and their assessment of hospital performance on patient safety and cost. They found that hospitals with lean six sigma reported better patient safety and cost savings than did hospitals that implemented only lean. In summary, these studies add to previous systematic reviews by using survey data from large samples to examine the association of lean and its related methodologies with hospital-wide performance. Overall, lean was reported to have a positive effect on performance measures whether gathered from survey reports or public data sources.

Research on Lean Redesign in Primary Care

A series of articles examined the implementation, impact, and sustainment of lean redesigns in primary care clinics within a single organization (Gray, Harrison, & Hung, 2016; Gray, Yakir, & Hung, 2018; Hung et al., 2015, 2017a, 2017b, 2018, 2019a, 2019b, 2021a, 2021b, 2022). These studies examined 46 primary care departments in a large ambulatory care system where organizational leaders introduced lean workflow redesigns in three phases. Phase 1 implemented changes among all primary care providers (PCPs) and staff in a single "pilot" clinic; Phase 2 did the same but in three "beta" clinics; and Phase 3 entailed rollout of the lean redesigns to all remaining primary care clinics located across the system. A total of six years of data were collected from 2011–2016, three of which were postinterventional.

Based on these longitudinal data, several studies used a nonrandomized, stepped-wedge study design with interrupted time series analysis to assess lean impacts on performance measures gathered from operational and electronic health record (EHR) data sources. One early study found that lean redesigns can improve primary care system-wide without negatively impacting the quality of clinical care (Hung, Harrison, Martinez, & Luft, 2017b). Provider efficiency increased in all examined workflow metrics (e.g., documentation/office visit chart closure, renewal of prescription refills, telephone call resolution). The workflow metric of timely response to electronic patient messages also improved over time, though this was not statistically significant (Hung, Truong, & Liang, 2021a). Physician productivity increased as measured by work-relative value units (wRVU) per physician per month. Seven clinical quality metrics were recorded and six were either improved (e.g., coordinated diabetes care) or unchanged after lean intervention. Patient satisfaction increased, most notably in access to care and overall experience. Similarly, improved patient experiences were confirmed by a subsequent study based on two additional years of postintervention data,

which included wait times as documented in the EHR (Hung, Mujal, Jin, & Liang, 2021b).

Experiences of PCPs and staff were also assessed using a survey distributed prior to and immediately following the lean redesigns (Hung et al., 2018). This study reports the results of 1,333 baseline surveys and 1,164 follow-up surveys fielded to all PCPs and staff, with overall response rates of 73% and 74%, respectively. The surveys evaluated workplace experiences in three key areas: workforce engagement, perceptions of the work environment, and job-related burnout. After a series of multivariate regressions, the authors found that although both occupational groups experienced greater engagement, teamwork, and participation in decision-making, there were also reports of increased burnout and experiences of workplace stress. Given the system-wide rollout of lean redesigns across the organization and absence of a control group, it is unclear whether this finding was due to new workflows or to secular trends in primary care, including increased insurance coverage and patient demand at the time under the Affordable Care Act.

Interestingly, these self-administered survey reports are contrasted by a subsequent study based on additional years of observational data sourced from the organization's EHR system (Epic®). The same researchers mined time-stamped EHR access logs to quantify how lean redesigns affected daily work time among PCPs (Hung, Mujal, Jin, & Liang, 2022). The most immediate change was a decrease in desktop medicine (i.e., time that physicians spend in the EHR on nonpatient facing clinical and administrative tasks), both throughout the day (10.9%) and particularly after clinic hours (8.3%). Total daily work hours decreased by 20% by the time lean redesigns had been implemented for two additional years across the system. These time savings should alleviate physician workload and could be expected to result in lower levels of burnout. Though the EHR-based study of physician work lagged the self-administered survey by two years, it is possible that the initial reduction in desktop time observed shortly after the redesign was not sufficient to mitigate overall physician burnout. Reassessment of physician experiences over time is warranted, particularly during the time period following the decrease in total daily work hours among PCPs.

Closely related to these findings, lean maturity and burnout in primary care has been a topic of study in other research. For example, Kaltenbrunner, Mathiassen, Bengtsson, and Engström (2019) used a questionnaire based on Liker's description of lean (Liker, 2004), a four-part model (philosophy, processes, people, and partners) that organizes 14 principles, to assess lean maturity in 42 primary care units across a region in central Sweden. This study examined how lean maturity affected staff perception of various outcomes such as caregiving, thriving, and exhaustion. Increased lean maturity was found to be associated with greater staff satisfaction in the areas of caregiving and thriving, as well as decreased exhaustion. These findings suggest that previous reports of physician and staff burnout, whether due to secular trends in primary care or the redesigns themselves, could potentially be mitigated in the long run as organizations progress into lean maturity.

SIX SIGMA AND LEAN SIX SIGMA

Six sigma is closely related to lean management but focuses explicitly on improving work processes through the reduction of defects. Although initially developed in the manufacturing sector, use of six sigma has expanded greatly into various other sectors, including health care. The principles of this management tool are well aligned with health care as errors could cause serious harm or death to patients. Originally implemented by Motorola in the mid-1980s, six sigma has two primary definitions. The first is as a business strategy, used to improve the efficiency of all operations to exceed customer expectations and increase profits (Antony & Banuelas, 2002). The second is statistical, seeking to achieve 99.9997% accuracy or less than 3.4 defects per million opportunities (Henderson & Evans, 2000).

There has been much interest in combining lean management with six sigma in what is referred to as "lean six sigma" (DelliFraine, Langabeer, & Nembhard, 2010; Glasgow, Scott-Caziewell, & Kaboli, 2010). In this complementary synthesis, the strengths of the two TPI approaches are combined while mutually correcting or covering for their individual weaknesses. Lean's strengths lie in its emphasis on standard work in addition to its focus on process and culture change, but may be relatively limited in terms of analytical tools. Six sigma, on the other hand, provides strong analytical tools and frameworks but offers fewer standardized solutions or attention to longer-term culture change. The integrated framework for lean six sigma has been described in detail by De Koning et al., (de Koning, Verver, van den Heuvel, Bisgaard, & Does, 2006).

What Do We Know About Lean Six Sigma in Health Care?

While there are numerous case studies and systematic reviews of six sigma alone (Aakre, Valley, & O'Connor, 2010; Bertolaccini, Rizzardi, Filice, & Terzi, 2011; Chassin, Mayer, & Nether, 2015; Christianson, Warrick, Howard, & Vollum, 2005; Hernández-Lara, Sánchez-Rebull, & Niñerola, 2021; Improta et al., 2017; Kim, Song, & Lee, 2009; Ko et al., 2016; Leaphart et al., 2012; LeBlanc, McLaughlin, Freedman, Sager, & Weissman, 2004; Niemejier et al., 2012; Niñerola, Sánchez-Rebull, & Hernández-Lara, 2020; Silich et al., 2012; Tosuner et al., 2016) fewer articles include both six sigma and lean TPIs or the combined "lean six sigma" approach. DelliFraine et al. (DelliFraine et al., 2010) conducted an early systematic review of lean and six sigma in health care in 2010. Evidence scores ranging from four to seven were reported, with lower scores indicating stronger research designs and data quality. Lean performance improvement tools had an average evidence score of 5.7, six sigma tools averaged an evidence score of 6.2, and lean six sigma tools had an average evidence score of 5. Although this ranking positively reflects on the use of lean six sigma, the authors note challenges in drawing conclusions due to the low sample size of studies.

