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Operationalizing the Learning Health Care System in an Integrated Delivery System

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Abstract

Introduction: The Learning Health Care System (LHCS) model seeks to utilize sophisticated technologies and competencies to integrate clinical operations, research and patient participation in order to continuously generate knowledge, improve care, and deliver value. Transitioning from concept to practical application of an LHCS presents many challenges but can yield opportunities for continuous improvement. There is limited literature and practical experience available in operationalizing the LHCS in the context of an integrated health system. At Geisinger Health System (GHS) a multi-stakeholder group is undertaking to enhance organizational learning and develop a plan for operationalizing the LHCS system-wide. We present a framework for operationalizing continuous learning across an integrated delivery system and lessons learned through the ongoing planning process.

Framework: The framework focuses attention on nine key LHCS operational components: Data and Analytics; People and Partnerships; Patient and Family Engagement; Ethics and Oversight; Evaluation and Methodology; Funding; Organization; Prioritization; and Deliverables. Definitions, key elements and examples for each are presented. The framework is purposefully broad for application across different organizational contexts.

Conclusion: A realistic assessment of the culture, resources and capabilities of the organization related to learning is critical to defining the scope of operationalization. Engaging patients in clinical care and discovery, including quality improvement and comparative effectiveness research, requires a defensible ethical framework that undergirds a system of strong but flexible oversight. Leadership support is imperative for advancement of the LHCS model. Findings from our ongoing work within the proposed framework may inform other organizations considering a transition to an LHCS.

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Keywords

Learning Health System, Context, Patient Involvement, Ethics, Health Information Technology, Delivery System, 2014 EDM Forum Symposium

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Operationalizing the Learning Health Care System in an Integrated Delivery System

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Introduction: The Learning Health Care System (LHCS) model seeks to utilize sophisticated technologies and competencies to integrate clinical operations, research and patient participation in order to continuously generate knowledge, improve care, and deliver value. Transitioning from concept to practical application of an LHCS presents many challenges but can yield opportunities for continuous improvement. There is limited literature and practical experience available in operationalizing the LHCS in the context of an integrated health system. At Geisinger Health System (GHS) a multi-stakeholder group is undertaking to enhance organizational learning and develop a plan for operationalizing the LHCS system-wide. We present a framework for operationalizing continuous learning across an integrated delivery system and lessons learned through the ongoing planning process.

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Introduction

In response to a multitude of factors—including rising costs, sub-optimal quality, and a turbulent policy environment—health care organizations are increasingly seeking to deliver high value care. Over time, a number of value-based strategies and interventions targeting various elements of care delivery have been proposed and implemented. However, few comprehensive models of care delivery capable of integrating these disparate programs and supporting systemwide transition to high value care have been proposed. The Learning Health Care System (LHCS) model proposed by the Institute of Medicine (IOM) has received a good deal of attention, but there remains a limited literature and limited practical experience in operationalizing the LHCS broadly across an integrated health system.¹

The LHCS model calls for the integration of clinical operations, research, and patient engagement—supported by health information technology (HIT)—in order to continuously generate, utilize, and disseminate generalizable knowledge in the service of improved quality, value, and innovation.¹⁻³ The IOM has purposefully

presented the LHCS as a broad-ranging model requiring collaboration from stakeholders across the health care sector. As a result, the model has been adapted and applied to a wide range of health care contexts from national networks to delivery systems and hospitals. For example, Friedman, Wong, and Blumenthal have proposed the development of a national learning network and information technology (IT) infrastructure to improve biomedical knowledge transfer and translation for public health and care delivery.⁴ Similarly, a number of national networks are organizing around LHCS concepts, including the American Society of Clinical Oncologists (CancerLinQ)⁵ and the Patient-Centered Outcomes Research Institute's National Patient-Centered Clinical Research Network (PCORnet) program.⁶

Organizational learning consistent with the LHCS model has also been applied in clinical settings, particularly integrated delivery systems; however, a fully integrated LHCS as proposed by the IOM remains largely theoretical.^{3,7} Applications of the LHCS model in delivery systems have mostly addressed specific research or operational issues or have guided development and use of data

¹Geisinger Health System

infrastructure and its application.^{8,9} There are few examples of integrated health systems attempting to implement the model systemwide.¹⁰⁻¹² One notable example was developed by researchers at Group Health Cooperative. In this model, Greene, Reid, and Larson present a six phase framework for implementing a learning health system.¹²

This article describes a framework of key components that a multidisciplinary team at Geisinger Health System (GHS) have identified as important when operationalizing a continuously LHCS, as well as early lessons learned based on our ongoing experience with the LHCS planning process at the GHS. Like the framework described by Greene and colleagues at Group Health Cooperative, our framework of components builds on the key features of the IOM model and the goal of continuous learning,³ and it complements Greene's model by supporting and expanding many of the characteristics needed for successful implementation of an LHCS.

