*Executive Summary*

Spreading Lean: Taking Efficiency Interventions in Health Services Delivery to Scale

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# Introduction

The purpose of this project was to study the implementation, spread, and sustainability of Lean-based redesigns in primary care departments at the Palo Alto Medical Foundation (PAMF). The objectives of this project were to:

1. Study the scaling and sustainability of Lean redesigns as an organizationwide initiative, with a particular focus on analyzing contextual factors affecting the success of implementation efforts.
2. Develop and disseminate knowledge and lessons learned about what factors affect the scale-up and sustainability of Lean across the organization.

The research team consisted of researchers from the Palo Alto Medical Foundation Research Institute (PAMFRI) (Dorothy Hung, Ph.D., M.A., M.P.H., Principal Investigator; Harold Luft, Ph.D.; Caroline Gray, Ph.D.; Su-Ying Liang, Ph.D.; and Meghan Martinez, M.P.H.) and Kaiser Permanente Northern California Division of Research (Julie Schmittdiel, Ph.D., Principal Investigator; and Deanne Wiley).

PAMFRI researchers develop and publish their findings according to strict standards of scientific integrity and transparency. In addition, they share their findings with PAMF leaders, staff, and managers. These findings can be used to inform organizational improvement efforts.

The findings reported here are based on primary and secondary data sources at PAMF, including:

* Nearly 200 indepth interviews and focus groups with organizational leaders, physicians leaders, and frontline physicians and staff;
* Patient, provider, and staff satisfaction surveys;
* Electronic medical records;
* Operational dashboards;
* Billing and financial sources;
* Scheduling systems; and
* A baseline and followup survey fielded to approximately 900 primary care physicians and nonphysician staff at PAMF.

Additional details on this study beyond those presented here can be found in the peer-reviewed literature (see Appendix).

# Background

Lean is an increasingly popular strategy to improve short-term efficiency and quality while also promising longer term system transformation.[1](#_ENREF_1),[2](#_ENREF_2) While views vary widely as to what constitutes Lean in health care, it is typically “used as a process improvement approach focusing on three main areas:

1. Defining value from the patient point of view,
2. Mapping value streams (i.e., step-by-step delivery of services), and
3. Eliminating waste in an attempt to create continuous flow.”[3](#_ENREF_3)

To date, most studies of Lean have focused on a narrow use of Lean techniques to solve isolated problems.[4](#_ENREF_4) Few studies have focused on Lean’s contributions to creating more systemic change. Furthermore, few studies rigorously examine Lean implementation in outpatient primary care settings.

In late 2011, in response to external market pressures for greater affordability, PAMF introduced Lean to improve quality and efficiency across the delivery system. PAMF is a large, not-for-profit, ambulatory care system with clinics very similar to those found in many not-for-profit medical groups across the United States.[5](#_ENREF_5)

The system’s nearly 1 million patients are primarily insured by commercial fee-for-service plans (70%); others are insured by commercial health maintenance organizations (HMOs) (12%), have Medicare/Medicaid (13%), or use other forms of payment (5%). Before Lean was introduced, workflows and processes were not highly standardized across PAMF clinics, but all used a single electronic record and financial system.

PAMF introduced Lean redesigns in three consecutive phases beginning in primary care (i.e., Family Medicine, Internal Medicine, and Pediatrics), each with an implementation period of approximately 4 to 6 months. Implementation of Lean redesigns started in primary care departments housed within one pilot clinic location at the end of 2011, followed in 2012 with three more “beta” clinics, and finally the remaining 13 “gamma” clinics at the end of 2012 through 2013 (a total of 46 primary care departments across PAMF).

At the pilot site, external Lean consultants worked with clinic leaders and frontline representatives to design standard workflows during a series of 5-day workshops. Similarly, Lean consultants and clinic representatives participated in workshops held at each beta site to implement and further refine the designs originally developed by the pilot site. Finally, leaders and staff in all remaining gamma clinics participated in 2-day workshops largely focused on implementing the work designs.