A different systematic review conducted in the same year examined lean, six sigma, and lean six sigma in the acute care setting (Glasgow et al., 2010). The review concludes that although publications generally suggest that lean, six sigma, and lean six sigma can be effective TPI approaches for a wide variety of

problems faced in acute care, assessments of the true long-term impact are limited. A lack of both follow-up data, especially for more than two years, and sufficient rigor in methodologic evaluation for various projects has led to this gap. The authors further acknowledge that other, more subtle metrics might be of interest as well. For example, a goal of lean management is to create a culture of continuous improvement. A focus on culture or work environment changes resulting from implementation of any of these three related TPI approaches could be of interest, but were discussed in very few articles.

HIGH RELIABILITY ORGANIZATIONS

The high reliability organization (HRO) is a TPI approach that defines an organization as one operating nearly error-free for extended periods of time (Roberts, 1990). In HROs, performance reliability serves as the primary goal and is particularly relevant to health care as the consequences of errors can be severe (Reinertsen & Clancy, 2006). Furthermore, Weick and Sutcliffe (2008) describe an environment of "collective mindfulness" that is central to HROs in health care, in which all staff actively search for and report unsafe conditions or small problems before they escalate into more hazardous problems.

Research in the literature shows that the safety and quality of health care in the United States is below what it should be. Some examples range from lapses in recommended preventive care to wrong site or wrong patient surgical errors (McGlynn et al., 2003; Minnesota Department of Health, 2013). The Institute of Medicine (IOM) published a series of influential reports outlining how health care can move toward high reliability (Donaldson, Corrigan, & Kohn, 2000; IOM, 2001). To measure improvement in areas identified by the IOM, particularly the area of patient safety, principles and methods for evaluating the overall reliability of a complex system are frequently used (Nolan et al., 2014).

What We Know About HROs in Health Care

Woodhouse et al. describe efforts to move toward high reliability in a large, multisite radiation oncology department (Woodhouse et al., 2016). Implementation of a comprehensive safety and quality program derived from HRO techniques was initiated in 2011 under guidance of senior leadership with implementation taking place through 2016. Knowledge from the Joint Commission published literature and experts in HROs were consulted to design six initiatives listed as follows:

(1) Implementation of a comprehensive quality and safety educational curriculum
(2) The development of a hard-stop policy to systematically standardize patient safety checks before administering radiation therapy
(3) Enhancement of peer review through an automated electronic system

(4) Increased leadership oversight and reinforcement
(5) Implementation of an electronic condition reporting system
(6) Routine assessment of serious events and incidents.

The initiatives were evaluated for effectiveness with the primary metric being state-reported medical events (SRMEs). For example, data analysis revealed that the average number of days between SRMEs increased from 174 days to 541 days, and the same was seen in fractions between each SRME with 21,678 fractions pre-intervention to 113,104 fractions postintervention. These changes were made despite increasing patient volumes, expansion of the radiation oncology department to multiple locations, and incorporation of new technologies such as proton therapy and stereotactic body radiation therapy.

A High Reliability Health Care Maturity (HRHCM) model was presented by The Joint Commission to promote HRO development in health care (Chassin & Loeb, 2013). Leadership, safety culture and robust process improvement are the three components at the core of this model used to guide organizations toward high reliability. Sullivan, Rivard, Shin, and Rosen (2016) describe their experiences applying the model to six different US Department of Veterans Affairs hospitals, including semistructured interviews with representatives from senior leadership, middle managers, and frontline clinical staff. The authors found that the HRHCM model has good content validity, with 12 out of the 14 components detected across the six hospitals. In addition, each individual hospital's level of maturity, categorized as in the beginning, developing, advancing, or approaching stage, was characterized for 9 of the 14 components.

KNOWLEDGE NEEDED TO ADVANCE THE FIELD

Based on our review, all forms of TPI described clearly have the potential to address a wide variety of challenges in health care. Yet the literature contains many studies based on fairly limited efforts to improve performance in selected departments, with few studies describing transformation initiatives that encompass whole-system change. Moreover, systematic reviews have revealed several inherent issues limiting the evidence on different approaches to TPI. One is that many published reports are not based on long-term, follow-up data and do not account for potentially confounding effects in their study designs. Given the nature of quality improvement as a "real world" activity in health care organizations, we further note the lack of appropriate study designs for evaluating such initiatives in practice-based settings. Methods that consider operational decisions for intervention, timeframes, and available data within organizations will be a subject of discussion in this chapter.

A major barrier to progress is the fact that many health care organizations struggle to spread TPI throughout the system. Many initiatives become stalled or slowed such that only a small percentage of those efforts become fully developed and functional. For example, only a few lean implementations in health care have incorporated performance improvement beliefs and practices into the

organizational culture (Kovacevic, Jovicic, Djapan, & Zivanovic-Macuzic, 2016). Consistent with Kovacevic et al., data from a 2017 national survey of hospitals revealed that only 12.6% (102) hospitals implementing lean self-reported that they had progressed to a mature hospital-wide stage of implementation, although an additional 46.4% (376 hospitals) believed they were spreading lean to multiple units and beginning to gain traction. The 102 "mature" lean hospitals averaged 7.8 years in their use of lean, while the 376 hospitals that were beginning to spread lean throughout the hospital averaged 5.3 years since adopting it, indicating that it takes considerable time before organization-wide use of lean TPI is achieved (Shortell et al., 2018).

In the absence of spread, there is incomplete implementation of change initiatives with corresponding quantification of those results, or at times, failed attempts to implement. Transformation efforts can be guided by conceptual frameworks drawn from the field of implementation science, which may assist program implementers, managers, and leaders in thinking more comprehensively about what is needed to achieve desired outcomes for the initiative. Such models or frameworks underscore key factors, including effectively introducing and managing change; ensuring adequate resources in staffing, time, or capital; and securing leadership buy-in and commitment. All are examples of what is needed for successful transformation. We describe one model, the Consolidated Framework for Implementation Research (CFIR) that was originally developed for clinical interventions, then adapted for organizational process redesigns (CFIR-PR), and apply this to case studies of lean implementation in health care. Another example of a relevant framework, the Organization Transformation Model (Lukas et al., 2007), has also been used to identify barriers and facilitators to successful lean TPI. We will discuss the importance of full TPI implementation by outlining these facilitators and barriers based on a recent evaluation of a large-scale Lean Enterprise Transformation (LET) at the Veterans Health Administration.

Conceptual Frameworks for Implementation

Given the challenges of implementation, mixed-method research can be used to examine not only the outcomes of an intervention but also the change process and experiences of staff and leaders. These aspects can influence the apparent results of a change initiative, yet frequently go unrecognized as they are not often featured in evaluative studies of the intervention. For example, foundational writings on lean management in hospitals assert that the deeper the philosophical commitment to lean among hospital leaders and staff and the more extensive the implementation of lean practices, the greater the expected improvement in the hospital's performance across a diverse array of metrics (Barnas, 2014; Chassin & Loeb, 2013; Harrison et al., 2016; Toussaint & Adams, 2015). A body of literature also now points to the importance of "context" when implementing interventions in health care settings (Damschroder et al., 2009; Greenhalgh, Robert, Macfarlane, Bate, & Kyriadidou, 2004; Ovretveit, 2011). TPI implementation requires workforce engagement and strategic alignment across all levels of the

organization, which depend heavily on the supportiveness of the micro and macro contexts in which changes are introduced (Harrison et al., 2016; Ulhassan et al., 2013). According to a review of major TPI approaches in health care, most research studies do not consider broader contexts and instead focus narrowly on the technique or intervention itself that is used to solve isolated problems (DelliFraine et al., 2010). This lack of study has consequences for transformation progress as key information is unavailable to support future change efforts.

