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'Trying to fly the plane while we were building it'. Applying a learning health systems approach to evaluate early-stage barriers and facilitators to implementing primary care transformation: a qualitative study

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ABSTRACT

Objective A learning health system (LHS) uses data to generate evidence and answer questions required to continually improve system performance and patient care. Given the complexities of practice transformation, an area where LHS is particularly important is the study of primary care transformation (PCT) as PCT generates several practice-level questions that require study where the findings can be readily implemented. In May 2019, a large integrated health delivery system in Minnesota began implementation of a population management PCT in two of its 40 primary care clinics. In this model of care, patients are grouped into one of five service bundles based on their complexity of care; patient appointment lengths and services provided are then tailored to each service bundle. The objective of this study was to examine the use of a LHS in PCT by utilising the Consolidated Framework for Implementation Research (CFIR) to categorise implementation lessons from the initial two PCT clinics to inform further implementation of the PCT within the health system.

Design This was a formative evaluation in which semistructured qualitative interviews were carried out. Observational field notes were also taken. Inductive coding of the data was performed and resultant codes were mapped to the CFIR.

Setting Two suburban primary care clinics in the Twin Cities, Minnesota.

Participants Twenty-two care team members from the first two clinics to adopt the PCT.

Results Seventeen codes emerged to describe care team members' perceived implementation influences. Codes occurred in each of the five CFIR domains (intervention characteristics, outer setting, inner setting, characteristics of individuals and process), with most codes occurring in the 'inner setting' domain.

Conclusions Using an LHS approach to determine early-stage implementation influences is key to guiding further PCT implementation, understanding modifications that need to be made and additional research that needs to occur.

Strengths and limitations of this study

► Learning health system research provides a nimble approach when other study designs, such as randomised control trials, are not always feasible or practical.
► Using the Consolidated Framework for Implementation Research, this provided a theoretical framework for outlining the results and illustrating where implementation influences exist (eg, among individuals vs the model itself vs the process of implementation).
► This study was carried out with the first two clinics that underwent primary care transformation, which may limit generalisability of the findings.
► As the primary care transformation expands to more clinics with different team environments and patient populations, it is possible that other implementation barriers and facilitators will emerge.

INTRODUCTION

A learning health system (LHS) is a healthcare system in which data and knowledge are intentionally produced that can be readily implemented into practice to improve patient outcomes and health system performance.[1] An LHS also creates value for the system by producing outcomes that support the Quadruple Aim of (1) improving population health, (2) decreasing healthcare costs, and improving (3) patient experience and (4) provider experience.[2 3] An area where LHS research is particularly relevant is during deimplementation, adaptation of existing practices and adoption of new practice approaches, such as with primary care transformation (PCT). It is widely recognised that primary care is foundational

to improving healthcare quality, increasing access to care and containing healthcare costs.[4 5] However, to get there, primary care practices must undergo PCT to adopt new team-based models of care that focus on high-quality comprehensive care with a population management focus.[6] During PCT, as with many clinical team-based innovations, there are modifications made to care team roles, workflows and care delivery routines that require timely research and evaluation to assess effectiveness and successful implementation.[7 8] In turn, these findings facilitate adoption, expansion and sustainment of transformation efforts.[8] Currently, an academic health system partnered with the University of Minnesota, M Health Fairview, is applying a LHS evaluation lens to study their population management-focused PCT.

In 2008, Minnesota enacted the Healthcare Home Initiative as part of their health reform law allowing Minnesota to be a national leader on developing and implementing Patient Centred Medical Homes (PCMHs).[9 10] Having already adopted the PCMH model in 2011, M Health Fairview is now building on that effort by implementing a population management-focused PCT based on risk stratification to place all primary care patients into one of five strata called 'service bundles'. Appointment lengths and services provided are then tailored to each service bundle (eg, patients in the most complex service bundle, service bundle 5, have initial visits that last 60 min and a nurse, pharmacist and physician are all present in the visit). In the USA, primary care visits, on average, last about 20 min.[11–13] This 20-min increment is often not enough time to address patient needs and short visit times have been linked to decreased patient satisfaction,[14] decreased provider satisfaction and increased burnout,[13] as well as reduced quality of care.[13 15 16] Therefore, practice transformation that incorporates risk stratification and uses a flexible, adaptable approach to determine visit length and tailored care delivery processes may be a promising approach to maximising primary care's role in addressing the Quadruple Aim.

