

Becoming a learning health system: Designing and implementing a patient-centred clinical intervention

Received (in revised form): 10th January, 2019



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Abstract An increasing number of healthcare systems embrace the concept of becoming learning health systems, particularly in response to pressure from payers and patients to provide high-value care. Yet many healthcare systems have little experience with the continuous process of using research findings and data analysis to inform the design of interventions that can be evaluated, modified and redeployed. This paper provides one system's experience with identifying a target patient population and determining an initial intervention that balances the interests of patients, providers and payers while also addressing numerous organisational barriers that need to be carefully navigated for successful implementation. It includes lessons learned to assist healthcare systems or providers who are interested in initiating the process of becoming learning health systems but are unsure of how to get started.

KEYWORDS: learning health system, diabetes prevention, employee health

BACKGROUND

As payers begin to shift towards alternative payment models^{1,2} in response to the rising cost of care, particularly for chronic diseases,^{3,4} some healthcare systems have responded by increasingly embracing models of care⁵ that incorporate the principles of a

learning health system (LHS).⁶ The Institute of Medicine⁷ and the Agency for Healthcare Research Quality⁸ define an LHS as having the following essential features: (1) the use of health information technology (IT) to capture and analyse real-time data from patient care; (2) real-time generation and

application of clinical knowledge; (3) inclusion of patients as vital members of care teams and (4) leadership-instilled cultures of learning in order to turn clinical research knowledge into practice.^{9,10}

Early evidence suggests that some healthcare delivery systems have successfully improved quality, lowered costs and improved efficiency as part of transitioning to and identifying as an LHS.^{11–13} For example, in 2004 the Veterans Affairs (VA) healthcare system developed the Clinical Assessment Reporting and Tracking (CART) Program to support quality improvement (QI) in their cardiac catheterisation laboratories. The programme incorporated a number of LHS features, including an enhanced electronic health record (EHR) system to provide clinicians with real-time data and to aid QI and research endeavours.^{14–17} Pre-populating all data fields in the EHR so clinicians no longer waste valuable time inputting basic patient data,¹⁵ the programme has since been incorporated into all VA catheterisation laboratories¹⁷ with evidence of improved efficiency of care. The CART program has also led to an EHR-based study discouraging the prescription of testosterone to men with low serum testosterone undergoing coronary angiography in view of an increased risk of cardiovascular events or death.¹⁸ Furthermore, research has led to the implementation of a risk assessment tool that includes mean pulmonary artery pressure (mPAP) based on EHR results showing that elevated mPAP independently predicts mortality.¹⁹

Similarly, Group Health Cooperative, a large integrated health system in the Pacific Northwest, implemented a system-wide ‘rapid learning health system’¹² that successfully reduced high-dose opioid prescriptions by 12–13 per cent per year for group practice physicians compared with contracted physicians.^{20,21} ImproveCareNow, a paediatric LHS throughout the United States, recently demonstrated that paediatric patients with Crohn’s disease

initiating anti-TNF α therapy experienced significantly greater rates of remission and corticosteroid-free remission with adjusted rate ratios of approximately 1.5–1.75.^{22,23} In addition, the University of Wisconsin employed a five-step approach to create a continuous LHS, showing significant increases in mammography, pneumococcal vaccination and colorectal cancer screening rates as well as a nearly 4 per cent improvement in top-box patient satisfaction scores.²⁴ Finally, Geisinger Health System implemented a genomics-informed precision health programme (MyCode), linking genetic data with the EHR for both clinical and research purposes.¹³ Providers can contact patients with confirmed, potentially pathogenic results to discuss follow-up care options.