Whole system TPI is a complex intervention with multiple, interacting components. It often operates at more than one level and affects a range of organizational groups, behaviors, and processes. Beyond evaluation of performance outcomes, research on TPI initiatives will ideally support quality improvement efforts by providing formative feedback on implementation processes or by sharing lessons that will be useful to program implementers. Research advancing these complex interrelations can benefit greatly from clear conceptual frameworks (Alexander & Hearld, 2011). In this section, we describe conceptual frameworks from the field of implementation science that can be used to study and guide transformation activities by providing leaders a comprehensive roadmap to achieve desired goals. This description will be followed by brief applications to lean transformation in health care.

CFIR and CFIR-PR for Complex Interventions

One model is the CFIR (Damschroder et al., 2009) originally developed for evaluating clinical evidence-based interventions in health care (Kirk et al., 2016). The CFIR brings together a set of key constructs, organized by domain, from a range of established implementation theories (Damschroder et al., 2009). The CFIR consists of five domains: (1) *Intervention*, referring to specific features characterizing the intervention itself (e.g., its components, complexity, cost); (2) *Inner setting*, which describes the organization or internal environment in which the intervention is implemented (e.g., practice culture, climate, local leadership); (3) *Outer setting*, consisting of forces in the external environment such as federal, national, or local laws, regulatory policies, and market pressures; (4) *Individuals*, relating to the participants involved in delivering the intervention (e.g., physicians, nurses, medical assistants); and (5) *Implementation process* that describes how the intervention is implemented, including its planning, rollout or spread, and evaluation.

General frameworks like the CFIR can contribute to continuity and synthesis across studies. Whereas the CFIR identifies contextual factors influencing successful implementation of clinical interventions, an adapted version known as the CFIR-PR is tailored to work process redesign, which is a common aspect of all TPI approaches described earlier in this chapter. Process Redesign (PR) in health care organizations involves "conceptualizing, mapping, testing, refining, and continuing to improve the many processes of health care" (Institute of Medicine, 2001; Locock, 2003). Typically, redesign aims to identify current processes in need of change, such as those involving suboptimal patient experiences of care, delays in care delivery, or medical errors arising from inconsistent workflows.

Once identified, organizational leaders and staff make fundamental changes to targeted processes. Redesign of this kind is challenging, usually requiring radical change in day-to-day operations, coordination among multiple teams, accurate and continuous measurement, and diligent reporting practices.

The CFIR-PR thus includes the five domains of the original CFIR but replaces the domain of *Individuals* with *Individuals/Teams* and extends the original framework by adding an intermediate domain measuring the degree of implementation success. This added "Implementation Measures" domain includes constructs such as the acceptance, adoption/abandonment, fidelity, reach, and sustainability of a new intervention (Proctor et al., 2011). Importantly, the CFIR-PR extends the CFIR by including a final domain of "Intervention Outcomes" which are often the organizational performance indicators or areas that TPI initiatives aim to impact. By adding these dimensions, the modified framework focuses attention on the way that context shapes intermediate results and conditions, such as user acceptance, which in turn influence classic measures of an intervention's ultimate goals or outcomes, such as efficiency, quality, or safety (Fig. 1).

Applications to Lean Transformation

Several case studies of lean implementation reveal challenges that are reflected in the CFIR and CFIR-PR. Comparative case studies of five hospital systems in the United States reveal that several characteristics affected implementation of organization-wide lean initiatives, often influencing the initiative's outcomes (Harrison et al., 2016). Features of the *inner setting* that facilitated positive outcomes included the CEO's commitment to lean and its alignment with the

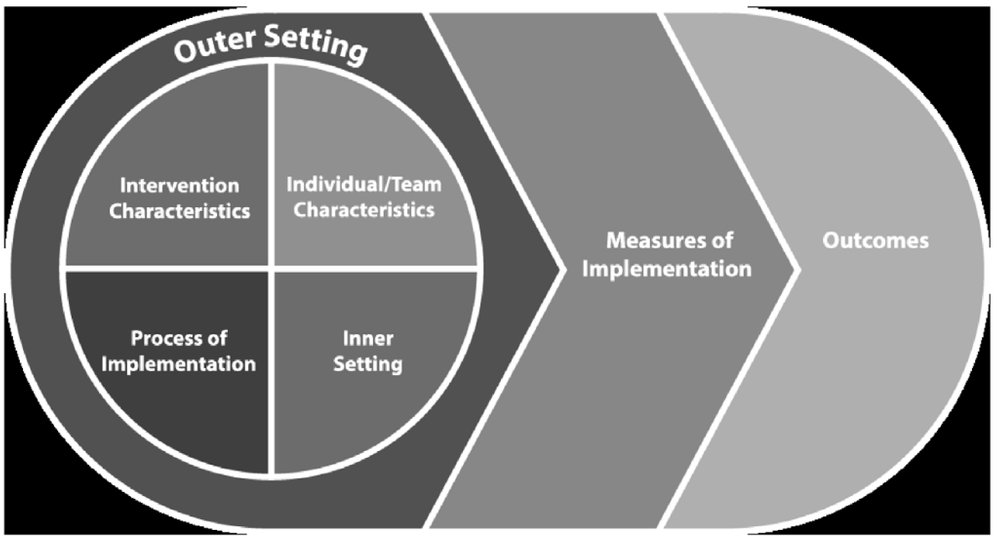

Fig. 1. Consolidated Framework for Implementation Research. *Source:* Adapted for Process Redesign (CFIR-PR) (Rojas-Smith, Ashok, Dy, Wines, & Teixeira-Poit, 2014).

organizational mission, while dependence of lean projects on new information technology was a barrier to success. Other facilitators involved the *implementation process*, such as dedication of resources and experts to lean rollout, plans for ongoing staff training, and establishing measurable and relevant project targets that could be used to evaluate progress. Contributions of *individuals/teams* to successful implementation included managing the burden placed on staff, and ensuring timely communication between project members and others affected by the change effort.

A study exploring the perceptions of nurse managers involved with implementing lean in a Canadian hospital system reveals the challenges they experienced (Udod et al., 2020). The authors report that in this provincial health system, lean was not successfully embedded into the organizational culture, and participants were unable to overcome organizational barriers and work demands to learn how to sustain changes over time. Content analysis of data collected via semistructured interviews identified six key challenges to transformation. In terms of the *implementation process*, some challenges included: (1) fragmented, confusing implementation protocols, (2) absence of or limited lean training and preparation, and (3) inadequate time allotted to educate and integrate lean into daily work. Reflective of the *inner setting*, (4) organizational leadership allocated limited financial resources for the effort, particularly for attending lean workshops or kaizen events. Barriers related to the *individuals/teams* involved in implementing the intervention were: (5) staff ambivalence toward the initiative and its ability to make a difference in patient care and workflows, and (6) inadequate communication and relationship building.

In a study that explicitly leveraged the CFIR-PR as an organizing framework, interviews and focus groups with PCPs, clinical support staff, and operational leaders were used to examine factors impacting acceptance of lean workflow redesigns in a large ambulatory care system (Hung, Harrison, et al., 2017b). Acceptance by change recipients is one of the intermediate constructs in the CFIR-PR "Implementation Measures" domain. The study found that during the *implementation process*, it was critical to engage frontline staff in designing the new workflows. Physicians and staff from the pilot intervention site, in particular, had engaged most deeply with initial workflow analysis and redesign efforts and were consequently the most positive and accepting of the changes. On the other hand, physicians and staff in the last phase of clinics to implement the new workflows not only had least involvement in the redesign process but were also most critical of it.

