Sustainment of Lean Redesigns for Primary Care Teams

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Background: Quality improvements are notoriously followed by "backsliding" or relapse to the status quo. This mixed-methods study examined the sustainment of Lean workflow redesigns for primary care teams several years after being implemented in a large, ambulatory care delivery system. **Methods:** We conducted qualitative interviews of 57 leaders and frontline providers, and fielded post-Lean implementation surveys to 1164 physicians and staff in 17 primary care clinics across the system. We analyzed interviews and conducted independent sample t tests to identify key factors that facilitated the sustainment of new workflows among primary care teams. All analyses were conducted after Lean redesigns were implemented and scaled across the system in 3 consecutive phases. **Results:** Adherence to Lean redesigns was highest in the pilot clinic, despite having the longest postdesign measurement period. Members of the pilot clinic reported greatest participation in designing workflows, were most highly engaged in quality improvement efforts, and held most favorable beliefs about Lean changes. Adherence to redesigns was lowest among clinic members in the second phase of implementation; these members also reported highest levels of burnout. **Conclusions:** Staff participation in Lean redesign is a key to facilitating buy-in and adherence to changes. Change ownership and continued availability of time for improvement activities are also critical to the long-term success of Lean implementation in primary care.

Key words: organizational management, patient care team, primary health care, total quality management, workflow

Although best practices for quality improvement are well studied, there is less research on sustaining changes.[1-3] Efforts to improve quality are notoriously followed by "backsliding" or relapse to the status quo.[4] A wide range of approaches have been taken to help maintain changes,[5] with health care practitioners proposing more systematic ways of integrating interventions into routine clinical practice.[6] Some have pointed to the importance of ensuring the support of organizational leaders, including governing boards,[7] and the need for "implementation-parallel" culture change such as acquiring the buy-in of physician leadership.[8] Such recommendations have come mainly from change experts and experiences of frontline managers. Although there is growing interest in practical techniques to sustain quality improvements, there is a need for further research on ways that both organizational and local workplace features affect the longer term prospects for implemented changes.[9,10]

This need for more research is especially great in primary care settings, where leaders are introducing a wide range of innovations that redesign the entire care delivery process.[11] One example of this trend has been the growing adoption of Lean thinking and management tools to enhance efficiency and quality of care.[1,3,12] Originally applied to manufacturing, Lean aims to introduce new ways of operating that empower frontline staff to make continuous improvements to their daily work.[13] Although past research in health care indicates clear benefits of work optimization using Lean techniques,[12,14] there have been a number of barriers to maintaining Lean practices and methodology for continuous improvement.[15,16]

In light of this need for research on longer term outcomes of quality initiatives, and particularly of Lean implementations, this study examines the sustainment of Lean workflow redesigns for primary care teams several years after being implemented in a large, ambulatory care delivery system. We use mixed methods to examine physician and staff experiences after new workflows were introduced and scaled to all clinics across the system. As researchers located within the organization, but fully independent in the conduct and reporting of findings, we were uniquely well positioned to observe a full range of activity, beginning with the initial implementation, subsequent spread, and finally,

the sustainment of process redesigns for primary care teams. In this article, we identify how potential differences in early implementation approaches and workplace environments may have contributed to varying levels of sustainment of Lean redesigns.

METHODS

Study setting and Lean intervention
This study was conducted in a not-for-profit, ambulatory care system serving over 1 million patients across 6 counties. Senior leadership planned to deploy Lean as the basis for a system-wide transformation beginning in primary care. This plan reflected the organization's proactive effort to address prevailing challenges, including growing patient demand and increasing pressure to contain costs. Leaders began by creating a Lean Promotion Office staffed by former operational leaders, clinic supervisors, and physician champions. Some of these individuals worked full time in the office, while others remained active in their clinics. Members received formal training in Lean methodology, took part in the training of clinical staff, and served as internal consultants. In addition, external consultants were hired by the organization to conduct initial Lean training for all clinic members, while training and coaching members of the Lean Promotion Office in their work across the delivery system.

Lean redesigns in primary care consisted of 3-day events attended by physician representatives and staff from each clinic. These events included a didactic session on Lean methodology for improving value, followed by mapping by participants of "current state" and envisioned "future state" care processes. After the training, clinic leaders and staff were responsible for implementing the redesigns. Internal consultants from the Lean Promotion Office provided leaders, frontline physicians, and other staff with onsite coaching during an intensive 2- to 3-month period. During this period, they reorganized patient examination rooms and work spaces, and streamlined workflows for delivering patient care. Internal consultants from the Lean Promotion Office provided weekly support to clinics during this time. These implementation and support arrangements were replicated in all clinics during the system-wide initiative.

Lean primary care redesigns were implemented in all clinics using the same sequence of events: (1) "5S" standardization of medical equipment, supplies, and health education materials in patient examination rooms; (2) call management and redesign of call center functions; (3) colocation of dyadic care teams consisting of physicians and medical assistants; and (4) redesign of care team roles and workflows (ie, "Flow" redesigns). Specific Flow redesigns for care teams included introduction and use of daily huddles, agenda setting by medical assistants at the start of patient visits followed by a "warm hand-off" to the physician, and joint management of the electronic inbox to address incoming items throughout the day (eg, test results, referrals, and patient messages).

These redesigns were systematically implemented across all primary care departments housed within 17 distinct clinic locations across the system.

