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Using lean thinking to improve hypertension in a community health centre: a quality improvement report

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ABSTRACT

Background Achieving better care at lower cost in the US healthcare safety net will require federally qualified health centres (FQHC) to implement new models of team-based population healthcare. Lean thinking may offer a way to reduce the financial risk of practice transformation while increasing the likelihood of sustained improvement.

Objective To demonstrate system-level improvement in hypertension control in a large FQHC through the situational use of lean thinking and statistical process control.

Setting Lynn Community Health Center, the third largest FQHC in Massachusetts, USA.

Participants 4762 adult patients with a diagnosis of hypertension.

Intervention First, we created an organisation-wide focus on hypertension. Second, we implemented a multicomponent hypertension care pathway. The lean tools of strategy deployment, standardised work, job instruction, Plan-Do-Study-Adjust, 5S and visual control were used to overcome specific obstacles in the implementation.

Measurements The primary outcome was hypertension control, defined as last measured blood pressure <140/90. Statistical process control was used to establish baseline performance and assess special cause variation resulting from the two-step intervention.

Results Hypertension control improved by 11.6% from a baseline of 66.8% to a 6 month average of 78.2%.

Limitations Durability of system changes has not been demonstrated beyond the 14-month period of the intervention. The observed improvement may underestimate the effect size of the full hypertension care intervention. The observed improvement may have occurred beyond the 14-month period of the intervention.

Conclusions Success factors included experienced improvement leaders, a focus on engaging front-line staff, the situational use of lean principles to make the work easier, better, faster and cheaper (in that order of emphasis), and the use of statistical process control to learn from variation. The challenge of transforming care delivery in the safety net warrants a closer look at the potential impact of lean thinking in FQHCs.

INTRODUCTION

Achieving better outcomes at lower cost in the healthcare safety net is a critical driver for improving health and slowing the growth of healthcare costs nationally.1–7 The healthcare safety net refers to ‘providers that organize and deliver a significant level of both health care and other health-related services to the uninsured, Medicaid, and other vulnerable populations.8,9 Federally qualified health centres (FQHC) are the preferred primary care provider (PCP) for over 25 million people in the safety net10 and have been shown to deliver higher quality care at lower cost.11–15 But in order to maximise Medicaid fee-for-service payments,16,17 FQHCs have developed care processes that emphasise increasing visit volume rather than improving population health.18,19 Medicaid’s recent experiments in value-based payments for accountable care organisations (ACO)20,21 help align financial incentives with higher value care for populations, but there is a timing problem: shared savings begin to accrue 12–18 months after costs are incurred for care redesign, putting the transition to new care models out of reach for many cash-strapped FQHCs.22–24 As a result, many FQHCs remain in a risk-averse position, unwilling or unable to make the investments needed for care transformation.

Lean thinking offers a potential solution: by broadly engaging front-line staff in scientific problem solving, FQHCs can create robust system-level improvement at relatively low cost. The translation of lean thinking from its original intentions25–29 to healthcare has largely focused on adopting the visible tools and practices of Toyota and other perceived lean experts,30–34 resulting in a perception that ‘doing lean’ is equivalent to following a prescribed order of steps to remove waste from a value stream. The perspective of the authors, and the approach described in this paper, is that lean thinking always begins with an understanding of the purpose-driven problem you are trying to solve, but every step after that depends on the specific
situation. The tools employed to understand the causes of the problem—including how precisely or thoroughly those tools are deployed—should be just what is needed to discover the root causes, and no more. Similarly, the countermeasures used to address those causes should be sufficiently sophisticated and robust to close the identified gap, and no more. Because people are at the centre of these efforts to understand and design improvements, a focus on developing vital, flexible and capable teams is a cornerstone of lean thinking. Lean thinking can therefore be summarised as a situational leadership practice that balances respect for people with continuous improvement to maximise customer value while minimising waste. 35-37