Reflective of the *inner setting*, practice culture was also identified as playing a key role in the acceptance of lean redesigns in primary care clinics. One clinic that appeared to be highly democratic in culture struggled to adapt to the standardization of new workflows. On the other hand, clinics with a hierarchal practice culture, those with strong local leaders supportive of the lean initiative, and those with access to performance data via clinic information systems were more accepting of the changes. Finally, professional work roles and relationships, including the professional identity among physicians and their interactions with support staff, reflected *individual/team* influences on implementation. Physicians who felt as if their work was already highly efficient and who perceived

standardization as a threat to professional autonomy were most likely to resist the redesigns. This was offset by good working relationships between physician–medical assistant care teams, which greatly facilitated implementation of changes.

The Role of Change Management

Following the aforementioned case studies, we make brief note of the importance of effective change management when implementing TPI initiatives. In practice, change management is the process of "preparing, equipping, and enabling individuals to adopt transformation correctly." (Fleishon, Muroff, & Patel, 2017) There are many theories with accompanying methods, tools, and rationales for accomplishing this (Beer & Nohria, 2000; Bowen, Stanton, & Manno, 2012; Mitchell, 2013; Shirey, 2013), all with the end goal of successfully transitioning from the status quo to a more desired state. Common barriers to effective change management include negative emotions experienced by individuals who must carry out the new work processes. Staff or other personnel affected by changes may feel threatened or disoriented, which could undermine the success of efforts to transform care. Based on a recent systematic review of change management models in health care (Harrison et al., 2021), enabling a culture for change is crucial particularly for clinician engagement. Given the imperative for physician buy-in regarding transformation efforts in health care, further research on how clinicians respond to various implementation approaches may offer insight into successful change initiatives.

Facilitators and Barriers to TPI Implementation

Several facilitators and barriers (henceforth individually referred to as facilitator/barrier, as typically the absence of a given facilitator to TPI implementation is a barrier and vice-versa) in hospitals and related health care organizations have been identified in a comprehensive evaluation of the LET in 10 Veterans Health Administration medical centers geographically dispersed across the United States (Azevedo et al., 2020). Site visit teams conducted 268 interviews during three rounds of interviews, one in-person site visit and two follow-up telephone visits, at six-month intervals. Expanding on the Organizational Transformation Model (OTM) developed by Lukas et al. (2007), the researchers developed the Lean Enterprise Transformation Evaluation Model (LEM), which focuses on organization-wide transformation as opposed to individual improvement projects. Similar to other implementation frameworks including the CFIR-PR, the LEM incorporates 10 domains of factors positively associated with transformation. Five domains come from the OTM: (1) Impetus to Transform that provides meaning and motivation for staff to engage in improvement work; (2) Leadership Commitment and Support for Change; (3) Improvement Initiatives that not only produce meaningful changes in work processes but also engage staff; (4) Alignment Across the Organization, i.e., setting a "True North" for the organization and aligning subunit goals, resources, and activities to those

organization-wide goals; and (5) Integration Across Intraorganizational Boundaries, i.e., alignment of goals and activities across subunits.

An expert panel advising the study team suggested augmenting the five OTM domains with five additional domains specific to LET program implementation. These domains are: (6) Communication; (7). Capability Development (staff training); (8) Use of Data to Inform Decision-Making; (9) Veteran/Patient Engagement; and (10) Organization Culture, since culture affects the processes of transformation as well as being an object of transformation.

The LEM provided a guide for interviews and qualitative analysis and structured the evaluation's findings. However, in addition to identifying many examples of these 10 domains in the LET initiatives, the analysis also identified three emergent themes: (11) Staff Engagement; (12) Staffing Levels; and (13) Use of Lean Experts. Some additional information and examples of each facilitator/barrier domain are briefly presented in the following. More detailed discussion of the study's findings can be found in Azevedo et al. (2020).

(1) *Impetus to Transform*: efforts to build and sustain an impetus to transform the organization were essential to engaging staff in the transformation initiative. The efforts included site visits to well-established lean health care organizations, leaders demonstrating continuing commitment to lean, and recognizing staff implementation efforts. Leaders listening to ideas proposed by staff and encouraging them to own the changes they were making were important to overcoming staff skepticism.
(2) *Leadership Commitment and Support for Change*: the extent to which leaders demonstrated commitment to the LET initiative and publicly supported the changes being made were important to the success of the initiative. Some leader activities that demonstrated commitment and support for change included engaging staff, promoting cultural change, setting priorities, providing resources, communicating successes, facilitating cooperation between departments, gemba walks, protecting staff time for lean events, and developing a long-term vision for lean implementation.
(3) *Improvement Initiatives*: work processes were improved primarily through systematic organizational efforts such as daily improvement activities and rapid process improvement events (RPIEs). Proper scoping of the lean value stream being worked on and limiting the number of value streams being worked on at one time were keys to successful change. However, staff reported that participating in lean program activities often increased their workload, which led to resistance.
(4) *Alignment of Organizational Strategy*: aligning daily improvement activities and RPIEs with organizational goals and True North metrics was important to successful LET implementation. Shifting and competing priorities made it difficult to maintain and execute a coherent implementation strategy.
(5) *Integration Across Intraorganizational Boundaries*: integration of work and communication across departmental and disciplinary boundaries was important for lean to spread across the organization. Working

collaboratively with others from different disciplines and units increased mutual respect among staff and created a willingness to cooperate rather than blame others when problems arose.

(6) *Communication*: sharing concerns and frustration as well as successes generated support for the lean initiative among staff and increased awareness of what progress was or was not being made on implementing lean. Recognizing employees for good work increased staff engagement. Communication across the organization and up and down the hierarchy in ways that enable leadership and frontline staff to connect promoted the lean transformation effort.

(7) *Capability Development*: to effectively implement the lean transformation, staff needed robust training, coaching, and educational opportunities to learn lean management concepts and build change management skills. Allowing staff the time to use recently acquired lean knowledge and skills to implement improvement projects was critical to solidifying knowledge of lean concepts and practices.

(8) *Use of Data to Inform Decision-making*: developing metrics for assessing performance problems and the effects of improvement projects, and identifying sources of reliable data for these metrics, were essential steps for successful LET implementation. Selecting appropriate metrics was especially challenging when there was not a good match between available data sources and the improvements being proposed.

(9) *Veteran/Patient Engagement*: although input to the lean transformation by Veterans was highly variable across the 10 sites, some respondents noted that Veterans were helpful in identifying gaps in quality and maintaining the customer focus on the Veteran rather than on clinical or administrative staff.

(10) *Organization Culture*: Two aspects of organization culture impacted the LET implementation – a culture of respect and a culture of accountability. These cultural dimensions are related. Sites that established a culture of respect created an environment where staff felt safe and were willing to, in turn, accept accountability for the work they were doing. Mechanisms and processes supporting accountability included developing action plans, convening weekly report-out meetings, using data and metrics, and completing follow-up assessments of improvement initiatives.

(11) *Staff Engagement*: interviewees reported that enthusiasm and engagement with lean were key components of LET implementation. Drivers of enthusiasm and engagement were employee satisfaction with the organization they work for, feeling that they have some voice in the decisions being made, and believing that they have some ownership of the improvements being made. A barrier was lack of recognition for participation in lean activities, which decreased morale and enthusiasm for the lean enterprise implementation.