The initiative occurred in 3 phases, starting with 1 pilot clinic (phase 1), followed by 3 test clinics (phase 2), and then completed in 13 remaining clinics (phase 3 of the Lean implementation). At the pilot site, executive leadership invited frontline physicians and staff to develop the new workflow redesigns. With the help of the Lean Promotion Office, these redesigns were then implemented in all other clinics across the system using an "adopt or adapt" approach. This approach meant that clinics in phases 2 and 3 could either adopt the designs originally developed at the pilot site, or alternatively, adapt them to fit their local environments.

Qualitative data collection and analysis
We used qualitative interview data to examine the sustainment of Lean workflow redesigns. Interviews took place nearly 3 years after the redesigns were fully implemented in the pilot site, approximately 2 years after being implemented in phase 2 sites, and an average of 1 year following implementation in all phase 3 clinics. We conducted a total of 57 interviews, which included members of the pilot clinic, members from the 3 "phase 2" clinics, and members from 3 additional clinics in the final "phase 3" of the Lean initiative. Together, these interviews included 30 leaders (eg, department managers, physician heads, clinic, and regional directors), 23 frontline physicians, and 4 medical assistants. We asked participants to describe how and to what extent redesigned workflows and Lean tools for continuous improvement were still in use. In addition, we asked about reasons why changes were or were not maintained. All interviews lasted between 30 and 60 minutes, and were transcribed for analysis by a professional transcription service. All transcripts were entered in Atlas.ti (version 7.0.83) to facilitate data management and analysis.

When analyzing interviews, we sought to understand the level of physician and staff adherence to workflow (Flow) redesigns and overall sustainment of Lean changes. Specifically, we were interested in ascertaining: (1) whether and to what extent Flow redesigns were still used by care teams; and (2) whether Lean management tools were used by leaders and frontline providers to support continuous improvement. We created a set of approximately 15 codes before the first phase of analysis. Some codes were informed by prior literature on factors that lead quality initiatives to lose momentum, including staff turnover, lack of champions for a project, and lack of funding for projects.[17] Other codes emerged through close analysis of the data, and captured recurring topics and concerns in interviews. We coded transcripts using this scheme, adding labels as new insights emerged. After completion, another member of the team independently coded a sample of transcripts. The reliability score or percentage of agreement was 76%.[18] We then developed broader themes related to sustainment based on these codes.

Quantitative data collection and analysis

We also fielded a self-administered survey to 1164 primary care physicians and nonphysician staff (eg, medical assistants, nurses, and receptionists) in all primary care clinics across the system. Depending on the clinic's implementation phase (ie, phases 1 to 3) and similar to interviews, this survey was administered up to 3 years after redesigns were fully completed in the pilot site, nearly 2 years after completion in the second phase, and 8 to 15 months afterward in the third phase. The average response rate across clinics was 74%, with a clinic range of 67% to 77%. This survey assessed the measures listed below and as further detailed in Table 1.

Sustainment of Lean flow redesigns.

We created an overall measure of sustainment based on adherence to the main features of workflow redesigns for care teams. Survey items included the frequency of: *(1) daily huddles* to plan each day; *(2) agenda setting* with patients at the start of each visit; and *(3) joint inbox management* to address incoming patient care items throughout the day. Survey items used a 5-point Likert scale, ranging from 1 (never) to 5 (always). These items were averaged across physicians and clinical staff members to create a composite measure of sustainment in each site.

Work experiences

We assessed levels of *physician and staff engagement* using an adapted version of an employee engagement survey.[19] This instrument had a Cronbach α coefficient of 0.91. Individual survey items assessed work satisfaction, perceptions among staff that their contributions are valued, and degree to which individuals contribute to and understand how their efforts relate to the organization's goals. We also assessed perceptions of each clinic's *work environment* using a validated instrument developed to measure organizational attributes in primary care practices.[20] Included in this instrument are 2 subscales measuring levels of teamwork and participation in decision-making with Cronbach α coefficients of 0.76 and 0.74, respectively.

We assessed *beliefs about Lean changes* using an adapted change readiness scale with high content and convergent validity and high reliability.[21] Beliefs about implemented changes were assessed in 3 domains including effectiveness, appropriateness, and benefits of Lean redesigns with Cronbach αs ranging from 0.68 to 0.89. Finally, the well-validated

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Table 1. Description of Survey Items

Domain	Description
Adherence to Lean workflow redesigns	*Daily huddles:* "In a typical week, how often do you use daily huddles to plan the day?"
	Agenda setting: "For a typical office visit, how often does your care team set the agenda with the patient before the visit begins?"
	Inbox management: "How consistently do you work with your dyad partner to manage messages arriving in the electronic inbox?"
	Overall sustainment: Composite measure of huddles, agenda setting, and inbox management
Physician and staff engagement	*Work satisfaction:* eg, "Overall, I think this is a great place to work."
	Work contributions are valued: eg, "My ideas and suggestions are valued by my clinic," and "My clinic recognizes excellent work."
	Degree to which individuals contribute to and understand how their efforts affect the organization's goals: eg, "I am willing to put in a great deal of effort to help my clinic succeed," and "I understand how my daily work contributes to my clinic's mission."
Work environment	*Teamwork:* eg, "Staff and clinicians in this department operate as a real team," and "We make sure we regularly take time to figure out ways to improve our work processes."
	Participation in decision-making: eg, "All staff members participate in important decisions about clinical operations," and "This clinic encourages staff input for making changes and improvements."
Beliefs about Lean changes	*Effectiveness:* Belief that Lean was an effective mechanism for closing performance gaps (eg, "Lean has improved our effectiveness.")
	Appropriateness: Extent to which Lean change efforts were justified and addressed situations in need of corrective action (eg, "Lean redesigns were the correct change for our situation.")
	Valence: Attractiveness of outcomes from the change with anticipated benefits (eg, "Lean redesigns have benefited me.")
Job-related burnout	*Emotional exhaustion:* Fatigue from delivering patient care (eg, "I feel emotionally drained from my work.")
	Depersonalization: Hardening of attitudes toward patients (eg, "I feel I treat some patients as if they were impersonal objects.")
	Personal accomplishment: Positive self-assessment of care provision (eg, "I feel I'm positively influencing people's lives through my work.")

