Acceptance of lean redesigns in primary care: A contextual analysis

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Background: Lean is a leading change strategy used in health care to achieve short-term efficiency and quality improvement while promising longer-term system transformation. Most research examines Lean intervention to address isolated problems, rather than to achieve broader systemic changes to care delivery. Moreover, no studies examine contextual influences on system-wide Lean implementation efforts in primary care.

Purpose: The aim of this study was to identify contextual factors most critical to implementing and scaling Lean redesigns across all primary care clinics in a large, ambulatory care delivery system.

Methodology/Approach: Over 100 interviews and focus groups were conducted with frontline physicians, clinical staff, and operational leaders. Data analysis was guided by a modified Consolidated Framework for Implementation Research (CFIR), a popular implementation science framework. On the basis of expert recommendations, the modified framework targets factors influencing the implementation of process redesigns. This modified framework, the CFIR-PR, informed our identification of contextual factors that most impacted Lean acceptance among frontline physicians and staff.

Findings: Several domains identified by the CFIR-PR were critical to acceptance of Lean redesigns. Regarding the *implementation process* acceptance was influenced by time and intensity of exposure to changes, "top-down" versus "bottom-up" implementation styles, and degrees of employee engagement in developing new workflows. Important factors in the *inner setting* were the clinic's culture and style of leadership, along with availability of information about Lean's effectiveness. Last, implementation efforts were impacted by *individual and team characteristics* regarding changed work roles and related issues of professional identity, authority, and autonomy.

Key words: Consolidated Framework for Implementation Research, context, intervention acceptance, lean process improvement, primary care redesign, qualitative research

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Practice Implications: This study underscores the need for change leaders to consider the contextual factors that surround efforts to implement Lean in primary care. As Lean redesigns are scaled across a system, special attention is warranted with respect to the implementation approach, internal clinic setting, and implications for professional roles and identities of physicians and staff.

A growing body of literature points to the influence of context when implementing clinical and organizational interventions in health care (Damschroder et al., 2009; Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004; Ovretveit, 2011). This study identifies contextual factors most critical to implementing "Lean" management, a leading methodology that is increasingly used in health care to improve short-term efficiency and quality while also promising longer-term system transformation (Meyer, 2010; Toussaint & Berry, 2013). Lean is a set of organizational principles, practices, and problem-solving tools designed for improving quality and business processes (Shah & Ward, 2007). Some defining features of a Lean system include streamlined work processes to enhance efficiency and "flow" of production, task standardization to establish a common baseline from which to measure continuous improvements, and redefinition of personnel roles to facilitate greater ownership over quality standards (Spear & Bowen, 1999; Womack, Byrne, Flume, Kaplan, & Toussaint, 2005).

Full Lean transformation (e.g., workforce empowerment, strategic alignment across all levels of the organization) depends heavily on the supportiveness of the context in which Lean initiatives are introduced (Harrison et al., 2014; Ulhassan et al., 2013). On the basis of a review of Lean in the health care sector, most research studies do not consider broader contexts and instead focus on the narrow use of Lean techniques to solve isolated problems (DelliFraine, Langabeer, & Nembhard, 2010). There have been few studies of Lean's contributions to systemic change. Moreover, almost no studies examine Lean implementation in outpatient settings. Many ambulatory physicians have limited experience with interprofessional teamwork, continuous quality improvement, and standardization of care practices, all of which are hallmarks of Lean improvement programs. In addition, managers in ambulatory care clinics and even at the medical group level often lack experience in change management; few also have the resources and infrastructures needed to hire and effectively deploy external experts. Hence, Lean implementation in ambulatory care may face greater barriers and distinctive challenges in comparison to inpatient settings.