Critical to any transformation effort, and a component of LHSs, is the organisational process of implementing the new model into practice. Implementation science is a growing field focused on promoting the systematic uptake of evidence-based practices into routine practice.[17] An important component of implementation, particularly implementing practice transformation, is context. Contextual factors, such as available resources, organisational structure and practice characteristics, can have a profound impact on the success or failure of that transformation.[18 19] A widely used framework that identifies the contextual influences on implementation is the Consolidated Framework for Implementation Research (CFIR). The CFIR provides a comprehensive list of factors that influence implementation in the healthcare setting, and therefore, provides a helpful framework for understanding the factors that may influence PCT implementation across clinics. The CFIR is composed of 39 constructs believed to influence implementation; these constructs are grouped into five domains (box 1): (1) intervention

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Box 1 CFIR Domains and Constructs[20]

1. Intervention characteristics
Intervention source
Evidence strength and quality
Relative advantage
Adaptability
Trialability
Complexity
Design quality and packaging
Cost

2. Outer setting
Patient needs and resources
Cosmopolitanism
Peer pressure
External policy and incentives

3. Inner setting
Structural characteristics
Networks and communications
Culture
Implementation climate
Readiness for implementation

4. Characteristics of individuals
Knowledge and beliefs about the intervention
Self-efficacy
Individual state of change
Individual identification with organisation
Other personal attributes

5. Process
Planning
Engaging
Executing
Reflecting and evaluating

CFIR, Consolidated Framework for Implementation Research.

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characteristics, (2) inner setting, (3) outer setting, (4) characteristics of individuals and (5) implementation process.[20]

Applying an implementation science lens to LHS research early in a transformative effort can help direct and improve the spread and uptake of transformation across primary care clinics. Furthermore, qualitative methods can provide in-depth insights into what is working and what is not. Therefore, incorporating implementation science and qualitative methods is key to providing early-stage findings to support the LHS model and inform PCT efforts. Thus, the objective of this study was to use the CFIR to categorise implementation lessons from the initial two M Health Fairview clinics that adopted the population management focused-PCT.

METHODS
Setting and PCT model
M Health Fairview is an integrated health system comprised of 10 hospitals and 40 primary care clinics across Minnesota and Wisconsin. In May 2019, the system

Table 1 Description of patient service bundles

	Bundle 1	Bundle 2	Bundle 3	Bundle 4	Bundle 5
Approximate patient volume	<1%	50%	35%–40%	15%–20%	2%–3%
Typical office visit length*	20 min	30 min	30 min	30 min	60 min
General description	Patients who decline a relationship with primary care	Patients with no active medical conditions or medical issues are well controlled	Patients adherent with care plan, but not meeting their goal(s)	Patients not engaged in their care or experiencing barriers to care	Patients with complex medical diagnoses taking multiple prescription medications and high healthcare utilisers
Patient-advocate and liaison	Team coordinator	Team coordinator	Nurse	Clinic health guide	Nurse

*There are many different visit types (eg, follow-up visit, preoperative visit) and visit lengths vary depending on visit type.

began a phased population management-focused PCT in two of their clinics, with a plan to ultimately expand the PCT across all 40 primary care clinics. To facilitate oversight and implementation, the two PCT clinics were selected because they were located in the same region. Characteristics of the patients of these two clinics have been presented previously.[21]

Although there are many elements that changed during the PCT, three key changes are (1) the placement of patients into service bundles which determined their appointment lengths and resources available, (2) the introduction of the patient advocate and liaison (PAL) role and (3) an increased emphasis on team-based care. In the PCT, patients are automatically placed into a service bundle using an algorithm of electronic health record (EHR) data; however, providers (ie, physician, nurse practitioner and physician assistant) can manually override the assignment thus reassigning patients to a different service bundle when appropriate. Table 1 provides a brief overview of the different service bundles.