Despite some of the early successes and hypothesised promises of the LHS, many healthcare organisations seeking to become an LHS or attempting to adopt its most salient features may find initiating the process difficult owing to a number of organisational constraints. First, many providers segregate research and healthcare delivery, resulting in many physicians having limited exposure to research and data.^{25–28} By gaining more readily accessible data, physicians may become more aware of patients’ needs and be better able to coordinate care^{26,27} and improve efficiency (eg helping patients to avoid unnecessary emergency department (ED) visits).²⁹ Second, external research support often emphasises discovery over application where dissemination and implementation funding is often much lower than funding for basic research.³⁰ As a result, many providers may lack the resources necessary to translate research into care practice.^{31,32} This can impede the systematic implementation of best practices throughout the organisation. Third, translating evidence into practice may be challenging as data collected in the clinical setting may not reflect patient experiences outside of the hospital.³³ Privacy issues and data sharing

must be balanced with adequate security protection — an area where health systems may struggle.³⁴ Finally, because the landscape of healthcare delivery and health policy is constantly changing, an LHS must have an infrastructure that is able to keep pace with these changes — for example, interventions may need to be updated as important changes occur.³⁵

The goal of this paper is to describe the experience of one healthcare system in the early stages of becoming an LHS and highlight the challenging and iterative process by which a healthcare system must make critical decisions and incorporate important stakeholder needs throughout the intervention design. It includes a discussion of organisational considerations, such as identification of areas of patient need and development of evidence-based interventions, and also provides details of the barriers encountered and lessons learned from the project team's initial efforts in transitioning the health system to an LHS.

ORGANISATIONAL CONTEXT

The project team includes Penn State Health (PSH) clinicians and administrators, Penn State University (PSU) researchers and representatives of the Penn State Human Resources (PSU HR) central office. PSH is a large, multisite, academic healthcare system. PSH's primary hospital, the Milton S. Hershey Medical Center (MSHMC), and the Penn State College of Medicine are located in Hershey, Pennsylvania. PSH also has satellite clinics located throughout State College, Pennsylvania, which is 100 miles from Hershey and home to the main PSU campus. Aside from a multisite project to create the EHR infrastructure necessary to become an LHS³⁶ as part of forming a clinical data research network, PSH has relatively limited experience with other projects or processes related to becoming an LHS. Despite limited experience with LHS programmes, PSH clinics at State College

have been actively seeking opportunities to better utilise data, analytics and care transformation.

State College has several unique characteristics that are important to understanding the area's healthcare market. First, PSU is by far the largest employer in the region³⁷ and, as a self-insured employer, is an important player in the local healthcare market, with approximately 43,000 covered lives across the Commonwealth, three quarters of whom live in Centre County (including State College). For healthcare providers looking to implement meaningful LHS interventions, PSU and its HR central office are critical stakeholders. From an employer's perspective, PSU has strongly supported the incorporation of LHS elements within PSH's operations to improve the quality and value of the care employees and their beneficiaries receive. Second, despite the relatively small population of State College (42,430 in 2017)³⁸ and its distance from major metropolitan areas, two other major healthcare systems serve the State College area — Mount Nittany Health and Geisinger Health System. Therefore, establishing partnerships with or receiving endorsement from PSU is vital for any provider in the State College market looking to innovate and pilot interventions to improve patients' health.

DEVELOPING THE INTERVENTION

Motivating the intervention

PSH's initial task was one that many healthcare systems encounter in the early stages of the transition to becoming an LHS, namely, how to initiate the design and implementation of a substantive project to improve patients' health while simultaneously balancing the interests of numerous stakeholders. For example, the project team needed to consider a range of diverse interests: (1) PSH clinicians' and administrators' interests to improve patient health while maintaining revenue

and workflow; (2) PSU HR interests as a purchaser of care to obtain value from the care provided for employees; (3) PSU administrators' interests to obtain value from the dollars being spent on benefits, as well as sustaining and strengthening a nationally recognised, high-quality academic healthcare system by becoming an LHS and (4) PSU researchers' interests in undertaking high-quality research. Although becoming an LHS involves developing and refining an organisational culture that allows for continuous change to improve patients' health, an initial intervention or proof of concept can be critical for launching project activities. While PSH ultimately chose an intervention based on the Diabetes Prevention Program,^{12,15,20,22} the primary focus of this paper is to describe the project team's design and implementation process, which may be beneficial for others to better understand how a healthcare system transforms, in practice, into an LHS.