This study furthers knowledge about Lean implementation in primary care by drawing on observations of a major improvement initiative in a large, ambulatory care delivery system. Using qualitative methods, we sought to identify the most salient contextual factors impacting the implementation and spread of Lean-based redesigns as they were scaled across all primary care clinics within the system. Specifically, our research aim was to draw on a recent modification of a well-established framework in implementation science to investigate the acceptance of Lean changes as they were introduced to frontline physicians and care team staff.
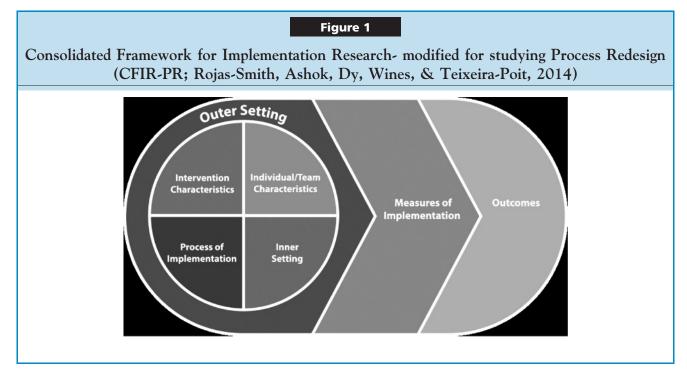
Conceptual Framework

Our analysis is informed by a recently modified version of the Consolidated Framework for Implementation Research (CFIR), a widely used implementation science framework (Damschroder et al., 2009). The original CFIR contains five domains: (a) *outer setting*, (b) *inner setting*, (c) *intervention characteristics*, (d) *implementation process*, and (e) *individual/ team characteristics*. The modified CFIR adds two additional domains: *intervention outcomes*, such as quality and efficiency, and *measures of implementation*. The *measures of implementation* domain includes constructs such as the acceptance, adoption/abandonment, cost, fidelity, reach, and sustainability of new interventions (Proctor et al., 2011). By adding these domains, the modified framework focuses the researcher's attention squarely 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 aims or outcomes (e.g., efficiency, quality). In addition, the modified CFIR introduces constructs and definitions relevant to research on specific types of complex system interventions. The version we used, shown in Figure 1 (hereafter CFIR-PR), reflects expert recommendations for research specifically targeting process redesigns (Rojas Smith, Ashok, Dy, Wines, & Teixeira-Poit, 2014).

Our study examines how implementation context affects intervention *acceptance*, one of the intermediate measures of implementation as previously described. We defined *acceptance* as the degree to which those impacted by the change effort embraced Lean redesigns, and we investigated this among frontline physicians and staff as the changes were scaled across all primary care clinics in the delivery system. We chose acceptance as our focal concept due to the importance of initial perceptions, understandings, and need for "buy-in" of Lean changes among frontline providers in achieving sought-for intervention outcomes. Acceptance may also be critical for the sustainment of Lean redesigns. Although frontline providers who do not fully accept the Lean initiative might conform to early mandates to implement changes, these providers would be likely to

Figure 1

Consolidated Framework for Implementation Research- modified for studying Process Redesign (CFIR-PR; Rojas-Smith, Ashok, Dy, Wines, & Teixeira-Poit, 2014)

abandon or inadequately support the redesigns once attention is diverted to other initiatives that compete for staff time and resources (Buchanan, Fitzgerald, & Ketley, 2007).

Although it does not single out acceptance, the CFIR does encourage researchers to consider implementation processes and intervention characteristics, which were also of potential importance for our study. Among the latter are the perceived evidence supporting an intervention, its advantages over alternatives, complexity, and adaptability to the local setting. CFIR-PR adds other factors that may affect acceptance and that are particularly relevant to process redesigns, including leaders' vision for the intervention and their change strategy, degree of reliance on end-users for implementation, alignment with the values and norms of users, and ways that the intervention impacts workflows and tasks (e.g., standardization).

Background

Study Setting

The organization studied is a large, not-for-profit, ambulatory care delivery system with clinics that are very similar to those found in medical groups across the United States. The system's nearly 1 million patients are primarily insured by commercial fee-for-service plans (70%); a minority belong to commercial HMOs (12%), Medicare/Medicaid (13%), or use other forms of payment (compare Cothran, 2013). Prior to the introduction of Lean, none of the clinics followed highly standardized clinical procedures,

but all used a single electronic record and financial system. Unlike many primary care groups, the physicians in the organization studied were all employees of the same organization.