Our framework extends Greene's model in several ways. First, our framework attempts to expand the scale and scope of current LHCS applications from individual learning activities, such as implementing a patient-centered medical home program or a medication-prescribing initiative, to integrated learning at the institutional level. We therefore place greater emphasis on the structure and organization of an LHCS to enable health care systems to develop systemwide mechanisms for continuous learning and dynamic application of knowledge. Our framework adopts an operational perspective building on and expanding Greene's model, which adopted a research perspective. Research, and the learning processes presented by Greene and colleagues, are important elements of any LHCS; however at the system level, the relationships, resources, structures, and approaches needed for continuous and integrated learning activities require contributions from a number of functional areas including research.

Learning activities are constantly being undertaken in health care organizations, however their impact or scalability may be limited by structural or organizational barriers. Application of the LHCS model at the institutional level may allow organizations to advance these activities, to make clear their import and anticipated outcomes, and to initiate related activities that, through their collective synergy, will help organizations better realize the aim of continuous learning in the service of continuous improvement.

Background

GHS places a strategic priority on quality and innovation, which includes development of new models of care based on value reengineering.¹³ In 2013, in support of this priority, the Geisinger Center for Clinical Innovation launched an effort to explore the relevance and potential significance of the LHCS model for GHS. That effort has been undertaken by a diverse group of stakeholders whose ranks have both grown and further diversified since the effort's launch. In addition to explicating the relevance and significance of the model for GHS, the group has undertaken a concerted initiative to develop a plan for gradually operationaliz-

ing the LHCS model on a broader scale at GHS. A brief overview of GHS to provide context to the scale of the project is presented in Figure 1.

Figure 1. Overview of Geisinger Health System (GHS)

- Not-for-profit integrated delivery system based in Central and Northeast Pennsylvania
- 8 hospital campuses
- Approximately 23,500 employees
- 1,200-member multispecialty group practice
- 467,000 member health plan
- Electronic medical record use since 1996

Currently, members of the group represent clinical operations, administration, research, bioethics, research and compliance, quality and safety, academic affairs, and clinical innovation. The group continues to consider the addition of representatives from other stakeholder groups or system units, divisions, and departments. The group itself is a microcosm of an LHCS, which has enabled it to identify challenges and opportunities that will be engaged on a larger scale with the ongoing effort to operationalize the LHCS model on a systemwide basis. For example, one such challenge is the difference between how research and clinical operations establish their programmatic and budget priorities. Such differences are not just bureaucratic in nature but are also cultural. Thus structural and operational alignment, as well as cultural understanding, are necessary in order to achieve a more integrated approach to learning.

We are at the very early stages of the process of integrating learning across the system. In order to structure our approach to operationalizing the LHCS, we developed a framework of key components to guide our work. Currently, these components are the focal points of discussions with senior leadership and have been usefully deployed in seeking their feedback and advice. These discussions are thus stimulants to the group's own continuous learning process, enhancing the group's understanding of the components of the framework such as alignment of learning activities with system and operational strategic goals, organizational- and department-level values, motivations, context, policy, and budget priorities, among others. Early challenges faced by the group have included defining a shared LHCS vision that can appeal to multiple stakeholders and developing a shared vocabulary, especially around learning, research, and patient engagement. Ongoing challenges include creating a funding infrastructure and appropriate involvement of our patient community as an active partner. Building senior leadership support is an ongoing process. A strategy has been developed by the group that involves identifying leaders for buy-in and face-to-face meetings, a white paper for circulation to senior leadership, and information sessions with other system leaders and staff.

Framework

The LHCS framework emerging at GHS consists of nine components that represent structures, actions, and initiatives that need to be addressed in order to advance systemwide learning

(Table 1). Initially, the group reviewed the key characteristics of the IOM model. Based on this review, group members were encouraged to suggest components they considered most important for operationalizing the LHCS characteristics in their area of practice. Similar components were integrated, leaving nine distinct components. Subsequent to this feedback, the resulting components of the framework include the following: Data and Analytics, People and Partnerships, Patient and Family Engagement, Ethics and Oversight, Evaluation and Methodology, Funding, Organization, Prioritization, and Deliverables.

The components are not discussed in any specific order, as operationalization of the components is expected to be concurrent. Also, while each component is discussed separately, elements of each component may overlap and have implications for one or more components. For example, patient engagement has implications for ethics and oversight, evaluation and methodology (e.g., patient-centered outcomes research), and data and analytics (e.g., patient reported data).

We consider each component to be necessary but not sufficient to achieve systemwide learning. The degree to which structures, actions, and initiatives of each component are needed and applied to support continuous system learning will be determined by the local context of individual institutions. The framework is purposefully broad for application across different organizational contexts.

Data and Analytics

Definition

The data and analytics component refers to the infrastructure, resources, processes, and mechanisms needed to leverage informatics for learning.

Key Elements and Considerations

GHS invests substantial resources into developing and maintaining a robust health informatics infrastructure. Key elements of this infrastructure include high flexibility in programming, high fidelity in data capture, low administrative burden in capturing and utilizing data, high data security, avoiding reliance on any single proprietary system, and continuous appraisal of HIT cost and value.