To date, PSH is in the process of project implementation as it works towards

successfully implementing the Penn State Diabetes Prevention Program (PSDPP). While the decision to implement the PSDPP followed much later, the process began in 2013. Similar to many employers across the country,³⁹ PSU was concerned about the growing cost of providing healthcare benefits. In response, the University convened a task force to understand the drivers of rapidly increasing costs and identify ways to mitigate cost increases as part of improving value as a large purchaser (see Figure 1 for project timeline). The task force produced a number of recommendations, including one about partnering with the Penn State College of Nursing to create an on-campus employee health centre, which opened in February 2017. The intent of the clinic was to provide a space where PSU employees could access acute care for minor illnesses or injuries, particularly when it might be more difficult or costlier to go to other providers. Following the opening of the clinic, the focus soon turned towards the prospect of providing wellness or other types of health

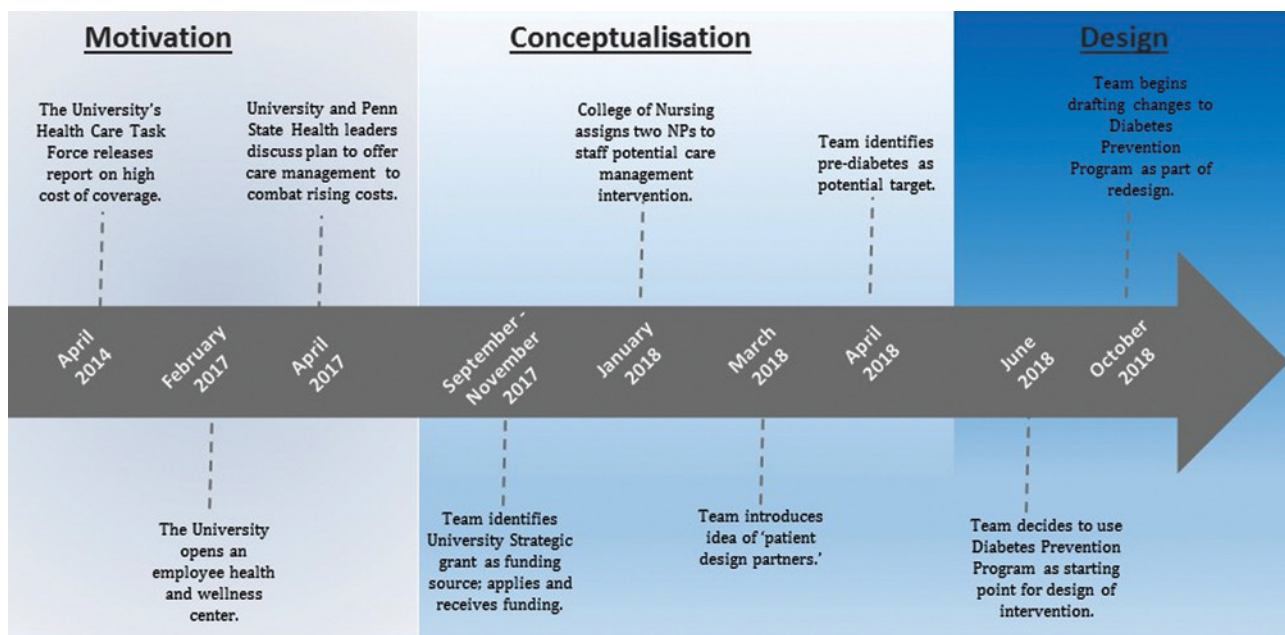


Figure 1: Detailed project timeline

services to employees. In April 2017, the project team was formed to discuss the possibility of offering chronic disease care management to PSU employees and their spouses with an eye to moving beyond 'business as usual' and providing value to both patients and payers while helping to establish the processes and culture necessary to begin operating as an LHS.