Lean Implementation

In response to external market pressures for greater affordability, senior executives with the support of a newly created Lean Unit introduced a strategic initiative to improve quality and efficiency across the delivery system. This was a proactive effort to address challenges underlying a changing national health care landscape, including health care reform, a growing patient population, and increasing pressure to contain costs. Such changes motivated leaders to find ways of "doing more with less," a fundamental aim of Lean thinking. Lean was also pursued as a way to meet distinctive challenges in primary care, such as physician fatigue and burnout. Senior leaders sought to make physician workloads more manageable by reducing their administrative burden and streamlining care processes. Lean was implemented to address these issues while also improving care quality and patient experience.

Organizational leaders envisioned a system-wide implementation of Lean, with redesign of clinical operations beginning in primary care. The organization introduced Lean redesigns in three consecutive phases, each with an implementation period of approximately 4–6 months (see Figure 2). Implementation started in one pilot clinic ("Phase 1") and then included three more test clinics ("Phase 2"); thereafter, the redesigns were implemented in all remaining primary care clinics ("Phase 3"). Hired

	Number of Primary Care Clinics	Implementation Length of Time[*]	Sequence of Redesign Activities
Phase 1 (Pilot)	1	6 months	The same set of redesigns were implemented in all clinics:
Phase 2	3	5 months	5S, Call Management, Co-location, Flow
Phase 3	13	4 months	

Figure 2

Lean implementation across delivery system

*Length of time provided for the average-sized clinic in each phase

Lean consultants and internal Lean Unit trainers consisting of local operational leaders and physician champions worked with frontline physicians and staff to redesign patient exam rooms, care team work spaces, and daily workflows. The following sequence applied to all clinics: (a) "5S" standardization of medical equipment, supplies, and health education materials in exam rooms; (b) call management and redesign of call center functions; (c) co-location of physician and non-physician teams in a shared workspace; and (d) redesign of care team workflows.

The 5S technique (i.e., Sort, Sweep, Shine, Standardize, Sustain) minimized searching for supplies by ensuring that all medical equipment, supplies, and patient education materials were located according to a standard arrangement in appropriate areas. Next, call center functions were redesigned to enable more efficient appointment scheduling, management, and triage of patient calls. To enhance communication and teamwork, physician and medical assistant (MA) dyads were co-located in open work spaces. Finally, standardized work processes were developed for care teams, with an aim of optimizing patient flow. These work processes, known as "Flow" redesigns, included daily morning huddles to review patient schedules, agenda setting with patients by the MA at the start of each visit, and increased MA responsibility for managing patient care tasks as the newly designated "Flow Manager." In this capacity, MAs were encouraged to retrieve all incoming items from the physician's inbox, including patient messages, lab/imaging results, prescription refills, and referral requests. As appropriate, MAs were directed to address the task or prepare it for the physician to act upon. When these redesigns were implemented well, care teams were said to be "in-flow."

Methods

Members of a research team affiliated with the organization and charged with conducting an independent evaluation of Lean implementation conducted this study. We used qualitative methods as implementation in practice-based settings involves complex processes that are best captured with in-depth, qualitative inquiry. Moreover, qualitative data can yield nuanced insights into the perceptions and experiences of clinic staff undergoing change. The team conducted in-depth interviews with 69 frontline physicians, 21 physician leaders, and 23 operational leaders at 10 different clinics, for a total of 113 one-on-one interviews (see Figure 3). In addition, we conducted 11 focus groups consisting of approximately three to six MAs per group, with two moderators present at seven of the focus groups (Kitzinger, 1995; Krueger & Casey, 2009). We preferred to use focus groups with MAs because we anticipated that they would be cautious about expressing views critical of the organization in a formal, one-on-one setting and would be more likely to air their opinions freely in a group where opinions would not be attributed to specific respondents.