Maslach Burnout Inventory (MBI—Human Services Version)[22] was used to assess levels of *job-related burnout* and how health professionals view their daily work activities. We used the MBI to measure 3 domains, including emotional exhaustion, depersonalization of patients, and a sense of personal accomplishment, with Cronbach α coefficients ranging from 0.70 to 0.91.

All measures of physician and staff engagement, work environment, and beliefs about Lean changes used 5-point Likert scales, ranging from 1 (strongly disagree) to 5 (strongly agree). Burnout items were assessed on 7-point scales, ranging from 1 (never) to 7 (every day). The items in each domain were averaged for each respondent.

Independent sample t tests were first used to compare sustainment levels as documented in the survey of clinical staff (N = 668), across each of the 3 major phases of Lean implementation. We also compared workplace experiences across the 3 phases after Lean redesigns were completed. We then examined overall correlations between sustainment and workplace features in all clinics, regardless of implementation phase. All quantitative and qualitative data collection and analysis activities were approved by the organization's institutional review board.

RESULTS

Sustainment of Lean flow redesigns
Both the qualitative and quantitative data sources show that Lean workflows continued to be in place across the system, but were adhered to most consistently at the pilot site. According to interviews with leaders and frontline providers in the pilot clinic, most members regularly continued to take part in Lean "standard work," a term used for the changes implemented in their practice environments. Many interviewees commented that Flow designs have become "just the way things are," indicating acceptance of the changes and reluctance to return to prior work patterns. The following quote from a physician in the pilot site underscores this process of routinization:

> I can't imagine not doing things this way anymore. I think everyone sees a lot of us have been getting home earlier and not spending so much time closing our charts. And the benefits of seeing our patients in a timely manner, having our MA [medical assistant] right next us - I don't think any of us want to go back to the way things were.

Phase 2 and 3 clinic members said that workflows were also maintained, but reported less adherence to workflows as compared with the pilot.

Interview findings were corroborated by our survey data. According to responses from frontline physicians and staff, there were substantial levels of sustainment of the main components of the redesigned workflow. The levels were somewhat higher for huddles and inbox management, where physicians and medical assistants

meet and work together, than for agenda setting where medical assistants act more independently to plan the patient's visit time with the physician. In addition, as suggested by the interviews, sustainment as reported in surveys among the second and third-phase clinics was consistently lower than in the pilot site. Figure 1 shows that the pilot had highest levels of overall sustainment and adherence to each Flow component. This is shown in independent sample t tests comparing sustainment across implementation phases, along with a specific comparison to the pilot site grouping phase 2 and 3 clinic responses together. Sustainment was significantly lower in the latter phases of Lean implementation as compared with the pilot site, both overall and for specific elements such as daily huddles and agenda setting. Disaggregated results show that sustainment was consistently lowest in the phase 2 clinics.

Engaging staff in continuous improvement
A key finding from the interviews was that the participative implementation approach used in the pilot clinic was critical to routinizing changes there and to minimizing "slippage," or falling back into previous habits and patterns. When pilot physicians and staff were initially introduced to Lean, they were invited by executive leadership to participate in redesigning their own daily workflows. This form of deep involvement in Flow design facilitated "buy-in" among staff members from the very start of implementation. For example, when asked why the pilot clinic had been so effective in sustaining changes, one physician remarked that, "Even though [Lean] came down from above . . . we really created Flow, and maybe that's because we were the first site. We really were involved in how it came about."

Besides participating in decisions about change, clinic leaders at the pilot site regularly used Lean management tools to foster adherence to the newly designed workflows. The Lean-based "Daily Engagement System," for example, was critical to fostering adherence to new work processes. This technique requires leaders to check-in regularly with frontline physicians and staff to monitor progress, and to provide opportunities for root cause analysis of emergent problems. A physician leader made this comment regarding the Daily Engagement System:

> That small investment upfront of saying, "You know what? I need you fully dedicated to making sure this goes well in the timeframe and with the right steps." I think the return on that investment is huge . . . . We were very intentional about checking in and seeing what's not working, [and asking] how can we tweak things.