Statistical process control (SPC) can augment the use of lean thinking in FQHCs by avoiding the twin problems of over-reacting to process noise inherent in the system and under-reacting to actual changes in system performance. 38-41 In a resource-limited setting, SPC is especially valuable in helping teams quickly confirm the effect of process changes (in order to build on and spread improvements) without wasting time and increasing change fatigue by chasing insignificant variation. Despite the successful use of lean principles in many industries, 42-44 including healthcare, 35-48 the current medical literature presents lean predominantly as a cost-cutting strategy that tends to undermine team cohesion, patient-centred care and professional autonomy. 49-54 As a result, healthcare organisations may overlook the potential of lean thinking to achieve the ‘quadruple aim’ 55 by enabling joy in work for staff, better experience for patients, better health for populations and lower overall cost.

The aims of this report are to: (1) demonstrate system-level improvement in hypertension control in a large FQHC contemplating a shift to Medicaid value-based payments; (2) describe the situation-specific use of lean thinking and SPC to engage teams in the design and implementation of a multicomponent hypertension care pathway; and (3) contribute to a fuller understanding of lean thinking as a leadership practice to engage people in purposeful, scientific problem solving—one that may have particular relevance for FQHCs seeking to transform care with limited financial resources.

**METHODS**

**Setting and participants**

Lynn Community Health Center (LCHC) is the third largest FQHC in the state of Massachusetts serving 4762 adult patients (18-85 years old) with a known diagnosis of hypertension, of whom 3148 (66.8%) were controlled, defined as a last measured blood pressure <140/90. A planning document (online supplementary appendix figure 1) noted that there was no agreed practice standard for hypertension at LCHC, PCPs were responsible for all prescribing decisions, there was no standard process for population health outreach and there was no prior experience with SPC.

**Intervention**

Appropriate treatment of hypertension has been estimated to prevent one death for every 125 patients treated, one stroke for every 67 patients and one heart attack for every 100 patients. 59 LCHC set a goal of improving hypertension control for 628 people (ie, 66.8% to >80% of LCHC’s patients with hypertension) and potentially preventing nine strokes, six heart attacks and five deaths. From a lean thinking perspective, this was the clear value for customer that defined our value-driven purpose for hypertension control and was communicated to our teams.
We designed and implemented a two-step intervention to improve hypertension control: (1) In June 2016, LCHC created organisational focus around hypertension improvement using lean ‘strategy deployment’; and (2) In December 2016, LCHC implemented a multicomponent hypertension care pathway designed using lean principles.

Step 1: focus on hypertension

Prior to the intervention, an exercise with LCHC leadership revealed that over 130 projects were in process or expected to start within the next 6 months (online supplementary appendix figure 2). Recognising that ‘if everything is a priority, nothing is a priority,’ LCHC leadership committed to using lean principles to help focus, align and engage its people around the few vital actions most likely to advance the organisation’s mission. The lean practice of ‘strategy deployment’ was selected as a countermeasure to prevent senior leaders from overwhelming the bandwidth of middle managers through lack of focus, too many priorities and constant firefighting.60 61

The first step in strategy deployment is to understand the organisational direction. Senior leaders created LCHC’s True North Compass, with ‘exceptional care, our commitment, every day’ at the centre and a limited set of metrics and priority actions in the four areas of Team, Patient, Quality and Financial Stewardship (figure 1). True North refers to ‘an organisation’s strategic and philosophical vision or purpose. It is a bond that may include ‘hard’ business goals such as revenue and profits as well as ‘broadbrush’ visionary objectives that appeal to the heart.’61 62

Five quality targets of varying difficulty were chosen with hypertension selected as a template chronic condition that would help LCHC establish a better system for population healthcare. The True North Compass and five quality areas were shared in an all staff meeting in June 2016, together with a renewed emphasis on the core mission of the organisation in the context of the coming Medicaid ACO.