The researchers e-mailed all organizational leaders, physicians, and MAs who were employed at the time that their clinics had undergone Lean redesigns. The interview request explained the purpose of the research and assured confidentiality. Interviewers used semistructured interview and focus group guides to elicit perceptions of the Lean initiative and acceptance of its redesigns, along with descriptions of major factors affecting the implementation and sustainment of Lean-based practice changes. In particular,

Figure 3

Interviews by professional role

	Contacted	Interviewed
Family Practitioners	72	26
Internists	58	19
Pediatricians	47	24
Physician Leaders	21	21
Operations Leaders	24	23
Total interviews	222	113

the guides directed attention to contextual factors identified by the CFIR-PR.

The organization's institutional review board approved all data collection activities. Participation was voluntary, and we obtained written informed consent. Audio recorded sessions lasted between 30 and 60 minutes, and a professional service transcribed all recordings. We used Atlas.ti version 7.0.83 software for qualitative data management and analysis of all transcripts, which were coded using a deductive approach for this study. We created an initial set of codes from the constructs and subconstructs identified in the CFIR-PR and anchored the data around the concept of intervention "acceptance." The constructs in the CFIR-PR were generally broad and comprehensive enough that they captured all of the relevant data. However, we found during analysis that some codes were oversaturated with data, whereas others were rarely used. For example, because the data revealed many insights into the implementation process, we refined some of the broad categories within this CFIR-PR domain so that our coding scheme captured the nuances. To ensure reliability, we engaged in independent parallel coding, and discrepancies were discussed and reconciled (Thomas, 2006). During analysis, we paid particular attention to factors impacting Lean implementation and to staff perspectives as they varied across clinics. Codes were grouped together around clusters of themes, which resulted in broader conclusions about Lean implementation and spread across the delivery system.

■ Findings

Implementation Process: Time and Intensity, Engagement Levels, and Overall Approach

One of the most important factors influencing providers' acceptance of Lean-based redesigns among physicians and staff was the *process* used to implement the changes. In Phase 1 of Lean implementation at the pilot site, frontline physicians, clinic staff, and local managers engaged deeply and at length in analyzing current workflows before designing changes to them. Workforce time and engagement in such activities decreased with each subsequent implementation phase. In particular, those in Phase 3 were the least engaged in planning Lean designs and had little opportunity to adapt changes to their own clinic environments. In parallel, our interviews showed that participants from Phase 3 were the most critical of the Lean initiative, whereas those in Phase 1 were most enthusiastic and accepting. To illustrate, according to a physician in the Phase 1 pilot clinic:

What helped [make the Lean redesign successful]…was the whole planning process, but [also] meeting very

frequently through the process. Every week, we would meet as we were going through the training…and meet with the doctors and the MAs all together…where everybody could hash out what's working, what's not working. Everyone got to be heard and felt like their input really made a difference rather than just saying, "Okay, here's what we're doing. Go for it. You're on your own." (Respondent ID: 32)

According to another comment from a Phase 1 physician leader: "*I really feel like…we really created it and maybe that's because we were the first site. We really were involved in how it came about*" (Respondent ID: 72). These comments reflect a sense of ownership of workflow changes that resulted from deep engagement in the redesign process. As Lean was scaled across clinics, the redesigned workflows became more and more solidified, and the implementation effort shifted from creation and design to training and adherence with less flexibility for change. As such, we heard few positive comments about Lean from those in subsequent phases of implementation. The following statement by a Phase 3 physician reflects the types of sentiments that arose as Lean was spread to remaining clinics:

The truth is, actually before [Phase 1 clinic] came out, I'd have to say I considered myself a partner in the [medical] group. I had a bit of a voice in the way things happened, at least in the group, and then honestly, after [Lean] rolled out, I feel much more just like an employee. I don't really feel like a partner here. I feel like I'm just here to follow commands, see patients and go from there. (Respondent ID: 138)