In addition, each patient is assigned a PAL to serve as their point of contact with the primary care team. Different care team members were assigned to different service bundles. For example, nurses were assigned to be PALs for the patients in service bundles 3 and 5, while team coordinators are the PALs for service bundles 1 and 2 and clinic health guides for service bundle 4. Other resources, such as clinical pharmacy services, behavioural health and care coordination, are also incorporated more frequently depending on the service bundle assignment. To test this as a value-based payment model, providers were compensated based on previous salaries, rather than productivity via relative value units in the traditional fee-for-service payment structure.

Study design
Study design entailed a formative evaluation relying on qualitative data from semistructured interviews and observational field notes. The University of Minnesota Institutional Review Board determined that this study did not require formal review.

Participants
To hear from a variety of care team members, individuals from different leadership and care team roles were identified with advice from system stakeholders. Individuals occupying each role were then either randomly or purposefully selected. For example, clinic administrators were purposefully identified because they were the only individuals holding those roles. However, other roles, such as providers, were randomly selected from employee lists from each clinic. Interviewees were selected to get representation from both clinics, as well as a variety of care team roles. This was also balanced with the number of interviews thought to be needed to achieve data saturation.

Patient and public involvement
There were no patients involved in this study; all participants were care team members who provided their consent.

Data collection
Interviews were conducted by an LHS researcher (DLP) embedded in the M Health Fairview system as part of a K12 career development award.[22] Interviews occurred January through March 2020 and lasted, on average, 32 min (range 19–48 min) (appendix 1). All interviews were audio recorded and transcribed verbatim. In addition, the first author (DLP) spent 6 months in the two model clinics observing clinic meetings, daily station huddles and shadowing different care team members. This was all done to support the embedded nature of LHS research. Field notes were taken during this time to aid in interpretation of the qualitative interview findings.

Data analysis
To code the data, we performed an inductive coding analysis using first-cycle holistic coding and subcoding methods[23] and then mapped emergent codes to CFIR domains and constructs. To begin, two authors experienced in qualitative research (DLP and KMW) independently reviewed four transcripts and met to discuss

Table 2 Interview participants by role

Role	Number of participants
Clinic administrator	2
Home health nurse	1
Medical assistant	2
Patient advocate and liaison	5
Patient care representative	2
Pharmacist	4
Provider (ie, physician, nurse practitioner, physician assistant)	5
Scheduler	1
Total	22

emergent codes to create an initial codebook. While the first author (DLP) went on to code the remaining transcripts in NVivo V.12 (QSR International), the two authors met throughout the coding process to discuss and refine codes and definitions. During the meetings, application and definitions of codes were discussed and debated until consensus was reached. Codes were also compared and confirmed with field notes that were taken. Additionally, the second author (KMW) reviewed the final NVivo file as an audit check to assess the concurrence of the application of codes to transcript excerpts and determine intercoder agreement. The two authors then mapped the codes to the domains and constructs of the CFIR.

RESULTS
Twenty-two care team members and leaders (11 from each clinic) working in the two initial PCT clinics participated in interviews (table 2).

From the coding method described above, 17 codes were derived which mapped to the CFIR constructs and domains. The CFIR domains were renamed to be consistent with the PCT intervention (eg, 'inner setting' was labelled 'clinic and system-level factors'). Appendix 2 lists the domains and codes mapped to the CFIR along with example quotes of each code. Following is a description of each CFIR domain as it relates to the PCT and their salient codes. Few codes mapped to the CFIR domains of 'outer setting' or 'characteristics of the individual', while most codes were related to the 'inner setting' and 'process' of implementation.