The LHCS needs a health informatics infrastructure that supports data requirements of multiple stakeholders. The infrastructure must also digitally capture the care experience and allow real-time access to knowledge for clinical care and learning. In order to enable clinical operations to become engines of learning without interrupting workflow, IT systems should be designed to capture the data needed for evaluation as part of routine clinical operations.

Not only should the technology and workflow of the data capture toolset be aligned with clinical operations and the needs of their patients, but the content and phasing of LHCS IT implementation

Table 1. The Nine Learning Health Care System (LHCS) Framework Components

Component	Definition	Example
Data and Analytics	Infrastructure, resources, processes, and mechanisms needed to leverage informatics for learning.	Geisinger (GHS)'s data warehouse collects clinical and administrative data from several sources (including EHR, financial decision support, and claims).
People and Partnerships	Personnel and relationships involved in establishing and maintaining learning activities within and external to the organization.	Actively identifying staff members who have an interest in operationalizing the LHCS within their clinical discipline or service line.
Patient and Family Engagement	Centrality of patients and their families as partners in the processes of learning, whether the immediate goal of a given process is to provide high value care to a given patient or is to elucidate the factors that advance or impede this goal.	In 2012, GHS convened a Patient and Family Advisory Council to advise physicians and other practitioners in the delivery of care in a number of disease states, including obesity.
Ethics and Oversight	Rethinking the traditional and strictly separate frameworks for clinical patient care and research, and developing both a conceptual and a practical framework more suited to the needs and aspirations of an LHCS.	An educational initiative was launched within the Institutional Review Board (IRB) to introduce members to the issues and challenges that lie at the convergence of Common Rule reform and innovation in the ethics of discovery for the LHCS.
Evaluation and Methodology	Activities and methodological approaches needed to identify, implement, measure, and disseminate learning initiatives.	GHS's Research Division has integrated the LHCS into its strategic plan, which will lend support and funding to build capacity and resources for LHCS evaluation activities that incorporate implementation science principles.
Funding	Mechanisms to fund the operational effort needed to enhance learning capability, as well as strategies for sustained funding of learning efforts.	The Institute for Advanced Application, which supports industry-initiated technology projects, was recently created.
Organization	Organizational and managerial activities and resources needed to operationalize a systemwide LHCS.	Meeting with a number of leaders in order to gain their understanding of the IOM's LHCS model.
Prioritization	Process in which learning activities and opportunities are aligned with strategic goals across different levels of the organization.	A careful assessment of initiatives in place, planned, and needed within each of the nine components will be introduced and utilized to inform strategic direction for operationalizing the LHCS.
Deliverables	Products or outcomes of learning activities across various levels of the system, and which draw attention to the need to embed learning across the system.	During the early stage of operationalization, there is a need to distinguish between deliverables related to the process of operationalizing an LHCS and the performance of an LHCS.

should also be aligned. We have not yet developed an integrated, systemwide IT learning system, due in part to large differences in data source, structure, volume, and flow across the system. For example, collection of patient reported data during a visit requires different workflows and structural considerations (such as inclusion of free text) to “big data” analytics, even though they may both be utilized at the point of care in real time. At the same time, data and advanced analytics should be accessible so as to benefit rapid systemwide learning. Finally, our group aims to build social support for developing a culture that continuously informs and shapes the organization’s technological landscape in order to support learning.

Examples and Ongoing Activities

GHS has several mechanisms for using data to identify learning and improvement opportunities within the clinical and operational domains. GHS’s data warehouse collects clinical and administrative data from several sources across the system including EHR, financial decision support, and claims, and includes digital information on more than three million GHS patients dating back to 1996. Data are used to generate quality and performance reports and to populate management dashboards. Data are also used to support the population management program. Using clinical analytics, data in the warehouse can be mined to identify care gaps and opportunities for improvement.

GHS has leveraged its IT infrastructure to improve population management (1) by enhancing stratification of patients into clinically meaningful subpopulations and risk categories (e.g., high mortality and high utilization risk); (2) by translating clinical guidelines into digital clinical concepts such as decision-support and patient-communication aides; and (3) by identifying and closing “care gaps” for over 400 clinical process measures for over 20 chronic condition and preventive care populations on 600,000 patients every day. For example, if a patient is identified as not having received an evidence-based screening test, the patient will receive automated reminders, and the provider will be informed so that an appointment can be scheduled. Prior to the visit, if there is a gap in patient information, pre-visit data may be captured directly from patients to enhance clinical screening, monitoring, population identification, and outcome tracking. During the visit, use of office-based decision support and, most recently, the development of a documentation software application designed to support efficient progress-note generation and clinical application can be used to close gaps in care. This advanced analytic program also supports identification of high-care and complex populations and population-level data for observational research studies.

People and Partnerships

Definition

The people and partnerships component refers to the personnel and relationships involved in establishing and maintaining learning activities within and external to the organization.