The overall implementation approach significantly impacted frontline perceptions and experiences of Lean changes. When asked to reflect on the implementation of Lean in their clinics, many participants distinguished between a "top-down" (i.e., management driven) versus "bottom-up" (i.e., driven by frontline staff) approach. With the exception of staff in the Phase 1 pilot clinic, most staff characterized Lean implementation as a top-down effort led by "higher ups" with little room for adjusting designs as needed. The pilot clinic and its leadership, largely because its members were committed to more of the hands-on design work, experienced the most "bottom-up" approach to Lean implementation, whereas participants in subsequent phases experienced a more "top-down" approach. Some clinic participants thought that, despite the negative connotation, this top-down approach was appropriate and necessary given the magnitude of system-wide changes. For others, it seemed at odds with Lean principles of workforce empowerment, and consequently, the most resistance was found in clinics where the implementation approach was perceived as being most top-down.

Inner Setting: Organizational Culture, Local Leadership, and Access to Information

The organizational culture within clinics also affected acceptance of Lean redesigns. Differences tended to cluster around whether or not clinic members described their culture as more or less democratic versus hierarchical. For instance, members at one clinic almost uniformly characterized it as highly democratic and nonhierarchical. Because of this, some found Lean severely at odds with their clinic's more democratic leadership style. As a Phase 2 clinic leader described it:

> *The problem with Lean in [our clinic's] culture is that we've been an organization, historically, that's worked well together and solved problems as they've come up. Lean came out of somewhere from the clouds, and we were told, "This is what is going to happen." And when you do that to people, and I think particularly people here, they tend to have a reflex rebellion.* (Respondent ID: 51)

Within the broader culture of any given clinic, microcultures also existed. Microcultures within our study organization were largely fostered by local leadership, namely physician department heads and clinical staff managers. Leaders who encouraged frontline engagement with the change effort, were receptive to feedback, and transparent in communicating messages were more able to foster a climate that supported Lean implementation. Even when staff described the change effort as difficult and expressed skepticism about some of the proposed workflows, they nevertheless had sufficient faith in their immediate managers and leaders that they were willing to at least "*try Lean out*" or "*give it a chance,*" thus enhancing the likelihood of successful adoption of Lean redesigns.

Access to information about the initiative and the proposed changes also emerged as a critical aspect of the inner setting, particularly when scaling Lean across clinics. Because providers in Phases 2 and 3 were not originally involved in creating the redesigned workflows, they needed to trust that those in the pilot had designed the most appropriate and beneficial system of delivering care. However, leaders and frontline physicians in Phases 2 and 3 expressed skepticism that what the pilot had developed were in fact the most useful and efficient workflows. Physicians and physician leaders in particular repeatedly expressed interest in seeing data that showed the effectiveness of the Lean redesigns. In fact, Lean lacks a documented track record in primary care from which program advocates could readily draw. Moreover, besides focusing on discrete problems or objectives, Lean operates as a general change strategy that can be applied to a wide range of problems and outcomes. Though the organization was compiling metrics that could document specific improvements in efficiency over time (e.g., patient chart closure times, provider response times to patient messages), much of these data were not available during the "roll-out" of Lean. Leadership acknowledged this limitation, with one primary care director commenting,

> *It is going to be a real barrier if we [have] good processes, [but] we don't have the analytical support to show that we achieved what we thought we were going to achieve. It is a recipe for failure if we go to the next roll-out site and they say, "Well, how did the previous site do?" and we say, "Well we think they did pretty well, but we have no numbers."* (Respondent ID: 33)

Most clinical interventions require a robust evidence base supporting their effectiveness before physicians are willing to accept them. Lack of this evidence during the spread of Lean redesigns contributed to some skepticism and unwillingness to embrace Lean fully, particularly on the part of rank-and-file physicians.

Individual/Team Characteristics: Work Roles and Relationships, Professional Identities

The social and occupational roles of physicians and nonphysician staff also affected their acceptance of Lean. As part of the Lean-based redesigns, organizational leaders reconfigured the MA's role. This redesign required behavior changes for both MAs and physicians. The newly defined roles for MAs in the dyadic care teams required more intensive interactions on a more equal footing than had been the case. Although the role change was more literal for newly designated MA Flow Managers, physicians also needed to adapt to major changes in their daily routines and the ways that they related to their dyad partners.