In contrast, implementation experiences in phases 2 and 3 differed markedly from the pilot. For example, a physician from a phase 2 clinic shared a very difficult and challenging perception as Lean was spread to his site:
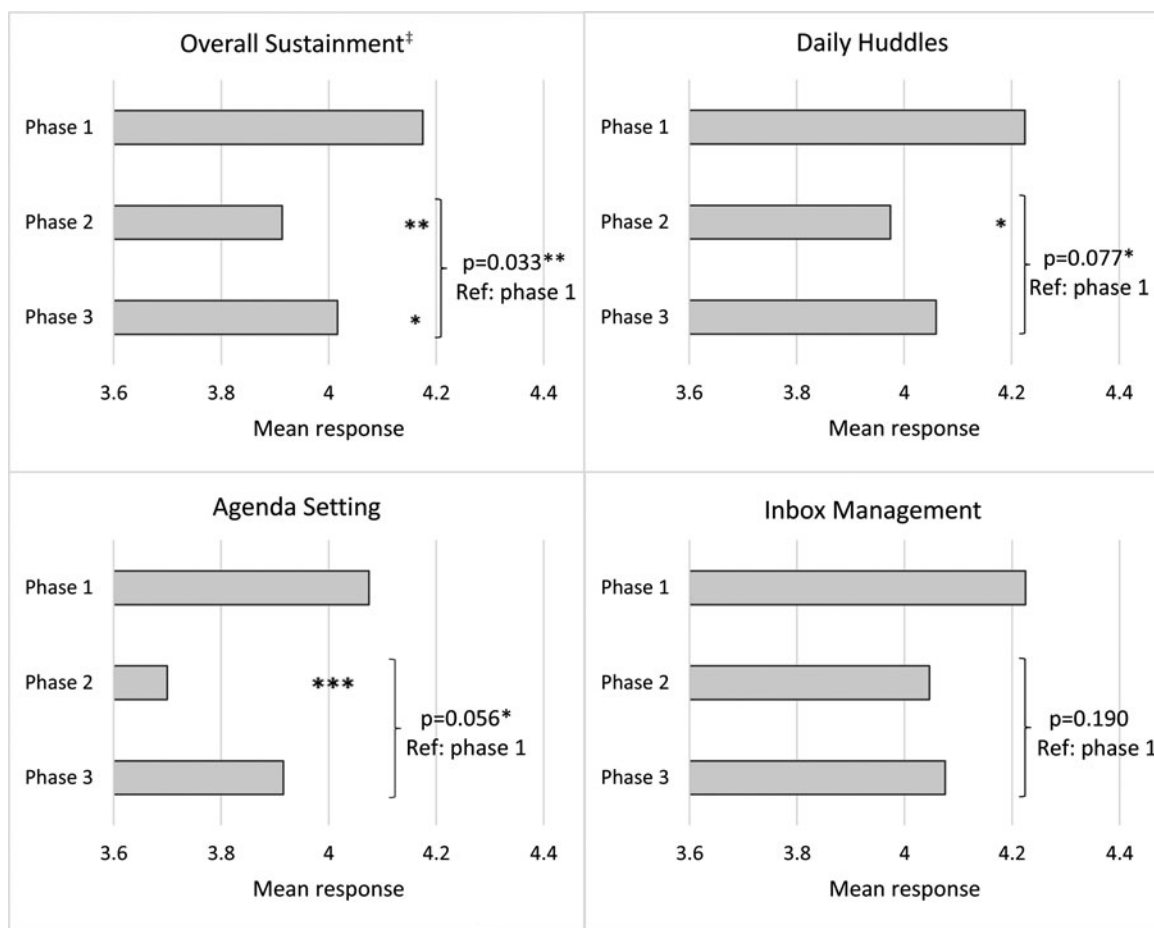
Figure 1. Sustainment of Lean redesigns for care teams. *$P < .10$, **$P < .05$, ***$P < .01$. Note: Asterisks left of the bracket indicate t-test significance of each individual phase compared with phase 1, whereas asterisks right of the bracket indicate t-test significance of phases 2 and 3 combined, compared with phase 1 as the reference group. ‡Overall sustainment is a composite measure of adherence to workflow redesigns, including daily huddles between care team members, agenda setting at the start of patient visits, and joint management of the electronic inbox by physician and medical assistant care teams. Ref indicates reference group.

[Clinic leaders] obviously did not think that my participation was going to be helpful to the system, to the change, to Lean rollout . . . . Do they want you to play in their sandbox? I think that the answer is yes and no. They want you to play in the sandbox if you play by their rules.

While this view may seem extreme, it was not atypical of perceptions held by other interviewees from the latter phases of Lean implementation. Survey data shown in Table 2 support this finding. Compared with the pilot site, physicians and staff in phase 2 and 3 clinics reported significantly lower levels of involvement in change efforts following Lean redesign. This measure included survey questions about one's perceived level of ownership of clinic activities and commitment to continuously improve. In contrast, members of the pilot site reported higher levels of teamwork and more frequent participation in decisions to improve care. Altogether, physician and staff ratings for participation in change efforts, teamwork, and employee engagement were significantly higher in the pilot clinic as compared with all other clinics across the system. These differences in workplace experiences are shown according to implementation phase in Figure 2.

Beliefs about Lean changes

According to the interviews, other factors facilitating sustainment included frontline beliefs about Lean as an organizational strategy for enhancing effectiveness. Several years after Flow redesigns were first implemented, interviewees in the pilot site confirmed they were still excited to be part of the organization's efforts to continuously improve. Physicians and staff commented specifically on the *benefits* of Lean, suggesting that they see true value in this methodology for optimizing care processes. Such perceptions appeared to have a strong impact on the staying power of Lean-based changes. As one pilot leader stated, "Here, we feel so strongly about [Lean's] benefits and its opportunities that you would have to shake us loose."