Intervention characteristics: the PCT model
According to the CFIR, intervention characteristics are aspects of the intervention itself that may enable or hinder implementation.[20] In this case, this means aspects of the PCT model itself. A characteristic of this PCT that was stressed by participants was the amount of change that had to occur (eg, greater emphasis on team-based care, placing patients into different service bundles and scheduling changes) at once. Consistent understanding

and application of the bundle criteria took time to establish, as did determining appropriate scheduling templates and workflows. The complexity of the care model, as well as its packaging, caused initial stress for the care team to manage the different components. However, a characteristic of the PCT that was seen as a positive was the lengthening of appointment times for certain patient bundles. While one person pointed out that there is still the need to agenda-set with some patients, many interviewees commented on the benefits of longer appointment lengths. They felt that patients could ask more questions during the visit, which could potentially decrease the need for subsequent visits. Also, many interviewees commented that fewer things (eg, documenting, placing referrals, ordering medications and looking into patient concerns) were likely to 'fall through the cracks' with longer appointments and that providers were less likely to fall behind.

Outer setting: patient factors
The outer setting refers to external influences on implementation, including patient needs and resources.[24] Not having a full understanding of patients' needs at the start of the PCT, two aspects that emerged on implementation were communicating the PCT to patients and helping patients to adjust their expectations to the new PCT model. For example, no formal communication was sent to patients about the PCT, and a few interviewees commented on the impact that had, particularly on patients not understanding why provider access had changed. One interviewee mentioned that sending out a letter to patients ahead of time may have prevented this frustration. In addition, a few interviewees discussed the need to orient patients to this new approach to care. They discussed how patients were used to coming in to see a provider for things that may not have been medically necessary, and that there was a need to 'train' patients to utilise alternate resources like EHR messaging (eg, MyChart) or other care team members, such as their PAL or the clinical pharmacist for such needs.

Inner setting: clinic and system-level factors
The inner setting comprises organisational characteristics that may affect implementation. In the case of the PCT, one system-level factor that was brought up was staffing. Not all staff, such as PALs and a designated bundle five provider—providers of the most clinically and socially complex patients—had been hired prior to the start of the PCT. Because of this, a number of interviewees commented that roles and workflows could not be adequately tested, which affected implementation. Conversely, other positions felt that they had been appropriately staffed at the start of PCT, but that their roles could not be maximised because of staffing shortages in other areas. With regard to staffing, there were also some questions related to panel sizes. Interviewees noted that there was a need to determine the right panel size for this

new model of care and how patient complexity should be factored into panel size.

Communicating changes and updates related to the PCT occurred through a variety of modes, including emails, staff meetings and a weekly newsletter. However, with all the changes that were occurring throughout the PCT, some expressed the desire for even more communication, particularly among stations and clinics, as one interviewee noted, 'We are just operating within our stations where we can talk a lot between ourselves, but have no idea what's going on at other stations or how they use their PALs or any of those things. There isn't a lot of cross-pollination with ideas'. Some interviewees also expressed that clinic leaders were working to implement the PCT on top of their existing administrative duties, which may have contributed to communication and implementation issues.

Characteristics of individuals: care team response

Characteristics of individuals represent the interplay between the intervention and the individuals involved in the implementation. When discussing the PCT, this was reflected as the care team's response to the PCT. One individual characteristic that impacted the PCT was the shift in mindset that needed to occur to provide increased team-based care. Some care team members seemed to readily adapt to operating as a team with shared interdependencies, whereas others found it especially difficult to share accountability and responsibility. For example, one participant commented, 'We're all interconnected. We're moving to a place where it's not, and this can be scary for some providers, it's not the doctor in their own office dictating the plan. It's going to be all of us as a team, sharing the work together, helping a population'. However, a couple of providers did share their struggle in moving to more team-based care, as one provider noted, 'For us, we've been doing this on our own for so long, it's hard to be like "OK, you can take over". I don't know how to do that'. Therefore, providers were in different stages of adopting and utilising team-based care.