MAs reported some challenges around learning their new roles and adjusting to changes in clinic operations. Physicians, on the other hand, were more openly resistant, though this was not the case for all respondents. More recently trained physicians were more likely to accept the redesigns compared to more veteran colleagues and showed greater familiarity and comfort with the concept of working as a care team. There were also some physicians who had been in practice longer, but nevertheless thought their work processes were inefficient and could benefit from extra help from the MAs. The physicians who were most resistant to change and least willing to accept new roles and workflows were individuals who believed that they were already highly efficient and hence doubted that they would benefit from a Lean approach to process improvement.

One of the most significant changes occurring with Lean implementation was the physical co-location of care teams. In all primary care departments, physicians and their dyad partners—typically an MA but in some instances a licensed vocational nurse—were assigned to sit side-by-side in a shared communal space. Designed to enhance work flow, co-location was an abrupt change for many physicians who

were accustomed to working privately in their offices. Some physicians described how challenging it was to work in a shared space with numerous potential distractions. Though rare, some physicians found the move to co-locate out of alignment with their identities as autonomous physicians. MAs and nurses, who were more accustomed to sharing work spaces prior to the redesign, did not experience this level of discomfort or encounter much difficulty in adjusting and adapting to the new physical arrangements. Despite some of these initial challenges, co-location proved to be one of the largest wins for the organization by facilitating communication and workflow. Notably, physicians routinely identified co-location as the most positive change to come out of the Lean redesign effort.

Related to issues of professional identity, some physicians were skeptical that nonclinical administrative leaders and "upper management" really understand what happens in clinics "on the ground." The following quote from a physician underscores this observation: *"I felt very much like, wait a minute here…I'm already being very efficient. …I've been patted on the back for being efficient and having good patient satisfaction [scores], and now someone else who's not a physician is coming in to tell me how to do my work"* (Respondent ID: 84). This sentiment illustrates the concern that some physicians had about Lean as a management-based intervention and its potential to threaten their authority as medical professionals.

This issue was also apparent around standardization of care team tasks and work processes, another essential feature of the Lean initiative. Leadership at all clinics acknowledged that the concept of work standardization is often met with unease, particularly among physicians. The following comment by a frontline physician represents such perspectives on the concept of standardization:

I think that there [have] been some things about the standard workflows which are very good and benefit everybody. But I do think that you can get into the problem of eliminating people's ability to feel like an individual. And I think somehow or another that needs to be maintained. (Respondent ID: 52)

Leadership consistently attempted to assuage these concerns by insisting that Lean redesigns aimed to improve the *process of delivering* care, not the actual clinical work of physicians. Indeed, physicians who perceived the Lean redesign as allowing for professional discretion and, in a sense, allowing them to "just be doctors," were most likely to accept Lean redesigns. Physicians who were concerned that it infringed on their professional autonomy or decision-making practices were more likely to either outwardly or subtly resist the effort. In contrast, MAs typically expressed appreciation for the new standardized workflows and thought that having expected and uniform "standards" around their work made the work environment more fair

and consistent. These different reactions to the notion of work standardization reflected the vastly different occupational and social roles of physicians and staff.