Table 2. Comparisons of Lean Sustainment and Workplace Experiences (N = 668)

Domains	Phase 1 Mean (SD)	Phase 2[a] Mean (SD)	Phase 3[a] Mean (SD)
Overall sustainment[b]	4.175 (0.750)	3.913[c] (0.859)	4.017[d] (0.814)
Work engagement and environment			
Physician/staff engagement	4.072 (0.685)	3.889[c] (0.696)	3.926[d] (0.730)
Participation in decisions	3.206 (0.757)	2.972[c] (0.840)	3.105 (0.846)
Teamwork	3.798 (0.630)	3.723 (0.675)	3.663[d] (0.719)
Beliefs about Lean changes			
Effectiveness	3.211 (0.551)	3.069[d] (0.671)	3.069[c] (0.742)
Appropriateness	3.828 (0.725)	3.772 (0.753)	3.676[d] (0.824)
Valence (personal benefits)	3.576 (0.939)	3.390 (0.919)	3.346[c] (0.972)
Job-related burnout			
Emotional exhaustion	3.375 (1.624)	3.813[c] (1.582)	3.572 (1.719)
Depersonalization	1.686 (1.044)	1.721 (1.108)	1.790 (1.221)
Personal accomplishment	2.061 (1.263)	1.736[c] (0.980)	2.048 (1.303)

Abbreviation: SD, standard deviation.
[a]Reference group for comparison: Phase 1 clinic.
[b]Overall sustainment of Lean redesigns is a composite measure of adherence to daily huddles, agenda setting, and joint inbox management by care teams.
[c]$P < .05$.
[d]$P < .10$.

There were also differences in attitudes and beliefs about Lean management tools among leaders in the pilot site and those of leaders in phase 2 and 3 clinics. These differences were illustrated by the use of a management technique known as "observation," which is a regular opportunity for clinic leaders to go to the frontlines and provide real-time feedback to staff on daily workflows. Observations, when done properly, involve coaching individuals on why and how to carry out the elements of each new work process. A key to sustainment, particularly according to the interviews at the pilot site, was a willingness to have one's work observed in order to receive feedback. One pilot leader explained how this helped clinic leaders spot and curb initial signs of "drift":

> We've gone back to do observation ... and we've already identified that they're picking and choosing bits and pieces of "Flow" that they really liked and they're not doing everything. So we're circling back now to provide that feedback to them ... . Because we can't slip on this. We have this standard and every part of the standard needs to be followed.
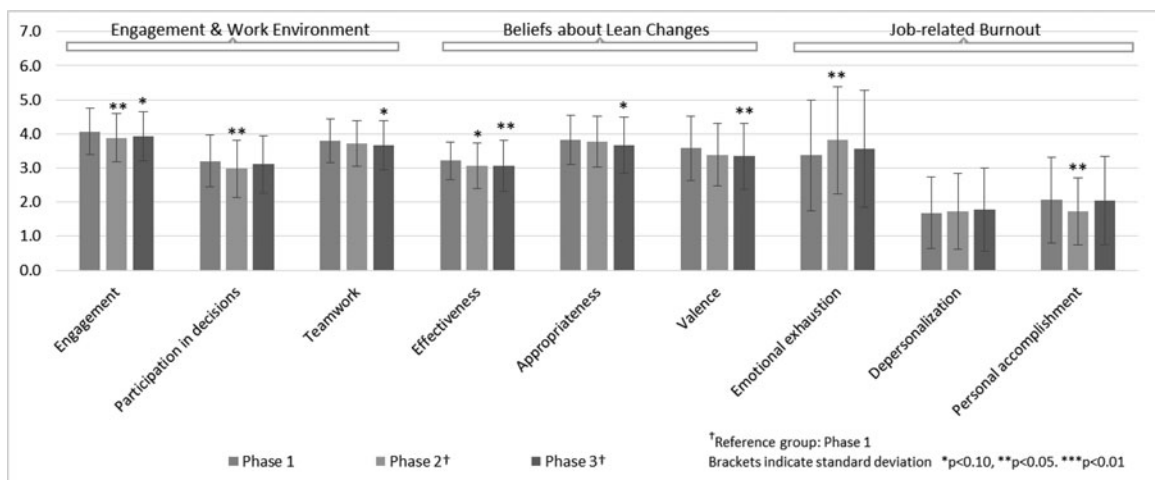

Figure 2. Workplace experiences by Lean implementation phase (N = 668).

Observations of this type were not consistently practiced in the later phases of Lean implementation. Leaders in many of the phase 2 and phase 3 clinics revealed in interviews that they did not believe such observations were appropriate or beneficial. This attitude had direct impacts on staff adherence to workflow redesigns. As one leader poignantly remarked, "The failure of most strategies that are not being sustained is due to a lack of observation and coaching." In clinics where it was a top priority to ensure that both leaders and staff adhere to Lean redesigns, commitment to the changes appeared to be strong. In other clinics where Lean leadership and daily activities were not emphasized or followed, interviewees noted that overall sustainment was "hit or miss."

The survey data shed additional light on attitudes about Lean changes across each phase of implementation. As Table 2 shows, across all belief domains, physicians and staff in the pilot consistently responded more positively than members in phases 2 and 3. Specifically, responses among pilot members indicated a stronger belief that Lean had effectively addressed performance gaps, as compared with responses from members in all other clinics. Phase 3 respondents reported particularly unfavorable opinions about both the appropriateness and perceived benefits or value of Lean redesigns.

Lack of time for improvement and provider burnout
Finally, lack of time and burnout were additional barriers to sustainment. Particularly in phase 2, clinics leaders indicated they simply do not have the bandwidth to take part proactively in Lean improvement work. One clinic supervisor gave this example of these barriers:

We're running so fast that I feel like constantly everyday I'm just putting out fires. I feel like I don't have time to really just sit down and think about the things that really need to be done because I'm constantly putting out the fires of the things that are already happening. So I can't get ahead of it. I can't get to the point where everything is stable.