Conceptualising the intervention

At the outset, the project team had a general task of improving care management for PSU employees and their spouses with chronic conditions, although no specific intervention or target population had yet been identified. A significant challenge, likely faced by other organisations wishing to become an LHS, was determining how to finance the collaborative intervention and related costs, particularly those considered to be outside the usual continuum of care.^{34,35,40} In September 2017 the project team was awarded an internal PSU strategic grant to support the design, implementation and evaluation of a targeted intervention of mutual interest to PSH and PSU. The initial aim of the project was to provide integrative intensive care management to control or prevent chronic disease in PSU employees and covered spouses.

In January 2018, with funding secured, a smaller, core team of PSU researchers and PSH clinicians set out to narrow the project scope. This was an iterative process whereby the core group divided into two separate teams — a research sub-team and a clinical sub-team — each responsible for a unique set of tasks. For example, the research sub-team was responsible for reviewing and synthesising the literature on chronic disease management in the workplace. Meanwhile, the clinical sub-team was responsible for configuring staffing patterns for the clinical intervention as well as using the EHR to identify the size of the potential target population. The iterative and collaborative

process resulted in the project's target area of interest shifting from a general intensive chronic disease care approach to one focused solely on the prevention of diabetes. The main factors driving this decision were that (1) a more targeted area of interest would allow for a clearer recruitment and intervention process and (2) with a diabetes management programme (ie the clinically integrated network) already in place at PSH, there was a concern that a programme focusing on diabetes treatment rather than diabetes prevention might have limited impact. The lack of diabetes prevention programmes in State College, coupled with strong research evidence demonstrating that diabetes prevention can lead to improved health and cost outcomes,^{41–47} also substantiated the PSDPP project team's decision, thereby effectively shifting the project away from its original goal towards the PSDPP. The change had the additional benefit of being an area of focus that could potentially add value for PSU as an employer and purchaser of care.

Designing the intervention

After settling on diabetes prevention as a goal, the PSDPP team decided to design and implement an intervention based on the Centers for Disease Control and Prevention (CDC) National Diabetes Prevention Program (DPP) curriculum as the organising framework. The National DPP, based on findings from the DPP research group study supported by the National Institutes of Health and the National Institute of Diabetes and Digestive and Kidney Disease,^{44,48} is a structured programme that includes lifestyle coaching in the form of 16 weekly sessions covering topics such as diet and exercise.⁴⁹ Although a distinct, established intervention was identified, several tasks remained.

First, the target population needed to be identified. While eligibility criteria for the CDC's National DPP specify targeting overweight adults with prediabetes,⁴⁹

determining the size of the eligible population required merging basic EHR demographics with data elements for body mass index (BMI) and blood glucose lab values. These actions, however, proved more difficult for the clinical sub-team than had originally been anticipated, primarily because of coordination difficulties between PSH administrative and IT units.

Secondly, the PSDPP team needed to decide where to house and how to staff the intervention. While initial talks centred on using the on-campus employee health centre, the location was ultimately not chosen, and it was decided that dedicated space within PSH primary care clinics would be utilised instead. Although conducting PSDPP activities within the primary care clinics could help to facilitate patient recruitment and retention, workflow and staffing details remained an important consideration. To assist with staff and space modelling concepts, the team consulted with the Montefiore Health System, who had previously implemented a successful diabetes prevention programme.^{50,51} Ultimately, the PSDPP team decided that a select group of nurse practitioners, physicians and care managers would staff the intervention.

Thirdly, while evidence regarding the efficacy of the National DPP is strong,^{44,46,48} results are more mixed in studies where diabetes prevention programmes were adapted and implemented in workplace settings,⁵² largely owing to varying study populations and variations in the intensity of the intervention.⁵² In addition, several studies have noted that most individuals recruited into the DPP do not ultimately enrol.^{50,53,54} As a result, the PSDPP team faced the decision of whether to implement the CDC-approved National DPP as designed or to modify and tailor the programme to PSH patients' needs and preferences. Incorporating patient engagement in the design of new care management and clinical programmes has become a mainstay of quality of care for many healthcare organisations.^{55,56} Therefore,

it was decided to implement the National DPP with the goal of ultimately convening and incorporating a subsequent patient design partners (PDP) component. While patient engagement generally focuses on improving patient and provider relationships throughout care decision making, there is increased interest in recruiting patients to assist in improving healthcare delivery.⁵⁷ Therefore, it was decided that collecting and integrating PDP views regarding the educational and logistical components of the PSDPP would strengthen future PSDPP modifications so as to best address the unique needs of PSH patients at risk for diabetes.