LCHC’s next step in strategy deployment was to link organisational priorities to the daily work of front-line teams. A True North Quality Flow Map (figure 2) was created, in which:

1. Leadership sets the direction and target (eg, achieve hypertension control of ≥80% by 31 December 2017).
2. A Clinical Standards Committee determines the relevant evidence-based practice standard.
3. Performance improvement teams engage front-line staff to design and test workflows.
4. The Primary Care Clinical Oversight Group (comprised of the medical directors and nurse managers of each of LCHC’s nine primary care teams) vets the workflows, votes to approve them for use across primary care and communicates the new standards to their teams.
5. A staff development function coaches front-line team members to be able to practise the new standard reliably.
6. A daily management system troubleshoots performance problems and routes training issues to staff development, process issues to the performance improvement team, or systems issues to senior leadership.

This six-step process represents a version of the lean practice of ‘catchball’, in which key stakeholders cascade and negotiate goals and specific actions to meet those goals from the top of the organisation through to the front line. While Epic implementation had followed this six-step process, in general this way of working was new to LCHC.

Step 2: implement a multicomponent hypertension care pathway

LCHC’s Hypertension Care Pathway was designed following the lean principle that all process improvement should have four goals in this order of emphasis83:

1. Easier (intuitive and easily understood, as little wasted motion as possible).
2. Better (higher quality).
3. Faster (shorten the time to achieving hypertension control at the patient and population level).
4. Cheaper (near term by safely sharing the work with lower cost team members; long term by preventing emergency visits, hospitalisations and cardiovascular disease).

To address the challenge of consistent and straightforward communication across nearly 200 clinical staff in different care settings, a design team created a five-step framework for the LCHC Hypertension Care Pathway (figure 3), based on review of the medical literature and lessons learnt from a successful hypertension improvement effort at Virginia Mason Medical Center. This simple visual was used consistently and ubiquitously (in
communications, during meetings, posted in clinical areas) to facilitate staff alignment and understanding of the essential steps in the care pathway.

Five separate design teams (comprising a mix of clinical staff and front-line managers, facilitated by a physician improvement leader) designed, tested and iterated ‘standardized work’64–66 for each of the five key steps over a period of 6 months (see online supplementary appendix figures 3–6). The two purposes of this standardised work were to (1) facilitate training and maintenance of a consistent approach across LCHC, and (2) more readily recognise when the standard needed to be improved in order to meet the defined targets. Throughout the design process, the goals of easier, better, faster and cheaper (in that order of priority) were emphasised and the standards continuously iterated and improved. For example, the outreach team opted to use Epic’s Reporting Workbench because its direct integration into the electronic health record would avoid the need to shift between two systems (easier) and eliminate the possibility of transcription errors (better). Within Reporting Workbench, the hypertension registry was redesigned (online supplementary appendix figure 7) to remove visual clutter, reducing from 30 to 11 columns (easier). Embedded data links were selected to enable a team member to work intuitively from left to right, answering each question in the workflow in turn without needing to switch to a different screen (easier). The result of this process was a set of clear, intuitive and collaboratively designed workflows that clinical teams readily accepted as sensible ways to accomplish the organisation’s goal of improving hypertension control.

We launched the LCHC Hypertension Care Pathway in December 2016 with an educational session on Eighth Joint National Committee standards for all PCPs and nurses, followed by in-service training for all clinical staff on how to accurately measure blood pressure (online supplementary appendix figure 4). To further
facilitate effective and efficient training, we used the lean ‘job instruction’ method,\textsuperscript{66–68} which uses 1:1 coaching and observed practice over time to emphasise a limited number of key points (the critical elements that make or break the process) and the reasons why those key points matter. This initial launch was followed by several rounds of training on the outreach workflow from January through March 2017, followed by team-by-team implementation of nurse hypertension care pathway visits (in which nurses adjust up to three medications on the care pathway following PCP delegated orders) beginning in April 2017.