Key Elements and Considerations

An operational infrastructure to achieve the goals of an LHCS is a combined effort requiring the commitment of administrators, scientists, clinicians, human subject protection and compliance officers, bioethicists, innovation staff, finance staff, and data and analytics staff. Particular emphasis should be given to team-based learning, especially in the clinical setting.

Effective internal partnerships are very important for learning. The needs of clinical operations and research must be harmonized across the clinical, financial, and learning components of a complex integrated health system. Based on previous successful projects at GHS, a staffing model comprises professionals with different educational backgrounds, skill sets, and experience—including medicine, operations, HIT, analytics, and evaluation and implementation sciences—that combine to create a learning engine. This team-based model has been applied in a few projects including the treatment of highly complex pediatric patients, pediatric asthma, and 72-hour unplanned postdischarge events. Nontraditional partnerships should also be considered in the LHCS. For example, collaboration with local review boards and compliance departments are instrumental to moving quickly through operational demands while protecting human subjects. Support from GHS patients and families through the development of patient advisory boards, for example, is also important to establish trust and transparency and to improve outcomes, and is discussed at greater length below in the Patient and Family Engagement component section.

It is also vital to build and maintain external partnerships. These partnerships increase exposure to innovation and learning, increase access to funding, and extend the resource and talent pool available. There are a number of potential partners that can contribute to the development and success of the LHCS, including consultants, research collaboratives and networks, academic institutions, industry partners, other integrated health systems and hospitals, public health resources, and patient advocacy groups. The key is to begin framing these relationships in the larger strategy of the LHCS, rather than single projects, which may have little impact to one or other parties. One mechanism to do this is through the use of enterprise-wide project portfolio-management tools, which can create a database of ongoing or planned projects that can be identified and prioritized according to desired strategic goals.

Examples and Ongoing Activities

At this early stage we are actively building internal partnerships through inclusion of stakeholders in the LHCS group and by actively identifying staff members who have an interest in operationalizing the LHCS within their clinical discipline or service line. As our group has identified gaps in our own knowledge and understanding of the system we have reached out to leaders across different disciplines—including medicine, surgery, academic affairs, and quality and safety—and included them in the process of enhancing learning. Recently we have added a second strategy, which is to identify clinicians who have an interest in

learning and system change and who may lead and support future learning activities (including quality improvement and implementation studies) and serve as peer leaders for learning.

Externally, we are developing learning collaboratives with other institutions in order to improve care for specific populations and to benchmark performance. One area that has been identified for such collaboration is cancer care, especially the collection and use of patient reported data and how it may be used for measuring performance across institutions. There are also active collaborations with external partners and patient-groups focusing on patients in both the clinical setting and with regard to research in an LHCS context. An example of this is a PCORI-sponsored project in which researchers at Johns Hopkins University, in collaboration with GHS, are seeking to better understand patients' views on consent, engagement, transparency, and accountability in PCOR. A second example is the DuchenneConnect Patient-Report Registry Infrastructure Project, which is a PCORI-funded, patient-powered research network. In this project, GHS has partnered with Parent Project Muscular Dystrophy (Duchenne-Connect), PatientCrossroads and the University of California, Los Angeles (UCLA) to develop and improve approaches for collecting data and enhancing patient benefit on a patient-report registry for Duchenne and Becker muscular dystrophies.

Patient and Family Engagement

Definition

The patient and family engagement component signifies the centrality of patients (as well as their families) as partners in the processes of learning, whether the immediate goal of a given process is to provide high value care to a given patient or is to elucidate the factors that advance or impede this goal. In light of empirical research, this centrality is critical to achieving improved health outcomes for patients.

Key Elements and Considerations

In a fully realized LHCS, patients are partners, both in their care as well as in research and discovery. Moreover, in such a system, every patient care experience presents an opportunity for learning. Although patient data are already shared and utilized for quality improvement, as well as for state and federal regulatory purposes, no system is in the position to unilaterally mandate that patients become consciously supportive participants in as many forms of learning as possible. Instead, an LHCS must solicit that support through engagement initiatives that can both secure the fruits of participation (e.g., data and specimens that can be broadly shared and utilized with few restrictions) and enhance trust to produce meaningful outcomes for patients. An important component of the LHCS is partnering with patients and families, both in the clinical and research arenas.

Examples and Ongoing Activities: Several initiatives underway at GHS are focused on increasing patient and family engagement. These include the establishment of patient and family advisory councils at all of the system's hospitals and the formation of a sys-

temwide Patient Experience (PX) Steering Committee. In the research arena, patient engagement has been pivotal to Institutional Review Board (IRB)-approved changes in biobank consent provisions and to the development of projects that address meaningful patient questions and concerns in tandem with scientific inquiries. During a recent strategic planning initiative, the research enterprise at GHS embraced patient engagement as a priority—as the “default” for all research projects that meet the definition of “human subjects research.” And to enable that process of prioritization, a standing working group on patient engagement has been established, in part, to educate the research community about the aims and methods of effective patient engagement in research and discovery. Finally, GHS is also one of the study sites for the OpenNotes initiative, a major milestone in patient-family engagement, which allows patients to access their clinical notes through a secure patient portal.¹⁴ GHS is also collaborating with Beth Israel Deaconess in the recently funded OurNotes initiative, a program designed to evaluate the impact of engaging patients and families to cogenerated their notes.