Discussion

We used a recent modification of a widely used implementation science framework (CFIR) to guide our study of contextual factors affecting acceptance of Lean redesigns as they were spread across primary care clinics in an ambulatory care delivery system. This modified framework for process redesign (CFIR-PR) directs attention to intermediate measures of implementation, such as intervention acceptance, that may moderate relations between context and ultimate outcomes of the intervention, such as quality and efficiency. In addition, the CFIR-PR specifies contextual factors likely to be particularly influential when implementing process redesigns. To start, we sought to account for all types of contextual influences on Lean implementation. During the course of analysis, several distinct factors (summarized in Figure 4) emerged as most salient to acceptance of the redesigns among frontline physicians and staff. These factors included features of the *implementation process*, particularly the time and intensity of exposure to redesigns when first introduced to care providers; whether the implementation approach was "top-down" or "bottom-up"; and the level of workforce engagement in developing new workflows. Other important contextual domains were the *inner setting*, which included the clinic culture, style of local leadership, and availability of evidence on Lean's effectiveness. Last, *individual and team characteristics* chiefly impacted the success of redesign efforts through changes in work roles and relationships between physicians and nonphysician staff and as these changes related to issues of professional identity, authority, and autonomy.

Although we discussed the effects of these factors separately, many contextual features were interrelated and contributed jointly to frontline responses to the implementation of Lean. For example, the top-down approach may have lent itself to increasing levels of standardization, particularly among those in the later adopting sites. The interaction of these factors may help explain much of the resistance to Lean changes. Another example involves the effects of decreasing levels of workforce engagement across implementation phases. This lack of frontline involvement clashed with clinic cultures in settings with a more democratic style and history of collective problem solving.

Regardless of whether the overall implementation approach is top-down or bottom-up, finding ways to engage the workforce seems necessary as Lean redesigns are scaled across multiple sites. Our findings suggest that a greater degree of "prework," or preparing the workforce prior to implementation, is important to later success of Lean change initiatives. As noted by other studies examining the influence of context on quality efforts including Lean

Figure 4

Summary of findings

Contextual Factors Impacting Acceptance of Lean Redesigns Among Frontline Primary Care Physicians and Staff
Implementation Process
❖ Time and intensity of exposure to intervention ❖ Implementation approach (top-down or bottom-up) ❖ Engagement levels in redesigning workflows
Inner Setting
❖ Organizational culture (democratic versus authoritarian) ❖ Leadership style (flexibility and transparency) ❖ Access to evidence of intervention's effectiveness
Individual/Team Characteristics
❖ Role expectations (physicians, medical assistants) ❖ Professional identities, authority, and autonomy

redesigns, necessary preparatory work includes facilitating workforce buy-in through engagement in problem solving and design of local workflows, actively involving staff across disciplines and hierarchical levels, establishing a culture of mutual trust with local leadership, and establishing a clear and consistent communication plan (Harrison & Kimani, 2009; Lukas et al., 2007). A literature review on Lean implementation confirms that successful transformation requires that all affected groups take an active role in planning Lean redesigns and that the effort takes an adaptive-oriented approach to fit local needs and cultures (Poksinska, 2010). Research on innovations (Rogers, 1995) also provides ample evidence of the contributions to acceptance of participant engagement and local adaptation of innovations during spread. When Lean is implemented in one pilot clinic before scaling to multiple additional sites, as was the case in this study, due diligence in preparing each site as a novel and unique "implementation environment" will likely yield desired results. Following these proactive measures of preparation, allowing adaptation of an intervention to local contexts is likely to lower barriers to adoption, thus increasing implementation success (Rogers, 1995).

An effective avenue for accomplishing such preparatory work is through local leadership. As both our study findings and others have noted, local leaders wield both practical and symbolic influence that can be very effective in priming the workforce for change (Ferlie & Shortell, 2001). Other studies of Lean process redesigns have identified mid-level and frontline leaders in particular, such as department managers or physician heads in our study organization, as motivators of change and knowledgeable procurers of resources needed for their own unique clinical environments

(Harrison et al., 2014; Lukas et al., 2007; Poksinska, 2010; Stephens, Carman, Smeeding, Paez, & Yegian, 2012). Mid-level and frontline leaders are best positioned to identify and address local barriers to change, communicate executive plans to the frontline, and provide symbolic as well as operational support for the overall implementation effort (Damschroder & Lowery, 2013; Harrison et al., 2014).