(12) *Staffing Levels*: considerable employee time is required for implementing lean programs. This makes lean enterprise implementation challenging even when there is full staffing. At sites that reported understaffing, clinicians and

support staff prioritized patient responsibilities over lean activities. For example, allocating time for RPIEs proved difficult for already busy, overworked clinics and their staff.

(13) *Use of Lean Experts*: Respondents overwhelmingly praised lean experts (*senseis*) for their ability to interpret data and improve the understanding and alignment of process improvement goals. Also, they helped with strategic planning, identifying appropriate metrics for improvement goals, and focusing value stream work. Although initially at some sites there was tension between the *senseis* and organizational leaders over role definitions and expectations, in most cases the tension was resolved with frequent, ongoing collaboration and communication.

Study Designs for Evaluating Real World Transformations

In addition to understanding the change process, there is increasing interest in formal evaluation of change efforts that are implemented over time. Health care organizations may attempt a broad redesign across the entire system, incremental scale-up of a successful pilot project, or translation of an already proven intervention into different settings. These initiatives can be deployed in different ways and timeframes, such as within a single clinic with subsequent roll out to the larger health care organization, or throughout a multisite health care network over time. In all cases, policymakers, payers, managers, and practitioners can benefit from appropriate measurement and evaluation of such initiatives. Thoughtful evaluation is necessary to ensure enough evidence supports successful changes and that ineffective changes do not become standard practice.

Measurable impact, when it exists, is best visible through rigorous a priori experimental design such as a randomized controlled trial (RCT). However, most TPI efforts are not initiated in this context and rarely do health care leaders or program implementers design such an experiment before the start of an improvement effort. If researchers are to be engaged in evaluating the effort, they may be consulted in the middle or even after operational activities have been completed. In this case, observational study of existing data infrastructures are an attractive alternative source to answer questions of best practices when RCTs are not possible or practical. Despite the limitations and possible biases introduced through neglect to plan for evaluation prior to implementation, researchers must make their best effort to discover meaningful insights that will inform practice and advance the field.

Several study designs can be used to assess whether significant changes in performance may be associated with the introduction of either a single or phased TPI implemented over time. For our purposes, a single intervention is an improvement initiative that occurs only at a single point in time. This is contrasted with a phased intervention, which is an initiative introduced in phases and potentially across multiple locations. Three popular approaches to evaluating outcomes, each building on the other, are the interrupted time series, multiple baseline, and stepped-wedge design (Biglan, Ary, & Wagenaar, 2000; Sanson-Fisher, D'Este, Carey, Noble, & Paul, 2014). An *interrupted time series*

design monitors a single outcome over time. An intervention is thought to have "interrupted" the time series at a specific point, and the time periods before and after the intervention are compared (Gebski, Ellingson, Edwards, Jernigan, & Kleinbaum, 2012). While not often used, an accompanying contemporaneous control may be studied in parallel to improve the strength of evidence, thereby creating a controlled interrupted time series (Goldberg et al., 2000). The interrupted time series design is an improvement over cross-sectional pre-post single point estimate comparisons. Typically, one measurement is available per unit of time (e.g., operating cost per month).

A *multiple baseline design* is appropriate for phased interventions as it allows for more than one start point and recipient or site of intervention (Biglan et al., 2000; Hawkins, Sanson-Fisher, Shakeshaft, D'Este, & Green, 2007), an example being a TPI initiative implemented in multiple locations within a large health system. When a multiple baseline design is used as an extension of interrupted time series analysis, multiple time series will be monitored instead of only one. In this case, it may be analytically advantageous to stagger the start times of each intervention. Specifically, if the expected impact following an intervention is replicated across multiple sites despite the different time periods, it adds to the strength of evidence if an effect is detected, independent of possible secular trends that may be affecting all sites. Similar to a single interrupted time series, with multiple baselines there is typically one measurement per unit of time (e.g., operating cost per month per site).

A type of multiple baseline design is the *stepped-wedge design*, which has gained recognition as a popular study design for real world implementations. This is particularly true when the decision to administer an intervention to some recipients but not others, as in a traditional RCT-based design, is not desired, feasible, or ethical (Hussey & Hughes, 2007; Mdege, Man, Taylor (nee Brown), & Torgerson, 2011; van der Tweel & van der Graaf, 2013; Viechtbauer, Kotz, Spigt, Arts, & Crutzen, 2014). The stepped-wedge design accounts for eventual receipt of an intervention by the entire study population. In this case, randomization to the start time of the intervention is ideal, though not always possible with TPI as health care organizations may implement changes opportunistically or strategically as opposed to randomly. Consequently, one should be very explicit in the description of any such design, noting nonrandomization when appropriate. Stepped-wedge designs are one example of a cluster randomized, one-way cross-over design in that, for example, all sites begin without the intervention, and eventually all sites in the system receive the same intervention over time. By the end of the study period, all have been exposed, albeit with differing amounts of pre- and postintervention time.

As TPI efforts become increasingly prevalent, the need for evidence-based evaluation is critical. Appropriate study design and analysis of operational data that are routinely collected as part of organizational activities are an attractive alternative to answer questions regarding best practices when RCTs are not practical, too expensive, or require more time than leaders and program implementers can afford. Nevertheless, evaluation is necessary to build up a rigorous evidence base for TPI in practice, and more importantly, to identify ineffective

approaches over time lest they become the status quo and legacy procedures. Not only are rigorous study designs needed to evaluate the impact of TPI initiatives, but there is also great value in considering mixed-methods study designs by combining quantitative and qualitative research methods, such as thematic analysis techniques. Both approaches can be considered for understanding TPI results and the change process needed to advance the field.

CONCLUSION

Health care organizations are implementing an array of initiatives to improve how care is delivered. These efforts are notoriously difficult with many initiatives resulting in only partial success, leading to the question addressed by this chapter on TPI and why progress tends to be slow. We suggest that the evidence on TPI interventions must be supported by appropriate study designs that are rigorous and that account for real world aspects of quality improvement in practice-based settings. Researchers must also consider the use of mixed methods to evaluate not only the impact of TPI initiatives but also their uptake to facilitate understanding of successful change processes. Conceptual frameworks in the field of implementation science are critical in assisting program implementers, managers, and leaders to think more comprehensively about the requirements for change in order to achieve desired objectives.

TPI in health care thus far has focused on improving work processes within hospitals, and to a lesser extent ambulatory care centers, to deliver high-quality patient care. In the future, health care organizations of all types will be called upon by policy makers, community members, and payers to address broader challenges such as prevention and control of pandemics, amelioration of the health effects of climate change, equitable access to advances in genomic medicine, and increasing use of artificial intelligence to identify and care for patients. These challenges will require the use of TPI frameworks and evaluation methods as described earlier. Such tools can enable expansion of the mission of many organizations, and related changes in work processes, to engage in community health promotion and disease prevention while assuring equitable access to services. Application of such approaches offers important insights and provides leaders with more evidence-based understanding of the organizational dynamics required for successful transformations in health care.