In 2012, GHS convened a Patient and Family Advisory Council to advise physicians and other practitioners in the delivery of care in a number of disease states, including obesity. These councils reflect a formal effort to solicit and incorporate patients and family perspectives into preventive and therapeutic care, communications, education, and research. Recognizing the complexity of obesity and weight management treatment, a Patient Advisory Council on Obesity (PACO) at GHS was formed. The PACO held an inaugural meeting in early 2014. Fifteen patients and their family members who previously received obesity treatment at GHS's Center for Nutrition and Weight Management agreed to become members. Clinician leaders and researchers invited the members to discuss mutual goals: (1) to provide a patient and family perspective to ensure that preventive and weight management care services are available, are accessible, and exceed their expectations; (2) to promote effective partnerships between patients, families, and staff; (3) to encourage opportunities for patients and families to recommend or give feedback on services, programs, research, and policies; and (4) to promote collaboration and develop creative lifestyle and clinical solutions to challenges faced by patients and their families in the region.

The PACO defined their charge from their own perspective: to actively collaborate with GHS to work toward achieving goals, establish a governance structure, and develop a working plan with actionable objectives and meaningful outcomes. The PACO meets quarterly and has developed an organic governance structure. True to intent, they provide input on (as well as feedback regarding) care, communications, education, and research. This has led to novel research projects, a deeper understanding of patient issues, and broadened engagement with clinical service lines such as orthopedics, nephrology, and psychology and community partners such as the YMCA.

Ethics and Oversight

Definition

The ethics and oversight component of the framework reflects the necessity of the following: (1) rethinking the traditional and strictly separate frameworks for clinical patient care and research and (2) developing both a conceptual and a practical framework more suited to the needs and aspirations of an LHCS. The challenge of this task is considerable: the current regulatory framework for human subjects research rests on the conviction that patient care and research are very distinct activities with differing precepts and obligations governing care-providing clinicians and research-conducting investigators. An LHCS turns, in part, on the deliberate blurring of these distinctions—and thus on a different and, for some, radical revisioning of ethics.

Key Elements and Considerations

As noted, a structural feature of an LHCS is its intentional blurring of the traditional distinction between biomedical research and clinical care. The health care delivery and discovery space have changed since 1979, when the Belmont report first presented ethical principles and guidelines for the protection of human research subjects.¹⁵ As a result delivery systems have become epicenters for interpreting and implementing federal revisions to oversight policy and a changing ethical paradigm.¹⁶ Initial steps have been taken at GHS to think through, as well as act upon, the implications of these developments—especially for the work of the IRB and the division of research and compliance.

Examples and Ongoing Activities

In spring 2014, an educational initiative was launched within the IRB to introduce its members to the issues and challenges that lie at the convergence of Common Rule reform and innovation in the ethics of discovery for LHCSs. This initiative has consisted of brief, targeted presentations and discussions of key issues at the beginning of every regularly scheduled IRB meeting, along with a daylong retreat and a lengthy follow-up session devoted to three fundamental themes: (1) enhancing the IRB's capacity for the conduct of rational, evidence-based risk assessments, because risk is the pivot on which oversight turns in an LHCS, (2) exploring IRB member attitudes toward different models of disclosure and consent for learning activities embedded in the routine processes of care, and (3) developing institutional guidance for navigating the differences, overlap, and similarities between quality improvement and research, as defined by the Office of Human Research Protections. At the same time, an initiative led by GHS Academic Affairs to develop a new oversight body for clinician (especially, physician)-driven quality improvement is under way. These efforts focus on addressing issues surrounding the integration of quality improvement and research. In addition, within the next few months, GHS will undertake to design an oversight scheme that serves two aims: (1) to ensure compliance with the relevant Office for Human Research Protections (OHRP) regulations, and (2) to optimize the quality of learning proposed in any project that falls somewhere along the continuum from quality improvement to research.

Evaluation and Methodology

Definition

The evaluation and methodology component refers to the activities and methodological approaches needed to identify, implement, measure, and disseminate learning initiatives.

Key Elements and Considerations

A key consideration within this component is that the opportunity for learning must be considered in the context of the strategic objectives of the health care system. Thus, within the context of an integrated delivery system, research should be linked to clinical or operational learning as system priorities. This can create a tension for researchers if their activities and incentives are not structured to support clinical and operational system priorities.¹⁰ Evaluation of the LHCS must by design be pragmatic, flexible, transparent, scalable, and of sufficient speed that findings are relevant to the situation in which knowledge is needed and learning applied.¹⁷⁻²² Evaluation should not create any unnecessary or additional burden on clinical operations or patient well-being. Thus, careful planning and patient engagement is needed in the formative phase, prior to implementing learning interventions.