This reflection illustrates how stressed environments can create real limitations on the time and energy needed for continuous improvement. Time constraints can also appear in less tangible ways, such as influencing how people think about improvement processes. For example, one phase 3 clinic supervisor, who had previously worked at the pilot site, commented on widely contrasting perspectives that she observed in the 2 locations:

It isn't the mindset here [phase 3 clinic] to work on frontline improvement . . . in contrast to [the pilot]. When I was there, I had staff who would come to me and say, "I'm really having an issue with this. This is how I'm going to start tracking it and this is what I'm going to do." They were ready for that and the mindset was there. Not

here. Right now I think, they can just handle what they're handling and not anything more.

In contrast, we did not hear any comments on the impact of work demands or burnout on efforts to improve in pilot interviews.

Results from our survey confirm and further specify the differences across clinics. Table 2 shows that higher levels of work stress were reported by physicians and staff in later implementing clinics, as compared with pilot members. In particular, phase 2 members reported significantly more burnout in the forms of higher emotional exhaustion and lower sense of personal accomplishment. Further corroborating these reports, data from the health system's operational sources also show significantly higher patient volumes per full-time equivalent physician in phase 2 clinics, as compared with both phase 1 and 3 clinics (independent-samples t tests, $P < .05$; data available upon request).

Survey results on work experiences and sustainment
Table 3 presents overall correlations between work experiences and Lean sustainment across all clinics, regardless of implementation phase. These results indicate that high employee engagement, participation in decisions to improve quality, and teamwork were universally associated with greater adherence to Lean redesigns among all care teams. These findings are supported by studies of Lean[23,24] and other types of quality improvement[25-27] that document the contributions to improvement and sustainment that flow from deeply engaging clinicians and other staff in the improvement process. Participation in decisions about processes such as quality improvement is recognized in

Table 3. Associations Between Workplace Experiences and Lean Sustainment, All Clinics and Implementation Phases (N = 668)

Domains	Overall Sustainment[a] Pearson's R
Work engagement and environment	
Physician/staff engagement	0.250[b]
Participation in decisions	0.265[b]
Teamwork	0.293[b]
Beliefs about Lean changes	
Effectiveness	0.324[b]
Appropriateness	0.320[b]
Valence (perceived benefits)	0.332[b]
Job-related burnout	
Emotional exhaustion	− 0.221[b]
Depersonalization	− 0.148[b]
Personal accomplishment	0.059

[a]Overall sustainment of Lean redesigns is a composite measure of adherence to daily huddles, agenda setting, and joint inbox management by care teams.
[b]$P < .01$.

management studies for its contribution to employee engagement and organizational performance.[28] Favorable beliefs about Lean changes—including their effectiveness, appropriateness, and perceived benefits—were also highly correlated with sustainment. In contrast, higher job-related burnout was associated with lower adherence to new workflows. Specifically, emotional exhaustion and depersonalization of patients were both correlated with lower sustainment of Lean redesigns. These relationships between workplace experiences and sustainment of changes are further supported by previous literature as described below.

DISCUSSION

We examined sustainment of Lean redesigns several years after being introduced in all primary care clinics at a large ambulatory care delivery system. Based on both qualitative and quantitative data, we found that Lean workflows for care teams and tools for continuous improvement were maintained to varying degrees across the system. Sustainment was highest in the pilot site despite its postdesign measurement period being substantially longer, as compared with sites in the latter phases of Lean implementation. We explored reasons for these differences using data gathered from semistructured interviews with organizational leaders and frontline physicians, as well as surveys fielded to all primary care physicians and staff.

According to interviewees, participation in planning redesigns was a key facilitator of sustainment. In particular, the pilot clinic served as a design center where members were invited to participate deeply in the change effort by developing their own new workflows. In contrast, clinics in subsequent phases of implementation were much less involved in the design and were instead advised to either adopt the pilot workflows or adapt them to fit local practice environments. By taking a more active role in organizational changes, members of the pilot clinic likely experienced a greater sense of "buy-in" and ownership in ways that did not exist among other clinics. This finding was further supported by survey data showing significantly higher levels of reported participation in decision-making to improve quality, teamwork, and staff engagement after Lean was implemented in the pilot clinic, as compared with all other clinics.

This finding highlights the widely documented importance of *change ownership*.[27,29-31] Ownership is facilitated by implementation approaches that specifically aim for high levels of communication and staff involvement in change efforts. It is also reinforced by specific tools fostering engagement and continuous improvement. Tools such as observation and coaching as part of a Daily Engagement System were well utilized by leaders at the pilot site, and are consistent with broader best practices for maintaining programs. For example, outcome measurement and accountability, professional development of both staff and leaders, regular meetings to give and receive feedback, and ongoing efforts to maintain the relevance of new practices—have all been identified as keys to sustaining change.[29,32-36]

Sustaining quality improvements also often calls for fundamental changes in staff identities, along with changes in corresponding assumptions about work roles and relationships.[37] As suggested by our study, relationships that are based on collaboration and trust will create contexts in which work redesigns can be better anticipated and accepted.[38] In turn, in contexts where relationships for mentoring or collaboration have been actively developed, changes can be more easily sustained through interpersonal relationships rather than reliance on formal policies.[27,30,31] Particularly among pilot members in our study, engagement through tools such as observations helped develop relationships by building support and coaching mechanisms that were clearly acknowledged by others as being a key to sustainment.