Process: implementing the PCT

The final CFIR domain is the process of implementation, which in this case represented the process of implementing the PCT. Some interviewees discussed that they felt certain parts of the PCT were not being implemented as planned and variation existed in how the PCT was being implemented between the two model clinics. For example, as part of the PCT, clinics were to move to a team medical assistant (MA) model where all MAs at a station worked interchangeably to support all the providers at that station, as opposed to the previous one MA for one provider model. However, one clinic reverted back to the one MA for one provider model a few months after the PCT began, which caused some frustration among care team members that were following this component of the PCT.

Finally, because certain roles and workflows were still being developed and refined throughout the implementation of the PCT, this created some challenges with understanding roles and responsibilities. For example, one interviewee discussed a lack of clarity around the bundle 3 PAL role, 'We did not really know what (the PAL) role would be like until we started it. We had visions of what it would be, but I guess we really didn't know what that role would encompass. I think having that role clearly defined would have really helped…I think that we are getting lost, and each provider is defining what they want that service bundle 3 role to be'. Along with roles, interviewees pointed out the difficulties of developing workflows in the midst of transformation and the challenge of having the time and resources to do so. Nevertheless, many interviewees commented that several months in, they felt that workflows were starting to stabilise and come together. With regard to engagement on defining roles and workflows, care team members from different roles were involved in initial planning of the PCT, but as the PCT went live, continued engagement of care team members waned. Many expressed a desire to be more involved in the process and have a means to provide feedback.

Summary

While barriers and facilitators occurred in all CFIR domains, the most common determinants, occurred within the 'inner setting'. However, certain barriers, such as shifting mindsets around roles, which occurred within 'characteristics of the individual'/care team response, appeared to be more impactful to the success of the implementation than others, such as training.

DISCUSSION

Applying principles of a LHS, this study sought to identify implementation lessons from two clinics undergoing a population management-focused PCT to inform expansion and sustainment of the PCT within the health system. PCT is a complex undertaking, but evaluating influences on implementation early in the transformation process can guide adaptations that need to be made and provide key insights into the progress and effectiveness of implementation efforts.[8] In addition, LHS research is well suited for this type of evaluation as it often focuses on complex, multifaceted interventions. While study designs, such as randomised control trials, allow for the assessment of causal relationships, randomisation is not always feasible, practical or appropriate for all interventions. In contrast, LHS research can provide a nimble approach that relies on a study design that is appropriate for the evaluation purpose or question, as well as the needs or expectations of stakeholders.[25]

There were a number of key take-aways from this study that may facilitate the adoption and spread of this PCT model across M Health Fairview as these learnings are applied and may also inform similar PCT work

in other clinics or health systems. For example, one of the implementation barriers cited by participants was the magnitude of changes that occurred simultaneously in implementing the PCT. Change management can be difficult in any setting, but the complexity of healthcare and the degree of change that can accompany PCT makes change that much more difficult. As a result of this learning, aspects of the PCT, such as bundling patients, are being phased into the next cohort of PCT clinics. For example, the bundling criteria are now being applied to clinic patient populations months before a clinic goes 'live' with the PCT so that providers and staff have more time to review and assess the patients' bundle assignment, adjust bundle assignment if needed and provide feedback on the bundling criteria, as well as staffing for the various bundles. In addition, patients of the new PCT clinics are sent a letter informing them of the changes that will be occurring and the new team structure to help facilitate their understanding and acceptance of this new model.