A transdisciplinary team approach that encompasses clinical, operational, research, and patient perspectives should be utilized when appropriate. While there will always be a tension between the pace of operations and evaluation, mutual understanding and respect is a necessity. Leadership should play a key role in spanning these different ideologies through providing support for multidisciplinary learning and ensuring that there is an alignment of system strategic goals with the learning activity. Leadership can also establish performance criteria and align incentives for employees that reflect work within these multidisciplinary learning activities. Finally, leadership can also support employees by giving them dedicated time to participate in learning activities. This strategy has been used in other industries for many years, with 3M as a prime example of a company that supported successful employee learning and innovation.

Examples and Ongoing Activities

Recently, recognizing the value of the LHCS model, GHS's Research Division has integrated the LHCS into its strategic plan. Going forward, this decision will lend support and funding to build capacity and resources for LHCS evaluation activities that incorporate implementation science principles. In part as a result of this strategic support, and due to researchers' participation in the LHCS group, a common context for implementation science is beginning to emerge among the group, which will advance evaluation of learning activities.

Pragmatic research designs, which recognize the context of the research setting, are also increasingly being implemented. Such designs build flexibility into the study, especially in the case where a new program or innovation is being introduced in real-world practice. For example, in developing a new, multicomponent program focusing on improving the care and needs of children with complex medical conditions and their caregivers, program

personnel, (including providers, administrative, clinical innovation, and evaluation members), recognized early on that there would be an ongoing need for adjustment of the program and its evaluation. This prompted the evaluation group to develop two evaluation designs, so that once the study was initiated and the practicalities of delivering a multicomponent intervention became apparent, an evaluation design most suitable to the context could be utilized. Since the program leveraged our HIT and clinical analytics capabilities and patient-reported data capture, there was no additional work burden on the clinical staff or evaluation team. In this case, rather than adapting a real-world intervention to a rigorous research approach, the research approach was adapted to the intervention and the context in which it was implemented. This type of pragmatic research approach highlights the continuous approach to learning that underpins our framework and promotes learning beyond the initial activity.

Funding Strategies

Definition

The funding strategy component focuses on mechanisms to fund the operational effort needed to enhance GHS's learning capability, as well as strategies for sustained funding of learning efforts.

Key Elements and Considerations

A key tenet of the LHCS is to lower costs and deliver value. While transformation to an LHCS will initially require financial investment, the goal is for rapid learning to lower cost and increase value through improved clinical and operational efficiencies, continuous performance improvement, improved patient outcomes, and population management. Potential sources of funding exist externally and internally, and the use of different sources may vary in the short- and long run.

Potential external funding sources that may support LHCS transition exist in several sectors. At the federal level, new funding initiatives placing emphasis on innovative delivery models and patient-centered outcomes research have a natural overlap with the LHCS. Examples of these funding sources include the Center for Medicare & Medicaid Innovation, Agency for Healthcare Research and Quality, and the Patient-Centered Outcomes Research Institute. Funding at the state and local levels, especially focused on community-based development and research, are another source of external funding.

Sources of internal funding may initially be from operational and dedicated research funds; however these should be offset through cost savings on improved efficiencies and revenue generated through performance improvement, innovation, and discovery as products are scaled, generalized, and commercialized. The use of analytical applications and smart learning technologies have improved efficiency in identifying care gaps, limiting duplication, and improving patient scheduling.

Examples and Ongoing Activities

Industry-sponsored research focusing on developing innovations and IT applications support a learning and discovery infrastructure. GHS has recently created the Institute for Advanced Application, which supports industry-initiated technology projects. The challenge is to develop an integrated strategy so that capacity building and discovery are integrated in support of clinical operations and improving patient outcomes. Multiorganizational learning collaboratives focused on clinical operations and research provide funding or resources to each other in order to benefit from shared learning. An example of this hybrid model is a multiorganizational research network such as the HMO Research Network of which GHS is a member, while on the clinical operations side, GHS is partnering with several organizations to develop a value-based learning system and to improve care delivery and outcomes.

Internally, partnerships between the Geisinger Clinical Enterprise and the Geisinger Health Plan have been another important source of funding. This partnership has led to a number of quality improvement and cost reduction programs. GHS's ProvenCare model, which integrates the best current evidence on a clinical problem with value-based payment strategies, and ProvenHealth Navigator, which seeks to enhance the care team through embedded case managers and to reengineer care to deliver best practice and avoid unnecessarily utilization, are major examples.

Organization

Definition

The organization component refers to the organizational and managerial activities and resources needed to operationalize a systemwide LHCS.

Key Elements and Considerations

A thorough understanding of the knowledge enterprise is needed to utilize learning to meaningfully influence care delivery, patient health, competitive advantage, and sustained growth. All health care organizations have learning activities, however the goal and challenge of the LHCS model are to have systemwide integration of learning activities. Being able to identify what learning is taking place and where it is occurring is the first step, and is by no means an easy task in a large delivery system.