Prior reviews of Lean and delivery system research show that participants' beliefs about change and their readiness to take part in such efforts are vital to success.[39,40] Participants who are less prepared or enthusiastic about an initiative tend to comply with new standards initially, but may fail to perceive longer term benefits either to organizational performance or to themselves.[29] Hence, reconciling organizational and individual values with those being imposed is critical to securing the permanence of changes.[27,41] As we found in our study, members of the pilot site were more likely to report favorable views of the Lean initiative, as compared with those in later phases of implementation. This favorability of views about Lean was also universally associated with increased sustainment across all clinics.

Both our interview and survey data further revealed a potential barrier to sustainment: lack of time and energy to participate actively in improvement activities. Although Lean tools were intended to improve work conditions, such tools were added on top of regular clinical or administrative duties. While initial efforts may be feasible in the short-term, longer term viability of both initial and ongoing improvement activities is at risk if they are not woven into practice.[4,32] In order to sustain practice transformations, some degree of task rearrangement or reprioritization, along with release time and other enabling resources, must accompany changes. Regardless of how engaged the workforce and favorable their beliefs about improved work designs, tangible resources must also be provided to support their sustainment.

Several limitations to our study warrant discussion. First, the time frames used to assess sustainment varied across the 3 implementation phases. This built-in feature nevertheless served to create variations, allowing us to explore differences in implementation as one important factor affecting sustainment levels. In addition, lack of a control group, a reflection of unrelated policy decisions made by the systems' leaders, makes it difficult to eliminate other possible differences among implementation stages, such as exposure to external developments and baseline clinic characteristics. Thus,

we cannot determine with certainty whether observed differences were due to either secular or existing trends or to the Lean redesign itself. Nor was our study based on a panel design to rule out potential bias from changing respondent characteristics. However, in our prior research conducted across all clinics,[42] minimal structural differences were found between baseline workforce characteristics and those of physicians and staff who responded to surveys after Lean implementation. Overall, we used our quantitative data to enrich and help validate the findings from the qualitative data, but could not readily test alternative explanations for the findings. Our study may be generalizable to other types of process redesign and to other delivery settings, but additional work is needed to further validate results.

CONCLUSIONS

This study of Lean sustainment highlights the importance of early approaches to implementing change in primary care clinics. Moreover, our findings reinforce the important role of employee participation in design efforts, use of supportive management tools, and staff identification with organizational goals for the redesign effort. Process redesigns need to be carefully planned to ensure that new workflows are feasible, acceptable, and sustainable among those responsible for implementing them. Additional time and effort will undoubtedly be required to fully involve staff in design efforts, but these time investments will likely help secure buy-in and adherence for the long term. Without this investment, maintenance of new professional roles and identities, workflows and relationships with other care team members, and management culture are less likely to occur. Transformation of these core elements will facilitate the sustainment of Lean and other similar innovations among primary care teams.