Measures

The next problem to solve was how to recognise if the new standardised work was occurring as intended, and if so whether it was advancing the overall goal of controlling hypertension in LCHC’s population. A newly designed hypertension scorecard tracked five metrics corresponding to the primary outcome (hypertension control) and key process steps in the LCHC Hypertension Care Pathway (table 1).

<table>
<thead>
<tr>
<th>Measure name</th>
<th>Type of measure</th>
<th>Type of chart</th>
<th>Operational definition</th>
<th>Data source(s)</th>
<th>Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>% BP at goal</td>
<td>Outcome</td>
<td>P chart</td>
<td>(N=\text{number of patients* with HTN and BP}&lt;140/90}) D=number of patients with HTN with PC billable visit in month</td>
<td>Epic (\rightarrow) DRVS(\ddagger), uploaded nightly</td>
<td>&gt;80% by 31 December 2017</td>
</tr>
<tr>
<td>% Recheck BP if elevated</td>
<td>Process</td>
<td>Run chart, then P chart</td>
<td>(N=\text{number of patients with first BP}&gt;140/90 and second BP check in same encounter}) D=number of patients with first BP&gt;140/90 in face-to-face encounter</td>
<td>Epic (\rightarrow) SQL (\rightarrow) Excel, output on Thursday before first Monday of each month</td>
<td>&gt;80% by 31 December 2017</td>
</tr>
<tr>
<td>% BP in last 6 months</td>
<td>Process</td>
<td>P chart</td>
<td>(N=\text{number of patients with BP check in last 6 months}) D=number of patients with HTN</td>
<td>Epic (\rightarrow) SQL (\rightarrow) Excel, output on Thursday before first Monday of each month</td>
<td>&gt;80% by 31 December 2017</td>
</tr>
<tr>
<td>% Outreach if BP not at goal</td>
<td>Process</td>
<td>Run chart, then P chart</td>
<td>(N=\text{(number of patients with last BP}&gt;140/90 or no BP check in last 6 months) and outreach telephone encounter in past 1 month}) D=number of patients with HTN last BP&gt;140/90</td>
<td>Epic (\rightarrow) SQL (\rightarrow) Excel, output on Thursday before first Monday of each month</td>
<td>&gt;80% by 31 December 2017</td>
</tr>
<tr>
<td>% HTN encounters by RN, BH, PharmD, CHW</td>
<td>Process</td>
<td>P chart</td>
<td>(N=\text{number of encounters (all types) with HTN visit diagnosis and rendering provider}) Ş D=number of encounters (all types) with HTN visit diagnosis</td>
<td>Epic (\rightarrow) Excel, output on Thursday before first Monday of each month</td>
<td>&gt;50% by 31 December 2017</td>
</tr>
<tr>
<td>100% Team members trained</td>
<td>System</td>
<td>Check sheet</td>
<td>Yes=100% of team members trained in HTN workflow No=&lt;100% trained</td>
<td>Team leader self-report at weekly PC improvement meeting</td>
<td>100% by 1 April 2017</td>
</tr>
</tbody>
</table>

Hyptension control data were downloaded nightly from Epic to a data warehouse (DRVS) where they were accessible to clinical team members in near real time. A quality analyst abstracted data from Epic to create the process metrics for blood pressure recheck if elevated, hypertension visits by provider type and outreach. Staff training on hypertension workflows was tracked weekly during Primary Care Clinical Oversight Group meetings (online supplementary appendix figure 8).