While all dimensions of organization will be important to integrate learning across the system, leadership and culture will be two key elements in successful transformation. System leaders can actively plan, execute, and reflect on all aspects of learning within and surrounding the organization. Full operationalization will require leaders to set expectations and communicate the importance of the learning system within the strategy of the organization and to maintain consistency between the vision, principles, and expectations of the learning system to both internal and external stakeholders. Alignment of system level strategy and goals with clinical department- and researcher goals will also be important in order to keep resources and energy and to focus on learning system objectives.

Organizational culture has been shown to have an impact on financial and operational performance in hospitals.^{23,24} Learning will need to be embedded into the culture of the organization. Modifying an existing culture can be a challenge, especially if institutional and administrative infrastructures are not adapted to the desired culture. We have not begun specific activities focused on developing a systemwide learning culture. However GHS has strong existing programs supporting innovation, safety, and quality—which are key supporting cultures for learning. Further development of a learning culture would require adjusted communication and coordination pathways and alignment of rewards and incentives with desired outcomes.

Since there are currently no fully operationalized LHCSs in the industry with which to benchmark progress, those overseeing the transformation will need a high degree of flexibility to make adjustments and should build contingencies for concurrent internal and external changes that will occur during such an organizational change. This will include adjustments to the capacity of clinical operations and research to match the needs of the organization.

Examples and Ongoing Activities

Our group is in the process of meeting with a number of GHS's leaders in order to gain their understanding of the IOM LHCS model, and their perspective on learning at GHS and the components of our framework. We are using our framework of components to structure and guide our discussions. Information gathered from these meetings has helped us gain a broader view of the potential opportunities and barriers in operationalizing the LHCS. Although we have not developed an internal marketing strategy for expanded LHCS operationalization, we anticipate that such a program will be a key step in socializing staff to the LHCS model in the future.

Prioritization

Definition

The prioritization component refers to the process in which learning activities and opportunities are aligned with strategic goals across different levels of the organization.

Key Elements and Considerations

Prioritization of strategic objectives, programs, and resources are keys to successful operationalization of the LHCS. Priority should be given to learning activities that are aligned with the systemwide strategic goals and where there is potential for a large impact on the value of care delivery. Alignment between systemwide goals and goals of hospitals, departments, or service lines is vital for systemwide learning to be implemented and is a potential barrier to change.

Examples and Ongoing Activities

With leadership support, a careful assessment of what LHCS initiatives are in place, what initiatives are planned, and what initiatives are needed within each of the nine components of our

framework will be initiated and utilized to inform strategic direction for operationalizing the LHCS at GHS. The purpose of the assessment is to identify opportunities to maximize systemwide learning and to limit duplication of effort and inefficient use of resources. The findings from the assessment will reveal systemwide and organizational strengths and needs for sustained, value-driven learning. Thus, these findings will inform the strategic direction for operationalizing the LHCS.

Operational needs assessment and strategic planning will drive prioritization with leadership support; however, service lines may be best positioned to identify gaps in their learning, identify priorities, and drive learning at the operational level. Service lines could identify a number of learning activities for implementation over a predefined period. These activities would be aligned first with systemwide strategic goals, and second with service line and platform operations goals. The learning activities that create value in alignment with strategic goals would be prioritized, with the expected outcome being improvements in quality, cost savings, and patient and population health. Development of communication and IT infrastructure for sharing and learning across service lines and platforms would enable scaling and generalization across service lines and platforms. Identifying who will be accountable for learning activities is important yet can be a sensitive issue. Caution must be taken not to overburden already busy departments with additional administration.

While there is no structure in place yet to prioritize learning in our institution, we propose that higher priority should be given to activities where evidence exists for improved care or operations through learning activities, or which integrate clinical operations and research activity—including oversight activities, patient engagement strategies, and comparative and patient-centered research that can lead to rapid-cycle evaluation and improvement of care delivery. Organizational change activities are of high priority but take longer to implement, especially the development of a sustainable learning culture and alignment of system and individual goals and incentives.

Deliverables

Definition

The deliverables component refers to the product or outcome of learning activities across levels of the system and draws attention to the need to embed learning across the system.

Key Elements and Considerations

The output of an LHCS is both internal scaling and dissemination of effective initiatives across service lines and platforms as well as translating and generalizing successful strategies through communication, partnership, the literature, and commercial ventures. The LHCS model can provide a platform for improvement and innovation activities that often succeed in planning, implementing, and achieving a predetermined goal, but have limited capacity to disseminate and embed learnings across the system.

Examples and Ongoing Activities

While we are at a very early stage of operationalization, we recognize the need to distinguish between those deliverables related to the process of operationalizing an LHCS and the performance of an LHCS. Both need to be planned, implemented, and measured according to predefined objectives; however the timing and sequencing of these processes will be different. In the short run, deliverables for operationalization should be established and reevaluated annually within the initial implementation period and should focus on financial, quality, operational, clinical, strategic, research, and patient-oriented deliverables. Over the long run, deliverables would reflect a sustainable learning culture, efficient use of resources, improved quality of care, and high value care delivery.