At each clinic location, implementation followed the same sequence of events:

1. “5S” standardization of medical equipment, supplies, and health education materials in exam rooms;
2. Call management and redesign of call center functions;
3. Co-location of physician and nonphysician teams in a shared workspace; and
4. Redesign of care team workflows.

Clinic site leaders, physicians, and staff participated in redesigning existing supply chains, physical organization of space, and patient care workflows according to Lean principles. As Lean spread throughout PAMF’s network of clinics, each was encouraged to adopt or adapt design elements to fit local needs and unique site characteristics.

Our analysis focused on contextual factors and processes affecting the spread and sustainability of this efficiency innovation in health care. We examined high-level metrics on both intervention uptake and outcomes, including:

* Lean performance indicators,
* Affordability and cost measures,
* Physician productivity,
* Patient access to care,
* Clinical quality indicators, and
* Satisfaction among patients, physicians, and staff.

We examined how trends in these metrics changed over time and across sites as Lean redesigns were implemented in primary care. We also looked at which key contextual factors affected the acceptance and adoption of Lean redesigns, as well as how systemwide efforts ultimately translated into transformed care delivery. As Lean implementation at PAMF occurred on an ambitious timeline, both successes and stumbling blocks emerged, highlighting the complex realities of even the most well-planned efforts to scale new interventions.

## Measures Used in the CFIR Evaluation Framework

Our analysis was informed by a recently modified version of the Consolidated Framework for Implementation Research (CFIR), a widely used implementation science framework.[6](#_ENREF_6) The original CFIR contained five domains:

1. Outer setting,
2. Inner setting),
3. Intervention characteristics,
4. Implementation process, and
5. Individual/team characteristics.

The modified CFIR adds two domains: intervention outcomes, such as quality and efficiency, and implementation measures. Implementation measures include constructs such as the acceptance, adoption/abandonment, cost, fidelity, reach, and sustainability of new interventions.[7](#_ENREF_7) By adding these domains, the modified framework focuses researchers’ attention on the way 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, hereafter the CFIR-PR, reflects expert recommendations for research specifically targeting process redesigns (Figure 1).[8](#_ENREF_8)

Diagram showing elements of framwork:
Outer Setting surrounding Intervention Characteristics, Individual/Team Characteristics, Process of Implementation, and Inner Setting. This leads to Measures of Implementation, which leads to Outcomes.Figure 1. Consolidated Framework for Implementation Research, modified for studying Process Redesign (CFIR-PR)[8](#_ENREF_8" \o "Rojas Smith, 2014 #1506)

Examples of the seven CFIR-PR domains are below:

1. **Outer Setting:** External pressures and policy changes
2. **Intervention Characteristics:** Flow redesign, co-location, standardization of tasks and processes
3. **Individual/Team Characteristics:** Physician and staff roles/scope of work
4. **Process of Implementation:** Receptivity to feedback, implementation style, execution of redesigns, employee engagement
5. **Inner Setting:** Structural characteristics, networks and communications, culture
6. **Measures of Implementation:**Acceptability, adoption, appropriateness of intervention
7. **Outcomes:** Workforce satisfaction, patient satisfaction, clinical quality, physician production, physician load, patient access

# Key Findings

We began this study with a focus on exploring the contextual themes surrounding initial implementation and scaling of Lean across primary care clinics at PAMF. Our qualitative work illustrated the influence of contextual factors on process redesigns and, in particular, how these contextual factors affected frontline acceptance of Lean practices. Complementing the qualitative analysis, we focused quantitatively on CFIR-PR measures of implementation, specifically implementation measures involving adoption or penetration of Lean redesigns on provider efficiency and broader organizational outcomes.

We also examined the *sustainment* of Lean redesigns, another key CFIR-PR measure of implementation. Qualitative analysis was based on followup interviews with PAMF physician leaders, department managers, supervisors, frontline physicians, and nonphysician staff. In a series of indepth quantitative analyses of performance metrics, we examined post-Lean trends spanning a total duration of 4 to 25 months after implementation of Lean redesigns in clinic sites.