REFERENCES

Aakre, K. T., Valley, T. B., & O'Connor, M. K. (2010). Quality initiatives: Improving patient flow for a bone densitometry practice: Results from a Mayo Clinic Radiology Quality initiative. *RadioGraphics*, *30*(2), 309–315. doi:10.1148/rg.302095735

Alexander, J. A., & Hearld, L. R. (2011). The science of quality improvement implementation. *Medical Care*, *49*. doi:10.1097/mlr.0b013e3181e1709c

Antony, J., & Banuelas, R. (2002). Key ingredients for the effective implementation of Six sigma program. *Measuring Business Excellence*, *6*(4), 20–27. doi:10.1108/13683040210451679

Azevedo, K. J., Gray, C. P., Gale, R. C., Urech, T. H., Ramirez, J. C., Wong, E. P., … Vashi, A. A. (2020). Facilitators and barriers to the lean enterprise transformation program at the Veterans Health Administration. *Health Care Management Review*, *46*(4), 308–318. doi:10.1097/hmr.0000000000000270

Barnas, K. (2014). *Beyond heroes: A lean management system for healthcare*. Appleton, WI: ThedaCare Center for Healthcare Value.

Beer, M., & Nohria, N. (2000). *Breaking the code of change*. Boston, MA: Harvard Business School Press.

Bertolaccini, L., Rizzardi, G., Filice, M. J., & Terzi, A. (2011). 'Six Sigma approach' — An objective strategy in digital assessment of postoperative Air Leaks: A prospective randomised study. *European Journal of Cardio-Thoracic Surgery*, *39*(5). doi:10.1016/j.ejcts.2010.12.027

Biglan, A., Ary, D., & Wagenaar, A. C. (2000). The value of interrupted time-series experiments for community intervention research. *Prevention Science*, *1*(1), 31–49. doi:10.1023/a:1010024016308

Bowen, C. M., Stanton, M., Manno, M. (2012, April, June). Using diffusion of innovations theory to implement the confusion assessment method for the intensive care unit. *Journal of Nursing Care Quality*, *27*(2), 139–145. doi:10.1097/NCQ.0b013e3182461eaf.10.1097/NCQ.0b013e3182461eaf

Chassin, M. R., & Loeb, J. M. (2013). High-Reliability health care: Getting there from here. *The Milbank Quarterly*, *91*(3), 459–490. doi:10.1111/1468-0009.12023

Chassin, M. R., Mayer, C., & Nether, K. (2015). Improving hand hygiene at eight hospitals in the United States by targeting specific causes of noncompliance. *Joint Commission Journal on Quality and Patient Safety*, *41*(1), 4–12. doi:10.1016/s1553-7250(15)41002-5

Christianson, J. B., Warrick, L. H., Howard, R., & Vollum, J. (2005). Deploying six sigma in a health care system as a work in progress. *Joint Commission Journal on Quality and Patient Safety*, *31*(11), 603–613. doi:10.1016/s1553-7250(05)31078-6

Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: A Consolidated Framework for advancing implementation science. *Implementation Science*, *4*(1). doi:10.1186/1748-5908-4-50

D'Andreamatteo, A., Ianni, L., Lega, F., & Sargiacomo, M. (2015). Lean in healthcare: A comprehensive review. *Health Policy*, *119*(9), 1197–1209. doi:10.1016/j.healthpol.2015.02.002

DelliFraine, J. L., Langabeer, J. R., & Nembhard, I. M. (2010). Assessing the evidence of Six sigma and lean in the Health Care Industry. *Quality Management in Health Care*, *19*(3), 211–225. doi:10.1097/qmh.0b013e3181eb140e

Donaldson, M. S., Corrigan, J. M., & Kohn, L. T. (2000). *To err is human: Building a safer health system*. Washington, DC: National Academies Press.

Fleishon, H., Muroff, L. R., & Patel, S. S. (2017). Change management for radiologists. *Journal of the American College of Radiology*, *14*(9), 1229–1233. doi:10.1016/j.jacr.2017.02.053

Gebski, V., Ellingson, K., Edwards, J., Jernigan, J., & Kleinbaum, D. (2012). Modelling interrupted time series to evaluate prevention and control of infection in Healthcare. *Epidemiology and Infection*, *140*(12), 2131–2141. doi:10.1017/s0950268812000179

Glasgow, J. M., Scott-Caziewell, J. R., & Kaboli, P. J. (2010). Guiding Inpatient Quality Improvement: A systematic review of Lean and six sigma. *Joint Commission Journal on Quality and Patient Safety*, *36*(12). doi:10.1016/s1553-7250(10)36081-8

Goldberg, H., Neighbor, W., Cheadle, A., Ramsey, S., Diehr, P., & Gore, E. (2000). A controlled time-series trial of clinical reminders: Using computerized firm systems to make quality improvement research a routine part of mainstream practice. *Health Services Research*, *34*(7), 1519–1534.

Gray, C. P., Harrison, M. I., & Hung, D. Y. (2016). The changing role of medical assistants in primary care. *Journal of Healthcare Management, 61*(2), 181–191.

Gray, C. P., Yakir, M. J., & Hung, D. Y. (2018). Physician engagement with metrics in lean primary care transformation. *Quality Management in Health Care*, *27*(3), 117–122.

Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., & Kyriadidou, O. (2004). Diffusion of innovations in service organizations: Systematic review and recommendations. *The Milbank Quarterly*, *82*(4), 581–629. doi:10.1111/j.0887-378x.2004.00325.x

Harrison, R., Fischer, S., Walpola, R. L., Chauhan, A., Babalola, T., Mears, S., & Le-Dao, H. (2021). Where do models for Change Management, improvement and implementation meet? A systematic review of the applications of Change Management Models in healthcare. *Journal of Healthcare Leadership*, *13*, 85–108. doi:10.2147/jhl.s289176

Harrison, M. I., Paez, K., Carman, K. L., Stephens, J., Devers, K. J., & Garfinkel, S. (2016). Effects of organizational context on lean implementation in five hospital systems. *Health Care Management Review*, *41*(4). 343–343 doi:10.1097/hmr.0000000000000127

Hawkins, N. G., Sanson-Fisher, R. W., Shakeshaft, A., D'Este, C., & Green, L. W. (2007). The multiple baseline design for evaluating population-based research. *American Journal of Preventive Medicine*, *33*(2), 162–168. doi:10.1016/j.amepre.2007.03.020

Henderson, K. M., & Evans, J. R. (2000). Successful implementation of Six sigma: Benchmarking General Electric Company. *Benchmarking: An International Journal*, *7*(4), 260–282. doi:10.1108/14635770010378909

Hernández-Lara, A.-B., Sánchez-Rebull, M.-V., & Niñerola, A. (2021). Six sigma in health literature, what matters? *International Journal of Environmental Research and Public Health*, *18*(16), 8795. doi:10.3390/ijerph18168795

Hung, D., Gray, C., Martinez, M., Schmittdiel, J., & Harrison, M. I. (2017a). Acceptance of lean redesigns in primary care. *Health Care Management Review*, *42*(3), 203–212. doi:10.1097/hmr.0000000000000106

Hung, D. Y., Gray, C. P., Truong, Q. A., & Harrison, M. I. (2019a). Sustainment of lean redesigns for primary care teams. *Quality Management in Health Care*, *28*(1), 15–24. doi:10.1097/qmh.0000000000000200

Hung, D. Y., Harrison, M. I., Liang, S.-Y., & Truong, Q. A. (2019b). Contextual conditions and performance improvement in Primary Care. *Quality Management in Health Care*, *28*(2), 70–77. doi:10.1097/qmh.0000000000000198

Hung, D., Harrison, M., Martinez, M., & Luft, H. (2017b). Scaling lean in primary care: Impacts on system performance. *American Journal of Managed Care*, *23*(3), 161–168.