Lessons Learned

We continue to learn about our group dynamics and to refine our processes. Important lessons have been learned around the following themes: (1) resources, infrastructure, and organization needed to transition to an LHCS; (2) patient and community engagement as a core focus; (3) ethical implications of an LHCS, and integration and oversight of clinical activity, research, and quality improvement; and (4) leadership.

First, a realistic assessment of the capacity and capabilities of the organization and its data and analytic infrastructure is critical to defining the scope of operationalization and setting expectations among leaders and staff. Integration of clinical operations, patients, their families, and research activities may be influenced by many factors—including communication, and the misalignment of goals and resources. These factors point to the importance of addressing organizational culture and attitudes toward learning early in the planning process and throughout the system. Internal communication strategies may need to address differences in staff knowledge and interpretation of the LHCS model, as well as possible skepticism of the model's potential. A further insight is that the LHCS model can be utilized as a primary strategic objective for an organization or as a mechanism to enhance existing strategic objectives, and that the particular intention for using the model must be clearly defined and communicated to leadership and staff.

Second, we have learned that patient and family engagement is core to the LHCS. Patient engagement requires trust, redefined relationships with the system, and consideration of health literacy so that patients can successfully navigate new LHCS practices. With so much activity surrounding patient engagement across the system, the LHCS can be utilized to create an integrated strategy and approach to patient-centeredness across the system.

Third, integrating patients and their families, clinical care, and various modes of discovery—including quality improvement and comparative effectiveness research—requires a defensible ethical framework that undergirds a system of strong but flexible

oversight. This requires both a cognitive shift and organizational redesign to accommodate the new learning paradigms and opportunities in the LHCS.

Fourth, supportive leadership is imperative for advancement of the LHCS model. All the leaders we encountered have been strongly supportive of efforts to continue enhancing our systems learning. However, in regard to the IOM LHCS model, we experienced a wide range of reactions from skepticism to strong support. Leaders' understanding of the model, its scope, and its potential value to the system is strongly shaped by their functional role and the organizational context and will differ across health care organizations.

We used several approaches to engage leadership in our discussions. The first of these is to clearly define and articulate the scope of the proposed LHCS operationalization so that leaders can begin to assess the potential costs and benefits to the organization. Second, the team should discuss how an LHCS model aligns with existing and future strategic goals of the organization to allow leaders to see the potential value that can be gained, without deviating from their current strategic vision. To extend the value of these discussions, we have found using examples to be very useful. We make use of current examples of learning activities within the organization—such as our ProvenCare program and complex child care program—as well as from the industry, such as other health systems that have used learning health system approaches.¹⁰⁻¹² Using examples, especially past or ongoing learning activities with potential for further dissemination and implementation internally or externally, can make the LHCS model less conceptual and more practical to audiences.

Finally, as with the IOM model, our framework is purposefully broad and can be applied across different organizational contexts. While our group feels that each component in the framework is important, we recognize that organizations will vary widely in the resources, capacity, and ability to apply them to learning. Organizations can use the framework to identify current learning resources and activities and those needed to support or enhance organizational learning on a systemwide level. For example, GHS has considerable IT infrastructure and capability (data and analytics component) but, until recently, has had limited focus on the structures and mechanisms necessary to support oversight of learning in an LHCS (oversight and ethics component). Greater knowledge of an organization's current, or future, learning activities and needs can help guide decision makers' decisions about whether to develop capacity within the organization or seek external partnerships to support learning.

Conclusion

The challenging environment of health care in the United States requires continual reflection and transformation of the way we deliver care. The LHCS model advanced by the IOM is built on real-time capture and use of data for integrating clinical care, dis-

covery, and advanced patient and family engagement. The promise of the LHCS lies in a more cohesive and efficient system of care delivery and improvement through alignment of system strategic goals with operational and research goals; alignment of incentives with value and improvement; a unifying learning culture; integration of clinical operations, research and patient engagement; and a robust learning IT system that supports utilization and sharing of data for clinical care, discovery, and management.

The LHCS model is a recent concept, and there is limited literature and practical experience available in operationalizing the LHCS in the context of an integrated health system. We present a framework of components that can be used by organizations interested in becoming LCHS to begin a discussion and to inventory organizational assets and support for operationalizing an LHCS using a common terminology and definitions. This framework consists of nine major components for consideration in understanding the current status of the organization, and the resources, actions, and leadership necessary to transition the organization to an LHCS. We believe the components are generalizable across institutions, however the degree to which each component can be leveraged for learning and can support other components will depend on the local institution. The framework provides a practical tool that organizations can use to plan and operationalize the LHCS. The key to successfully operationalize an LHCS will ultimately lie in the ability of leadership to support and translate the LHCS model into a sustainable culture of learning. Lessons from our ongoing work and the framework begin to add to the knowledge base around LHCSs and may assist other organizations with similar goals.

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