We examined efficiency metrics that served as proxies for adoption of Lean redesigns:

* Office visit charts closed within 2 hours of seeing the patient,
* Electronic reply within 4 hours of receiving a patient message sent via online portal,
* Prescription medications refilled within 4 hours of receiving the request via online portal, and
* Telephoned patient care items resolved within 4 hours as indicated in the electronic health record.

We also examined broader metrics or outcomes that Lean was intended to affect, such as patient and workforce satisfaction, physician productivity, clinical quality, and operating expense.

Finally, using survey data collected 1.5 to 3 years after Lean was first implemented in clinics, we summarized the post-Lean experiences of primary care physicians and staff with regard to:

* Employee engagement,
* Features of organizational climate (e.g., teamwork, participation in decisionmaking),
* Job-related burnout, and
* Adherence to Lean redesigns.

We used the same survey data to describe the contextual factors associated with physicians who demonstrated high post-Lean performance improvements (i.e., top third) in a range of metrics, including efficiency, clinical quality, productivity, and patient satisfaction.

Key findings are summarized below:

* The **outer setting** had the most impact on frontline employees’ acceptance of Lean as a general strategy and approach to improving value *in principle*. Other contextual domains played influential roles in whether frontline employees adopted Lean *in practice*. These domains included **intervention characteristics**, **inner setting**, **characteristics of individuals and teams**, and **process of implementation**.
* The **implementation approach** was critical to institutionalizing changes. The pilot site had effective, thoughtful leaders who routinely followed up with frontline physicians and staff to ensure that the redesign was working. The pilot site continues to experience one of the highest levels of sustainment of Lean redesigns. In locations where the implementation approach was more top down and less well received, the Lean approach has not been as fully implemented or sustained.
* Despite some initial resistance from frontline physicians, the largest successes of Lean redesigns in terms of sustaining changes included **co-location** of medical assistants and physicians and **5S**, which involved reorganizing and standardizing exam room supplies.
* The most significant post-Lean improvements evident in our statistical analyses involved **workflow efficiencies**, **physician productivity**, **clinical quality**, and **patient satisfaction** (Table 1).
* Employees indicated a high level of adherence to Lean redesigns, with both physicians and nonphysician staff reporting that they used **huddles** most of the time to carry out their work and could conduct **agenda setting** with patients for more than half of visits.
* While survey respondents reported that they could manage messages in the physician’s **in basket** “most of the time,” many interviewees thought that in-basket management had yet to be optimized due to an increasing volume of items.
* Some evidence suggested that PAMF engendered **cultural change** in terms of its management structure and employee engagement. However, the changes were not enough to counteract effects of continuing pressures on caregivers and fee-for-service reimbursement. .
* Some physicians and administrative leaders cited **inadequate staff training** and a lack of **role competency**, particularly among the medical assistants, as reasons for Lean redesigns not being sustained.
* While clinics and departments continue to engage in continuous frontline improvement activities, finding **adequate time** to do so has been challenging. There is considerable interest among frontline staff in participating in these activities, but busy clinic schedules coupled with a need to prioritize real-time problems have proved to be significant obstacles.
* Survey respondents reported that the medical assistant-physician **dyads** created by the Lean redesign were a positive change, and they believe that Lean has improved **overall flow and efficiency**. On the other hand, the **speed of implementation** and the **current staffing levels** were noted frequently as areas for improvement.
* **High-performing physicians** were more likely to be found in departments identified as less busy or chaotic and departments with a low level (vs. high or medium level) of burnout in the form of depersonalizing patients.

Table 1. Summary of Key Quantitative Findings (Lean compared to without Lean, i.e., counterfactual)

| Topic | Conclusions |
| --- | --- |
| Workflow Efficiency | Increase in timeliness of completing 3 of 4 patient encounter measures: office visit chart closures, medication renewals, telephone responses. |
| Physician Productivity | Higher wRVUs\* generated per physician per month. No change in wRVUs per office visit. |
| Operating Expenses | Lower total operating expenses (including constituent components of staff compensation, and drug and supply costs) standardized per tRVU↑. |
| Clinical Quality | Improvements in coordinated diabetes care metrics, no change in preventive screening metrics, and decreased meningococcal immunization among adolescents. |
| Patient Satisfaction | Higher satisfaction overall and in specific domains, including access to care and handling of personal issues. Lower satisfaction with interactions with care providers. |
| Staff Satisfaction | Higher satisfaction overall and in specific domains, including credible leadership, employee engagement, growth and development, connection to purpose, healthy partnerships, empowerment, and autonomy. |
| Physician Satisfaction | In pilot and beta clinics: Higher satisfaction overall and in specific domains, including time spent working and relationships with staff. Lower satisfaction overall in final phase of implementing clinics. Across all clinics, physician satisfaction increased in key areas, including relationship with staff, quality of care, resources available, and time spent working. |