REFERENCES

1. Mazzocato P, Savage C, Brommels M, Aronsson H, Thor J. Lean thinking in healthcare: a realist review of the literature. *Qual Saf Health Care*. 2010;19(5):376-382.
2. Vest JR, Gamm LD. A critical review of the research literature on Six Sigma, Lean and StuderGroup's Hardwiring Excellence in the United States: the need to demonstrate and communicate the effectiveness of transformation strategies in healthcare. *Implement Sci*. 2009;4:35.
3. Centauri F, Mazzocato P, Villa S, Marsilio M. System-wide lean implementation in health care: a multiple case study. *Health Serv Manage Res*. 2018;31(2):60-73.
4. Bowman CC, Sobo EJ, Asch SM, Gifford AL; HIV/Hepatitis Quality Enhancement Research Initiative. Measuring persistence of implementation: QUERI series. *Implement Sci*. 2008;3:21.
5. Lennox L, Maher L, Reed J. Navigating the sustainability landscape: a systematic review of sustainability approaches in healthcare. *Implement Sci*. 2018;13(1):27.
6. Murphree P, Vath RR, Daigle L. Sustaining Lean Six Sigma projects in health care. *Physician Exec*. 2011;37(1):44-48.
7. Jiang HJ, Lockee C, Bass K, Fraser I. Board oversight of quality: any differences in process of care and mortality? *J Healthc Manag*. 2009;54(1):15-30.
8. Nelson M. *Sustaining Lean in Healthcare: Developing and Engaging Physician Leadership*. Boca Raton, FL: CRC Press; 2011.
9. Wiltsey Stirman S, Kimberly J, Cook N, Calloway A, Castro F, Charns M. The sustainability of new programs and innovations: a review of the empirical literature and recommendations for future research. *Implement Sci*. 2012;7:17.
10. Tricco AC, Ashoor HM, Cardoso R, et al. Sustainability of knowledge translation interventions in healthcare decision-making: a scoping review. *Implement Sci*. 2016;11:55.
11. Friedman A, Hahn KA, Etz R, et al. A typology of primary care workforce innovations in the United States since 2000. *Med Care*. 2014;52(2):101-111.
12. D'Andreamatteo A, Ianni L, Lega F, Sargiacomo M. Lean in healthcare: a comprehensive review. *Health Policy*. 2015;119(9):1197-1209.
13. Toussaint JS, Berry LL. The promise of Lean in health care. *Mayo Clin Proc*. 2013;88(1):74-82.
14. Hung DY, Harrison MI, Martinez MC, Luft HS. Scaling Lean in primary care: impacts on system performance. *Am J Manag Care*. 2017;23(3):161-168.
15. Barnas K. ThedaCare's business performance system: sustaining continuous daily improvement through hospital management in a lean environment. *Jt Comm J Qual Patient Saf*. 2011;37(9):387-399.
16. Wood D. A prescription for Lean healthcare. *Healthc Q*. 2014; 17(2):24-28.
17. Buchanan D, Fitzgerald L, Ketley D. *The Sustainability and Spread of Organizational Change*. New York, NY: Routledge; 2007.
18. Gwet KL. *Handbook of Inter-rater Reliability: The Definitive Guide to Measuring the Extent of Agreement Among Raters*. Gaithersburg, MD: Advanced Analytics, LLC; 2014.
19. The Advisory Board. Helping you build a high-performance culture *Survey Solutions Employee Engagement* [Web page]. http://www.advisory.com/talent-development/employee-engagement-initiative. Published 2017. Accessed February 20, 2017.
20. Ohman-Strickland PA, John Orzano A, Nutting PA, et al. Measuring organizational attributes of primary care practices: development of a new instrument. *Health Serv Res*. 2007;42(3, pt 1):1257-1273.
21. Armenakis A, Bernerth JB, Pitts JP, Walker HJ. Organizational change recipients' beliefs scale: development of an assessment instrument. *J Appl Behav Sci*. 2007;43:481-505.
22. Maslach C, Jackson SE, Leiter MP, Schaufeli WB, Schwab RL. *Maslach Burnout Inventory (Human Services)*. Palo Alto, CA: Consulting Psychologists Press; 1986.
23. Poksinska B. The current state of lean implementation in health care: literature review. *Qual Manag Health Care*. 2010;19(4):319-329.
24. Toussaint J. Writing the new playbook for U.S. health care: lessons from Wisconsin. *Health Aff (Millwood)*. 2009;28(5):1343-1350.
25. Dixon-Woods M, McNicol S, Martin G. Ten challenges in improving quality in healthcare: lessons from the Health Foundation's programme evaluations and relevant literature. *BMJ Qual Saf*. 2012;21(10):876-884.
26. Bate P, Mendel P, Robert G. *Organizing for Quality: The Improvement Journeys of Leading Hospitals in Europe and the United States*. Oxford, England: Radcliffe Publishing; 2008.
27. Willis CD, Saul J, Bevan H, et al. Sustaining organizational culture change in health systems. *J Health Organ Manag*. 2016;30(1):2-30.
28. Scheck McAlearney A, Garman AN, Song PH, McHugh M, Robbins J, Harrison ML. High-performance work systems in health care management, part 2: qualitative evidence from five case studies. *Health Care Manage Rev*. 2011;36(3):214-226.
29. Buchanan D, Fitzgerald L, Ketley D, et al. No going back: a review of the literature on sustaining organizational change. *Int J Manag Rev*. 2005;7(3):189-205.
30. Chreim S, Williams BE, Janz L, Dastmalchian A. Change agency in a primary health care context: the case of distributed leadership. *Health Care Manage Rev*. 2010;35(2):187-199.
31. Greenhalgh T, Macfarlane F, Barton-Sweeney C, Woodard F. "If we build it, will it stay?" A case study of the sustainability of whole-system change in London. *Milbank Q*. 2012;90(3):516-547.
32. Chin MH, Kirchhoff AC, Schlotthauer AE, et al. Sustaining quality improvement in community health centers: perceptions of leaders and staff. *J Ambul Care Manage*. 2008;31(4):319-329.

33. Parrish MM, O'Malley K, Adams RI, Adams SR, Coleman EA. Implementation of the care transitions intervention: sustainability and lessons learned. *Prof Case Manag*. 2009;14(6):282-295.

34. Bray P, Cummings DM, Wolf M, Massing MW, Reaves J. After the collaborative is over: what sustains quality improvement initiatives in primary care practices? *Jt Comm J Qual Patient Saf*. 2009;35(10):502-503.

35. Compas C, Hopkins KA, Townsley E. Best practices in implementing and sustaining quality of care. A review of the quality improvement literature. *Res Gerontol Nurs*. 2008;1(3):209-216.

36. Looney JA, Shaw EK, Crabtree BF. Passing the baton: sustaining organizational change after the facilitator leaves. *Group Facilitation*. 2011;11:15-23.

37. Crabtree BF, Nutting PA, Miller WL, et al. Primary care practice transformation is hard work: insights from a 15-year developmental program of research. *Med Care*. 2011;49(suppl):S28-S35.

38. Hung D, Gray C, Martinez M, Schmittdiel J, Harrison MI. Acceptance of Lean redesigns in primary care: a contextual analysis. *Health Care Manage Rev*. 2017;42(3):203-212.

39. Radnor Z. Implementing Lean in health care: making the link between the approach, readiness and sustainability. *Int J Ind Eng Manag*. 2011;2(1):1-12.

40. Al-Balushi S, Sohal AS, Singh PJ, Al Hajri A, Al Farsi YM, Al Abri R. Readiness factors for lean implementation in healthcare settings—a literature review. *J Health Organ Manag*. 2014;28(2): 135-153.

41. Amis J, Slack T, Hinings CR. Values and organizational change. *J App Behav Sci*. 2002;38(4):436-465.

42. Hung DY, Harrison MI, Truong Q, Du X. Experiences of primary care physicians and staff following lean workflow redesign. *BMC Health Serv Res*. 2018;18(1):274.