Data analysis

SPC was used to understand the effect of the two-step intervention on hypertension control, using the previous 24 months to establish baseline performance. The methods and application of SPC in healthcare have been thoroughly described.\textsuperscript{40 69–71} Attribute data with varying subgroup sizes were represented in P charts using QI Macros 2016 software. The Institute for Healthcare Improvement rules were used to differentiate special cause variation.\textsuperscript{69} Both system and team-level data were analysed to understand variation and correlation of cause and effect as teams implemented the hypertension

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*All patients were enpanelled to an LCHC primary care provider (PCP).
†Blood pressure goal of <140/90 defined by the Uniform Data System (UDS) for community health centres.
‡DRVS from Azara, Data Reporting and Analytics Solutions software.
§Rendering provider: RN, behavioural health, PharmD or community health worker.
BH, behavioural health; BP, blood pressure; CHW, community health worker; HTN, hypertension; LCHC, Lynn Community Health Center; PC, primary care; RN, registered nurse; SQL, Structured Query Language for data analysis.
care pathway at different times and with varying degrees of success. The physician improvement leader sent a monthly communication to all clinical staff and LCHC leadership with results and interpretation of the hypertension scorecard, noting special cause and likely correlation with teams’ improvement efforts.

Ethical considerations and funding
Clinical care consent was obtained from all patients at LCHC. All interventions followed evidence-based guidelines and were funded as part of usual clinical operations at LCHC. The Revised Standards for Quality Improvement Reporting Excellence 2.0 was used to prepare this report.

RESULTS
Baseline hypertension control at LCHC from March 2014 through May 2016 averaged 66.8% (figure 4). Lower control rates from December 2014 through March 2015 (special cause attributed to a winter with record-breaking snowfall) were omitted from the baseline calculation to avoid overestimating the effect size of the intervention.

In June 2016, step 1 of the intervention (organisation-wide focus on hypertension) resulted in an immediate improvement in hypertension control to 72.3%. From December 2016 through August 2017, step 2 of the intervention (implementation of a multicomponent hypertension care pathway) resulted in an aggregate increase in hypertension control to 78.2%. The overall improvement from baseline to the average of the most recent 6 months was 11.6%.

Analysis of team-level data showed that six out of the seven adult primary care teams achieved special cause improvement during the intervention period. The improvement occurred at different times and was closely correlated with teams’ success at implementing various steps of the hypertension care pathway (figure 4).

The process data facilitated several rounds of rapid cycle improvement. For example, initial blood pressure recheck rates were low, prompting an investigation into potential barriers. Two root causes were identified: (1) the correct blood pressure cuffs often were not available in the exam room; and (2) communication of elevated blood pressure was often omitted when medical assistants did not have time to talk with providers between visits. One series of Plan-Do-Study-Adjust (PDSA) cycles improved availability of correct blood pressure cuffs from 50%–70% to >95% (verified in random audits) by using the lean principle of ’5S’ to create a standard location for the four cuff sizes in all exam rooms (online supplementary appendix figure 9b). To facilitate communication of elevated blood pressure from medical assistants and provider recheck of blood pressure, a second PDSA series used the lean principle of ‘visual control’ to create two additional signals of elevated blood pressure: a standard blood pressure column on the Epic clinical schedule (online supplementary appendix figure 10) and a red stop sign on the exam room door that the provider takes into the room and turns over to green after they recheck the pressure (online supplementary appendix figure 11). The result of both PDSA series was improvement in blood pressure recheck rates from 19.5% to 43.5% (figure 5).

DISCUSSION
We achieved an 11.6% system-wide improvement in hypertension control among 4762 adult patients over a period of 14 months in a large FQHC without external funding or additional staff using lean thinking and SPC. Our two-step intervention began by creating organisation-wide focus on hypertension, then introduced a multicomponent hypertension care pathway. Within that two-step intervention, we applied a consistent approach of situational lean thinking to understand and address specific problems and obstacles discovered along the way. We used SPC to demonstrate a clear link between implementation of the pathway and improved hypertension control as well as facilitate shared learning among seven integrated primary care/behavioural health teams. In August 2017, hypertension control exceeded LCHC’s True North target of 80% 4 months ahead of schedule. In November 2017, LCHC was selected as a 2017 Million Hearts Hypertension Control Champion by the US Centers for Disease Control and Prevention.