Hung, D. Y., Harrison, M. I., Truong, Q., & Du, X. (2018). Experiences of primary care physicians and staff following lean workflow redesign. *BMC Health Services Research*, *18*(1). doi:10.1186/s12913-018-3062-5

Hung, D., Martinez, M., Yakir, M., & Gray, C. (2015). Implementing a lean management system in primary care. *Quality Management in Health Care*, *24*(3), 103–108. doi:10.1097/qmh.0000000000000062

Hung, D. Y., Mujal, G., Jin, A., & Liang, S. Y. (2021a). Patient experiences after implementing lean primary care redesigns. *Health Services Research*, *56*(3), 363–370. doi:10.1111/1475-6773.13605

Hung, D. Y., Mujal, G., Jin, A., & Liang, S.-Y. (2022). Road to better work-life balance? Lean redesigns and daily work time among Primary Care Physicians. *Journal of General Internal Medicine*, *37*(10), 2358–2364. doi:10.1007/s11606-021-07178-6

Hung, D. Y., Truong, Q. A., & Liang, S.-Y. (2021b). Implementing lean quality improvement in primary care: Impact on efficiency in performing common clinical tasks. *Journal of General Internal Medicine*, *36*(2), 274–279. doi:10.1007/s11606-020-06317-9

Hussey, M. A., & Hughes, J. P. (2007). Design and analysis of stepped wedge cluster randomized trials. *Contemporary Clinical Trials*, *28*(2), 182–191. doi:10.1016/j.cct.2006.05.007

Improta, G., Balato, G., Romano, M., Ponsiglione, A. M., Raiola, E., Russo, M. A., … Cesarelli, M. (2017). Improving performances of the knee replacement surgery process by applying DMAIC principles. *Journal of Evaluation in Clinical Practice*, *23*(6), 1401–1407. doi:10.1111/jep.12810

Institute of Medicine. (2001). *Crossing the quality chasm: A new health system for the 21st century*. Washington, DC: National Academies Press.

Isfahani, H., Tourani, S., & Seyedin, H. (2019a). Features and results of conducted studies using a lean management approach in emergency department in hospital: A systematic review. *Bulletin of Emergency and Trauma*, *7*(1), 9–20. doi:10.29252/beat-070102

Isfahani, H., Tourani, S., & Seyedin, H. (2019b). Lean management approach in hospitals: A systematic review. *International Journal of Lean Six Sigma*, *10*(1), 161–188. doi:10.1108/ijlss-05-2017-0051

Jones, D. T., & Womack, J. P. (2003). *Lean thinking: Banish waste and create wealth in your corporation, revised and updated*. New York: Free Press.

KaiNexus. (2019). What is incremental improvement? Kainexus. Retrieved February 11, 2022, from https://www.kainexus.com/continuous-improvement/best-practices-for-continuous-improvement/incremental-improvement

Kaltenbrunner, M., Mathiassen, S. E., Bengtsson, L., & Engström, M. (2019). Lean maturity and quality in primary care. *Journal of Health Organization and Management*, *33*(2), 141–154. doi:10.1108/jhom-04-2018-0118

Kim, Y. K., Song, K. E., & Lee, W.-K. (2009). Reducing patient waiting time for the outpatient phlebotomy service using Six sigma. *Annals of Laboratory Medicine*, *29*(2), 171–177. doi:10.3343/kjlm.2009.29.2.171

Kirk, M. A., Kelley, C., Yankey, N., Birken, S. A., Abadie, B., & Damschroder, L. (2016). A systematic review of the use of the consolidated framework for implementation research. *Implementation Science*, *11*(1). doi:10.1186/s13012-016-0437-z

Ko, A., Murry, J. S., Hoang, D. M., Harada, M. Y., Aquino, L., Coffey, C., … Alban, R. F. (2016). High-value care in the surgical intensive care unit: Effect on ancillary resources. *Journal of Surgical Research*, *202*(2), 455–460. doi:10.1016/j.jss.2016.01.040

de Koning, H., Verver, J. P., van den Heuvel, J., Bisgaard, S., & Does, R. J. (2006). Lean six sigma in Healthcare. *Journal for Healthcare Quality*, *28*(2), 4–11. doi:10.1111/j.1945-1474.2006.tb00596.x

Kovacevic, M., Jovicic, M., Djapan, M., & Zivanovic-Macuzic, I. (2016). Lean thinking in healthcare: Review of implementation results. *International Journal for Quality Research*, *10*(1), 219–230. https://doi.org/http://dx.doi.org/10.18421/IJQR10.01-12

Leaphart, C. L., Gonwa, T. A., Mai, M. L., Prendergast, M. B., Wadei, H. M., Tepas, J. J., & Taner, C. B. (2012). Formal quality improvement curriculum and DMAIC method results in interdisciplinary collaboration and process improvement in renal transplant patients. *Journal of Surgical Research*, *177*(1), 7–13. doi:10.1016/j.jss.2012.03.017

LeBlanc, F., McLaughlin, S., Freedman, J., Sager, R., & Weissman, M. (2004). A six sigma approach to maximizing productivity in the cardiac cath lab. *The Journal of Cardiovascular Management*, *15*(2), 19–24.

Lee, J. Y., McFadden, K. L., & Gowen, C. R. (2018). An exploratory analysis for lean and Six sigma implementation in hospitals: Together is better? *Health Care Management Review*, *43*(3), 182–192. doi:10.1097/hmr.0000000000000140

Leite, H. dos, & Vieira, G. E. (2015). Lean philosophy and its applications in the service industry: A review of the current knowledge. *Production*, *25*(3), 529–541. doi:10.1590/0103-6513.079012

Liker, J. K. (2004). *The Toyota way: 14 management principles from the world's greatest manufacturer*. New York, NY: McGraw-Hill Education.

Liker, J. K. (2021). *The Toyota way: 14 management principles from the world's greatest manufacturer*. New York, NY: McGraw-Hill Education.

Locock, L. (2003). Healthcare redesign: Meaning, origins and application. *Quality and Safety in Health Care*, *12*(1), 53–57. doi:10.1136/qhc.12.1.53

Lukas, C. V. D., Holmes, S. K., Cohen, A. B., Restuccia, J., Cramer, I. E., Shwartz, M., & Charns, M. P. (2007). Transformational change in Health Care Systems. *Health Care Management Review*, *32*(4), 309–320. doi:10.1097/01.hmr.0000296785.29718.5d

McGlynn, E. A., Asch, S. M., Adams, J., Keesey, J., Hicks, J., DeCristofaro, A., & Kerr, E. A. (2003). The quality of health care delivered to adults in the United States. *New England Journal of Medicine*, *348*(26), 2635–2645. doi:10.1056/nejmsa022615

Mdege, N. D., Man, M.-S., Taylor (nee Brown), C. A., & Torgerson, D. J. (2011). Systematic review of stepped wedge cluster randomized trials shows that design is particularly used to evaluate interventions during routine implementation. *Journal of Clinical Epidemiology*, *64*(9), 936–948. doi:10.1016/j.jclinepi.2010.12.003

Minnesota Department of Health. (2013). *Adverse health events in Minnesota*. Retrieved from https://www.health.state.mn.us/facilities/patientsafety/adverseevents/docs/2013ahereport.pdf. Accessed on February 12, 2022.