BARRIERS

Several studies have detailed the process by which healthcare systems become an LHS, highlighting their interventions and the technical, often IT-related issues.^{13–15,40} However, few describe the iterative and complicated process of selecting and agreeing on an initial project and target population, particularly within healthcare systems with a shorter history of innovation. As the concepts of an LHS system shift from the early adopters to diffusing more widely, a central research and practice-oriented question remains: how can healthcare systems build an organisational culture that focuses on using research findings and data analysis to continuously improve clinical knowledge, patient outcomes and the patient experience to begin the process of becoming an LHS? To this end, the following discussion describes the project team's encounters with a number of barriers that may be instructive for other healthcare systems in the early stages of their transition to an LHS, particularly for those that may be unsure of where or how to start thinking about an initial project.

First, despite the expansion and improvement in health IT systems, barriers often thwart the implementation of QI measures or programmes related to

becoming an LHS.^{27,58,59} In many cases, systems are tailored more towards clinical care than research, presenting potential issues for extracting real-time, population-level data.^{58,60,61} In the current study, the research sub-team had difficulty obtaining estimates of the size and composition of the eligible sample population, information that is critical to identifying individuals who might be eligible for inclusion in the sample. The lack of readily available data also presented challenges for calculating, and potentially recruiting, an adequate sample for subsequent study. While individual patient data was readily available to providers, there was no clear system in place to provide the PSDPP team with population-level data to identify and recruit potential participants.

Secondly, healthcare systems may not have resources dedicated specifically to research or the types of activities involved in continuous improvement, a fundamental characteristic of an LHS. Although the PSDPP team was able to obtain a strategic University grant to support its activities, such funding may be unavailable to health systems not affiliated with a large research university. A number of externally funded government or foundation grants may, however, be available for these types of pursuits, as well as the potential to secure funds via philanthropy. Moreover, since resources may not be available for research activities, forward-thinking healthcare systems may need to consider reallocating operational resources for these purposes. Although LHS efforts may not generate short-term revenue streams, healthcare systems should be aware of the changing healthcare landscape and invest accordingly so as to be flexible and quick to change as payers increasingly shift towards value-based reimbursement.^{2,62} To do so requires leadership, financial resources and a clear administrative charge providing individuals with the authority to steer the healthcare system in this direction, all of which were difficult to coordinate and obtain in the present case. Even when these

requirements exist on paper, their translation into meaningful and timely action is critical.

A final, major barrier is that staffing and resources for day-to-day clinical operations are often misaligned with the data-driven, continuous improvement processes necessary to become an LHS. Specifically, data needs, as well as the staff required to provide and analyse data and synthesise the existing research literature, may be quite different from what is required for typical clinical or administrative operations. Furthermore, most newly developed interventions prompt changes in typical workflow. While having a clinical sub-team member designated to lead the clinical intervention was advantageous, a major constraint was procuring sufficient institutional buy-in from both senior PSH administrators and other PSH administrative and clinical staff who were needed to provide sufficient time and resources to incorporate the intervention into the clinic's daily operations. To achieve sustained success with an intervention and to allow for the development and implementation of future interventions, broader consensus and support from all levels of the health system is essential.

LESSONS FOR THE FIELD

Get started!

The first lesson, although seemingly simple, is that it is critical to just get started. While healthcare organisations, understandably, want to choose the right intervention and adapt it in a way that responds to patient and stakeholder needs, selecting an appropriate intervention is often the most critical first step. Although the project began as a general chronic disease care management project, a critical task for the PSDPP team was to decide on a specific intervention. Ultimately, this decision, which took several months, allowed the PSDPP team to focus on intervention logistics to move the intervention from the hypothetical to the real in terms of implementation.