There were also some learnings that require further study as the PCT is expanded. For example, many care team members felt that they were providing higher quality of care through the PCT and some providers noted that the longer appointment times decreased the amount of time they spent documenting outside of clinic hours. However, longer appointment lengths meant that providers were able to see fewer patients face-to-face on a daily basis, which resulted in access issues. Prompt access to care is one of Bodenheimer *et al*'s 10 Building Blocks of High-Performing Primary Care,[26] as access to primary care has been shown to decrease healthcare costs.[27] The health system has taken some measures to improve access by hiring a full-time bundle 5 provider and physician extenders (ie, providers that do not establish care with patients as their primary care provider, but are available to address acute needs, hospital follow-ups, etc). However, some interviewees also suggested that access may be alleviated if patients used additional modes of care, such as telephone, virtual or electronic messaging in order to free up face-to-face provider time. As a result of COVID-19, a significant portion of care has currently shifted to being non face-to-face, so further research will be necessary to evaluate if patients still utilise these modes of care beyond the COVID-19 pandemic and the impact this has on access. Research examining patient experience and outcomes using these different care modalities will also be needed. Furthermore, applying a systems science approach that leverages the expertise of healthcare system engineers to optimise coordination of scheduling protocols may also be necessary.[28]

Greater involvement of other care team members, such as nurses, pharmacists and behavioural health, could also increase access. For example, at M Health Fairview, clinical pharmacists have the ability to prescribe medications under their collaborative practice agreement, so patients needing medication management could be seen by a pharmacist instead of their primary care provider. To address this, the system now has workgroups in

place focused on increasing the use of interprofessional services. However, a number of providers also discussed how this shift to provide more team-based care was difficult for them to make. Team-based care is central to many healthcare reforms and offers many potential advantages,[29] yet it comes with a number of challenges, including identity issues (eg, what is a care team member's role to the patient and care team?), role and team development, culture shift and behaviour change.[30–33] One strategy the system is currently using to foster teamwork is daily huddles at each station where different care team members can share updates, wins or barriers they are facing. While the shift to enhance team-based care throughout the health system's PCT will likely require many approaches, including enhanced communication, trust building and further training on roles and expectations, understanding the development need for this early in the PCT is critical to its success.

One interviewee described the process of implementing the PCT as 'Trying to fly the plane while we were building it'. Once a PCT is implemented in practice, there is a significant amount of learnings and adaptations that emerge, making it important to conduct formative evaluations early in the process of PCT implementation, as well as throughout. The CFIR is a valuable tool because it gives structure for guiding formative evaluations by providing an organisational framework of key implementation determinants. Linking determinants to specific domains, as was done in this study, helps to support the LHS because it illustrates where certain barriers may exist (eg, among individuals vs the model itself vs the process of implementation) which, in turn, can inform adaptations that may need to be made, training, communication and other implementation strategies.

LHS research is an iterative process. While learnings from these two clinics that were the first to adopt the PCT provide critical insights into initial barriers and facilitators, continued research on the implementation and effectiveness of the PCT is necessary. Context is a key component in many implementation and evaluation frameworks.[34 35] Therefore, it will be important to monitor the development of the implementation influences of the PCT and to assess the emergence of any new barriers or facilitators as the PCT expands. In addition, these influences can be linked to outcomes in the postimplementation phase to determine how certain outcomes may have been affected by these implementation barriers and facilitators and to what extent.[20]

Limitations
A potential limitation of this work is that this PCT model was tested under value-based payment conditions and providers were compensated based on previous salaries, rather than productivity via relative value units or fee-for-service. Had the PCT occurred in a strictly fee-for-service payment environment, then the PCT model cost may have presented as a more prominent barrier. In addition, to assess initial barriers to the PCT, the study was carried out

with the first two clinics that underwent the PCT, which may limit generalisability of the findings. Finally, as the PCT expands to more clinics with different team environments and patient populations, it is possible that other implementation barriers and facilitators will emerge.

CONCLUSION

PCT is essential to providing efficient, quality care that improves patient outcomes and decreases healthcare costs. Given the complexities of healthcare and transformation efforts, it is critical to adopt a LHS approach to study the progress and outcomes of PCT. This iterative process to research ensures that barriers are identified and addressed, and that the transformation is being implemented as intended and achieving desired outcomes. Furthermore, applying an implementation science lens during the research process provides structure and a theoretical framework to guide research methods, analyses and interpretation of findings. Integrating these two approaches—LHS and implementation science—can accelerate the implementation process to achieve maximum benefit to patients and care teams.

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