\*wRVU = work relative value unit.

↑tRVU = total relative value unit.

# Conclusions

As organizations across the spectrum—ranging from hospitals and physician practices to government programs such as the Veterans Health Administration—implement Lean to improve efficiency and value, a better understanding is needed of how Lean can be effectively scaled and sustained in outpatient settings. In particular, more study is needed on whether Lean can help health care delivery systems identify waste and redesign care processes to enhance outcomes, particularly in fee-for-service ambulatory care settings where the vast majority of health care is delivered.

Some questions remain as to whether productivity gains will undermine quality and worsen levels of burnout or discontent among primary care providers. Therefore, research is needed on balancing parallel priorities of productivity gains, value, satisfaction, and clinical quality.

By bringing together study findings on the implementation, scaling, and sustainment of Lean redesigns across our organization, we contributed to understanding key contextual factors that affect Lean initiatives in health care. These factors include the implementation approach; characteristics of the inner setting (e.g., local culture, work climate); individuals and teams (including clinical roles and leadership approaches); and intervention characteristics (e.g., co-location). 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.

We also found that for Lean initiatives to succeed, organizations must ensure that leaders at all levels are leading in a “Lean” way—seeking the input of frontline employees and coaching rather than directing employees. Among clinics that experienced noticeable culture shifts, these changes were largely a product of managers using this Lean-based management style. In addition, departments that had leaders highly committed to and conversant with Lean philosophy, language/terminology, and techniques appeared to have higher levels of sustainment.

In terms of efficiency and value, Lean implementation led to improved workflow efficiencies (i.e., timely chart closures and prescription refills), physician productivity, and patient satisfaction, all without discernible negative effects on clinical quality. Furthermore, data available at an aggregated level indicated lower operating costs and higher satisfaction among staff and physicians after Lean was implemented.

We also assessed whether high-performing physicians post-Lean were clustered in departments that were also high performing with respect to certain contextual features (e.g., teamwork, adherence to Lean redesigns. We found that two contextual factors were associated with greater likelihood of being a high-performing physician in a post-Lean practice environment. These factors were low levels of recent change and less burnout in the form of depersonalizing patients.

Our findings are particularly relevant for system leaders and managers of any organization attempting to implement and scale process improvements across multiple sites of a large health care system. Our work has highlighted the areas where leadership at all levels, including executives, department managers, and physician or staff champions, can focus their efforts to enhance success.

Results from this study also show that, particularly for a large health care system, leaders may find it easier to implement Lean in phases rather than at a single point in time. However, in doing so, they need to ensure that frontline physicians and staff at every phase feel equally invested and involved in designing new Lean workflows. Despite the challenges, a large ambulatory care system new to process innovation can implement and scale Lean redesigns with largely beneficial results.

Our work has also identified areas for continued research. Lean requires a significant amount of teamwork, particularly between physicians and medical assistants. In our study organization, physicians were required to give up their personal offices to work in a shared space and relied heavily on their medical assistant dyad partner. As our findings show, co-location was considered a positive change resulting from Lean redesigns, but physicians often felt their medical assistant lacked the necessary training to take on the role of “flow manager.”

Additional study to understand how different professional roles can be integrated using Lean principles and how communication-focused interventions can create more productive relationships between care team members is needed to facilitate Lean applications in health care settings. Also, additional research on ways that continuous improvement activities can become standard practice, particularly given the time constraints in primary care, will be critical to Lean as a transformative solution in health care.

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# Appendix: Publications and Other Sources on This Study

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