Although paved with inevitable roadblocks, the iterative process of recognising and overcoming barriers is intrinsic to building an infrastructure, nurturing a culture and strengthening procedures for future data-driven solutions — features that are inherent to an LHS. Two critical steps in this process are (1) synthesising the existing clinical literature and best practices to identify candidate system changes that could be adopted to improve patients' health and (2) being able to identify the size of the target population using data within the EHR (see Table 1). Table 1 synthesises the following lessons learned into eight essential skills and functional requirements

that a healthcare system needs to begin the successful transition to an LHS.

From the literature to the field

Generally, it can be difficult for a healthcare system to digest and process new evidence, particularly when the evidence suggests the system add a programme or make significant changes that may be outside the usual care processes. While the research sub-team shared and reviewed the literature on diabetes prevention with the clinical sub-team, translating the most pertinent evidence into practice was challenging. For example, the literature showed that an

Table 1: Essential skills and functions needed by a healthcare system to become an LHS

Skill	Function requirement
1. Ability to estimate size of target patient population by location along with key clinical characteristics	Use EHR and data analysis to focus on main populations or sub-populations rather than just individuals as they present for care
2. Ability to identify existing published research evidence of clinical and care management advances that can improve the health of a healthcare system's patients but that is not currently being implemented	Dedicated staff with the job function and knowledge of the system's existing care protocols and initiatives as well as expertise to identify and synthesise the literature
3. Ability to translate gaps identified in (2) into organisational business information by estimating finance/budget/reimbursement initiatives and organisational clinical redesign to assign a priority value and assess feasibility	Dedicated staff to make the business case for implementing evidence-based interventions to healthcare system management and to translate into practice
4. Clinical practice transformation leadership	Staff or unit with the authority and budget to identify and pursue opportunities to improve clinical care for patients and payers
5. Balancing the research model with the implementation and practice transformation model	Interdisciplinary staff or collaborators who can bring both research design and analytic capabilities together with ability to redesign practice and workflow
6. Assessing the value from the purchaser's perspective to determine how to best align incentives	Staff to liaise with payers to understand needs and incorporate into management and care plans to meet patient and payer needs and to obtain the resources to implement these changes
7. Meaningful consideration of the patient perspective and incorporation into clinical and practice operation transformation	Staff to meaningfully meet with patients to understand needs, particularly those most likely to be affected by specific care or practice changes, in order to ensure that changes are beneficial to patients and meet their varied needs
8. Rigorous analytic capabilities to provide meaningful feedback about the effect of an intervention on patient, payer and healthcare system outcomes	Staff with strong data analytic and research capabilities to provide feedback on the effectiveness of a programme so management can make informed decisions about changes to the mix of interventions in place

essential component in diabetes prevention processes is to have the necessary staff and resources to translate the proposed intervention into a business case to achieve sufficient administrative buy-in. This, necessarily, required estimating revenue and budgetary impact as well as the potential effect on patient health. In this case, multiple stakeholders discussed how improvements in patients' health could help meet PSU HR's goal of improved value for its beneficiaries. Discussions also focused on how to assist the PSH administrators in charge of operations in order to determine the logistics of implementing the intervention in practice.

Staffing and space

Adopting innovative approaches to care can disrupt current workflows, which may either impact staff, who need to assume different or supplemental roles, or require hiring of additional staff. Often, new workflow also entails alterations in the use of current space or the acquisition of additional space. Such adjustments likely require extra resources that may be difficult to secure. The PSDPP team spent considerable time identifying both PSH clinical and administrative staff who could help design and implement the DSDPP, as well as allocating physical space in PSH clinics. As the healthcare and reimbursement landscapes continue to shift, forward-looking healthcare systems need processes in place to readily adapt to these potential requirements. To achieve this goal, healthcare systems must have strong leadership of clinical practice transformation and the capability to tailor research-based interventions to the specific healthcare system's practice constraints. While this may require an upfront cost, as a healthcare system continues to work as an LHS and deploy additional interventions, it can leverage the advantage of economies of scale so existing personnel can staff multiple projects at once. Furthermore, for certain interventions, such as the DPP, healthcare

systems can creatively make use of offsite physical space to accommodate emerging ventures. While it may be challenging to amend existing staff responsibilities, recruit, hire and train new staff or find new physical space, developing and institutionalising decision-making processes that enable teams to recognise and implement solutions is fundamental to becoming a flexible, dynamic, data-driven LHS.