Finally, our study highlights ways that Lean-based redesigns can change roles and interactions among members of a care team. In health care, many of these roles and interactions are deeply institutionalized; hence, significant retraining or shifts in routines and assumptions are needed to facilitate the types of collaborative teamwork and open communication that are needed for continuous improvements in quality and efficiency. The skills underlying these work modes are not typically emphasized in clinical training. Therefore, it is not surprising that studies identify status differences, physician autonomy, and the hierarchical structure of medical care as significant barriers to Lean implementation (Mazzocato, Savage, Brommels, Aronsson, & Thor, 2010; Poksinska, 2010).

Although implementation of Lean in the primary care clinics we studied had much in common with that occurring in inpatient settings, our study suggests that some implementation challenges may loom particularly large in primary care. Primary care physicians are often used to acting as the sole health care provider and frequently lack experience working in interdisciplinary teams. Such physicians may be particularly resistant to initiatives that call for interprofessional teamwork, even to the extent of giving up personal offices to work in a shared space. In addition, the clinics in which many primary care physicians work and

the entities to which these clinics belong often lack the internal expertise needed to train and manage staff during an organization-wide improvement initiative. Nor do most primary care systems have the resources to purchase and deploy outside expertise or to provide staff with sufficient released time to learn to implement proposed redesigns.

In contrast, the organization we studied did allocate substantial resources to Lean training and planning and created an entire new unit to oversee the initiative. This organizational capacity and history may limit the generalizability of findings from our study to other less well-resourced primary care systems. Generalizability to other settings may also be limited by the fact that the frontline providers we interviewed were all employed by the same organization. In addition, our study may suffer from self-selection bias among frontline physicians and staff who agreed to participate in interviews. Related to this, operational and physician leaders may have censored what they revealed in interviews, though assurances were made to protect their identities and that of all other study participants. Nevertheless, we found responses to be quite candid in which both positive and negative viewpoints were well represented.

In addition to illuminating Lean implementation in primary care, our study illustrates potential applications of a popular research framework as recently modified based on expert opinion. CFIR-PR, unlike the original CFIR, directed out attention to the intermediate outcomes of implementation, labeled as *measures of implementation* as shown above in Figure 1. Drawing on this modified framework, we assumed that these intermediate outcomes mediate between implementation context and sought-for outcomes such as efficiency. That assumption led to our focus on physician and staff acceptance of the Lean initiative and its redesigns of primary care teams and workflows. In addition, some constructs included in the *inner setting* within the CFR-PR, but not in the original CFIR, alerted us to potentially influential features. Chief among the features that emerged from interviews as being important to implementation were aspects of the Lean intervention itself—including the degree to which the intervention called for standardization of work, altered current workflows, and affected special arrangements of practice. More generally, the CFIR-PR directed our attention to the degree to which Lean seemed to staff to require radical departure from current ways of operating. The CFIR-PR also highlighted the extent to which the organization as a whole and the implementing units had the expertise and skills needed to put the redesigns in place. As we saw, lack of experience with interprofessional teamwork was a barrier to implementation for some physicians.

Practice Implications

This study underscores the need for change leaders to consider carefully the contextual factors that affect uptake and success of Lean process improvements in health care. We suggest that redesign initiatives in primary care settings may face some distinctive challenges that deserve attention by both senior and mid-level managers. Although studies generally support the idea that context matters, we highlight particularly salient features—including the implementation approach, alignment with clinic cultures and local leadership, and professional roles and identities—that critically shaped the acceptance of Lean redesigns among frontline physicians and staff. Our study findings are particularly relevant for organizations attempting to implement and scale process improvements across entire care systems, as they highlight areas where leadership at all levels, including executives, department managers, and physician or staff champions, can focus their efforts to enhance the success of new care delivery models. For example, encouraging frontline engagement with change efforts, allowing flexibility in tailoring the intervention to local environments, and keeping lines of communication open for feedback across work functions all served to facilitate uptake of Lean redesigns among those in our study. This interplay between implementation approach, internal clinic environment, and work roles and relationships offers a complex picture of how Lean can be implemented and scaled across multiple sites of a delivery system.

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