Four key success factors included:
1. Experienced improvement leaders.
2. Organisational focus on empowering and engaging front-line staff to understand the problem and design intuitive processes that made the work easier, better, faster and cheaper (in that order of emphasis).
3. Situational, context-specific use of lean principles (eg, strategy deployment, standardised work, job instruction, PDSA, 5S, visual control).
4. Use of SPC to learn from variation and facilitate the spread of improvement.

Interpretation
The initial 5.5% improvement likely resulted from a Hawthorne effect (in which individuals modify their behaviours in response to the awareness of being observed), amplified by LCHC’s organisational focus on hypertension. The subsequent 5.9% improvement likely resulted from implementing the multicomponent hypertension care pathway, specifically the first three pathway steps where we observed broad adoption: (1) check blood pressure accurately, (2) recheck blood pressure if elevated, and (3) diagnose and treat hypertension correctly. Given only partial adoption to date, it is not yet clear what the full effect will be of implementing step 4 (coach lifestyle changes while sharing the care with other team members) and step 5 (outreach if blood pressure is above goal or has not been checked within the last 6 months). Though much work remains to be done, our results to date demonstrate that as a group, nearly 200

LCHC clinical staff changed their approach to hypertension and sustained that change over 14 months.

Our report also presents lean thinking as a situational, balanced approach to engaging people, understanding root cause and improving processes that is not adequately represented in the current medical literature.50–54 83–86

The consequences of this incomplete understanding of lean thinking include:

![Figure 4](A) Lynn Community Health Center (LCHC) hypertension control, March 2014 to August 2017 (P chart). (B) Hypertension control by primary care team (P chart). (A, B) Statistical process control charts tracking hypertension control performance at the system and individual team levels were shared monthly with brief interpretation by the physician improvement leader. This helped teams understand the effect of implementing the LCHC Hypertension Control Pathway on improved performance. BP, blood pressure; CL, center line; HTN, hypertension; MSWA, Market Square/Western Avenue.

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The consequences of this incomplete understanding of lean thinking include:

Our experience—not to replicate the specific steps, but rather to develop the capability for lean thinking in their organisation—can enable healthcare organisations to deliver extraordinary value to their patients, create meaningful and well-remunerated work for employees and accelerate health system transformation towards the quadruple aim. Lean thinking may be a particularly good fit for FQHCs who, like LCHC, face the existential crisis of achieving care transformation with limited resources and without the necessary cash flow to absorb 1–2 years of losses before investments in care redesign materialise into financial savings. LCHC was able to accomplish important first steps in care transformation without external funding or additional staff. Others may be able to benefit from our experience—not to replicate the specific steps, but rather to develop the capability for lean thinking in their organisation and thereby reduce both uncertainty and risk in embarking on systemic change.

Limitations
Our study has several limitations. We have not demonstrated durable results beyond 14 months. If our organisational focus wavers, our processes may degrade, and performance may regress towards baseline. Since part of the hypertension care pathway has not been fully implemented across all teams, we are unable to estimate the effect of the full pathway on hypertension control in our patient population. Despite these significant limitations, we believe our results are generalisable to the extent that the problems we faced are widely shared among FQHCs and the approach to engaging staff and applying situational lean thinking and SPC would likely be successful in other FQHC contexts.

Conclusions
There is a proven way to achieve the quadruple aim: the situational use of lean principles to engage and empower people in scientific problem solving. The challenge is developing capability for lean thinking while avoiding the pitfalls of top-down interventions, copy/paste thinking and aiming for easier, better, faster and cheaper out of sequence—and then finding the courage to persist. We embraced lean thinking 3 years ago and successfully began the journey towards improving population health at lower cost. We invite other FQHCs, health system leaders and policymakers to take a closer look at the principles, relevance and potential impact of lean thinking in resource-limited settings.

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Contributors
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