Competing business models

Whether or how a new or updated programme fits within the healthcare system's current business model has important implications for the ease and speed of implementation, regardless of how sound the clinical evidence is. One source of major delay for this project was that there was no clear, initial revenue stream for diabetes prevention. The project therefore did not naturally fit within PSH's business model. As a result, securing initial administrative buy-in was difficult. This was despite the project's focus on improving employee health and reducing healthcare costs — two principal aims of the PSU HR central office's business model. Notwithstanding the close alignment and clear business overlap between PSH and PSU, the lack of a shared business model between these respective administrative units led to significant delays in moving the project from conception to implementation. Thus, in cases where project partners are distinct but closely affiliated, aligning competing interests may prove to be more difficult than anticipated. Healthcare systems need staff that can work with payers as well as meaningfully incorporate the patient perspective into the design and implementation of the intervention to ensure sufficient buy-in from all stakeholders.

Rigorous evaluation

Another lesson is that research and clinical experts each play a complementary role

in moving a healthcare system towards becoming an LHS. Because not all team members may have knowledge and experience in both research and clinical practice, it is vitally important to have multiple team members who have experience in each. Despite consistently meeting, the PSDPP team ultimately found it necessary to more closely involve PSH administration, particularly since they were the ones with the necessary authority to assign space and personnel required for implementation of the PSDPP.

As the project moved towards implementation, the PSDPP team needed to balance the timely implementation of the PSDPP with the need to thoughtfully develop a research study design. The latter is critically important to being able to understand whether an intervention 'worked', which relies on carefully planned and organised evaluations. Depending on feasibility and the needs of the organisation, this may require designing and administering a randomised control trial (eg an intervention with a staggered roll-out) or it can entail designing an observational study. Regardless of the evaluation method, careful and rigorous design of the study, data collection and analysis plans is important to ensure study findings are reliable and valid. This allows the organisation to truly learn the effects of an intervention and whether the resources spent were worth it from the perspective of patient outcomes, financial outcomes, staff satisfaction or a variety of other potential perspectives.

Process documentation

Finally, it is vital for healthcare systems to document decision-making processes throughout the intervention design process so as to better inform future interventions that are likely to be established by a new set of team members. In so doing, project teams can reference lessons learned to more efficiently overcome similar barriers. In the

current case, careful process documentation provided the basis for this paper as well as a report to PSU administration highlighting where additional resources might be needed at the organisational level to facilitate the transition to an LHS.

CONCLUSION

As more healthcare systems move towards becoming LHS, many may be unsure about how to best identify and implement a project that moves them closer to being an LHS. This paper provides one system's experience with confronting these tasks as a possible roadmap for other healthcare systems looking to overcome potential barriers. The project team's main lessons learned emphasise the need for healthcare systems to (1) just get started; (2) be aware of and work towards navigating organisational constraints on staff and space; (3) provide leaders with appropriate authority and autonomy to independently carry out necessary activities while being aware of organisational needs in terms of revenue and the business model generally and (4) have team members or partners who can navigate the entire research process to identify and design an intervention with the best chance of success among the target population. Although this process is necessarily iterative and complex, understanding the roadblocks that can arise may help other health systems in their quest to become an LHS and improve patients' health and value of care.

FINANCIAL SUPPORT

Support for this paper was provided by The Pennsylvania State University through a University Strategic Initiative Seed Grant through the Office of the Executive Vice President and Provost. The content is solely the responsibility of the authors and does not necessarily reflect the views of The Pennsylvania State University or the Office of the Executive Vice President and Provost.

AUTHOR'S NOTE

The authors would like to thank Emmanuel Houndo, Isabelle Stull and Sarah Hohman for excellent research assistance.

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