Mitchell, G. (2013). Selecting the best theory to implement planned change. *Nursing Management*, *20*(1), 32–37. doi:10.7748/nm2013.04.20.1.32.e1013

Moraros, J., Lemstra, M., & Nwankwo, C. (2016). Lean interventions in healthcare: Do they actually work? A systematic literature review. *International Journal for Quality in Health Care*, *28*(2), 150–165. doi:10.1093/intqhc/mzv123

Niemeijer, G. C., Flikweert, E., Trip, A., Does, R. J., Ahaus, K. T., Boot, A. F., & Wendt, K. W. (2012). The usefulness of Lean Six Sigma to the development of a clinical pathway for hip fractures. *Journal of Evaluation in Clinical Practice*. doi:10.1111/j.1365-2753.2012.01875.x

Niñerola, A., Sánchez-Rebull, M.-V., & Hernández-Lara, A.-B. (2020). Quality improvement in healthcare: Six sigma systematic review. *Health Policy*, *124*(4), 438–445. doi:10.1016/j.healthpol.2020.01.002

Nolan, T., Resar, R., Griffin, F., & Gordon, A. B. (2004). *Improving the reliability of Health Care*. Boston, MA: Institute for Healthcare Improvement.

Ohno, T. (1988). *Toyota production system: Beyond large-scale production*. New York, NY: Productivity Press.

Ovretveit, J. (2011). How does context affect quality improvement? The Karolinska Institutet.

Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., Bunger, A., … Hensley, M. (2011). Outcomes for implementation research: Conceptual distinctions, Measurement Challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research*, *38*(2), 65–76. doi:10.1007/s10488-010-0319-7

Radnor, Z. J., Holweg, M., & Waring, J. (2012). Lean in healthcare: The unfilled promise? *Social Science & Medicine*, *74*(3), 364–371. doi:10.1016/j.socscimed.2011.02.011

Reinertsen, J. L., & Clancy, C. (2006). Foreword to: Keeping our promises: Research, practice, and policy issues in health care reliability. A special issue of Health Services Research*. *Health Services Research*, *41*(4p2), 1535–1538. doi:10.1111/j.1475-6773.2006.00616.x

Rojas-Smith, L., Ashok, M., Dy, S., Wines, R., & Teixeira-Poit, S. (2014). *Contextual frameworks for research on the implementation of complex system interventions: Methods research report*. Agency for Healthcare Research and Quality, Rockville, MD. www.ncbi.nlm.nih.gov/books/NBK196199/

Sanson-Fisher, R. W., D'Este, C. A., Carey, M. L., Noble, N., & Paul, C. L. (2014). Evaluation of systems-oriented public health interventions: Alternative research designs. *Annual Review of Public Health*, *35*(1), 9–27. doi:10.1146/annurev-publhealth-032013-182445

Shigeo, S. (2008). *A study of the Toyota production system: From an industrial engineering viewpoint*. New York, NY: Productivity Press.

Shirey, M. R. (2013). Lewin's theory of planned change as a strategic resource. *The Journal of Nursing Administration*, *43*(2), 69–72. doi:10.1097/nna.0b013e31827f20a9

Shortell, S. M., Blodgett, J. C., Rundall, T. G., Henke, R. M., & Reponen, E. (2021). Lean management and hospital performance: Adoption vs. implementation. *Joint Commission Journal on Quality and Patient Safety*, *47*(5), 296–305. doi:10.1016/j.jcjq.2021.01.010

Shortell, S. M., Blodgett, J. C., Rundall, T. G., & Kralovec, P. (2018). Use of lean and related transformational performance improvement systems in hospitals in the United States: Results from a national survey. *Joint Commission Journal on Quality and Patient Safety*, *44*(10), 574–582. doi:10.1016/j.jcjq.2018.03.002

Shortell, S. M., Rundall, T. G., & Blodgett, J. C. (2021). Assessing the relationship of the human resource, finance, and information technology functions on reported performance in hospitals using the Lean management system. *Health Care Management Review*, *46*(2), 145–152.

Silich, S. J., Wetz, R. V., Riebling, N., Coleman, C., Khoueiry, G., N, A. R., … Szerszen, A. (2012). Using Six sigma methodology to reduce patient transfer times from floor to critical-care beds. *Journal for Healthcare Quality*, *34*(1), 44–54. doi:10.1111/j.1945-1474.2011.00184.x

Souza, D. L., Korzenowski, A. L., Alvarado, M. M. G., Sperafico, J. H., Ackermann, A. E., Mareth, T., & Scavarda, A. J. (2021). A systematic review on lean applications' in emergency departments. *Healthcare*, *9*(6), 763. doi:10.3390/healthcare9060763

Sullivan, J. L., Rivard, P. E., Shin, M. H., & Rosen, A. K. (2016). Applying the high reliability health care maturity model to Assess Hospital Performance: A VA case study. *Joint Commission Journal on Quality and Patient Safety*, *42*(9). doi:10.1016/s1553-7250(16)42080-5

Tlapa, D., Zepeda-Lugo, C. A., Tortorella, G. L., Baez-Lopez, Y. A., Limon-Romero, J., Alvarado-Iniesta, A., & Rodriguez-Borbon, M. I. (2020). Effects of lean healthcare on patient flow: A systematic review. *Value in Health*, *23*(2), 260–273. doi:10.1016/j.jval.2019.11.002

Tosuner, Z., Gucin, Z., Kiran, T., Buyukpinarbasili, N., Turna, S., Taskiran, O., & Arici, D. S. (2016). A Six sigma trial for reduction of error rates in pathology laboratory. *Turkish Journal of Pathology*. doi:10.5146/tjpath.2015.01356

Toussaint, J., & Adams, E. (2015). *Management on the mend: The healthcare executive guide to system transformation*. Appleton, WI: ThedaCare Center for Healthcare Value.

van der Tweel, I., & van der Graaf, R. (2013). Issues in the use of stepped wedge cluster and alternative designs in the case of pandemics. *The American Journal of Bioethics*, *13*(9), 23–24. doi:10.1080/15265161.2013.813603

Udod, S. A., Duchscher, J. B., Goodridge, D., Rotter, T., McGrath, P., & Hewitt, A. D. (2020). Nurse managers implementing the lean management system: A qualitative study in Western Canada. *Journal of Nursing Management*, *28*(2), 221–228. doi:10.1111/jonm.12898

Ulhassan, W., Sandahl, C., Westerlund, H., Henriksson, P., Bennermo, M., von Thiele Schwarz, U., & Thor, J. (2013). Antecedents and characteristics of Lean thinking implementation in a Swedish hospital. *Quality Management in Health Care*, *22*(1), 48–61. doi:10.1097/qmh.0b013e31827dec5a

Viechtbauer, W., Kotz, D., Spigt, M., Arts, I. C. W., & Crutzen, R. (2014). Response to keriel-gascou et al.: Higher efficiency and other alleged advantages are not inherent to the stepped wedge design. *Journal of Clinical Epidemiology*, *67*(7), 834–836. doi:10.1016/j.jclinepi.2014.02.015

Woodhouse, K. D., Volz, E., Maity, A., Gabriel, P. E., Solberg, T. D., Bergendahl, H. W., & Hahn, S. M. (2016). Journey toward high reliability: A comprehensive safety program to improve quality of care and safety culture in a large, multisite radiation oncology department. *Journal of Oncology Practice*, *12*(5). doi:10.1200/jop.2015.008466

Zepeda-Lugo, C., Tlapa, D., Baez-Lopez, Y., Limon-Romero, J., Ontiveros, S., Perez-Sanchez, A., & Tortorella, G. (2020). Assessing the impact of lean healthcare on inpatient care: A systematic review. *International Journal of Environmental Research and Public Health*, *17*(15), 5609. doi:10.3390/ijerph17155609